Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015)

ACTOR study

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Acknowledgement

In this study NIVEL reports on the uptake and impact of the EU Action Plan on organ donation and transplantation (2009 – 2015). In 2011, an offer[1] for this study, as a "Health report", was published by the Executive Agency for Health and Consumers (EAHC) in the context of the Framework Contract No. EAHC/2010/Health/01. After and based on the evaluation of the proposals received, a contractor was chosen: NIVEL (Netherlands institute for health services research). The study was taken up in January 2012 and has been performed in close cooperation with representatives from the European Commission (EC). Throughout the study, National Competent Authorities (CAs) in charge of organ donation and transplantation in their country were regularly consulted and asked for input. The authors thank both the EC representatives and the Competent Authorities for their kind cooperation and input. The two experts who were asked to comment on this study, prof. mr. Herman Nys, from the Catholic University in Leuven and dr. R. Coppen from NIVEL are also sincerely thanked for their feedback.

Utrecht, April 2013

[1] http://ec.europa.eu/eahc/health/sc_awarded_under_fwc_2011.html

Executive Summary

Background

In December 2008, after a public consultation including views of the EU Member States, the European Commission (EC) adopted the *European "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States"*.[2] The Action Plan is a non-binding instrument to help the Member States address the shortage of organs, enhance transplant systems and improve quality and safety of transplant procedures. In the Action Plan, 10 Priority Actions are identified, assembled under 3 challenges: 1) increasing organ availability; 2) enhancing the efficiency and accessibility of transplant systems; and 3) improving quality and safety. In the first three years since the adoption of the Action Plan, various efforts have been made by the Member States, both at the national level and at the European level. With this study NIVEL, Netherlands institute for Health Services research, provides the EC with an overview of the efforts during the first-half period of the Action Plan and the state of its implementation in 35 countries. Besides the 27 EU Member States, 8 neighbouring non-member States were included.[3] The study concludes with recommendations at national and European levels. Data were collected through desk research, through an online structured questionnaire/database and through an online focus group. Competent Authorities (CAs) and policy officers of the EC were consulted and asked to verify the gathered data, however NIVEL, as contractor of this survey, remains the author of this study.

Individual country data

The ACTOR-study provides an overview of the state of implementation of the Action Plan in each of the 35 countries. What becomes most apparent is the great diversity between countries, for instance regarding the number of transplantations from deceased donors or the importance of living donors. Also regarding the Action Plan differences between countries exist. This diversity suggests that there is room for improvement and that there are many opportunities for countries to share their experiences and learn from each other.

Country activities related to Priority Actions

<u>Priority Action 1</u>: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Design indicators to monitor this action.

Activities related to Priority Action 1, especially the appointment of transplant donor coordinators, have been taken up by almost all countries, be it in different ways. A slight increase compared to 2009 can be noted. Regarding the profiles of these coordinators and the level at which they are employed (national/regional/hospital level), there is still a huge diversity, which is normal given the differences in the size of the countries and in the health and educational systems, and which is also needed for an appropriate coverage from hospital level to national coordination. Bringing this action one step further is likely to be welcomed by many countries. In almost one third of the countries transplant donor coordinators receive both initial training at their appointment as well as regular training. In the remaining countries transplant donor coordinators receive one of these two types of training, or another form of training. The EU might consider further supporting trainings of transplant donor coordinators. Furthermore, the importance of precisely defining their role and profile was stressed, as well as the need for more quantitative data for the purpose of evaluation. Countries that have not yet taken up efforts regarding this Priority Action, may learn from the experiences of other countries.

[2] http://ec.europa.eu/health/archive/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf

[3] Iceland, Norway, Croatia, Macedonia (fYRoM), Switzerland, Turkey, Liechtenstein and Montenegro

Priority Action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.

This study shows that most countries have stimulated initiatives to improve the quality of at least one aspect of the organ donation process. Most often these concern the quality of the identification of potential donors and the procurement process. Quality improvement programmes on the transplantation process and follow up care are lagging behind. The need for a solid organisation of the donation process within individual countries is important. This may also imply the allocation of enough time and facilities to the professionals involved. Data suggest that there has been an increase in the uptake of this action. This Priority Action has a great potential for further development, in particular on the transplantation process and follow-up care, as well as for mutual learning through an exchange of experiences, for instance in the form of twinning activities and based on deliverables of projects already funded (ODEQUS: quality criteria and indicators at hospital level).

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.

Most countries have living donation programmes with related donors, while fewer countries have programmes on living donation with unrelated donors. Country differences primarily exist in whether or not a legal or genetic relationship is required for donation and whether living liver donation occurs. With respect to the protection of living donors, the majority of countries has independent bodies that evaluate living donors, and in almost all countries organ trafficking is prohibited by law. Another important observation is that about half of the countries have established registers to evaluate the well-being of the living donor. This number has increased compared to 2009. It has also become an obligation under Directive 2010/53/EU, which states that "Member States shall ensure that a register or record of the living donors is kept…". All countries are therefore expected on the short-term to set up registers and monitor the health and safety of the living donors over a longer period of time. Countries that have not taken up efforts regarding this Priority Action, may benefit from the experience of other countries, also via EU funded projects (ACCORD).

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.

Many different activities on this topic have been taken up by many countries: such as national campaigns on TV or social media (including testimonies of patients and of donors and their relatives), setting up 24/7 phone line to answer media questions, training courses of health professionals including communication aspects… However, these efforts have not always been very systematic. Many CAs report that activities have been carried out with regard to improving knowledge and communication skills of health professionals, since about two-thirds report that programmes are deployed for health professionals to improve these skills. Similarly two thirds of the CAs report that some programmes are deployed to improve these skills of patient support groups. A possible strategy to ensure further progress on this action might be to reconsider the national priorities and develop national communication plans on organ donation. Such plans may help to move this action into a more professional, consistent and effective direction. In making these plans, countries can benefit from the experience of those with successful communication activities and from the expertise developed in the context of the European Organ Donation Days and EU-funded project EDD. Additionally, these plans should allow for ad-hoc actions and should contain strategies on how to react to sudden cases of 'bad publicity'. Coordination of communication and messages between Member States can contribute to address (increasing) cross-border media attention in a consistent way. Ample knowledge and experience to make communication plans and deal with cases of negative publicity is available within the Member States, which could lead to a more systematic approach while further developing this Priority Action, also with the support of EU-funded projects (FOEDUS).

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.

The provision of clear information to European citizens on their legal options as a potential donor is lagging behind. A minority of countries provide this information to citizens. Also, differences exist between countries regarding who can be a donor. In many countries regulations are in place to clarify the legal position of non-residents as potential donors. A majority allows non-residents and residents with a foreign nationality to be donors, and fewer countries permit organ donation from illegal persons. No change compared to 2009 could be noted. Because of the potential impact of such decisions and because of the differences between countries in the role of next-of-kin, investing more in this topic is advisable. The new EU-funded Joint Action FOEDUS could help to further develop this Priority Action, while the new legal mandate (Implementing Directive 2010/25/EU) would accompany these developments.

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

To enhance organisational models, it seems effective to exchange best practices between countries, often achieved through 'twinning projects'. Little more than half of the countries have been involved in twinning or similar projects. Moreover, about half of these indicate that these projects have led to changes. Compared to 2009, more countries participated, or are participating (ACCORD Joint Action), in twinning activities. However, the potential of learning from other countries is still underused, and could be deployed more effectively. Another tool could be the use of structural funds or other community instruments to further improve organisational models. The use of such funds is not yet always known to the CAs (they can be used outside the scope of CAs activities: in the research field, and/or via Finances/Health Ministries). Several of the countries expressed interest in exploring this possibility.

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

A limited number of countries indicate that they have agreements in place, allowing for example within bilateral agreements or in the case of "European Organ Exchange Organisations" (such as Eurotransplant and Scandiatransplant) to improve transplant results by an optimised match between donor and recipient, to improve the follow-up of transplanted patients (thanks to the EU-funded project EFRETOS) or to agree on common principles for allocation criteria and inclusion on/exclusion from waiting lists (where common listing exit). However, in the formulation of this Priority Action it is unclear what is meant by 'EU-wide' agreements. Are these bilateral agreements between individual countries, e.g. neighbouring countries, or are these multilateral agreements that are shared by many or all EU countries. Also to what purpose should there be such agreements? Should they be seen as a first step towards implementation in a Directive, or should they be seen as useful, professional instruments only? Although this Priority Action refers to fundamental issues, the scope and purpose should be reconsidered and clarified, probably with the CAs and with scientific societies as it is clearly linked to "transplantation medicine".

Priority Action 8: Facilitate the interchange of organs between national authorities

This study shows that almost all countries are part of at least one fixed collaboration with other countries for the purpose of facilitating the interchange of organs. 13 countries are now officially part of Eurotransplant or Scandiatransplant, but more countries indicate that they have bilateral agreements with one or more other countries. Exchanging organs between countries is a good way to ensure all donated organs can be used at best, in particular if each individual does not have (yet) the means to set up every transplant programme. A new initiative is the Southern Europe Transplant Alliance between Spain, France and Italy which also foresees future exchange of organs. Compared to the 2009 assessment, a slight increase in exchange activities was noticed. Countries that have not taken up efforts regarding this Priority Action, may benefit from the experience of other countries

and eventually might make sure that available organs are optimally used. The Joint Action FOEDUS will provide for tools (IT-tool and templates for agreements) for this Priority Action.

Priority Action 9: Evaluation of post-transplant results.
The relevance of collecting post-transplant results to improve the quality of the donation process is shared by most countries and most countries indicate they analyse these results. A majority of the countries systematically collect post-transplant results in a database/register, mostly at 12 months after transplantation. Compared to the 2009 assessment, activities on this action increased. This Priority Action has a great potential for mutual learning through an exchange of experiences. This will however require further efforts in ensuring comparability of data collection as well as data completeness.

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.
More than half of the countries have made plans or have undertaken actions to promote a 'common' accreditation system for organ donation/procurement and transplantation programmes**.** A closer look at the plans or accreditation systems suggests a great deal of variability in topics, in thoroughness and in whether or not accreditation is evaluated. It seems that the accreditation systems are rather diverse. It should be reconsidered and clarified to what degree these accreditation systems should be harmonised, as is suggested by the formulation of this Priority Action. In addition, the adoption of Directive 2010/53/EU might create new conditions to look at and implement this Priority Action.

In general
The state of uptake and implementation of the specific Priority Actions differs between countries.

- Activities related to donor coordinators, living donation and interchange of organs (Priority Actions 1, 3 and 8) are increasingly being taken up by almost all countries. EU-funded projects reflect the state of these Actions: many countries are involved and efforts go further than providing insight and sharing knowledge, they aim at implementation. This means that these Priority Actions have a great potential for actual and EU-wide implementation.
- Priority Actions (PA) related to quality improvement programmes, organisational models and post-transplant follow-up (PA 2, 6 and 9) have been taken up by most countries. For these Priority Actions there is a great potential for mutual learning through an exchange of experiences. The uptake of these Priority Actions seems to have increased as compared to 2009.
- Fewer countries have taken up activities in relation to communication skills, cross-border donation, EU-wide agreements and accreditation systems (PA 4, 5, 7 and 10). One reason is that the meaning of these Priority Actions was not always clear to all CAs. It would therefore be beneficial to have further discussions on each of these Priority Actions in order to come to a shared, more precise and common understanding.

Although the Priority Actions are formulated as separate Actions, working on one Action may help the progress on other Actions. For instance, the implementation and accreditation of transplant donor coordinators (PA 1) may also support the promotion of quality improvement programmes (PA 2). This implies that the decision to work on certain PAs should be based on an analysis of how activities can be aligned so that they provide synergy. This would require CAs to define a roadmap for their national action plans that optimises synergy. CAs are suggested to consider defining a logical order in pursuing Priority Actions. An analysis of this order can lead to the construction of a roadmap. This roadmap provides a policy agenda that may help to align all activities on organ donation, thus supporting the effective use of scarce resources.

The role of the European Commission (EC) and other organisations

EC's action

The EC has several means to support the process of organ donation in member states. Firstly, there are two directives (Directive 2010/53/EU and implementing Directive 2012/25/EU) that put down binding requirements. Secondly, there is the EU Action Plan on Organ Donation and Transplantation. With regards to the legal mandate and to the Action Plan, the EC makes use of two additional tools or coordination mechanisms: financing projects from the public health programme and organising meetings of national CAs, working groups and workshops.

To promote the Action Plan, the EC primarily uses its coordination mechanism: it brings together expertise and authorities from all relevant States and involves them in the development and implementation of the Action Plan. The importance of biannual meetings of the CAs was underlined in this study, but the effectiveness could be further improved, for example by having less points on the agenda but more time for discussion on these different agenda points, or by putting presentations of the different speakers earlier at disposal of the whole CA group (these two points require coordination by the EC, but also the active involvement of CAs, who are actors of the discussions and often the speakers with presentations). In addition, opportunities are seen within the exploration of other EC funds, like structural funds or research funds. Some obstacles for Member States to implement some Priority Actions are the difference in national realities and the lack of resources and staff.

EU-funded projects

EU-funded projects may serve as a 'bottom-up' strategy to support the Action Plan: projects mobilise experts and expertise towards achieving the Priority Actions. Projects are not evenly distributed over the Priority Actions with some receiving more attention than others, not necessarily meaning that more progress is made when more projects are tied to one Priority Action. In addition, it is not always clear whether projects complement each other and whether new projects continue where previous projects have stopped. This could be improved. Another observation is that some new EU Members participate less in EU-funded projects or obviously participate in more recent projects. For the Action Plan to have an overall impact, a more active involvement of these countries might be beneficial.

A closer look at the projects suggests an evolutionary development has taken place. Early projects focused more on the issue of gathering information or expertise, followed by the development of tools and expertise, whereas later projects have a clearer focus on the exchange of knowledge and expertise. Over time, the main actors (in particular coordinators) of these projects have: with the adoption of the EU legislation and the creation/consolidation of CAs, the national organisations are now more often involved in the projects, in particular in the "Joint Actions". Direct implementation was hardly an objective of the projects. The EC through its funding primarily takes up a supportive role, leaving the final realisation of the Action Plan to the individual States. Since the establishment of a new Directive, a new instrument has become available in the form of these "Joint Actions", which have a great potential for implementation, involving more countries and at country-level the CAs.

Other organisations

The activities of the Council of Europe and the WHO provide an important context for the Action Plan. They provide a common ground of norms and principles regarding organ donation that is shared by many countries, such as the Oviedo Convention, stressing the ethics and fundamental rights of all people and the 'Guiding Principles', stressing issues like the voluntary character of donation and non-commercialisation. In addition, organisations foreseen in the Directive as "European Organ Exchange Organisations" (EOEOs), such as Eurotransplant, Scandiatransplant and now the Southern Transplant Alliance play a central role in the exchange of donor organs, but also function as a source of expertise. At national, but also international levels, professional societies also have a key role to play as a source of expertise. A key partner in this regard is the European Society for Organ Transplantation (ESOT), that has different sections and platforms, under which the "European Donation Committee" (EDC)

merged in September 2011 with the European Transplant Coordinators Organization (ETCO) to create a strong, visible and active section within ESOT. Other actors such as EASL (European Association for the Study of the Liver), EKHA (European Kidney Health Alliance), Donor action… can play an supporting role in the process of acquiring, disseminating and application of knowledge on organ donation, with some focus on specific aspects.

All in all

All in all, many activities within the context of the Action Plan have been undertaken. Progress on several Priority Actions has been made. But still there remains room for further developments. Countries differ in how the process of organ donation and transplantation is organised and in the issues they tackle. These differences can be rather substantial: some countries have a tightly monitored and well developed system of organ donation but still face a wide gap between the demand for donor organs and their supply. In other countries, a system for organ donation and transplantation is just being set up. The practical problems these countries face are different and often unique. Also the routes to tackle problems differ for different countries. Countries have different legal systems, the role of next-of-kin differs, and whereas in some countries living donation is vital in other countries it may be absent. The challenge for the EU will be to find a suitable answer to this diversity, through projects and supportive actions that take these differences into account. However, these differences also prove to be an opportunity for collaboration and sharing expertise for mutual learning. This should be used to its full potential.

1 Introduction and methods

1.1 Introduction

Due to medical advances over the past 50 years, organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the most cost-effective treatment for end-stage renal diseases, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment. Also most European countries increased their donor efficiency (Coppen, Friele, Gevers, Blok, & van der, 2008) in the last decade. In 2009, the European Union population amounted to about 500 million inhabitants.[4] During this year, nearly 29 000 transplants were performed within the 27 EU Member States. In spite of this, at the end of the same year, 67 000 patients still remained on waiting lists, irrespective of the type of organs, and 3 800 died while waiting for a new organ (Council of Europe, 2010). In 2011 the total number of transplants increased by 5% compared to 2009, to a total of more than 30.000 (Council of Europe, 2011). The demand for organs in the EU territory far exceeds the supply, which points to an organ shortage. This phenomenon is observed in every Member State, although to varying degrees, and it is the main topical issue in the field of organ transplantation, alongside its major consequences: organ trafficking and transplant tourism (Council of Europe, 2010; Council of Europe, 2011; European Commission, 2007).

The scarcity of organs has many intertwined causes, for example an increase in the number of indications for transplants, failure to detect brain-dead donors in intensive care units, family refusals, the way waiting lists are created and managed or more generally the way the health systems are organised nationally and even regionally. Organ scarcity is furthermore influenced by several complex factors that affect both its nature and extent (Abadie & Gay, 2006; Squifflet, 2011; Weimar, Bos, & Busschbach, 2011). While it may therefore be complicated to fully understand the issues concerned, there is nonetheless one clear trend, namely that organ shortage is an increasingly acute problem in the context of an ageing population. It will remain a concern even if the number of organ transplants steadily increases. The need to tackle the problem of organ shortage within this particular context has attracted widespread attention, not only within the individual countries, but also at the international level (Squifflet, 2011).Thus, governments and international organisations have been seeking ways to increase the availability of organs in order to reduce the gap in the waiting lists. One of these ways consists of enacting new legal instruments or bringing changes to the existing legal framework with the aim of encouraging the activity of transplantation and removing the remaining obstacles that impede it. As far back as the early 1990s, - through a Council Resolution - the subject of the availability of organs for transplants was considered a subject that warranted joint efforts between Member States and European Commission.[5] The Treaty on the functioning of the European Union (TFEU) reflects the willingness of EU Member States to work together on certain issues. This Treaty[6] has granted a specific competence to the EU to handle public health problems (article 168) relating to quality and safety of "substances of human origin" including quality and safety of human organs intended for transplantation (Hervey & McHale, 2004).

In 2007 the Commission adopted a Communication to the European Parliament and to the Council on

[4] http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&language=en&pcode=tps00001&tableSelection-=1&footnotes=yes&labeling=labels&plugin=1, Retrieved on 02-10-2012

[5] Res. (EC) of the Council and the Ministers for Health, meeting within the Council of 11 November 1991 concerning fundamental health-policy choices, J.O.C.E., C 304, 23 November 1991, pp. 5-6.

[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0047:0200:en:PDF

organ donation and transplantation,[7] outlining a set of actions the Commission was proposing to take to respond to the main policy changes in relation to organ donation and transplantation. In the following Impact Assessment,[8] a number of suggestions for actions (so-called "policy options") at Community and Member States levels were made. These were designed to help increase the supply of donor organs across the EU and to ensure the quality and safety of the procedures. This finally materialised in the adoption by the European Commission of an "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States"[9] (in short "the Action Plan") in December 2008 (see table 1.1). The Action Plan is a non-binding instrument that has been established and is complementary to the Treaty and to the organ-specific legislation developed since then (Directives 2010/53/EU and 2012/25/EU).

Table 1.1 Action Plan on Organ Donation and Transplantation (2009-2015)[10]

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

In the Action Plan, 10 Priority Actions are identified, assembled under 3 challenges: (1) increasing organ availability, (2) enhancing the efficiency and accessibility of transplant systems and (3) improving quality and safety. To increase organ availability Member States are recommended to reach the full potential of deceased donations by promoting the role of transplant donor coordinators (Priority Action 1) and Quality Improvement Programmes (Priority Action 2) in every hospital where there is a potential for organ donation. Furthermore, Member States are encouraged to promote the

[7] Communication from the Commission to the European Parliament and the Council Organ Donation and Transplantation: policy actions at EU level. Com(2007) 275 final

[8] 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; COM(2008) 819; SEC(2008) 2957

[9] Communication From The Commission Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States SEC(2008) 2956; SEC(2008) 2957

[10] A more detailed version of the Action Plan can be found in annex 2.

exchange of best practices on living donation programmes (Priority Action 3). In addition, the Action Plan proposes to increase public awareness of organ donation by improving the knowledge and communication skills of health professionals and patient support groups (Priority Action 4). Member States are also encouraged to facilitate organ donor identification and cross-border donation in Europe (Priority Action 5). With regard to enhancing the efficiency and accessibility of transplant systems, the Action Plan mentions improving the organisational models of organ donation and transplantation in the EU (Priority Action 6) and adopting EU-wide agreements on various aspects of transplantation medicine should be supported (Priority Action 7). Moreover, it proposes that the interchange of organs between national authorities should be facilitated (Priority Action 8). Finally, to improve quality and safety, the Action Plan suggests evaluating post-transplant results (Priority Action 9) and promoting a common accreditation system for organ donation/procurement and transplantation programmes (Priority Action 10).
Directly linked to each of these Priority Actions, some specific actions (28 totally) were also defined to help implementing concretely the goals proposed. These "sub-actions" will be looked at when considering each Priority Action.

Given the voluntary nature of this Action Plan, each Member State has a different starting position and is free to decide whether and how to follow these guidelines. In order to adapt measures to their own situation, needs and resources are to be translated into a Set of National Priority Actions,[11] following the structure of the EU Action Plan for the ease of comparison and discussion. These sets of National Priority Actions are regularly presented in Brussels, on a voluntary basis, by national authorities in charge during European meetings firstly called "Action Plan meetings", and - after the adoption of Directive 2010/53/EU in July 2010 - "Competent Authorities Meetings" (CA meetings).

The extensive therapeutic use of organs for transplantation demands that their quality and safety should be guaranteed as to minimise any risks, and the core legal mandate at EU level is focused on quality and safety aspects, for the legislation relating to blood, tissues and cells and also organs. Well organised national and international transplantation systems and the use of the best available expertise, technologies and innovative medical treatments may significantly reduce the associated risks of transplanted organs for recipients. To address the challenge of improving the quality and safety of organ donation and transplantation, the European Parliament and the Council adopted on 7 July 2010, based on drafts previously prepared and discussed by the European Commission and EU Member States, a Directive[12] which set minimum standards of quality and safety of organs, but does not prevent Member States from introducing or maintaining more stringent rules. This Directive 2010/53/EU applies to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation. The Competent Authorities (CAs) that must be designated within each Member State play the central role by being in charge of introducing, monitoring and ensuring the proper functioning of the whole national donation and transplantation system, notably by establishing a framework for quality and safety. CAs also play a vital role in the management of waiting lists and allocation, but this remains fully under national mandate, as well as consent systems, waiting lists management and allocation criteria, which are also essential aspects to take into consideration in the chain from donation to transplantation. Both, waiting lists and allocation, require fair and transparent management in order to gain/keep public trust.

The EU legal framework focusing on quality and safety via the National CAs covers the entire organ

[11] Communication From The Commission Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States SEC(2008) 2956; SEC(2008) 2957

[12] Directive 2010/53/EU of the European Parliament and of The Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. (2.08.2010)

donation chain right up to transplantation and the Directive points out specific elements at each stage of the chain. Organ procurement must be performed in optimal material and technical conditions by an organisation that has been authorised by the national CA. Throughout the whole process, the Member States must ensure the existence and proper functioning of a traceability system, as well as a reporting system and a management procedure for serious adverse events and reactions. They also have to ensure that health care personnel are suitably qualified or trained. Other provisions establish principles for protecting donors and recipients (altruism, non-payment, consent, etc.), support the exchange of information between CAs or set out the basis for organ exchanges.[13] EU Member States were expected to transpose the Directive 2010/53/EU by 27 August 2012 into national laws and the Commission has started a transposition check in March 2013. In order to look at the implementation, next to the transposition, the Commission will also launch an "implementation survey" by the end of 2013.

The ACTOR study aims to provide the European Commission and therefore also the EU Member States with an overview of the efforts during the first-half period of the Action Plan 2009-2015) and its state of implementation in every EU Member State as well as Iceland, Norway, Croatia, Macedonia (fYRoM), Switzerland, Turkey, Liechtenstein and Montenegro and at the EU level. The present study also offers more general information on organ availability and transplant systems.

The following objectives were formulated for the ACTOR study, in the original tender specifications drafted before applications of the contractors. They were divided into **four work packages (WP)** and formulated as follows:

WP1: To provide an assessment of organ donation and transplantation systems and activities in each of the Member States at different levels.

WP1 focuses on describing and evaluating organ donation and transplantation systems and activities in each of the EU Member State, and also - if possible - indications of activities for the EEA and candidates countries Croatia, Iceland, Liechtenstein, Norway, Macedonia (fYRoM[14]), Montenegro, Turkey and Switzerland.[15] For each Member State, country background data will be described before being analysed, such as the number of organ donations, the legislative framework and actual key figures on the involvement in de Action Plan. The efforts of every country will then be presented and assessed.

WP2: To provide a State specific mapping, analysis and assessment of the state of implementation of Priority Actions in each of the Member States.

WP2 focuses on providing a State specific mapping on the state of implementation of the 10 Priority Actions defined in the Action Plan. In order to perform this mapping, indicators for each of the priority areas were developed. The country-specific assessment on the state of implementation of the Action Plan includes not only activities already carried out, but also on-going and planned activities.

WP3: To provide an assessment of the engagement of Member States and Commission in common EU initiatives and the outcomes of these initiatives in relation to the 10 Priority Actions.
In the field of organ donation and transplantation, there is a large potential for exchange of

[13] http://ec.europa.eu/health/blood_tissues_organs/docs/organs_factsfigures_en.pdf, Retrieved on 02-10-2012

[14] former Yugoslav Republic of Macedonia

[15] for these non EU countries, less information might be available and as these countries are not bound to EU efforts, but just even more freely cooperating, it might also be that less information will be presented.

experiences and expertise among EU Member States. A good collaboration among EU Member States, as well as with the European Commission, can lead to improved quality and safety of organ transplantation, can help tackling the organ shortage problem and making transplantation systems more efficient and accessible. WP3 provides an assessment of engagement in common EU initiatives/projects for each of the relevant EU Member States as well as for the Commission. A first list of EU-funded projects[16] and activities is already provided for in the Tender specifications.

Within this WP, the assessment of the outcomes of these international co-operations is structured around the 10 priority areas specified in the Action Plan: the study will therefore provide a mapping of how these activities relate to the common objectives of the Action Plan. Additionally, this WP provides an overview and assessment of the interaction of the Commission Action Plan with the international initiatives undertaken by WHO, Council of Europe, Eurotransplant and Scandiatransplant, (international) professional associations and other relevant (international) initiatives.

WP4: To provide an assessment of strengths, weaknesses, opportunities and threats of and for the implementation of the Action Plan and recommendations for the second half-period of the Action Plan, both at EU and national level.

This fourth WP provides a summary of the previous WP 1-3 and analyses strengths and weaknesses for each of the 10 priority areas. Within this WP, challenges and gaps in the implementation of the Action Plan have been identified on country level, project level and EU level. Based on the findings, recommendations are proposed for the second-half period of the Action Plan. This report enables EU Member States as well as the European Commission to strengthen and, if necessary, to (re)focus their activities in the field of organ donation and transplantation from 2013 to 2015 in areas where gaps in the implementation of the Action Plan might be identified and to provide suggestions to reformulate some Priority Actions if needed.

These four work packages directly relate to the four tasks detailed - as well as the whole set-up of the service - in the Tender specifications for requesting specific services (N° EAHC/2011/Health/16), whereas the general frame for this service is provided for in the Framework contract N°EAHC/2010/Health/01 (lot 1: Health reports).

1.2 Methods

The study is based on a combination of desk research and consultations of experts through online structured questionnaires and focus groups, carried out by a multidisciplinary project team. The desk research was executed first (during the first half of 2012) to collect the information needed for WP1 to WP3. Secondly, Competent Authorities of all 35 countries included in the study were contacted and invited to check and confirm the collected data. After the Kick-off meeting with the contractor in January 2012, an announcement letter was prepared by the Commission to prepare the ground for a fruitful collaboration between the NIVEL ACTOR-research team and the CAs. Representatives for the CAs were asked to provide information on the Priority Actions in the Action Plan, based on their expertise and involvement in activities around organ donation and transplantation. Information in this report on developments related to the Action Plan is primarily based on their responses. In addition, information was used from publicly available information and from the presentations of their National Action Plans made by CAs during CA meetings in Brussels. Not all Competent

[16] A list of abbreviations and acronyms of the EU-funded projects, and of different organisations, can be found in annex 1.

Authorities may be fully aware of developments outside the scope of their activities on organ donation and transplantation, such as on specific EU-funding mechanisms. It should therefore be considered that this information, as presented in this report, may not always be complete. The research team was invited during the CA meetings in Brussels: to present the study beginning of March 2012 and to present preliminary results mid-September 2012 and final results in March 2013.

The research methods used for the various WPs will now be discussed.

Included countries

The following 35 countries are included in this study, with the following acronyms:
EU Member States: Austria (AUT), Belgium (BEL), Bulgaria (BGR), Cyprus (CYP), Czech Republic (CZE), Denmark (DNK), Estonia (EST), Finland (FIN), France (FRA), Germany (DEU), Greece (GRC), Hungary (HUN), Ireland (IRL), Italy (ITA), Latvia (LVA), Lithuania (LTU), Luxembourg (LUX), Malta (MLT), Netherlands (NLD), Poland (POL), Portugal (PRT), Romania (ROU), Slovakia (SVK), Slovenia (SVN), Spain (ESP), Sweden (SVN), United Kingdom (GBR)
Acceding countries: Croatia (HRV)
Candidate countries: Iceland (ISL) (EEA = European Economic Area), Macedonia (MKD, former Yugoslav Republic of Macedonia, fYRoM), Montenegro (MNE), Turkey (TUR)
Other European countries: Liechtenstein (LIE, EEA), Norway (NOR, EEA), Switzerland (CHE)

WP1 and WP2: Assessment of organ donation and transplantation activities and state of implementation of the Priority Actions in EU Member States

The data for WP1 consists of the provision of country background indicators, which were based on the existing indicators which are used by the European Commission and the European Transplant Community such as the Council of Europe annual Transplant Newsletters[17] prepared with the support of the Spanish Competent Authority ONT.

The indicators for WP2 measuring country actions which are in line with goals of the Action Plan were developed by the research team and based on the Priority Actions and sub-actions. These indicators were then transferred to a web-based database/survey, to be filled in by the CAs. The research team was frequently asked to limit the number of indicators' questions, for the ease of comparison and in order to minimise the burden of work for the CAs. Concepts that were multi-interpretable, unclear or in some other way problematic were therefore excluded. Also, some aspects, such as funding mechanisms or the organisation of organ donation and transplantation at hospital level, need far more elaboration and context than could be asked for in this database and were therefore similarly excluded. Still, in general formulations chosen were as close as possible to those in the Action Plan.

The indicators' questions were consequently checked by policy officers of the European Commission and volunteer CAs from the Netherlands, Norway and Spain. A number of very valuable comments were made during this feedback round. It was indicated that the terms "Quality Improvement Programmes", "altruistic donation" and "networks of centres of reference" were not entirely clear. Furthermore, it was remarked that the concept of expanded donor criteria was up for discussion. Also, the concept of National Action Plans did not always exist as separate concept. In concrete, some CAs had made use of the possibility to present their national situation and objectives in a PowerPoint Presentation during a CA meeting and some CAs had not (yet). Whether and how CAs had presented

[17] http://ec.europa.eu/health/blood_tissues_organs/docs/organs_factsfigures_en.pdf, Retrieved on 02-10-2012
http://www.edqm.eu/en/organ-transplantation-projects-1452.html
http://www.ont.es/publicaciones/Paginas/Publicaciones.aspx

these ‘National Action Plans’ is not necessarily indicative of their involvement, progress or degree of policy making related to the Priority Actions. Referring to the concept of National Action Plans in the questionnaire therefore caused ambiguity. For some countries such a document exists, but other countries have an organ donation policy, which entails domains as referred to in the Action Plan, without using the name ‘National Action Plan’.

After processing the feedback of the EC representatives and the CAs, the definite ACTOR database/survey was set up. Although the initial objective had been to incorporate questions from the (very first) 2009 Commission survey for the sake of comparison, the feedback on the questions led to decide against this. However, in the final analysis results of the 2009 assessment were used in as much as possible to determine changes over the years.

The final survey consisted of questions about involvement in projects, country background data and indicators following the 3 challenges and 10 Priority Actions of the Action Plan (see Annex 4, as well as Table 1.1 above). CAs were asked to answer 136 questions in total, of which 110 were more specifically on WP1 and WP2.

For WP1 and WP2, the desk research followed the same steps, providing a review of what is currently known in recent scientific and non-scientific literature and electronic information sources about the organisation of organ donation and transplantation in the countries involved. A first important source of information for the desk review was the dedicated page for CAs in charge of organ donation and transplantation on the collaborative platform CIRCA (BC). This is the internal platform used by the Commission to share documents and presentations with CAs, such as National Action Plans. This platform has been used by the Organs' CAs since February 2011 and the EC used the momentum of the 2012 review to update the page with documents from previous meetings and projects (2008, 2009, 2010), to enable wide access to CAs and NIVEL. The research team was granted access to this data and was therefore able to assess which topics and data Member States and EC are working on. The minutes of the CA meetings are also freely available to the general public on EC website.[18]

In addition, the electronic databases PubMed, Embase, and Google Scholar were searched for the period 2000-early 2012, without limits to the language used. In addition to the electronic databases, to cover relevant policy or professional literature on the subject, relevant websites dealing with “organ donation” or “organ transplantation” were searched using different searching engines such as Google. The websites that were screened included: the Ministries of Health, websites of the national organisations dealing with transplantation and organ donation (often designated as CAs), the websites of the European Commission (see Public Health > Blood, Tissues and organs[19]) and Executive Agency for Health & Consumers[20] (for EU-funded projects in the field), the websites of these projects and of European organisations dealing with organ donation and transplantation issues, such as ESOT, Eurotransplant and Scandiatransplant, as well as international organisations such as the Council of Europe and WHO. An overview of the references that were used is given in the annex of this report.

Last, national documents were screened for information on organ donation and transplantation. Information in languages unfamiliar to the research team was searched for and translated with the help of Google Translate. There was a substantial difference between countries in the quantity of documents found. However, because CAs were asked to upload any documents they found relevant, the research team believes that this search has been fairly comprehensive.

[18] For example: http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20110926_mi_en.pdf

[19] http://ec.europa.eu/health/blood_tissues_organs/organs/index_en.htm

[20] http://ec.europa.eu/eahc/projects/database.html

In the next step, country data were filled in in the ACTOR database/survey by the research team, to limit the work for the CAs. Subsequently, CAs of the 35 countries received an invitation per e-mail with login information to access the ACTOR database. Instructions on how to fill in the survey was presented in the database. CAs were asked to validate the answers that had already been filled in and to provide answers to the remaining questions. Initially, a period of three weeks was given to complete the survey. However, this proved too short for most CAs and after this first deadline the response was low. Taking into consideration the possibly inconvenient timing of the data collection in the summer period, it was decided to postpone the deadline with six weeks to give the CAs more time to complete the survey. After a total of nine weeks until the beginning of September, 28 countries reported that they had validated and completed the surveys. For these countries, there is data on a large part of the indicators, but not on all, since some questions have not been filled in by countries. For the remaining 7 countries, partial data were obtained based on publically available data which was found through the desk research. As a result, the response per indicator varies. This is always indicated in both the graphs and the accompanying text. Furthermore, it is important to stress that data were collected until the start of September. Data about developments after this date were therefore not included in this study.

For each question, CAs were given the opportunity to insert comments and upload relevant documents. The indicators proposed by the contractor for this study were checked in April 2012 by policy officers of the European Commission and CAs from the Netherlands, Norway and Spain. In spite of this, and because it is linked to the initial wording of the Action Plan, it was noticed that for a few country-representatives some definitions were still unclear. 'Organ trafficking', 'difficult to treat patients', 'structural funds and other Community instruments' were said to be vague or multi-interpretable. The data presented is therefore the data validated by CAs, or if they did not respond, the data found in other sources. Because of the structure of the online survey and the versatility of the matters touched upon, it may have been difficult for country-representatives to answer some of the questions. By providing them with the possibility of giving more information through comments or other documents, representatives were given an opportunity to further explain their country's situation.

Data obtained from the ACTOR database were transferred to a statistics software package.[21] Results of the implementation of the Action Plan are presented in two ways: 1) for each country individually and 2) as an overview for the 35 countries. On the individual country level, recommendations were made for every country separately based on the following considerations. In case of a country that has not taken up a certain Priority Action where several other countries have, it is suggested that this country might benefit from the experience of the other countries. For Priority Actions for which only few countries have taken up efforts, it was recommended that countries get together to redefine this Priority Action and to reconsider the ways countries could benefit from investing efforts in this subject. Finally, for Priority Actions that have been taken up by some countries, those that did not take up efforts are suggested to reconsider the importance of this Priority Action and the ways they could benefit from investing efforts in this subject.

On the EU-level an overview of the degree to which the Action Plan is taken up will be given, followed by recommendations on further steps. To be able to present a bird's eye view on the progress in the Action Plan for every Priority Action, one key indicator most closely related to the key issue in a Priority Action was selected by the research team (see Table 1.1). The scores on these indicators are presented in the bird's eye view (Fig 2.1, chapter 2.1)

[21] STATA version 11.2

Table 1.1 Key indicators per Priority Action

Priority Action	Key indicator chosen by research team
Priority Action 1: Promote the role of transplant donor coordinators	Have transplant donor coordinators been appointed in your country?
Priority Action 2: Promote Quality Improvement Programmes	Has the government stimulated initiatives to improve the quality of at least one of the following aspects of the organ donation process? - Identification of potential donors - The donation process - The procurement process - The transplantation process - Follow up care
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	Does your country have directed living donation programmes?[22]
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	Has your country implemented at least one of the following efforts concerning public awareness? - Communication guidelines for informing the public - Periodic meetings with journalists - Monitoring of mention in newspapers - Monitoring of mention on TV
Priority Action 5: Facilitate the identification of organ donors across Europe	Does your country provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU?
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Has your country been involved in twinning projects, peer reviews or similar projects?
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Is there at least one of the following agreements in place in your country concerning aspects of transplantation medicine? - Basic rules for internal EU patient mobility and transplantation - Transplant medicine for extra-Community patients - Monitoring organ trafficking - Common priorities and strategies for future research programmes
Priority Action 8: Facilitate the interchange of organs between national authorities	Is your country part of at least one of the following fixed collaborations with other countries? - Eurotransplant - Scandiatransplant - Bilateral collaborations - Other
Priority Action 9: Evaluation of post-transplant results	Does your country evaluate post-transplant results of organ recipients on a national level?
Priority Action 10: Promote a common accreditation system	Are there additional plans or actions regarding Priority Action 10 that are undertaken in your country?

The country sheets, once completed, were sent to all CAs for a final validation (in April 2013).

WP3: Assessment of the engagement of Member States and Commission in common EU projects

For data about EU-funded projects and EC-managed activities, the search strategy, study selection, inclusion process and analysis of the scientific literature were similar to the desk research for the country data, but with adjustments in the search terms. Data which were found concerning participation in countries in these kinds of projects or other activities were again filled in in the ACTOR database/survey by the research team, to limit the strain for CAs.

The search of non-scientific literature was also similar to the desk research on the level of Member States, but with adjustments in the search terms. In addition, the research team once more consulted the websites of the European Commission and the Executive Agency for Health and Consumers (EAHC), as well as the websites of European organisations and networks dealing with organ donation and transplantation issues, namely Council of Europe, WHO, ESOT, Eurotransplant and

[22] "Directed living donation programmes" are living donation programmes with related donors.

Scandiatransplant. Special efforts were directed at assessing the contribution of the different European projects that focus on donation and transplantation, namely ETPOD, EULID, EULOD, EFRETOS, ELIPSY, EDD, COORENOR, ODEQUS, ELPAT, MODE, ACCORD, Train the trainers and FOEDUS. Websites of these projects were used as a primary source of information. Furthermore, mid-term and/or final reports and products were gathered at the EAHC in Luxembourg and analysed. The engagement of involved countries as well as of the European Commission was assessed, together with the impact of the projects on the goals of the Action Plan. Next to the European projects mentioned, information on EU activities as conferences, expert meetings and journalist workshops in the area of organ donation were also screened for relevant data. For this purpose, the research team undertook a visit in May 2012 to EAHC's office, to assess documented information on the projects. Finally, two CA meetings were attended in March and September 2012, both to present the ACTOR study and progress made as well as to learn from the discussions in the CA group. Additional information was gathered thanks to these meetings that put already available documents in context.

WP4: Assessment of strengths, weaknesses, opportunities and threats and recommendations for further implementation of the Action Plan

After organising and describing the data the process of analysis started. For every Priority Action an indicator was chosen that most accurately described or included the relevant key actions. This was done as to make progress on the different Priority Actions visible and comparable. For all countries, their progress on these indicators is demonstrated in a graph on their country sheet (chapter 2.2). At the aggregated level, progress of the countries on the various Priority Actions is made visible in chapter 2.1. Also, based on these indicators, an analysis of the opportunities and threats to the successful implementation of the Action Plan is provided.
The projects were looked at, analysed and sorted out by their type of action (knowledge acquisition, development of tools, exchange of knowledge and implementation) to give insight into their exact relation to the Action Plan. For all projects, the link to the relevant Priority Actions was also determined. These overviews make it possible to clearly describe the focus of projects up until now and the types of actions deployed in relation to the 10 Priority Actions.

The final assessments were presented to the project leaders of the projects, the national contacts and the Commission for validation, through surveys and an online focus group. The European organisations and projects mentioned earlier and the European Commission were also contacted for additional information and for validation of the information gathered by the research team via desk research at the European level. A set of main conclusions of the study were presented to the CAs by means of an online focus group to gather extra input. The CAs were able to log in and discuss the results of this study online. Initially they were given 10 days to participate, but due to continued interest this was extended to a period of 4 weeks in September 2012. In total, CAs from 11 countries participated in the online discussion. The overviews of activities by both Member States and the European Commission give a clear insight into progress made on the various Priority Actions.

In the following chapters of this report the results of the work packages will be presented in the order of the work packages (WP1 to WP4).
This study relied on a great variety of information sources such as the input of country representatives, publicly available information, information on the CIRCA platform, personal communications during and around the meetings of competent authorities an information from the EAHC. This lead to a great variety in information, that had to be related to the Action Plan. The amount and diversity of the available information was rather impressive, reflecting the diversity and the amount of the work that is done in this area.

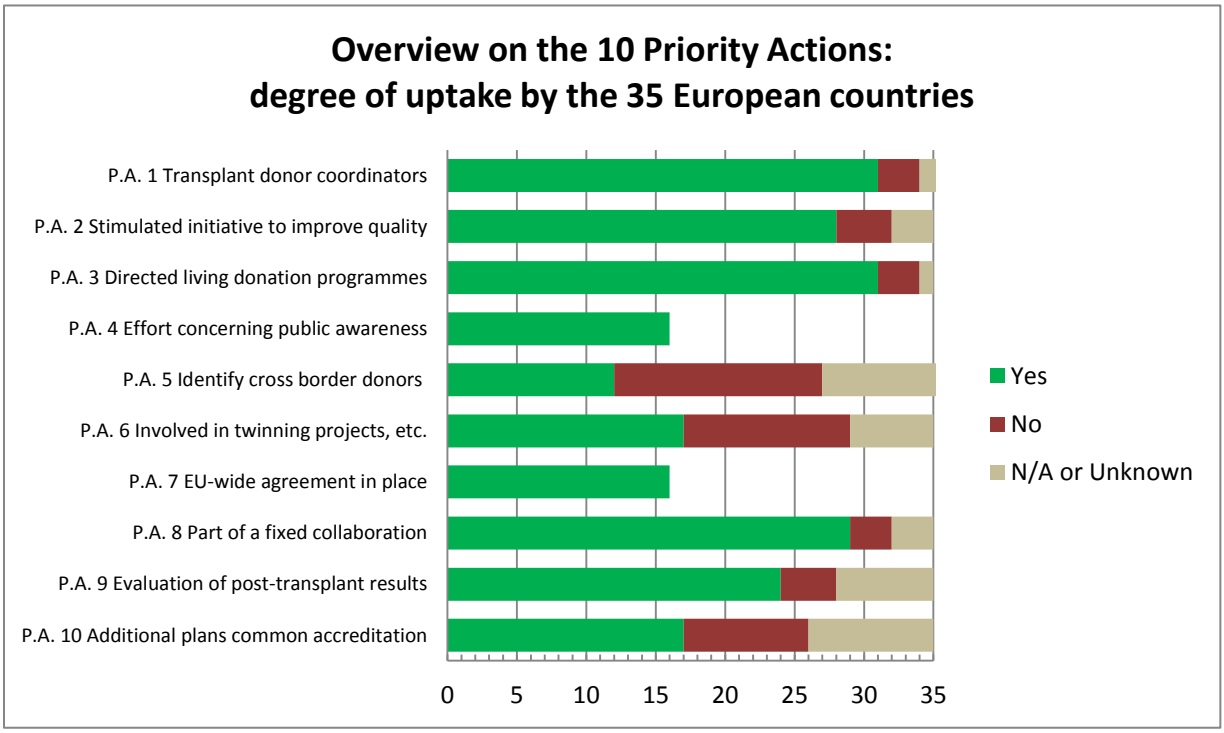
2 The implementation of the EU Action Plan at national level in 35 European countries

2.1 Introduction

In this chapter, an overview is given of the implementation of the Action Plan in the 35 countries included in the study (all 27 EU Member States as well as Iceland, Norway, Croatia, Macedonia (fYRoM), Switzerland, Turkey, Liechtenstein and Montenegro). The results are based on the data gathered in the ACTOR survey/database. These data were either found through desk research and validated by the CAs, or provided directly by them.
First, a bird's eye view of these data is presented, based on a selection of indicators as presented in table 1.1, in the previous chapter. Secondly, results are presented for individual countries and finally results are presented about the implementation of the Action Plan as a whole.
Furthermore, it is important to stress that data were collected until early September 2012. Data about developments after this date were therefore not included.

Before presenting results on a national, country-specific basis, a first general overview can be given here, for capturing a first impression and set the context:

Figure 2.1[23]



Yes: indicates that countries have taken up this action
No: indicates that countries have not taken up this action
N/A: indicates that countries did not provide information, nor that information could be retrieved from other sources.

This overview shows that there is variety to the degree in which activities have been carried out. In addition, it is important to note that a "yes" (country has taken up this action) does not always mean

[23] For the key indicators for P.A. 4 and 7 it was not possible to adequately distinguish between the answers No / No, not yet, N/A and Unknown, therefore only the number of countries that have at least implemented one effort are presented.

a full/comprehensive/final "yes": some sub-actions might have been taken but are still on-going, some other sub-actions might not (yet) been taken up… Therefore this overview provides an impression of where some efforts have been made. For a number of Priority Actions, efforts have been carried out by almost all countries. The results show that almost all country-representatives indicate that transplant donor coordinators have been appointed, that directed living donation programmes have been set up and that there has been participation in fixed collaborations. However, other Priority Actions were only taken up by a minority of countries. This is for instance the case with efforts concerning public awareness, EU-wide agreements and common accreditation systems.
A more detailed description of the results, for each Prioriy Action, will be provided in the subsequent subchapters. First, information on the individual countries is presented, followed by an overview of the 35 countries altogether.

2.2 Individual country background data and implementation Action Plan (WP1 and WP2)

In this chapter, an overview is given of background data on organ donation and transplantation for each of the 35 countries included in this study (WP1). Also, their actions related to the ten Priority Actions are summarised (WP2). The results are based on data found through desk research or data provided or validated in the ACTOR survey/database.[24]

Results give a general description of the organ donation and transplantation systems in the countries in this study. National data are presented on the organ consent system,[25] donation (living and deceased), transplantation activity, waiting list and family refusal. In addition, information is provided about the country's involvement in EU-funded projects and the national legislative framework concerning organ donation in the country in question. Furthermore, similar to the bird's eye view presented in chapter 2.1 an overview is given of the activities undertaken by the country regarding the Action Plan, incorporating one key indicator of each Priority Action (for a complete description see Table 2.1, p. 11-12). Last, country-specific recommendations are given relating to the Priority Actions.
As said, some questions might not have been filled in by the CAs. The research team tried to collect the missing data through publicly available information. As a result, the response per indicator varies, and for some countries not all information is available.

Common sources used for all countries (this will therefore not be repeated in each country sheet):

Council of Europe (2009). *Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity*. Year 2008 Strasbourg: Council of Europe.

Council of Europe (2011). *Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2010* Strasbourg: Council of Europe.

Council of Europe (2012). *Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2011* Strasbourg: Council of Europe.

[24] The questions of this survey can be found in Annex 4

[25] Basically, two main kinds of consent systems can be distinguished: systems of explicit consent and systems of presumed consent. In the former the donor himself has to authorize or to refuse organ removal after his death. This system is also called "opting in" or "contracting in". In the so called presumed consent or "opting out" or system, no explicit consent is required in order to be a potential donor: it is sufficient that the deceased person has not objected during his life according to national law (Nys, 2007). In addition, some different practicalities exist around consent systems: existence (or not) of registers for the "yes" or "no" to donation.

1. Austria

Background information[26]

In Austria the first human kidney transplantation was performed in 1965. The first combined liver and kidney transplantation was performed in 1983, as well as the first heart transplantation.

With a **deceased donation rate** per million population higher than 20 in 2011, Austria's deceased donation rate per million population is amongst the highest of the countries in this study. However, it is indicated that there are extreme differences in the emergence of deceased donors between regions / Federal States. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a **living kidney donation** rate per million population lower than 10 in 2011, Austria's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver. Austria is part of Eurotransplant[27] and donor organs are allocated through Eurotransplant (IT system).

Regarding EU-funded projects Austria was initially work package leader in EDD[28], but withdrew from this position and was replaced by Croatia. Austria was also initially work package leader in COORENOR, but withdrew from this position and was replaced by France. The country was furthermore an associated partner in two projects, namely ETPOD and ODEQUS.

In 2011 the country participated in the working group on indicators[29]. In addition, it is a member of the Council of Europe "Committee (Partial Agreement) on Organ Transplantation" (CD-P-TO[30]).

A National Action Plan was presented at a Competent Authority meeting in September 2011.

Financing of organ donation

In case of deceased donation, the costs are covered by the national health insurance of the recipient. In case of living donation, all costs connected to the organ removal and the preparations are covered by the donor's health insurance. The cost of the implantation is covered by the recipients' health insurance.

Consent system

Since 1982, an **opting-out system** is in place, in which organ retrieval is not possible when a person has explicitly indicated refusal to post mortem donation. Refusals are **registered** in the opting-out register kept by the Austrian Health Institute. **The next-of-kin** are not legally provided with any means of intervention preceding the removal when no objection of the deceased has been recorded. However, in practice it is likely that in most cases the next-of-kin are informed about an intended organ removal.

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[26] **Sources for Austria, in addition to common sources**: ACTOR survey filled in by national Competent Authority,
Competent Authority Austria. (2011). Presentation National Action Plan Austria, September 2011.,
Information provided by H. Nys, November 2012,
Lopp, L. (2012). Final Report: A Common Frame of Reference for European Laws on Living Organ Donation, Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe / Part I: Unrelated Organ Donation (EULOD project) EULOD,
Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven,
Transplant Jahresberichte 2008 und 2010 (Annual reports 2008 and 2010 of the Austrian Coordination office).

[27] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR (but left the project after one year, even if it was Work Package coordinator).

[28] For more information about EU-funded projects, see §3.1

[29] For more information about the working groups, see §3.2

[30] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	8.3	8.4	8.4
Family refusal rate (refusals/times asked)	53/158	-	-
Actual deceased donation rate (total/per million population, pmp)	167/20.1	191/22.8	205/24.4
Multi-organ donation rates (% of total)	76.7	81.6	72.7
Number of utilised donors (total/pmp)[31]	-	-	-
Number of donors after circulatory death - DCD	3	-	6
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	-	-	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	303/36.5	348/41.4	360/42.9
Liver	112/13.5	139/16.5	126/15
Heart	62/7.5	69/8.2	51/6.1
Lung	119/14.3	114/13.6	120/14.3
Pancreas	34/4.1	39/4.6	16/1.9
Number of living donor transplant procedures (total/pmp)			
Kidney	58/7.0	58/6.9	55/6.5
Liver	4/0.5	2/0.2	2/0.2
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	883	810	743
Liver	113	137	112
Heart	59	74	67
Lung	62	58	66
Pancreas	37	26	17
Number of mortalities while on waiting list			
Kidney	39	39	45
Liver	31	40	36
Heart	7	7	9
Lung	13	9	20
Pancreas	-	1	3

- = unknown to the research team

[31] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the local/hospital and the regional level. It is indicated that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the government has stimulated initiatives to improve the quality of the donation process, the procurement process and the transplantation process.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	The country-representative indicates that directed living donation programmes exist, but that they are not regulated by law, although there is a "position paper". It is reported that there are no undirected living donation programmes in Austria. In addition, it is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals. It is reported that these kinds of programmes do not exist for patient support groups. The country-representative reports that no efforts have been made with regards to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV and organising periodic meetings with journalists. In 1998 Austria organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative reports that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also reports that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Austria indicates that it has been involved in a twinning project with Cyprus, Estonia, Hungary, Slovakia and Slovenia on lung transplantation.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that Austria has no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Austria is part of Eurotransplant and has a bilateral collaboration with Southern Tyrol, Italy, and Hungary.
Priority Action 9: Evalua-tion of post-transplant results	It is reported that post-transplant results of organ recipients are evaluated. It is unknown to the research team at which moments post-transplant results are measured.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the identification of potential donors and follow-up care.

With regard to **Priority Action 3**, Austria could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Actions 4, 5 and 7**, it could be beneficial for Austria to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Austria could benefit from investing efforts in these subjects.
With regard to Priority Action 10 other countries could benefit from Austria sharing its experiences with these efforts. Furthermore, it could be beneficial if Austria comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action.

2. Belgium

Background information[32]

With a deceased donation rate per million population higher than 20 in 2011, Belgium's deceased donation rate per million population is amongst the highest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas. With a living kidney donation rate per million population lower than 10 in 2011, Belgium's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver. Belgium is part of Eurotransplant[33] and donor organs are allocated through Eurotransplant.

Regarding EU-funded projects, Belgium was core work package leader in the EU funded project EULOD[34] and is associated partner in FOEDUS.

In 2010 and 2011 the country participated in the working group on indicators[35]. Furthermore, it participated in the working group on deceased donation and the working group on living donation. In addition, Belgium is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[36]).

A National Action Plan was presented at a Competent Authority meeting on 25-26 November 2009.

Financing of organ donation

In case of deceased donation, the financial intervention is regulated by the National Health Care. Moreover, for each organ of a donor that is transplanted, the intensive care receives a conditional financial support. The surgical team also receives financial support for each organ used for transplantation. The transplant team receives a financial support for the organisation of a transplant. In case of living donation, a state owned or state-controlled institution pays the expenses incurred by the donor.

Consent system

Since 1986, an opting-out system is in place, in which Belgian citizen or resident in Belgium since 6 months is a donor except when the person himself/herself has given objection. Belgian citizen or resident in Belgium since 6 months can go to the townhouse for registration in the national donor register (consent or objection).

If the deceased has given explicit consent, no objection to organ removal is possible. Physicians have to inquire about the existence of an objection expressed by the donor: via the official registries and contact with next-of-kin of the deceased.

If the deceased is not Belgian citizen or resident in Belgium since 6 months, she/he must have expressly given her/his consent for the procurement.

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[32] **Sources**: ACTOR survey filled in by national Competent Authority, and information additionally provided,, Competent Authority Belgium. (2009). Presentation National Action Plan Belgium, 25-26 November 2009, Information provided by H. Nys, November 2012.

[33] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR.

[34] For more information about EU-funded projects, see §3.1

[35] For more information about the working groups, see §3.2

[36] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	10.7	10.8	11
Family refusal rate (refusals/times asked)	-	-	-
Actual deceased donation rate (total/pmp)	265/24.8	263/24.3	331 / 30.1
Multi-organ donation rates (% of total)	73.6	74.9	77.3
Number of utilised donors (total/pmp)[37]	-	-	-
Number of donors after circulatory death - DCD	48	45	64
Number of donors older than 65	38	50	-
Number of transplant centres			
Kidney	-	-	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	448/41.9	408/37.8	474/43.1
Liver	217/20.3	228/21.1	264/24
Heart	75/7.0	67/6.2	76/6.9
Lung	149/13.9	197/18.2	111/10.1
Pancreas	51/4.8	40/3.7	14/1.3
Number of living donor transplant procedures (total/pmp)			
Kidney	45/4.2	49/4.5	40/3.6
Liver	13/1.2	33/3.1	35/3.2
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	813	914	883
Liver	189	193	172
Heart	43	67	59
Lung	76	90	119
Pancreas	27	39	51
Number of mortalities while on waiting list			
Kidney	18	34	35
Liver	44	47	54
Heart	19	18	23
Lung	6	6	8
Pancreas	1	-	1

- = unknown to the research team

[37] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital and the regional level. The country-representative indicates that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process and the procurement process.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	The country-representative indicates that directed living donation programmes exist, as well as undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors, but that it is planned to establish them in 2013, as required by Directive 2010/53/EU. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, the country-representative indicates that mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented. It is unknown to the research team if **c**ommunication guidelines for informing the public about organ transplantation have been set up. If this is not the case, Belgium **could** benefit from investing in setting up this kind of guidelines. In 2013 Belgium will organise the European donation day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also indicated that there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation & transplantation	Belgium indicates that it has not been involved in any twinning projects on this topic. Belgium contributed in the Working Group on deceased donation, on how to set up transplant donor coordination.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that Belgium has no agreements in place regarding organ trafficking. It is unknown to the research team whether there are agreements in place about basic rules for internal EU patient mobility and transplantation or, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Belgium is part of Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	The country-representative indicates that post-transplant results of organ recipients are evaluated. It is unknown to the research team at which moments post-transplant results are measured.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regards to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the transplantation process and follow up care.

Regarding **Priority Actions 4, 5 and 10** other countries could benefit from Belgium sharing its experiences with these efforts. Furthermore, it could be beneficial if Belgium comes together with countries who have not taken up efforts on these Priority Actions to help redefine them.
Regarding **Priority Action 7**, it could be beneficial for Belgium to come together with countries who have taken up efforts regarding this Priority Action to help redefine it and to reconsider the ways Belgium could benefit from investing efforts in these subjects.

With regards to **Priority Action 6**, Belgium could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

3. Bulgaria

Background information[38]

With a deceased donation rate per million population under 10 in 2011, Bulgaria's deceased donation rate per million population is amongst the lowest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, and heart. With a living kidney donation rate per million population lower than 10 in 2011, Bulgaria's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver. Donor organs are allocated at national level.

Regarding EU-funded projects Bulgaria was leader of a core[39] work package in the projects EULOD[40] and was an associated partner in ETPOD and is an associated partner in ACCORD and FOEDUS.

In 2010, 2011 and 2012, the country participated in the data collection under the working group on indicators[41]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[42]).

Financing of organ donation

In case of deceased donation, financing is regulated by the Law on Transplantation of Organs, Tissues and Cells, Regulation No. 29/2007. In case of living donation, a state owned or state-controlled institution pays the expenses incurred by the donor, based on the Law on Transplantation of Organs, Tissues and Cells Regulation No.29/2007.

Consent system

Since 2007, an **opting-out system** is in place.

[38] **Sources**: ACTOR survey filled in by national Competent Authority, Information provided by H. Nys, November 2012,
Lopp, L. (2012). Final Report: A Common Frame of Reference for European Laws on Living Organ Donation, Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe / Part I: Unrelated Organ Donation (EULOD project) EULOD.

[39] Core means that the focus of the work package is more on the content of organ donation and transplantation, while other types of work packages are more focused on coordination, evaluation and dissemination of the results.

[40] For more information about EU-funded projects, see §3.1

[41] For more information about the working groups, see §3.2

[42] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	7.0	7.5	7.4
Family refusal rate (refusals/times asked)	8/10	4/24	3/10
Actual deceased donation rate (total/per million population)	8/1.1	20/2.7	4/0.5
Multi-organ donation rates (% of total)	70	80	50
Number of utilised donors (total/per million population)[43]	-	-	-
Number of donors after circulatory death - DCD	-	-	0
Number of donors older than 65	0	0	-
Number of transplant centres			
Kidney	-	4	6
Liver	-	2	2
Heart	-	2	2
Lung	-	1	0
Pancreas	-	0	0
Number of deceased donor transplant procedures (total/pmp)			
Kidney	8/1.1	36/4.8	8 / 1.1
Liver	5/0.7	13/1.7	3/0.4
Heart	3/0.4	5	2/0.3
Lung	0	0	0
Pancreas	0	0	0
Number of living donor transplant procedures (total/pmp)			
Kidney	11/1.6	12/1.6	9/1.2
Liver	4/0.6	2/0.3	3/0.4
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	811	600	950
Liver	52	26	27
Heart	45	25	28
Lung	76	6	-
Pancreas	27	-	0
Number of mortalities while on waiting list			
Kidney	-	76	2
Liver	5	10	4
Heart	8	8	1
Lung	6	0	0
Pancreas	1	-	0

- = unknown to the research team

[43] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital level. The country-representative indicates that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process and the procurement process.
Priority Action 3: Exchange of best practices on living donation programmes	The country-representative indicates that there are no directed or undirected living donation programmes in Bulgaria. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	Bulgaria indicates that no efforts have been made with regards to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV and organising periodic meetings with journalists. In addition, it is indicated that there are no programmes deployed to improve knowledge and communication skills of health professionals and patient support groups.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU, but that it is intended. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is indicated that under the Joint Action ACCORD Bulgaria is involved in a twinning project with France on assisting Member States in reaching the full potential of deceased and living organ donation.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Bulgaria indicates that there are agreements in place organ trafficking, since they have signed the Declaration of Istanbul on Organ Trafficking and Transplant Tourism. Other countries could benefit from Bulgaria sharing its experiences with this effort. Furthermore, it could be beneficial if Bulgaria comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. It is indicated that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes. It could be beneficial for Bulgaria to further look into setting up these kinds of agreements.
Priority Action 8: Facilitate the interchange of organs between national authorities	It is indicated that Bulgaria is not part of any fixed collaborations with other countries for the interchange of organs between national authorities. The country-representative does indicate that there is a collaboration within the Joint Action ACCORD until 2015.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3 and 12 months after transplantation and the rest of a patient's life.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the transplantation process and follow up care.

With regard to **Priority Actions 3 and 8**, Bulgaria could benefit from the experiences that other countries have with these Priority Actions. This is especially relevant for Priority Action 3, since living donations are carried out in the country. With regard to Priority Action 3, Bulgaria could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Actions 4, 5 and 10**, it could be beneficial for Bulgaria to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways it could benefit from investing efforts in these subjects.

With regard to **Priority Action 7**, other countries could benefit from Bulgaria sharing its experiences with agreements to monitor organ trafficking. On the other hand, it could be beneficial for Bulgaria to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.

4. Croatia

Background information[44]

With a deceased donation rate per million population higher than 20 in 2011, Croatia's deceased donation rate per million population is amongst the highest of the countries included in this study. In 2012, Croatia even obtained among the highest rates for deceased donation and kidney transplants over the world. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart and pancreas. With a living kidney donation rate per million population lower than 10 in 2011, Croatia's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding liver and kidney. Croatia is part of Eurotransplant[45] and donor organs are allocated through Eurotransplant.

Regarding EU-funded projects Croatia was core work package leader in the project EDD[46] (replacing Austria) and associated partner in ODEQUS, and partner in DOPKI. The country is an associated partner in ACCORD and FOEDUS.

In 2011 and 2012, the country participated in data collection for the Working group on indicators[47]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[48]).

A National Action Plan was presented at an Action Plan meeting (future Competent Authority meeting) on 25-26 November 2009.

Financing of organ donation

In case of deceased donation, incentives are paid to the donor hospital.

Consent system

An **opting-out system** is in place.

[44] **Sources**: ACTOR survey filled in by national Competent Authority,
Competent Authority Croatia. (2009). Presentation National Action Plan Croatia, 25-26 November 2009,
Eurotransplant (2009). Yearly Statistics 2008, Eurotransplant (2011b). Yearly Statistics 2010.

[45] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR.

[46] For more information about EU-funded projects, see §3.1

[47] For more information about the working groups, see §3.2

[48] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	4.4	4.4	4.4
Family refusal rate (refusals/times asked)	-	32/167	42/192
Actual deceased donation rate (total/per million population)	83/18.7	135/30.7	150/34
Multi-organ donation rates (% of total)	83.1	85.8	87.8
Number of utilised donors (total/per million population)	79/17.6	127/28.6	144/33.5
Number of donors after circulatory death - DCD	0	0	-
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	-	4	4
Liver	-	3	3
Heart	-	2	2
Lung	-	0	0
Pancreas	-	1	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	149/33.9	224/50.9	228/51.8
Liver	64/14.5	103/23.4	121/27.5
Heart	20/4.5	36/8.2	38/8.6
Lung	-	-	-
Pancreas	14/3.2	6/1.4	12/2.7
Number of living donor transplant procedures (total/pmp)			
Kidney	9/2.0	20/4.5	9/2.0
Liver	1/0.2	2/0.5	3/0.7
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	349	225	172
Liver	61	75	78
Heart	18	11	21
Lung	-	0	-
Pancreas	3	1	9
Number of mortalities while on waiting list			
Kidney	5	-	11
Liver	23	-	18
Heart	7	-	12
Lung	-	-	-
Pancreas	1	-	1

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital and the national level. The country-representative indicates that these transplant donor coordinators receive initial training at the moment of appointing.
Priority Action 2: Promote Quality Improvement Programmes	The country-representative indicates that the government has stimulated initiatives to improve the quality of the donation process and the procurement process.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is indicated that directed living donation programmes exist, as well as undirected living donation programmes. It is furthermore indicated that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	The country-representative indicates that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that communication guidelines for informing the public exist, mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is unknown to the research team whether additional plans or actions are undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Croatia indicates that it has been involved in a twinning project with Austria, in the framework of the University of Vienna Lung Transplant Program.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Croatia indicates that it has agreements in place regarding basic rules for internal EU patient mobility and transplantation. It is unknown to the research team whether there are agreements in place about transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Croatia is part of Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	Croatia indicates that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the identification of potential donors, the transplantation process and follow up care.

With regard to **Priority Actions 4, 5, 7 and 10**, other countries could benefit from Croatia sharing its experiences with these efforts. Furthermore, it could be beneficial if Croatia comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions. Regarding Priority Action 7 it could be beneficial for Croatia to further look into setting up agreements regarding transplant medicine for extra-Community patients, monitoring of organ trafficking or common priorities and strategies for future research programmes.

5. Cyprus

Based on publicly available information

Background information[49]

With a deceased donation rate per million population under 10 in 2011, Cyprus' deceased donation rate per million population is amongst the lowest of the countries included in this study. In 2011, deceased donor transplant procedures were only carried out regarding kidney.
With a living kidney donation rate per million population higher than 10 in 2011, Cyprus' living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 transplant procedures from living donors were carried out for kidney transplants only.

Regarding EU-funded projects Cyprus was initially core work package leader in the EU funded project ELIPSY[50], but withdrew from this position.[51] Furthermore, it was an associated partner in the projects ETPOD, COORENOR and EULID. In COORENOR, Cyprus withdrew from participation. It is an associated partner in ACCORD and FOEDUS.

In 2011 and 2012, the country participated in the annual data collection of the working group on indicators[52]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[53]).
Cyprus, during its Presidency of the council of the EU in the second half 2012, decided to put organ donation and transplantation as a priority on the political agenda for health topics. Under the Cypriot leadership and with the support of the European Commission and other Member States, Council conclusions[54] were adopted by all EU Health Ministers on 7 December 2012, covering various aspects of organ donation and transplantation tackled in the Action Plan, and encouraging Member States and Commission to continue their common efforts towards more and safer transplants.

Financing of organ donation

In case of living donation, the costs and expenses related to the living donation are directly funded by the insurance of the donor.

Legislative framework

No information available to the research team

[49] **Sources:** Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[50] For more information about EU funded projects, see §3.1

[51] Personal communication with policy officer European Commission

[52] For more information about the working groups, see §3.2

[53] For more information about CD-P-TO, see §3.3

[54] Council conclusions on organ donation and transplantation (2012/C 396/03)
http://ec.europa.eu/health/blood_tissues_organs/docs/organs_council_ccl_2012_en.pdf

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	0.7	0.9	1.1
Family refusal rate (refusals/times asked)	-	3/7	3/9
Actual deceased donation rate (total/per million population)	13/18.6	4/4.4	6/5.5
Multi-organ donation rates (% of total)	100	100	100
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	-	0	-
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	1	1	2
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	24/34.3	8/8.9	12/10.9
Liver	-	-	0
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of living donor transplant procedures (total/pmp)			
Kidney	34/48.6	24/26.7	19/17.3
Liver	-	-	-
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	111	100	41
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	3	5	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the national level. It is reported that these transplant donor coordinators receive training through Transplant Procurement Management (TPM) courses, more specifically Training for Trainers in organ donation.
Priority Action 2: Promote Quality Improvement Programmes	It is reported that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is reported that directed living donation programmes exist and that there are no undirected living donation programmes in Cyprus. It is reported that there are no registers established yet to evaluate and guarantee the health and safety of living donors, but that these are intended for in the future.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is reported that programmes have been deployed to improve knowledge and communication skills of health professionals and patient support groups. It is reported that no efforts have been made with regard to monitoring mention of organ transplantation in newspapers or on TV and organising periodic meetings with journalists**.** It is unknown to the research team if communication guidelines for informing the public about organ transplantation have been set up. In 2003 Cyprus organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is reported that Cyprus provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is unknown to the research team whether additional plans or actions are undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is reported that Cyprus has been involved in a twinning project with Italy. It is reported that the subject of the project was to develop a system for accreditation and audit of donation and transplantation activities, based on the Italian Model. Austria indicated that they have been involved in twinning project with Cyprus on lung transplantation.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether there are agreements in place in Cyprus regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	It is unknown to the research team if Cyprus is part of any fixed collaborations with other countries for the interchange of organs between national authorities.
Priority Action 9: Evaluation of post-transplant results	It is unknown to the research team if post-transplant results of organ recipients are evaluated.
Priority Action 10: Promote a common accreditation system	It is reported that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 2, 5 and 10**, other countries could benefit from Cyprus sharing its experiences with these efforts. Furthermore, it could be beneficial if Cyprus comes together with countries who have not taken up efforts on these Priority Actions to help redefine them.
With regard to **Priority Actions 3 and 8**, Cyprus could be able to benefit from the experiences that other countries have with these Priority Actions. This is especially relevant for setting up registers for living donors, since living donations constitute an important part of the Cypriot organ donation system, and since it becomes mandatory with the Directive 2010/53/EU.
With regard to **Priority Actions 4 and 7**, it could be beneficial for Cyprus to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways Cyprus could benefit from investing efforts in these subjects.
With regard to **Priority Action 9**, Cyprus could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

6. Czech Republic

Background information[55]

With a deceased donation rate per million population between 10 and 20 in 2011, the Czech Republic belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Czech Republic's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney. Donor organs are allocated at national level.

Regarding EU-funded projects the Czech Republic was core work package leader in COORENOR[56], MODE and was an associated partner in EFRETOS and EDD, and partner in DOPKI. It is a core work package leader in FOEDUS and an associated partner in ACCORD.

In 2010 and 2011, the country participated in the annual exercise on indicators[57]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[58]).

A National Action Plan was presented at a Competent Authority meeting on 25-26 November 2009.

Financing of organ donation

In case of living donation, the recipient's health insurance has to cover all costs connected to the living organ donation. In addition, the medical institution has the duty to take out insurance for the donor that covers all injuries that might result due to the organ removal.

Legislative framework

Since May 30th 2002 an opting-out system is place. Removal from the body of a deceased person can only be performed if the deceased during his/her lifetime, or a legal representative of a minor, or a legal representative of a legally incompetent person have not demonstrably expressed his/her disapproval. This is registered with the National Registry of Persons Disapproving to Post-mortem Removal of Tissues and Organs, or recorded in the person's medical record.
In the event of not being established that a deceased has during his/her lifetime demonstrably expressed a disapproval to post-mortem removal the person is considered to have consented to a removal.

[55] **Source**: ACTOR survey filled in by national Competent Authority, and information additionally provided,
Competent Authority the Czech Republic. (2009). Presentation National Action Plan the Czech Republic, 25-26 November 2009,
Lopp, L. (2012). *Final Report: A Common Frame of Reference for European Laws on Living Organ Donation, Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe / Part I: Unrelated Organ Donation (EULOD project)* EULOD,
Nys, H. (2007). *Removal of Organs in the EU, European Ethical-Legal Papers N°4*. Leuven.

[56] For more information about EU-funded projects, see §3.1

[57] For more information about the working groups, see §3.2

[58] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	10.4	10.5	10.5
Family refusal rate (refusals/times asked)	10/263	13/278	13/285
Actual deceased donation rate (total/per million population)	198/19.1	206/19.6	185/17.6
Multi-organ donation rates (% of total)	54.1	58.3	56.8
Number of utilised donors (total/per million population)[59]	-	-	-
Number of donors after circulatory death - DCD	1	2	1
Number of donors older than 65	26	24	21
Number of transplant centres			
Kidney	7	7	7
Liver	2	2	2
Heart	2	2	2
Lung	1	1	1
Pancreas	1	1	1
Number of deceased donor transplant procedures (total/per million population)			
Kidney	305/29.3	347/33.0	320/30.5
Liver	97/9.3	102/9.7	88/8.4
Heart	59/5.7	70/6.7	68/6.5
Lung	20/1.9	17/1.6	18/1.7
Pancreas	26/2.5	20/1.9	32/3.0
Number of living donor transplant procedures (total/per million population)			
Kidney	29/2.8	17/1.6	40/3.8
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	546	651	667
Liver	56	66	43
Heart	77	89	84
Lung	53	43	30
Pancreas	39	41	45
Number of mortalities while on waiting list			
Kidney	12	25	25
Liver	11	14	12
Heart	14	5	11
Lung	10	20	18
Pancreas	0	3	4

[59] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital level and the regional level. The country-representative indicates that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	The country-representative indicates that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that communication guidelines for informing the public exist, mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing organisational models of organ donation & transplantation	It is indicated that the Czech Republic has been involved in a twinning project with Italy. The subject of the project was to develop a system for accreditation and audit of donation and transplantation activities, based on the Italian Model.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	The Czech Republic indicates that there are agreements in place about basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking and common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	It is indicated that for the interchange of organs between national authorities, the Czech Republic has bilateral collaborations with Poland and Italy and an agreement with Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 2, 4, 5, 7 and 10**, other countries could benefit from the Czech Republic sharing its experiences with these efforts. Furthermore, it could be beneficial if the Czech Republic comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions.

7. Denmark

Based on publicly available information

Background information[60]

With a deceased donation rate per million population between 10 and 20 in 2011, Denmark belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart and lung.

With a living kidney donation rate per million population higher than 10 in 2011, Denmark's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney. Denmark is part of Scandiatransplant[61] and donor organs are allocated through Scandiatransplant.

Regarding EU-funded projects Denmark is an associated partner in the Joint Action FOEDUS[62]. In 2011 the country participated in the annual data collection prepared by the working group on indicators[63]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[64]).

Consent system

Since June 13th 1990, an **opting-out system** is in place. Amendments of the legislation in 2001 lay down that the deceased's **next-of-kin** may not oppose an intervention to which the deceased has given his written consent, unless the deceased has stipulated that the decision to carry out removal is subject to acceptance by the next-of-kin.

[60] **Source**: Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven. Scandiatransplant (2011). Transplantation and waiting lists figures 2011.

[61] Regarding EU- funded projects, Scandiatransplant participated as a partner in EFRETOS.

[62] For more information about EU-funded projects, see §3.1

[63] For more information about the working groups, see §3.2

[64] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	5.5	5.6	5.6
Family refusal rate (refusals/times asked)	-	-	-
Actual deceased donation rate (total/per million population)	65/11.8	73/13	73/13
Multi-organ donation rates (% of total)	65	70	68.5
Number of utilised donors (total/per million population)[65]	-	-	-
Number of donors after circulatory death - DCD	-	0	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	4	3	3
Liver	1	1	1
Heart	2	2	2
Lung	1	1	1
Pancreas	0	0	0
Number of deceased donor transplant procedures (total/pmp)			
Kidney	122/22.2	130/23.2	135/24.1
Liver	44/8	47/8.4	51/9.1
Heart	20/3.6	22/3.9	29/5.2
Lung	18/3.2	31/5.5	30/5.4
Pancreas	-	-	-
Number of living donor transplant procedures (total/pmp)			
Kidney	74/13.5	102/18.2	100/17.9
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	489	337	322
Liver	36	32	26
Heart	17	17	16
Lung	52	43	26
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	44	5	28
Liver	4	5	4
Heart	1	2	5
Lung	7	9	9
Pancreas	-	-	-

[65] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the national level. It is reported that these transplant donor coordinators do not receive regular training, but that this is intended for in the future.
Priority Action 2: Promote Quality Improvement Programmes	It is reported that the Danish government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process and the transplantation process.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	It is reported that directed living donation programmes exist, as well as undirected living donation programmes.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is reported that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. It is unknown to the research team whether efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if Denmark provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also unknown to the research team if Denmark has undertaken any additional plans or actions regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is unknown to the research team if Denmark is involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether Denmark has any agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	It is reported that for the interchange of organs between national authorities, Denmark is part of Scandiatransplant.
Priority Action 9: Evaluation of post-transplant results	It is unknown to the research team if post-transplant results of organ recipients are evaluated. If this is not the case, Denmark could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken. If this is not the case, it could be beneficial for Denmark to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways it could benefit from investing efforts in this subject.

Recommendations

With regard to **Priority Actions 1 and 3**, Denmark could benefit from the experiences that other countries have with these Priority Actions.

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of follow up care. Moreover, other countries could benefit from Denmark sharing its experiences with quality improvements regarding the transplantation process.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Denmark to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Denmark could benefit from investing efforts in these subjects.

With regard to **Priority Actions 6 and 9**, Denmark could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

8. Estonia

Background information[66]

In Estonia the first human kidney transplantation was performed in 1968 and the first liver transplantation was performed in 1999. In 2010 the first lung transplantation was carried out. With a deceased donation rate per million population between 10 and 20 in 2011, Estonia belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver and lung.
With a living kidney donation rate per million population lower than 10 in 2011, Estonia's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney. Donor organs are allocated at national level.

Regarding EU-funded projects,[67] Estonia was associated partner in ETPOD, EULOD and MODE . It is associated partner in ACCORD and FOEDUS.

In 2010 and 2011, the country participated in the annual data collection proposed under the working group on indicators[68]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[69]).

A National Action Plan was presented at a Competent Authority meeting in September 2011.

Financing of organ donation

In case of deceased and living donation, financing occurs through a (national) health insurance fund.

Consent system

Since 2002, an **opting-out system** is in place. If there is no information about the deceased person's opinion regarding post mortem removal the doctor who provided treatment is required, if possible, to ascertain the opinion of the deceased through the **next-of-kin**. Apart from this, the next-of-kin have no right to give consent or refuse organ removal.

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[66] **Sources**: ACTOR survey filled in by national Competent Authority and additional information provided by Competent Authority; Competent Authority Estonia. (2011). Presentation National Action Plan Estonia, September 2011; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[67] For more information about EU-funded projects, see §3.1

[68] For more information about the working groups, see §3.2

[69] For more information about CD-P-TO, see §3.3

Key Figures

- = unknown to the research team

	2008	2010	2011
Population in millions	1.3	1.3	1.3
Family refusal rate (refusals/times asked)	16/50	7/30	10/40
Actual deceased donation rate (total/per million population)	31/23.8	23/17.7	22/16.9
Multi-organ donation rates (% of total)	2	6	59.1
Number of utilised donors (total/per million population)[70]	-	-	-
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	0	0	-
Number of transplant centres			
Kidney	1	1	1
Liver	1	1	1
Heart	-	-	-
Lung	-	1	1
Pancreas	-	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	54/41.5	35/26.9	40/30.8
Liver	2/1.5	3/2.3	8/6.2
Heart	0	-	-
Lung	0	1/0.8	3/2.3
Pancreas	-	-	-
Number of living donor transplant procedures (total/pmp)			
Kidney	3/2.3	4/3.1	4/3.1
Liver	-	-	-
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	-	-	43
Liver	-	-	6
Heart	-	-	-
Lung	-	-	2
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	3	3	4
Liver	-	-	1
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-

[70] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital and the national level. It is indicated that these transplant donor coordinators receive training through Transplant Procurement Management (TPM) courses and the European Transplant Coordinators Organization (ETCO).
Priority Action 2: Promote Quality Improvement Programmes	The country-representative indicates that the Estonian government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process and the procurement process.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors, but that this is planned for 2014.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	The country-representative indicates that no efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists. In addition, it is indicated that there are no programmes deployed to improve knowledge and communication skills of health professionals and patient support groups.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is indicated that Estonia has been involved in a twinning project with Austria, in the framework of the University of Vienna Lung Transplant Program.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Estonia indicates that it has agreements in place regarding basic rules for internal EU patient mobility and transplantation. It is indicated that there are no agreements in place about transplant medicine for extra-Community patients or common priorities and strategies for future research programmes. It is unknown to the research team if there are agreements in place regarding organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, the country-representative indicates that there is an agreement with Eurotransplant and Scandiatransplant. In addition a twinning agreement with Vienna and a Baltic collaboration are mentioned.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are continuously evaluated.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the transplantation process and follow up care.

With regard to **Priority Action 3**, Estonia could benefit from the experiences that other countries have with setting up these kinds of registers, especially since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Actions 4 and 5**, it could be beneficial for Estonia to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Estonia could benefit from investing efforts in these subjects.
With regard to **Priority Actions 7 and 10**, other countries could benefit from Austria sharing its experiences with these efforts. Furthermore, it could be beneficial if Austria comes together with countries who have not taken up efforts on these Priority Actions to help redefine this Priority Actions. Regarding Priority Action 7, It could be beneficial for Estonia to further look into setting up agreements regarding transplant medicine for extra-Community patients, common priorities and strategies for future research programmes or monitoring of organ trafficking.

9. Finland

Background information[71]

With a deceased donation rate per million population between 10 and 20 in 2011, Finland belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas. With a living kidney donation rate per million population lower than 10 in 2011, Finland's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney. Finland is part of Scandiatransplant[72] and donor organs are allocated through Scandiatransplant and at national level.

Regarding EU-funded projects, Finland did not participate recently in a project related to organ donation and transplantation funded by the EU Health Programme.

In 2010 and 2011, the country provided data for the annual Indicators' exercise prepared in the working group on indicators[73]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[74]).

Financing of organ donation

In case of deceased and living donation, financing occurs through residence based public funding, since transplantation takes place in public hospitals.

Consent System

Since February 2nd 2001 an **opting-out system** is in place. The **next-of-kin** have no right to object to organ removal.

[71] **Sources**: ACTOR survey filled in and additional information provided by national Competent Authority; Scandiatransplant (2011). Transplantation and waiting lists figures 2011; Scandiatransplant (2008). Transplantation and waiting lists figures 2008.

[72] Regarding EU funded projects, Scandiatransplant participated as a partner in EFRETOS

[73] For more information about the working groups, see §3.1

[74] For more information about CD-P-TO, see §3.3

Key Figures

	2008	2010	2011
Population in millions	5.3	5.4	5.4
Family refusal rate (refusals/times asked)	-	-	-
Actual deceased donation rate (total/per million population)	81/15.2	92/17.0	93/17.2
Multi-organ donation rates (% of total)	65.0	63.0	65.6
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD [75]	9%	18.7%	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	1	1	1
Liver	1	1	1
Heart	1	1	1
Lung	0	1	1
Pancreas	-	1	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	141/26.6	164/30.4	164/30.4
Liver	47/8.9	50/9.3	56/10.4
Heart	21/4.0	22/4.1	18/3.3
Lung	12/2.3	15/2.8	23/4.3
Pancreas	-	2/0.4	1/0.2
Number of living donor transplant procedures (total/pmp)			
Kidney	9/1.7	11/2.0	13/2.4
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	398	267	292
Liver	7	7	11
Heart	10	20	22
Lung	6	9	8
Pancreas	-	0	3
Number of mortalities while on waiting list			
Kidney	14	4	13
Liver	1	0	1
Heart	1	4	4
Lung	2	4	2
Pancreas	-	0	0

- = unknown to the research team

[75] Only percentages were given for 2008 and 2010.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	The country-representative indicates that no transplant donor coordinators have been appointed, but that some hospitals do have appointed coordinators, however this is not obligatory on a national level.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the Finnish government has not stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process or follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is unknown to the research team if programmes are deployed to improve knowledge and communication skills of health professionals or patient support groups. It is indicated that efforts have been made with regard to setting up communication guidelines for informing the public. It is indicated that monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists have not been set up.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if Finland provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also unknown to the research team if Finland has undertaken any additional plans or actions regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Finland indicates that it has not been involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that Finland has no agreements in place regarding basic rules for internal EU patient mobility and transplantation. It is unknown to the research team whether there are any agreements in place regarding transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Finland is part of Scandiatransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3, 6 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

Finland could reconsider how to benefit from participating in an EU funded project.

With regard to **Priority Action 1**, it could benefit from the experiences that other countries have with this Priority Action.

With regard to **Priority Actions 2 and 6**, the country could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

With regard to **Priority Action 4**, other countries could benefit from Finland sharing its experiences with setting up communication guidelines for informing the public. On the other hand, it could benefit from setting up efforts regarding monitoring how often organ transplantation is mentioned in newspapers or on TV or organising periodic meetings with journalists.

With regard to Priority Action**s** 5, 7 and 10, it could be beneficial for Finland to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Finland could benefit from investing efforts in these subjects.

10. France

Background information[76]

With a deceased donation rate per million population higher than 20 in 2011, France's deceased donation rate is amongst the highest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung, heart-lungs, pancreas and small bowel.
With a living kidney donation rate per million population lower than 10 in 2011, France's living kidney donation rate per million population is among the lowest of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
Donated organs are allocated at the national level.

Regarding EU-funded projects, France was coordinator of the Alliance-O project[77] and core work package leader in COORENOR (replacing Austria), ELIPSY and ODEQUS. The country is core work package leader in ACCORD and FOEDUS. France was a partner in DOPKI, ETPOD, EULID and EFRETOS.

In 2010, 2011 and 2012, the country participated in the working group on indicators[78] and in the data collection exercise launched by the working group. It also participated in the working group on deceased donation and the working group on living donation.

In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[79]). At the Council of Europe, the "Agence de la Biomédecine" (National Transplant Organisation) representative is also the CD-P-TO representative for discussions with European countries for the implementation of an international convention against organ trafficking.

A National Action Plan was presented at a Competent Authority meeting on 27 September 2011.

Financing of organ donation

In case of deceased and living donation the costs and expenses related to the donation are directly funded by the national health insurance system.

Consent system

Since 1976 ("Caillavet law"), an **opting-out system** (presumed consent) is in place. In practice, if the will of the deceased is not known, the opinion of the **next-of-kin** is nevertheless respected if they have strong objections against organ donation. Refusal to be an organ donor can be expressed in the non-donor **registry** from the age of 13 years.

[76] **Sources**: ACTOR survey filled in and information additionally provided by national Competent Authority. Guide don d'organes 2012; Competent Authority France. (2011). Presentation National Action Plan France, 27 September 2011.

[77] For more information about EU-funded projects, see §3.1

[78] For more information about the working groups, see §3.2

[79] For more information about CD-P-TO, see §3.3

Key Figures

- = unknown to the research team

	2008	2010	2011
Population in millions	63.6	64.7	65.1
Family refusal rate (refusals/times asked)	976/-	559/-	616/-
Actual deceased donation rate (total/per million population)	1610/25.3	1538/23.8	1630/25
Multi-organ donation rates (% of total)	93.7	86.4	89.4
Number of utilised donors (total/per million population)	1490/23.4	1433/22.1	-
Number of donors after circulatory death - DCD	47	62	58
Number of donors older than 65	399	407	-
Number of transplant centres			
Kidney	44	44	44
Liver	24	23	23
Heart	26	26	26
Lung	13	13	13
Pancreas	11	12	16
Number of deceased donor transplant procedures (total/per million population)			
Kidney	2663/41.9	2609/40.3	2674/41.1
Liver	1011/15.9	1075/16.6	1150/17.7
Heart	379/6.0	375/5.8	410/6.3
Lung	215/3.4	263/4.1	324/5.0
Pancreas	81/1.3	96/1.5	73/1.1
Number of living donor transplant procedures (total/per million population)			
Kidney	222/3.5	283/4.4	302/4.6
Liver	10/0.2	17/0.3	14/0.2
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	6509	7616	8942
Liver	140	806	941
Heart	270	304	302
Lung	140	178	17
Pancreas	150	158	144
Number of mortalities while on waiting list			
Kidney	201	193	200
Liver	107	169	135
Heart	66	76	60
Lung	29	21	489
Pancreas	5	9	5

Implementation Action Plan

Recommendations

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital level and that they are assigned specific clearly defined tasks. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	The country-representative indicates that the French government has stimulated initiatives notably through a national action plan to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care. Certification of Hospital Coordination for organ retrieval is also an important point within the quality improvement program, and there is as well the ISO 9001 certification of the allocation platform
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. However, it is indicated that developments are ongoing regarding unrelated donation, and laws are revisited. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that there are communication guidelines for informing the public about organ transplantation, mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, notably since adoption of the Action Plan.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU; a document with information about this is available at the website of the National Transplant Organisation. It is reported that there are additional plans or actions undertaken for this PA.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	The country-representative indicates that it has been involved in twinning projects with Bulgaria, Italy, Malta, Cyprus, Belgium, Lithuania, the Czech Republic, the Netherlands and Hungary. It is indicated that transplantation cooperation between Bulgaria and France in the field of transplantation started in 2001 and was firstly dedicated in supporting liver transplantation activity and training hospital coordinators and secondly in supporting the development of paediatric kidney transplantation. France participated in a Working Group on deceased donation, on setting up a transplant donor coordination system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	France indicates that there are agreements in place about common priorities and strategies for future research programmes. The country-representative indicates that it has no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, France indicates that it has a convention with Switzerland, on urgent paediatrics and liver transplantations. Furthermore France has a collaboration with Bulgaria and Moldova towards the development of their transplant system.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated 12 months after transplantation and 3/5/10/15 years after transplantation if possible. Results are disseminated to professionals and public at large.
Priority Action 10: Promote a common accreditation system	The country-representative indicates that additional plans are undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes, both on national and international level.

With regard to **Priority Action 2**, other countries could benefit from France sharing its experiences with quality improvements regarding the transplantation process and follow up care.

With regard to **Priority Actions 4, 5, 7 and 10**, other countries could benefit from France sharing its experiences with these efforts. Furthermore, it could be beneficial if France comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions. Regarding **Priority Action 7**, France could continue its good work on this subject, especially organ trafficking, and might further look into setting up agreements regarding basic rules for internal EU patient mobility, transplant medicine for extra-Community patients or organ trafficking.

11. Germany

Background information[80]

With a deceased donation rate per million population between 10 and 20 in 2011, Germany belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population of almost 10 in 2011, Germany's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
Germany is part of Eurotransplant[81] and donor organs are allocated through Eurotransplant.

Regarding EU-funded projects Germany was core work package leader in the projects ELIPSY[82] (replacing Norway), EULOD and ODEQUS. The country is core work package leader in FOEDUS. Furthermore it was a partner in DOPKI, Alliance-O, ETPOD and EFRETOS and is a partner in ACCORD.

In 2010, and again in 2012, the country participated in the working group on indicators[83] as well as in the annual data collection. The country also participated in the working group on living donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[84]).
A National Action Plan was presented at a Competent Authority meeting on 6-7 September 2010.

Financing of organ donation

In case of deceased and living donation the recipient's insurance company pays for the expenses.

Consent system

Since November 5th 1997 an **opting-in system** is in place, in which one can decide to give consent to organ donation, refuse removal or delegate the decision to consent or refuse to a representative. New legislation was added in August 2012 (first part of transposition of the Directive 2010/53/EU), proposing to ask citizens more frequently about their position towards donation (for example via health insurances). In case the will of the deceased is unknown, the responsible physician is obliged to ask the **next-of-kin** - or a possible appointed representative - if any declaration of the will of the deceased regarding removal exists. If this is not the case, organ removal can only take place with consent of the next-of-kin – or a possible representative – who have to decide in accordance with the presumed will of the deceased. Every person of 16 years and older can give consent to organ donation in a "**donation-declaration**" or, if 14 years and older, refuse removal.

[80] **Sources**: ACTOR survey filled in by national Competent Authority; Competent Authority Germany. (2010). Presentation National Action Plan Germany, 6-7 September 2010; Deutsche Stiftung Organtransplantation (2006). Report on the general European situation: technical, legal and sociosanitary point of view (deliverable project DOPKI) DOPKI; DSO: Jahresbericht 2008; Eurotransplant (2009). Yearly Statistics 2008; Eurotransplant International Foundation: Annual Report 2010; Eurotransplant (2011b). Yearly Statistics 2011; Institut für Qualität und Patientensicherheit (BQS): www.bqs-qualitaetsreport.de/2008; Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen GmbH (2011), Qualitätsreport 2010.

[81] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR.

[82] For more information about EU-funded projects, see §3.1

[83] For more information about the working groups, see §3.2

[84] For more information about CD-P-TO, see §3.3

Key Figures

- = unknown to the research team

	2008	2010	2011
Population in millions	82.2	81.8	81.8
Family refusal rate (refusals/times asked)	-	-	-
Actual deceased donation rate (total/per million population)	1198/14.6	1296/15.8	1200/14.7
Multi-organ donation rates (% of total)	86.7	87.0	86.8
Number of utilised donors (total/per million population)	1184/14.4	1271/15.5	-
Number of donors after circulatory death - DCD[85]	-	-	-
Number of donors older than 65	323	393	-
Number of transplant centres			
Kidney	-	40	41
Liver	-	23	24
Heart	-	24	22
Lung	-	13	14
Pancreas	-	24	23
Number of deceased donor transplant procedures (total/pmp)			
Kidney	2188/26.6	2272/27.8	2055/25.1
Liver	1067/13.0	1192/14.6	1128/13.8
Heart	382/4.6	393/4.8	366/4.5
Lung	270/3.3	298/3.6	337/4.1
Pancreas	134/1.6	163/2.0	171/2.1
Number of living donor transplant procedures (total/pmp			
Kidney	565/6.9	665/8.1	795/9.7
Liver	55/0.7	90/1.1	71/0.9
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	8003	7869	7873
Liver	1948	2161	2119
Heart	873	981	1039
Lung	593	642	606
Pancreas	263	304	282
Number of mortalities while on waiting list			
Kidney	267	374	-
Liver	339	463	-
Heart	149	199	-
Lung	112	104	-
Pancreas	22	25	-

[85] Donation after Circulatory Death (DCD) is, by law, not allowed in Germany.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the regional and the national level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	Germany indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes have been deployed to improve knowledge and communication skills of health professionals and patient support groups. It is indicated that no efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists. In 2009 Germany organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is indicated that Germany provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that no additional plans or actions are undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models	It is indicated that Germany has not been involved in twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Germany indicates that there are agreements in place on organ trafficking. It is indicated that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities Germany is part of Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated 3 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 2, 5 and 10**, other countries could benefit from Germany sharing its experiences with these efforts. Furthermore, it could be beneficial if Germany comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions. With regard to Priority Action 7, other countries could benefit from Germany sharing its experiences with monitoring organ trafficking**.** Furthermore, it could be beneficial if Germany comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. It could be beneficial for Germany to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.

With regard to **Priority Action 3**, Germany could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Action 4**, it could be beneficial for Germany to come together with countries who have taken up efforts regarding public awareness to help redefine this Priority Action and to reconsider the ways Germany could benefit from investing efforts in this subject.

With regard to **Priority Action 6**, Germany could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

12. Greece

Background[86]

In Greece the first human kidney transplantation was performed in 1968 and the first liver transplantation was performed in 1990. In 1990 the first heart transplantation was carried out. With a deceased donation rate per million population under 10 in 2011, Greece's deceased donation rate per million population is amongst the lowest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, heart and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Greece's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.
Donor organs are allocated at national level.

Regarding EU-funded projects Greece is horizontal work package leader in the EU funded project FOEDUS[87] (work package on evaluation). Greece withdrew from participation in COORENOR. In addition it was a partner in ETPOD and EFRETOS and is a partner in ACCORD.

In 2011, the country participated in the annual data collection launched by the working group on indicators[88] and in the annual data collection. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[89]).

A National Action Plan was presented at a Competent Authority meeting in March 2011.

Financing of organ donation

In case of deceased and living donation the national insurance of the recipient pays all the expenses.

Consent system

Since 1999, an **opting-out system** is in place. If the deceased's will is unknown, post mortem removal can take place, unless the **next-of-kin** refuses it.

[86] **Sources**: ACTOR survey filled in by national Competent Authority, and information additionally provided; Competent Authority Greece (2011). Presentation National Action Plan Greece March 2011; Information provided by H. Nys, November 2012; Lopp, L. (2012). Final Report: A Common Frame of Reference for European Laws on Living Organ Donation, Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe / Part I: Unrelated Organ Donation (EULOD project) EULOD.

[87] For more information about EU-funded projects, see §3.1

[88] For more information about the working groups, see §3.2

[89] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	11.0	11.2	11.4
Family refusal rate (refusals/times asked)	53/158	6/13	-
Actual deceased donation rate (total/per million population)	176/16.0	57/5.1	79/6.9
Multi-organ donation rates (% of total)	79.6	87.0	64.6
Number of utilised donors (total/per million population)	98/8.9	45/4.0	-
Number of donors after circulatory death - DCD[90]	-	-	-
Number of donors older than 65	17	8	-
Number of transplant centres			
Kidney	4	-	-
Liver	2	-	1
Heart	1	-	1
Lung	1	-	-
Pancreas	0	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	186/16.9	108/9.6	139/12.2
Liver	58/5.3	25/2.2	-
Heart	16/1.5	5/0.4	6/0.5
Lung	3/0.3	2/0.2	-
Pancreas	3/0.3	-	1/0.1
Number of living donor transplant procedures (total/pmp)			
Kidney	51/4.6	27/2.4	46/4.0
Liver	0	0	-
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	880	895	1112
Liver	67	62	94
Heart	24	24	30
Lung	2	16	-
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	15	11	-
Liver	12	10	17
Heart	1	2	3
Lung	1	3	-
Pancreas	-	-	-

[90] Donation after Circulatory Death (DCD) is not allowed in Greece.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital, the national level and the clinical level. It is indicated that these transplant donor coordinators receive training through Transplant Procurement Management (TPM) courses.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	It is indicated that directed living donation programmes exist, it is unknown to us whether undirected living donation programmes exist. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that there are communication guidelines for informing the public about organ transplantation, mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented. In 2004 Greece organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also indicated that there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Greece indicates that it has not been involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Greece indicates that it has no agreements in place regarding organ trafficking or common priorities and strategies for future research programmes. It is unknown to the research team whether there are agreements in place about basic rules for internal EU patient mobility and transplantation or transplant medicine for extra-Community patients.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Greece indicates that it has an agreement with the European Transplant Network and bilateral agreements with Italy and Cyprus. It is furthermore planned to reach an agreement with Germany.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 6 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 2, 4, 5 and 10**, other countries could benefit from Greece sharing its experiences with these efforts. Furthermore, it could be beneficial if Greece comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions.

With regard to **Priority Action 6**, Greece could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

With regard to **Priority Action 7**, it could be beneficial for Greece to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Greece could benefit from investing efforts in this subject.

13. Hungary

Background information[91]

In Hungary the first human kidney transplantation was performed in 1962. With a deceased donation rate per million population between 10 and 20 in 2011, Hungary belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Hungary's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.
Donor organs are allocated at national level.

Regarding EU-funded projects, Hungary is horizontal work package leader in the project FOEDUS[92] (work package on dissemination)and was core work package leader in COORENOR, DOPKI and MODE. Hungary was a partner in Alliance-O, EUROCET and is a partner in ACCORD.

In 2010, 2011 and 2012, the country participated in the working group on indicators[93] and in the annual data collection exercise launched by the working group. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[94]).

A National Action Plan was presented at a Competent Authority meeting on 28 February 2011.

Financing of organ donation

In case of deceased donation the costs of the hospitals' reporting on donors and the remuneration of the workgroup preparing the organ for transplantation have been determined by section 47 of Government Decree No. 43/1999 (III. 3) on the detailed rules of financing public health services from the Health Insurance Fund. The donation fee is the fee due for the care (personal and material costs) from the report on the donor until the procurement of the organ, and must be paid to the hospital providing the donor. The national health insurance company (NHIC) has financed the costs to the donor hospitals and procurement teams All solid organ transplantation programs are financed by NHIC according to the 9/1993 NM. ministerial degree on highly expensive health care treatments, including kidney, liver, heart, pancreas (combined kidney) HLA tissue typing, Blood Group Serology and virus serology tests. In case of living donation a state owned or state-controlled institution pays the expenses incurred by the donor.

Consent system

Since 1997 an **opting-out system** is in place. The **next-of-kin** have no right to consent or refuse organ removal. There is no donor **registry**.

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[91] **Sources**: ACTOR survey filled in by national Competent Authority, and information additionally provided; Borsi, J. D., Borka, P., Tornai, E., Mihaly, S., Deme, O., & Mina, A. (2005). Results of a multilateral approach to donation-transplantation process in Hungary in the past 2 years. Transplant Proc, 37, 3260-3261; Deutsche Stiftung Organtransplantation (2006). Report on the general European situation: technical, legal and sociosanitary point of view (deliverable project DOPKI) DOPKI; Information provided by H. Nys, November 2012; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven; Sándor, J., Beširevіæ, V., Demény, E., Tudor Florea, G., Codreanu, N., Ambagtsheer, F. et al. (2012). Improving the effectiveness of the organ trade prohibition in Europe (Deliverable WP-2 EULOD) EULOD; Tiessen, J., Conklin, A., Janta, B., Rabinovich, L., de Vries, H., Hatziandreu, E. et al. (2008). Improving Organ Donation and Transplantation in the European Union Assessing the Impacts of European Action Santa Monica: Rand Corporation.

[92] For more information about EU-funded projects, see §3.1

[93] For more information about the working groups, see §3.2

[94] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	10.1	10.0	10.0
Family refusal rate (refusals/times asked)	11/148	14/243	11/209
Actual deceased donation rate (total/per million population)	148/14.7	159/15.9	131/13.1
Multi-organ donation rates (% of total)	41.2	43.4	41.2
Number of utilised donors (total/per million population)	134/13.3	151/15.1	-
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	6	7	-
Number of transplant centres			
Kidney	4	4	4
Liver	1	1	1
Heart	2	2	2
Lung	0	0	0
Pancreas	2	2	2
Number of deceased donor transplant procedures (total/pmp)			
Kidney	235/23.3	265/26.5	204/20.4
Liver	36/3.6	43/4.3	41/4.1
Heart	22/2.2	20/2	14/1.4
Lung	-	-	-
Pancreas	5/0.5	9/0.9	10/1
Number of living donor transplant procedures (total/pmp)			
Kidney	24/2.4	42/4.2	47/4.7
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	685	771	833
Liver	67	83	128
Heart	11	14	13
Lung	5	3	7
Pancreas	16	19	21
Number of mortalities while on waiting list			
Kidney	28	20	34
Liver	15	16	19
Heart	7	1	5
Lung	2	1	0
Pancreas	1	2	3

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that 9 transplant donor coordinators have been appointed in Hungary recently, and it is not clear on which level.
Priority Action 2: Promote Quality Improvement Programmes	Hungary indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors. It is unknown to the research team if initiatives are stimulated to improve the quality of the donation process, the procurement process, the transplantation process or follow up care.
Priority Action 3: Exchange of best practices on living donation programmes	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that there are communication guidelines for informing the public about organ transplantation, mention of organ transplantation in newspapers is monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented. It is unknown to the research team if mention of organ transplantation on TV is monitored. In 2012 Hungary organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also indicated that there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is indicated that Hungary has been involved in twinning projects with Austria, the Netherlands and neighbour countries. It is indicated that with the Netherlands, the aim is to improve quality and safety on organ recover, based on the transfer of the Dutch Curriculum on donor recovery surgery. It is indicated that with neighbour countries and Austria the subject is lung transplantation and high urgent liver transplantation. Furthermore, patients from neighbouring countries can undergo living related kidney transplant in Hungarian transplant centres.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that Hungary has no agreements in place regarding basic rules for internal EU patient mobility and transplantation or transplant medicine for extra-Community patients. It is unknown to the research team if there are agreements in place regarding organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, it is indicated that Hungary has an agreement with Eurotransplant and the European Transplant Network and a bilateral agreement with Austria.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are not evaluated, but the country-representative indicates that this is planned by 2013.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 1**, Hungary has improved but might still benefit from the experiences that other countries have with this effort. Regarding **Priority Action 2**, it could be beneficial for Hungary to stimulate initiatives regarding quality of the processes for donation, procurement, transplantation or follow-up care. With regard to **Priority Action 3**, Hungary could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Action 4**, other countries could benefit from Hungary sharing its experiences with communication guidelines for informing the public about organ transplantation, mention of organ transplantation in newspapers is monitored and periodic meetings with journalists. Hungary could benefit from investing in monitoring mention of organ transplantation on TV. With regard to **Priority Actions 5 and 10**, other countries could benefit from Hungary sharing its experiences with these efforts. Furthermore, it could be beneficial if Hungary comes together with countries who have not taken up efforts on these Priority Actions to help redefine them. Regarding **Priority Action 7**, it could be beneficial for Hungary to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Hungary could benefit from investing efforts in this subject.

14. Iceland

Based on publicly available information

Background[95]

With a deceased donation rate per million population under 10 in 2011, Iceland's deceased donation rate per million population is amongst the lowest of the countries included in this study. In 2011, no deceased donor transplant procedures were carried out regarding liver and kidney and it is unknown to the research team if deceased donor transplant procedures were carried out regarding heart, lung and pancreas.
With a living kidney donation rate per million population higher than 10 in 2011, Iceland's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.

Iceland is part of Scandiatransplant[96] and donor organs are allocated through Scandiatransplant.

Regarding EU-funded projects Iceland is an associated partner in the Joint Action project FOEDUS[97].

Iceland is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[98]).

Consent system

An **opting-in system** is in place.

[95] **Sources**: Scandiatransplant (2008). Transplantation and waiting lists figures 2008; Scandiatransplant (2011). Transplantation and waiting lists figures 2011; http://grapevine.is/Home/ReadArticle/Firemen-And-Paramedics-Support-Organ-Donor-Proposal

[96] Regarding EU-funded projects, Scandiatransplant participated as a partner in EFRETOS

[97] For more information about EU funded projects, see §3.1

[98] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	0.3	0.3	0.3
Family refusal rate (refusals/times asked)	-	-	-
Actual deceased donation rate (total/per million population)	2/6	3/10	2/6.7
Multi-organ donation rates (% of total)	100	100	100
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	1	1	1
Liver	0	-	-
Heart	0	-	-
Lung	0	-	-
Pancreas	0	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	-	0	0
Liver	-	0	0
Heart	-	0	-
Lung	-	0	-
Pancreas	-	0	-
Number of living donor transplant procedures (total/pmp)			
Kidney	5/16/7	5/16/7	11/36.7
Liver	5/16.7	0	-
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	-	-	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	-	0	-
Liver	-	-	-
Heart	-	0	-
Lung	-	-	-
Pancreas	-	-	-

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is unknown to the research team if transplant donor coordinators have been appointed.
Priority Action 2: Promote Quality Improvement Programmes	It is reported that the Icelandic government has stimulated initiatives to improve the quality of the identification of potential donors.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is reported that directed[99] living donation programmes exist. It is unknown to the research team if undirected living donation programmes exist and whether registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is unknown to the research team if there are programmes deployed to improve knowledge and communication skills of health professionals and patient support groups. It is also unknown to the research team if efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV and organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also unknown to the research team if there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is unknown to the research team if Iceland is involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether Iceland has any agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Iceland is reported to be part of Scandiatransplant.
Priority Action 9: Evaluation of post-transplant results	It is unknown to the research team if post-transplant results of organ recipients are evaluated.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 1 and 3**, Iceland could benefit from the experiences that other countries have with these Priority Actions.

With regard to **Priority Action 2**, it is reported that the Icelandic government has stimulated initiatives to improve the quality of the identification of potential donors. It could be beneficial if initiatives are also stimulated to improve the quality the donation process, the procurement process, the transplantation process and follow up care.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Iceland to come together with countries who have taken up efforts regarding public awareness to help redefine these Priority Actions and to reconsider the ways Iceland could benefit from investing efforts in these subjects.

With regard to **Priority Actions 6 and 9**, Iceland could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

[99] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

15. Ireland

Background information[100]

With a deceased donation rate per million population between 10 and 20 in 2011, Ireland belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Ireland's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.
Donor organs are allocated at national level.

Regarding EU-funded projects, Ireland participates as partner in the Joint Action ACCORD[101].

In 2010 the country participated in the working group on indicators[102]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[103]).

Financing of organ donation

There is no protocol in place.

Consent system

Legislation is at an advanced stage.

[100] **Sources**: ACTOR survey filled in and additional information provided by national Competent Authority.
Costello, P. (2012). Irish Medicines Board: Organs Directive IMB Implementation.

[101] For more information about EU-funded projects, see §3.1

[102] For more information about the working groups, see §3.2

[103] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	4.4	4.4	4.5
Family refusal rate (refusals/times asked)	24/105	23/119	19/-
Actual deceased donation rate (total/per million population)	81 (18.4)	58 (12.6)	93/20.7
Multi-organ donation rates (% of total)	-	-	92.5
Number of utilised donors (total/per million population)[104]	-	-	-
Number of donors after circulatory death - DCD	0	0	1
Number of donors older than 65	9	6	-
Number of transplant centres			
Kidney	1	1	1
Liver	1	1	1
Heart	1	1	1
Lung	1	1	1
Pancreas	1	1	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	136/30.9	151/34.3	165/36.7
Liver	58/13.2	38/8.6	61/13.6
Heart	4/0.9	3/0.7	6/1.3
Lung	4/0.9	4/0.9	8/1.8
Pancreas	12/2.7	8/1.8	8/1.8
Number of living donor transplant procedures (total/pmp)			
Kidney	10/2.3	23/5.2	27/6
Liver	-	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	-	-	460
Liver	-	-	20
Heart	-	-	17
Lung	-	-	36
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	19	10	15
Liver	5	5	10
Heart	-	2	0
Lung	-	8	10
Pancreas	0	0	0

- = unknown to the research team

[104] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	Transplant donor co-ordinators have not been appointed at local level, there are a cohort of Transplant donor co-ordinators in the procurement office in one Transplant Centre, and a cohort of recipient donor co-ordinators in the 3 Transplant centres.
Priority Action 2: Promote Quality Improvement Programmes	Ireland indicates that the government has not stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process or follow up care. Histopathology and Immunology for Organ Donation and Transplantation have Quality Programmes.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is indicated that directed[105] living donation programmes exist and that there are no undirected living donation programmes. It is indicated that there are no registers established yet to evaluate and guarantee the health and safety of living donors. The country indicates that they intend to set up these kinds of registers.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that there are no programmes deployed to improve knowledge and communication skills of health professionals or patient support groups. It is indicated that no efforts have been made with regards to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists. In 2007 Ireland organised the European donation day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU, but that this is intended in the future. Work up of living Donors to facilitate transplantation abroad has been undertaken.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	There is a Service Level Agreement with the UK with costs paid for specific transplant services
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether Ireland has any agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Ireland indicates that it has some collaboration with the United Kingdom for specific transplant services.
Priority Action 9: Evaluation of post-transplant results	It indicated that post-transplant results of organ recipients are not evaluated for all organs, but the country indicates that they intend to do this in the future. Ireland publishes the results every second year for kidney transplantation short and long term outcomes.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regards to **Priority Action 2**, Ireland could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Ireland to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways Ireland could benefit from investing efforts in this subject.

[105] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

16. Italy

Background information[106]

With a deceased donation rate per million population higher than 20 in 2011, Italy's deceased donation rate per million population is amongst the highest of the countries included in this study.
In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung, and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Italy's living kidney donation rate per million population is among the lowest of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
Donor organs are allocated at national level for specific cases (urgent patients, HIV-patients, paediatric patients, hyperimmunised) and on the regional level for general cases.

Regarding EU funded projects Italy is horizontal work package leader of the EU funded project ACCORD[107] and coordinator of FOEDUS. It was coordinator of COORENOR and MODE and core work package leader of EFRETOS and ODEQUS and partner in Alliance-O, DOPKI, ETPOD and EULID.

In 2010 and 2011 the country participated in the working group on indicators[108]. It also participated in the working group on deceased donation and living donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[109]).

Financing of organ donation

In case of deceased donation, funding is part of the general health care system. In case of living donation, the costs and expenses related to living donation are also directly funded by the healthcare system.

Legislative framework

Since April 1st 1999 an **opting-out system** is in place with presumed consent to donation, if informed by means of a sent notification. All citizens are required to explicitly consent to or refuse post mortem donation and are informed that a missing declaration equals tacit consent to donation. Because of the lack of possibility to ask all citizens directly whether they consent to or refuse donation, a transitional disposition was issued in 2000 indicating that **next-of-kin** are asked for non-opposition to organ retrieval if the decision is unknown. The will (consent/refusal) is **collected** in a national database system.

[106] **Sources**: ACTOR survey filled in and additional information provided by national Competent Authority; COORENOR (2011). Deliverable 7.2: Overview of national legislation and international cooperation in cross border organ exchanges, defining basic parameters of future IT-portal; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven; Tiessen, J., Conklin, A., Janta, B., Rabinovich, L., de Vries, H., Hatziandreu, E. et al. (2008). Improving Organ Donation and Transplantation in the European Union Assessing the Impacts of European Action Santa Monica: Rand Corporation; Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[107] For more information about EU funded projects, see §3.1

[108] For more information about the working groups, see §3.2

[109] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	56.9	60.1	60.8
Family refusal rate (refusals/times asked)	749/2299	722/2289	651/2271
Actual deceased donation rate (total/per million population)	1201/21.1	1298 /21.6	1325/21.8
Multi-organ donation rates (% of total)	80.3	75.4	69.8
Number of utilised donors (total/per million population)	1094 /19.2	1095/18.2	-
Number of donors after circulatory death - DCD	3	3	6
Number of donors older than 65	345	408	-
Number of transplant centres			
Kidney	43	43	43
Liver	22	22	22
Heart	19	19	19
Lung	13	13	13
Pancreas	13	13	13
Number of deceased donor transplant procedures (total/pmp)			
Kidney	1533/26.9	1694/28.2	1540/25.3
Liver	996/17.5	1002/16.7	1019/16.7
Heart	326/5.7	273/4.5	278/4.6
Lung	94/1.7	107/1.8	120/2.0
Pancreas	61/1.1	47/0.8	58/1.0
Number of living donor transplant procedures (total/pmp)			
Kidney	123/2.2	182/3.0	211/3.5
Liver	19/0.3	12/0.2	15/0.2
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	7214	7126	6542
Liver	1504	1297	1000
Heart	730	726	733
Lung	329	342	382
Pancreas	253	259	236
Number of mortalities while on waiting list			
Kidney	160	159	162
Liver	173	195	162
Heart	126	98	94
Lung	69	59	57
Pancreas	6	1	3

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital, regional, interregional and national level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	Italy indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is indicated that directed[110] living donation programmes as well as undirected living donation programmes exist. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented. It is indicated that communication guidelines for informing the public about organ transplantation have not been set up.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU, but that this is intended for in the future. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Italy indicates that it has been involved in twinning projects with Slovakia, the Czech Republic, Lithuania, Malta and Cyprus. The country-representative indicates that they ran a PHARE twinning program with Slovakia for improving safety and quality of organ and tissue donation and transplantation systems. Furthermore it is indicated that under the ACCORD project Italy takes part in the twinning work package under which best-practices for quality assurance system of transplant centres will be exchanged between the Czech Republic, Lithuania, Malta, Cyprus and Italy. Italy participated in the Working Group on deceased donation, on setting up a transplant donor coordination system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Italy indicates that there are agreements in place on organ trafficking. It is indicated that the country has no agreements in place regarding basic rules for internal EU patient mobility and transplantation or transplant medicine for extra-Community patients. It is unknown to the research team if there are agreements in place about common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Italy indicates that it has bilateral agreements with European countries such as Malta, Greece and Slovak Republic. Furthermore, Italy, France and Spain have constituted the South Alliance for transplantation.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

[110] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

Recommendations

With regard to **Priority Action 2**, other countries could benefit from Italy sharing its experiences with these efforts.

With regard to **Priority Action 4**, other countries could benefit from Italy sharing its experiences with monitoring mention of organ transplantation in newspapers or on TV and organising periodic meetings with journalists. It could benefit from setting up communication guidelines for informing the public about organ transplantation.

With regard to **Priority Actions 5 and 10**, it could be beneficial for Italy to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways Italy could benefit from investing efforts in these subjects.

With regard to **Priority Action 7**, other countries could benefit from Italy sharing its experiences with monitoring of organ trafficking. It could on the other hand be beneficial for the country to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.

17. Latvia

Background information[111]

With a deceased donation rate per million population between 10 and 20 in 2011, Latvia belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver and heart.
With a living kidney donation rate per million population lower than 10 in 2011, Latvia's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.

Regarding EU-funded projects Latvia participates as a partner in ACCORD and participated as a partner in COORENOR.

In 2011 the country participated in the data collection launched by the working group on indicators[112]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[113]).

Financing of organ donation

In case of living donation, a state owner or state-controlled institution pays for the expenses incurred by the donor. The donor is entitled to state guaranteed medicinal aid free of charge until the end of his or her life.

Consent system

Since September 29th 1995 an **opting-out system** is in place, in which post mortem organ retrieval is possible if the deceased has not prohibited it. In case no information is available regarding consent to or refusal of organ donation **next-of-kin** have the right to inform a medical centre of the deceased's will expressed while alive. Consent or refusal is **registered** in the residents' register.

[111] **Sources**: ACTOR survey filled in by national Competent Authority. Lopp, L. (2012). Final Report: A Common Frame of Reference for European Laws on Living Organ Donation, Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe / Part I: Unrelated Organ Donation (EULOD project) EULOD; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[112] For more information about the working groups, see §3.2

[113] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	2.3	2.3	2.2
Family refusal rate (refusals/times asked)	13/24	9/19	6/25
Actual deceased donation rate (total/per million population)	30/13.0	34/14.8	40/18.2
Multi-organ donation rates (% of total)	-	-	10
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	11	11	13
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	1	1	1
Liver	0	1	0
Heart	1	1	1
Lung	0	0	0
Pancreas	1	0	0
Number of deceased donor transplant procedures (total/pmp)			
Kidney	53/23.0	64/27.8	74/33.6
Liver	0	0	1/0.5
Heart	0	0	3/1.4
Lung	0	0	0
Pancreas	1/0.4	0	0
Number of living donor transplant procedures (total/pmp)			
Kidney	1/0.4	2/0.9	3/1.4
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	300	65	55
Liver	0	3	0
Heart	7	6	3
Lung	0	0	0
Pancreas	2	0	0
Number of mortalities while on waiting list			
Kidney	10	12	5
Liver	0	0	0
Heart	1	0	0
Lung	0	0	0
Pancreas	0	0	0

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the regional level. It is indicated that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	Latvia indicates that the government has stimulated initiatives to improve the quality of the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is indicated that there are no directed[114] or undirected living donation programmes, but that these are intended for the future. It is unknown to the research team if registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is unknown to the research team if programmes are deployed to improve knowledge and communication skills of health professionals or patient support groups. It is unknown to the research team if efforts have been made with regard to setting up communication guidelines for informing the public, monitoring of mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is unknown to the research team if Latvia has been involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether there are agreements in place in Latvia regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Latvia indicates that it has an agreement with Balttransplant.
Priority Action 9: Evaluation of post-transplant results	It is unknown to the research team if post-transplant results of organ recipients are evaluated.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Action 2**, other countries could benefit from Latvia sharing its experiences with these efforts.

With regard to **Priority Action 3**, Latvia could benefit from the experiences that other countries have with this Priority Action. This is especially relevant, since living donations are carried out in the country.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Latvia to come together with countries who have taken up efforts regarding public awareness to help redefine this Priority Action and to reconsider the ways Latvia could benefit from investing efforts in this subject.

With regard to **Priority Actions 6 and 9**, Latvia could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

[114] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

18. Liechtenstein

Background information[115]

Donor organs are allocated through Eurotransplant. The country representative indicated that no organ donation and transplantation is performed in Liechtenstein. Therefore most of the Priority Actions are not applicable to Liechtenstein (or not completely applicable), this should be taken into account.

Regarding detailed information on key data for organ donation and transplantation, only numbers relating to the population of the country is available (0,036 million inhabitants in 2010), for the same reasons.

Consent system

Not applicable

Implementation Action Plan[116]

Priority Action 1: Promote the role of transplant donor coordinators	In Liechtenstein, no transplant donor coordinators have been appointed.
Priority Action 2: Promote Quality Improvement Programmes	Liechtenstein's government has not stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process or follow up care, because no transplantations are performed.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	Liechtenstein does not have directed or undirected living donation programmes. No registers are established to evaluate and guarantee the health and safety of living donors. Only calls for living donors from neighbour countries (AT, CH) are also extended to Liechtenstein.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	No programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups, as this is not applicable.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Liechtenstein has not been involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that there are agreements in place regarding basic rules for internal EU patient mobility and transplantation. It is unknown to us whether Liechtenstein has any agreements in place regarding transplant medicine for extra-Community patients. It is indicated that there are no agreements regarding organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Liechtenstein reports that it has a bilateral collaboration with Switzerland.
Priority Action 9: Evaluation of post-transplant results	Post-transplant results of organ recipients are not evaluated, as no transplantations are performed.
Priority Action 10: Promote a common accreditation system	No additional plans regarding promoting a common accreditation system for organ donation /procurement and transplantation programmes are undertaken.

[115] **Sources**: ACTOR survey filled in and additional information provided by national Competent Authority; Gesundheitsgesetz, LR 811.01, see www.gesetze.li; Schweizerisches Transplantationsgesetz, SR 810.21, see www.bag.admin.ch/transplantation.

[116] Due to the small size of the country it should be taken into consideration that not each Priority Action might be applicable.

Recommendations

No transplantations are performed in Liechtenstein and it is not planned in the future. Recommendations regarding the Priority Actions are not directly applicable to transplant procedures. However for citizens from Liechstenstein possibly in need for a transplant (and therefore who would need to access transplant waiting lists) or applying to be living donors in other/neighboring European countries, Liechtenstein could take inspiration/benefit from the Action Plan and from experiences and tools shared at EU level..

19. Lithuania

Background information[117]

With a deceased donation rate per million population between 10 and 20 in 2011, Lithuania belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Lithuania's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.

Regarding EU-funded projects Lithuania was core work package leader of the Joint Action MODE[118] and partner in ETPOD and COORENOR. It is a partner in the Joint Actions ACCORD and FOEDUS.

In 2010 and 2011 the country participated in the data collection for the annual Indicators' exercises of the working group on indicators[119].

Financing of organ donation

In case of deceased donation financing is part of the general health care system. In case of living donation, financing occurs through the health insurance.

Consent system

Since December 21st 1999 an **opting-out system** is in place**.** If the next-of-kin are not known and there is no other way of learning the will of the deceased, post mortem organ retrieval is possible in an emergency case after approval of the "medical council" of the health care institution concerned. Post mortem retrieval is possible if the deceased did not express his will and if the **next-of-kin** do not object to removal after being asked about their opinion. Consent or refusal is **registered** in the Register of Donors and Recipients of Human Tissues and Organs.

[117] **Sources**: ACTOR survey filled in by national Competent Authority, as well as additional information provided; COORENOR (2011). Deliverable 7.2: Overview of national legislation and international cooperation in cross border organ exchanges, defining basic parameters of future IT-portal; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[118] For more information about EU-funded projects, see §3.1

[119] For more information about the working groups, see §3.2

Key figure

	2008	2010	2011
Population in millions	3.4	3.3	3.2
Family refusal rate (refusals/times asked)	19/61	25/75	34/89
Actual deceased donation rate (total/per million population)	33/9.7	36/10.9	39/12.2
Multi-organ donation rates (% of total)	30.3	58.3	40.0
Number of utilised donors (total/per million population)	33/9.7	34/10.3	38/11.8
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	3	10	11
Number of transplant centres			
Kidney	2	2	2
Liver	2	2	2
Heart	2	2	2
Lung	2	1	1
Pancreas	1	1	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	42/12.3	63/19.1	69/21.6
Liver	6/1.8	13/3.9	12/3.8
Heart	5/1.5	10/3	5/1.6
Lung	2/0.6	0	1/0.3
Pancreas	4/1.2	0	3/0.9
Number of living donor transplant procedures (total/pmp)			
Kidney	5/1.5	8/2.4	3/0.9
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	252	155	214
Liver	24	27	41
Heart	33	27	18
Lung	3	2	2
Pancreas	11	15	18
Number of mortalities while on waiting list			
Kidney	8	13	7
Liver	2	7	8
Heart	5	5	7
Lung	-	0	0
Pancreas	-	0	0

- = unknown to the research team

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital and the national level. It is indicated that these transplant donor coordinators receive both initial training at moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	Lithuania indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, donation process, procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors. A draft law is in preparation about paired undirected kidney living donation. A registry will be developed which will evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	The country-representative indicates that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that there are communication guidelines for informing the public about organ transplantation, mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists, since the Action Plan was implemented.
Priority Action 5: Facilitate the identification of organ donors across Europe	Lithuania provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Lithuania indicates that it has been involved in a twinning project with Italy. The subject of the project was to develop a system for accreditation and audit of donation and transplantation activities based on the Italian Model adapted to national realities.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Lithuania indicates that it has agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients and organ trafficking. It is indicated that a draft law is being prepared which addresses the mentioned subjects.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Lithuania indicates that it collaborates with the European Transplant Network.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated 3 months, 6 months and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that there are additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes. The country-representative indicated that, due to the economic situation in the country, the plans are not sufficient.

Recommendations

With regard to **Priority Action 2**, Lithuania could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.
With regard to **Priority Action 3**, Lithuania could benefit from setting up a register of living donors, since it becomes mandatory with the Directive 2010/53/EU.
With regard to **Priority Actions 4, 5 and 10**, other countries could benefit from Lithuania sharing its experiences with these efforts. Furthermore, it could be beneficial if Lithuania comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions.
With regard to **Priority Action 7** other countries could benefit from Lithuania sharing its experiences with agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients and monitoring of organ trafficking. It could be beneficial for Lithuania to further look into setting up agreements regarding common priorities and strategies for future research programmes.

20. Luxembourg

Background information[120]

With a deceased donation rate per million population between 10 and 20 in 2011, Luxembourg belongs to the majority of the countries included in this study. In 2011, no deceased donor transplant procedures were carried out regarding liver and kidney and it is unknown to the research team if deceased donor transplant procedures were carried out regarding heart, lung and pancreas.
No living donation transplant procedures were carried out in 2011.
Luxembourg is part of Eurotransplant[121] and donor organs are allocated through Eurotransplant.
Given the size of the country, the numbers of donation and/or transplant procedures, might vary form a year to another (2 kidney transplants in 2009, but no donor, whereas in 2011 Luxembourg had 9 deceased donors but no kidney transplant).

Luxembourg did not participate directly in an EU-funded project, and it could reconsider how it could benefit from participating in such a project. However, with its membership in Eurotransplant, Luxembourg can also take benefit from the experience and tools shared via EU-funded projects.

In 2011 the country participated in the working group on indicators[122]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[123]).

Consent system

Since November 25th 1982 an **opting-out system** is in place, in which post mortem organ retrieval may occur when the deceased has not explicitly indicated refusal to be a donor. **Next-of-kin** have no right to be informed. Neither can they give consent to or refuse organ removal.

[120] **Sources:** ACTOR survey filled in by national Competent Authority; Eurotransplant (2009). Yearly Statistics 2008; Eurotransplant (2011). Yearly Statistics 2011; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[121] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR.

[122] For more information about the working groups, see §3.2

[123] For more information about CD-P-TO, see §3.3

Key figure

	2008	2010	2011
Population in millions	0.5	0.5	0.5
Family refusal rate (refusals/times asked)	-	3/7	-
Actual deceased donation rate (total/per million population)	9/18	3/6	9/18
Multi-organ donation rates (% of total)	100	100	88.9
Number of utilised donors (total/per million population)[124]	-	-	-
Number of donors after circulatory death - DCD	-	0	-
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	-	0	0
Liver	-	0	0
Heart	-	0	0
Lung	-	0	0
Pancreas	-	0	0
Number of deceased donor transplant procedures (total/pmp)			
Kidney	3/6	6/12	0
Liver	0	0	0
Heart	0	0	-
Lung	0	0	-
Pancreas	0	0	-
Number of living donor transplant procedures (total/pmp)			
Kidney	0	0	0
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	10	0	0
Liver	-	0	0
Heart	-	0	0
Lung	-	0	0
Pancreas	-	0	0
Number of mortalities while on waiting list			
Kidney	0	-	0
Liver	0	-	0
Heart	0	-	0
Lung	0	-	0
Pancreas	0	-	0

- = unknown to the research team

[124] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the national level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing
Priority Action 2: Promote Quality Improvement Programmes	Luxembourg indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors. It is unknown to the research team if initiatives are also stimulated to improve the quality of the donation process, the procurement process, the transplantation process and follow up care. It could be beneficial if these initiatives are stimulated as well.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed and undirected living donation programmes exist. It is indicated that there are registers established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. It is indicated that no efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Luxembourg indicates that it has not been involved any twinning project.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to us if Luxembourg has agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, or organ trafficking. The country-representative indicates that there are no agreements in place about common priorities and strategies for future research programmes. It could be beneficial for Luxembourg to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Luxembourg could benefit from investing efforts in this subject.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, the country-representative indicates that there is an agreement with Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are not evaluated.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Action 2**, it could be beneficial for Luxembourg to stimulate initiatives regarding the quality of the donation process, the procurement process, the transplantation process and follow up care.

With regard to **Priority Actions 4, 5 and 10**, it could be beneficial for Luxembourg to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways it could benefit from investing efforts in these subjects.

With regard to **Priority Actions 6 and 9**, the country could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

21. Macedonia (former Yugoslav Republic of Macedonia)

Background information[125]

In Macedonia in 2011, one liver (paediatric) transplant was carried out from a deceased donor.

With a living kidney donation rate per million population lower than 10 in 2011, Macedonia's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011, six kidney transplants were carried out from living donors.

It seems that more transplant procedures took place in 2012, compared to 2011.

As it is not an EU Member State, the country does not participate in EU-funded projects, but as a candidate country[126], it can benefit from the support of EU-funding for "TAIEX grants" (Directorate General for Enlargement of the European Commission). It also regularly participates in meetings of the Competent Authorities in Brussels. In 2012, it also took part in the annual data collection launched by the Indicators' working group.

Financing of organ donation

In case of deceased donation, a donor code is provided by the Health Insurance fund with allocation of around 5000 euros per deceased donor. Living donation is fully covered by insurance.

Consent system

Explicit written consent is required for organ retrieval.

[125] **Sources**: ACTOR survey filled in by national Competent Authority.; Spasovski, G., Busic, M., Raley, L., Pipero, P., Sarajlic, L., Popovic, A. S. et al. (2012). Current status of transplantation and organ donation in the Balkans--could it be improved through the South-eastern Europe Health Network (SEEHN) initiative? Nephrol Dial Transplant, 27, 1319-1323; http://www.sitel.com.mk/dnevnik/makedonija/vladata-go-prifati-predlog-zakonot-za-presaduvanje-chovechki-organi-i-tkiva

[126] http://ec.europa.eu/enlargement/countries/detailed-country-information/former-yugoslav-republic-of-macedonia/index_en.htm

Key figures

	2008	2010	2011
Population in millions	2.1	2.0	2.1
Family refusal rate (refusals/times asked)	-	-	2/2
Actual deceased donation rate (total/per million population)	-	0	0
Multi-organ donation rates (% of total)	0	0	0
Number of utilised donors (total/per million population)	0	0	-
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	-	2	2
Liver	-	0	1
Heart	-	0	0
Lung	-	0	0
Pancreas	-	-	0
Number of deceased donor transplant procedures (total/pmp)			
Kidney	-	0	0
Liver	-	0	1/0.5
Heart	-	0	-
Lung	-	0	-
Pancreas	-	0	-
Number of living donor transplant procedures (total/pmp)			
Kidney	-	12/6	6/2.9
Liver	-	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	-	-	5
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	-	-	0
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-

- = unknown to the research team

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have not been appointed, but the country-representative indicates that this is planned.
Priority Action 2: Promote Quality Improvement Programmes	Macedonia indicated that the government has stimulated initiatives to improve the quality of the donation process and the transplantation process. It is unknown to the research team whether initiatives are stimulated to improve the quality of the identification of potential donors, the procurement process and follow up care.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is unknown to the research team if registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	The country-representative indicates that there are no programmes deployed to improve knowledge and communication skills of health professionals and patient support groups. It is indicated that no efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models	It is indicated that Macedonia has not been involved any twinning project.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	The country-representative indicates that there are no agreements in place about basic rules for internal EU patient mobility and transplantation, organ trafficking or common priorities and strategies for future research programmes. It is unknown to the research team if Macedonia has agreements in place regarding transplant medicine for extra-Community patients.
Priority Action 8: Facilitate the interchange of organs between national authorities	Macedonia indicates that it is not part of a fixed collaboration, for the interchange of organs between national authorities.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, although not in a systematic way.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if there are additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Actions 1 and 8**, Macedonia could benefit from the experiences that other countries have with these Priority Actions.
With regard to **Priority Action 2**, it could be beneficial if initiatives are stimulated to improve the quality of the identification of potential donors, the procurement process and follow up care. On the other hand, other countries could benefit from Macedonia sharing its experiences with quality improvements regarding the transplantation process.
With regard to **Priority Action 3**, Macedonia could benefit from setting up registers for living donors, since it becomes mandatory with the Directive 2010/53/EU.
With regard to **Priority Actions 4, 5, 7 and 10,** it could be beneficial for Macedonia to come together with countries who have taken up efforts regarding these Priority Actions to help redefine them and to reconsider the ways Macedonia could benefit from investing efforts in these subjects.
With regard to **Priority Action 6** the country could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.
With regard to **Priority Action 9**, the country could invest effort in setting up a systematic way of evaluating post-transplant results of organ recipients.

22. Malta

Based on publicly available information

Background information[127]

With a deceased donation rate per million population higher than 20 in 2011, Malta's deceased donation rate per million population is amongst the highest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney and heart.
With a living kidney donation rate per million population higher than 10 in 2011, Malta's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.
Donor organs are allocated at national level and through cooperation with other EU countries.

With regard to EU-funded projects, Malta is a partner in the Joint Action project FOEDUS[128] and is an associated partner in the Joint Action ACCORD.

In 2012, the country participated in the data collection launched by the working group on indicators[129]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[130]).

Financing of organ donation

In case of deceased donation, funding is part of the general health care system. In living donation, health care is publically funded for the care of organ donors and recipients.

Consent system

Prior to transposition of Directive 2010/53/EU, there is no specific legislation on post-mortem removal in Malta.

[127] **Sources**: COORENOR (2011). Deliverable 7.2: Overview of national legislation and international cooperation in cross-border organ exchanges, defining basic parameters of future IT-portal.; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[128] For more information about EU-funded projects, see §3.1

[129] For more information about the working groups, see §3.2

[130] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	0.4	0.4	0.4
Family refusal rate (refusals/times asked)	-	1/10	2/18
Actual deceased donation rate (total/per million population)	-	9/22.5	12/30
Multi-organ donation rates (% of total)	-	100	66.7
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	-	0	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	-	1	1
Liver	-	-	0
Heart	-	1	1
Lung	-	0	0
Pancreas	-	0	0
Number of deceased donor transplant procedures (total/pmp)			
Kidney	-	11/27.5	12/30
Liver	-	0	-
Heart	-	1/2.5	1/2.5
Lung	-	0	-
Pancreas	-	0	-
Number of living donor transplant procedures (total/pmp)			
Kidney	-	3/7.5	6/15
Liver	-	0	-
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	-	156	90
Liver	-	2	-
Heart	-	1	-
Lung	-	-	-
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	-	10	11
Liver	-	0	-
Heart	-	1	-
Lung	-	-	-
Pancreas	-	-	-

- = unknown to the research team

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the national level. It is reported that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is unknown to the research team if the Maltese government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process or follow up care.
Priority Action 3: Exchange of best practices on living donation	It is reported that directed[131] living donation programmes exist, but it is unknown to the research team if there are any undirected living donation programmes. It is reported that there are no registers established to evaluate and guarantee the health and safety of living donors, but that this is planned.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is reported that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. It is reported that no efforts have been made with regard to monitoring of mention of organ transplantation on TV or organising periodic meetings with journalists. It is unknown to the research team if efforts have been made with regard to setting up communication guidelines for informing the public or monitoring of mention of organ transplantation in newspapers.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is unknown to the research team if additional plans or actions are undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is reported that Malta has been involved in a twinning project with Italy. Subject of the project was to develop a system for accreditation and audit of donation and transplantation activities based on the Italian Model.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is reported that Malta has no agreements in place regarding monitoring of organ trafficking. It is unknown to the research team whether there are any agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	It is unknown to the research team if Malta is part of any fixed collaborations for the interchange of organs between national authorities..
Priority Action 9: Evaluation of post-transplant results	It is unknown to the research team if post-transplant results of organ recipients are evaluated.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 2 and 9,** Malta could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

With regard to **Priority Actions 3 and 8**, Malta could benefit from the experiences that other countries have with these Priority Actions. With regard to Priority Action 3, Malta could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Malta to come together with countries who have taken up efforts regarding public awareness to help redefine these Priority Actions and to reconsider the ways Malta could benefit from investing efforts in these subjects.

[131] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

23. Montenegro

Background information[132]

Transplantations are not yet carried out in Montenegro (or activities are just starting), but patients from Montenegro went in different countries abroad for kidney transplantation, for living transplantation and for deceased transplantations.
First kidney transplantations from related living donors were performed in Montenegro on 25th and 26th of September 2012. A transplantation program from living donors is being developed and the development of a deceased donation program is also intended.

As it is not an EU Member State, the country does not participate in EU-funded projects, but as a candidate country[133], it can benefit from the support of EU-funding in the form of "Pre-accession assistance" (Directorate General for Enlargement of the European Commission). It also regularly participates in meetings of the Competent Authorities in Brussels.

Financing of organ donation

In case of deceased donation, funding is covered by the public health insurance. In case of living donation, funding is covered by the public budget.

Consent system

Explicit written consent is needed for organ retrieval.

[132] **Sources**: ACTOR survey filled in by national Competent Authority and information provided additionally. Spasovski, G., Busic, M., Raley, L., Pipero, P., Sarajlic, L., Popovic, A. S. et al. (2012). Current status of transplantation and organ donation in the Balkans--could it be improved through the South-eastern Europe Health Network (SEEHN) initiative? Nephrol Dial Transplant, 27, 1319-1323

[133] http://ec.europa.eu/enlargement/instruments/funding-by-country/montenegro/index_en.htm

Key figures

	2008	2010	2011
Population in millions	0.7	0.7	-
Family refusal rate (refusals/times asked)	0/0	0/0	-
Actual deceased donation rate (total/per million population)	-	0	-
Multi-organ donation rates (% of total)	0	0	-
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	0	0	-
Number of donors older than 65	0	0	-
Number of transplant centres			
Kidney	-	-	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of deceased donor transplant procedures (total/pmp)			
Kidney	0	0	-
Liver	0	0	-
Heart	0	0	-
Lung	0	0	-
Pancreas	0	0	-
Number of living donor transplant procedures (total/pmp)			
Kidney	14	1	-
Liver	0	0	-
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	-	-	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-
Number of mortalities while on waiting list			
Kidney	-	-	-
Liver	-	-	-
Heart	-	-	-
Lung	-	-	-
Pancreas	-	-	-

- = unknown to the research team

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital level. It is indicated that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	Montenegro indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	It is indicated that there are no directed or undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors, but that this is intended for the future.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that there are no programmes deployed to improve knowledge and communication skills of health professionals and patient support groups. It is indicated that no efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists**.**
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Montenegro indicates that it has not been involved in any twinning project, but that this is intended.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	The country-representatives indicates that there are agreements in place about organ trafficking and common priorities and strategies for future research programmes. It is indicated that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation or transplant medicine for extra-Community patients.
Priority Action 8: Facilitate the interchange of organs	For the interchange of organs between national authorities, Montenegro indicates that it has a bilateral agreement with Croatia.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3, 6 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Action 2**, other countries could benefit from Montenegro sharing its experiences with quality improvements regarding the transplantation process and follow up care.
With regard to **Priority Action 3**, Montenegro could benefit from the experiences that other countries have with these efforts. This is especially relevant, since living donations constitute an important part of the organ donation system. Montenegro could benefit from setting up registers of living donors.
With regard to **Priority Actions 4 and 10**, it could be beneficial for Montenegro to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Montenegro could benefit from investing efforts in these subjects.
With regard to **Priority Action 5**, other countries could benefit from Montenegro sharing its experiences with these efforts. Furthermore, it could be beneficial if Montenegro comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action.
With regard to **Priority Action 7**, other countries could benefit from Montenegro experiencing its experiences with monitoring of organ trafficking and common priorities and strategies for future research programmes. On the other hand, it could be beneficial for Montenegro to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation or transplant medicine for extra-Community patients.

24. The Netherlands

Background information[134]

With a deceased donation rate per million population between 10 and 20 in 2011, the Netherlands belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population higher than 10 in 2011, the Netherlands' living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
The Netherlands is part of Eurotransplant[135] and donor organs are allocated through Eurotransplant.

Regarding EU-funded projects,the project EULOD[136] had a Dutch coordinator, and Dutch authorities participated as a partner in the project EFRETOS. The country is core work package leader in the Joint Action ACCORD: work package on registers of living donors.

In 2010, 2011 and 2012, the country participated in the working group on indicators[137] and in the annual exercises via data collection. Furthermore, the country participated in the working group on living donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[138]).

A presentation of the state of play concerning organ donation and transplantation in the Netherlands was given at a Competent Authority meeting in February 2011.

Financing of organ donation

In case of deceased donation, costs are partly covered by insurers of patients on the waiting lists, through special 'registration rates'. When actual donation takes place, the insurers of patients on the waiting list also cover a 'removal rate'. Thus, these costs are also covered in case no recipient is connected to the donation (e.g. when organs or tissues prove to be unfit or are not accepted). In case of living donation, the recipient's insurance company is responsible for costs for evaluation of suitability of (potential) donor, operation, hospital stay, etc. (donor and recipient) and follow up of donor to three months after transplantation. The ministry department makes a reimbursement to additional (non-medical) costs made by the donor, e.g. travel, telephone and hotel costs. The donor's insurance company covers the costs regarding follow up of the donor after three months.

Consent system

Since May 24th 1996, an **opting-in system** is in place, combined with elements of a **less strict opting-out system**. Every citizen receives a donor form when they turn 18 with several options, namely consent to organ removal or to removal of specific organs, refusal or delegate the decision to consent or refuse to relatives or to another named individual. An element of a less strict opting in system is in place, since in case a person has not expressed a will, organ removal is possible with the consent of **next-of-kin**. In practice relatives are still asked whether they agree with organ removal even if the deceased has consented to it. Consent or refusal is **registered** in a donor register.

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[134] **Sources**: ACTOR survey filled in by national Competent Authority, and information additionally provided; Competent Authority the Netherlands. (2011). Presentation National Action Plan the Netherlands, February 2011; Haase, B. (2011). Presentation: Living donor kidney transplantation in the Netherlands, 28-01-2011; Nederlandse Transplantatiestichting (2011). Jaarverslag 2010; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven; http://www.eurotransplant.org/cms/mediaobject.php?file=year_20083.pdf; http://www.eurotransplant.org/cms/mediaobject.php?file=year_2010.pdf; http://statistics.eurotransplant.org/

[135] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR.

[136] For more information about EU funded projects, see §3.1

[137] For more information about the working groups, see §3.2

[138] For more information about CD-P-TO, see §3.3

Key figures[139]

- = unknown to the research team

	2008	2010	2011
Population in millions	16.4	16.6	16.7
Family refusal rate (refusals/times asked)	250/456	257/495	289/552
Actual deceased donation rate (total/per million population)	201/12.3	216/13.0	221/13.2
Multi-organ donation rates (% of total)	69	69	71
Number of utilised donors (total/per million population)	240/14.6	259/15.6	275/16.5
Number of donors after circulatory death - DCD	82	73	111
Number of donors older than 65	24	28	41
Number of transplant centres			
Kidney	8	8	8
Liver	3	3	3
Heart	3	3	3
Lung	3	3	3
Pancreas	2	2	2
Number of deceased donor transplant procedures (total/pmp)[140]			
Kidney	351/21.4	388/23.4	408/24.4
Liver	129/7.9	131/7.9	140/8.4
Heart	25/1.5	48/2.9	38/2.3
Lung	81/4.9	118/7.2	131/7.8
Pancreas	16/1	17/1	23/1.4
Number of living donor transplant procedures (total/pmp)			
Kidney	413/25.2	473/28.0	440/26.3
Liver	2/0.1	5/0.3	10/0.6
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	952	892	883
Liver	118	121	123
Heart	54	67	57
Lung	185	214	235
Pancreas	30	35	38
Number of mortalities while on waiting list			
Kidney	91	95	89
Liver	22	17	29
Heart	12	11	11
Lung	28	18	21
Pancreas	1	3	3

Recommendations

With regard to **Priority Action 2**, countries could benefit from the Netherlands sharing its experiences with quality improvements regarding the transplantation process and follow-up care.

With regard to **Priority Action 4** other countries could benefit from the Netherlands sharing its experiences with communication guidelines for informing the public about organ transplantation and monitoring how often organ transplantation is mentioned in newspapers or on TV. Furthermore, it could be beneficial if the Netherlands comes together with countries who have not taken up efforts on this Priority Action to help redefine it. The Netherlands could also benefit from investing in organising periodic meetings with journalists.

[139] Numbers are based on Statistics of Eurotransplant and the Transplant Newsletter of the Council of Europe

[140] Figures are actual transplantations, failed procedures are not taken into account.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital and regional level. These transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the Dutch government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed[141] and undirected living donation programmes exist. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that there are communication guidelines for informing the public about organ transplantation and that mention of organ transplantation in newspapers and on TV are monitored. It is indicated that periodic meetings with journalists have not been organised, but that this is intended.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	The Netherlands indicates that it has been involved in a twinning project with Hungary. The subject was procurement surgery, more specifically training surgeons in the procurement of abdominal organs.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	The Netherlands indicates that it has agreements in place regarding basic rules for internal EU patient mobility and transplantation and transplant medicine for extra-Community patients. It is indicated that there are no agreements in place regarding common priorities and strategies for future research programmes. In addition, it is unknown to the research team if there agreements in place regarding organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, the Netherlands is part of Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3 and 12 months after transplantation and yearly after that.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

With regard to **Priority Actions 5 and 10**, other countries could benefit from the Netherlands sharing its experiences with these efforts. Furthermore, it could be beneficial if the Netherlands comes together with countries who have not taken up efforts on this Priority Action to help redefine it.

With regard to **Priority Action 7**, other countries could also benefit from the Netherlands sharing its experiences regarding agreements about basic rules for internal EU patient mobility and transplantation and transplant medicine for extra-Community patients. Furthermore, it could be beneficial if the Netherlands comes together with countries who have not taken up efforts on this Priority Action to help redefine it. It could be beneficial for the Netherlands to further look into setting up agreements regarding common priorities and strategies for future research programmes or monitoring of organ trafficking.

[141] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

25. Norway

Background information[142]

With a deceased donation rate per million population higher than 20 in 2011, Norway's deceased donation rate is amongst the highest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas. With a living kidney donation rate per million population higher than 10 in 2011, Norway's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney. Norway is part of Scandiatransplant[143] and donor organs are allocated through Scandiatransplant.

Regarding EU-funded projects, Norway was core work package leader of the EU funded project EULID[144] and participates as partner in ACCORD, and FOEDUS. Norway participated in ELIPSY as a partner, but withdrew from participation.
In 2010 the country participated in the working group on indicators[145]. Furthermore, the country participated in the working group on living donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[146]): in 2010/2012, the CD-P-TO had even a Norwegian Chairman.

Financing of organ donation

In case of deceased donation, funding is covered by the public health system. In case of living donation, clinical tests and consultations before and after donation, peri-operative care and hospital stay after donation are fully covered by healthcare systems or insurances in which organ donation is free of charges for the donors. Travel expenses before and after donation are covered in Norway. Financial losses related to the professional activities discontinuation are covered in Norway. In Norway, Poland and Sweden, they are supported by the health insurance of the recipient

Consent system

Since January 1st 1974 an **opting-out system** is in place. **Next-of-kin** are consulted before organ removal and have the possibility to refuse to it. In case no next-of-kin can be found, organs can be removed. There is no **registry** in place.

[142] **Sources**: Abadie, A. & Gay, S. (2006). The impact of presumed consent legislation on cadaveric organ donation: a cross-country study. Journal of Health Economics, 25, 599-620; ACTOR survey filled in by national Competent Authority, as well as information additionally provided. Scandiatransplant (2008). Transplantation and waiting lists figures 2008; Scandiatransplant (2011). Transplantation and waiting lists figures 2011; Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[143] Regarding EU-funded projects, Scandiatransplant participated as a partner in EFRETOS

[144] For more information about EU funded projects, see §3.1

[145] For more information about the working groups, see §3.2

[146] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	4.8	4.9	5.0
Family refusal rate (refusals/times asked)	42/143	42/149	35/162
Actual deceased donation rate (total/per million population)	98/20.5	102/20.9	127/24.5
Multi-organ donation rates (% of total)	90.0	92.0	88.2
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	15	17	-
Number of transplant centres			
Kidney	1	1	1
Liver	1	1	1
Heart	1	1	1
Lung	1	1	1
Pancreas	1	1	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	180/37.5	180/36.7	229/45.8
Liver	79/16.5	89/18.2	89/17.8
Heart	39/8.1	32/6.5	30/6
Lung	30/6.3	32/6.5	28/5.6
Pancreas	10/2.1	15/3.1	20/4
Number of living donor transplant procedures (total/pmp)			
Kidney	98/20.4	83/16.9	73/14.6
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	228	223	189
Liver	7	10	13
Heart	4	11	16
Lung	35	42	40
Pancreas	21	4	5
Number of mortalities while on waiting list			
Kidney	8	6	6
Liver	0	2	2
Heart	0	3	3
Lung	12	3	3
Pancreas	1	0	1

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital level and the national level. It is indicated that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	Norway indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors. Initiatives have also been taken to improve the quality of the donation process, the procurement process, the transplantation process and the follow-up care.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed living donation programmes exist including donation from spouses / cohabitates and close friends, but no program for altruistic non directed donation exists. It is indicated that there are registers established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. It is indicated that no efforts have been made with regard to setting up communication guidelines) for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists. An official sponsored foundation (Stiftelsen Organdonasjon) is responsible for informing and promoting organ donation towards mass media and the general population.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models	It is indicated that Norway has not been involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that there are agreements in place regarding common priorities and strategies for future research programmes. It is unknown to the research team whether Norway has any agreements in place regarding transplant medicine for extra-Community patients. It is indicated that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation of organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Norway is part of Scandiatransplant.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3, 6 and 12 months after transplantation and yearly thereafter.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes undertaken.

Recommendations

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the processes for donation, procurement, transplantation and follow-up care.

With regard to **Priority Actions 4, 5 and 10**, it could be beneficial for Norway to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Norway could benefit from investing efforts in these subjects.

With regard to **Priority Action 6**, the country could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

With regard to **Priority Action 7**, other countries could benefit from Norway sharing its experiences with agreements regarding common priorities and strategies for future research programmes. Furthermore, it could be beneficial if Norway comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. It could be beneficial for Norway to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or monitoring of organ trafficking.

26. Poland

Background information[147]

With a deceased donation rate per million population between 10 and 20 in 2011, Poland belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, Poland's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
Donor organs are allocated at national level only.

Regarding EU-funded projects Poland was core work package leader in the COORENOR[148] project and participated as partner in ETPOD, EULID, EULOD, and ODEQUS. It participates as a partner in the Joint Actions ACCORD and FOEDUS.

In 2010, 2011 and 2012 the country participated in the working group on indicators[149] and in the annual exercises. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[150]).

A National Action Plan was presented at a Competent Authority meeting on 27 September 2011.

Financing of organ donation

In case of deceased donation, funding is covered by the National Healthcare System (NFZ) and National Budget funds managed by the Ministry of Health. In case of living donation, the costs and expenses are directly funded by the healthcare system.

Consent system

Since October 26th 1995, an **opting-out system** is in place. By law the **next-of-kin** have no rights, but in practice relatives are informed about donation and in case of their opposition their will is accepted. Refusal of post mortem organ removal can be expressed through the **Central Register of Objections**.

[147] **Sources**: ACTOR survey filled in by national Competent Authority; Competent Authority Poland. (2011). Presentation National Action Plan Poland, 27 September 2011. Czerwiński J, Antoszkiewicz K, Pszenny A, Malanowski P, Dudkiewicz M, Woderska A, Kobus G, Ciszek M, Wałaszewski J. Present data on organ donation and transplantation in Poland. Transpl Proc 2009, 41, 2955-2958; Czerwiński J, Pszenny A, Ciszek M, Antoszkiewicz K, Wałaszewski J. Data On Organ Donation And Transplantation In Poland. 2009 Organ Donation Congress. 10 ISODP & 16 ETCO. Berlin 2009.10.4-7. Abstract #80; Deutsche Stiftung Organtransplantation (2006). Report on the general European situation: technical, legal and sociosanitary point of view (deliverable project DOPKI) DOPKI; Information provided by H. Nys, November 2012; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven; Poltransplant Bulletin nr 1 (20) April 2012; Poltransplant Bulletin nr 1 (17) March 2009; Poltransplant Bulletin nr 1 (19) March 2011; Poltransplant Bulletin nr 1 (20) April 2012; Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[148] For more information about EU-funded projects, see §3.1

[149] For more information about the working groups, see §3.2

[150] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	38.1	38.1	38.3
Family refusal rate (refusals/times asked)	54/497	51/587	68/732
Actual deceased donation rate (total/per million population)	427/11.2	509/13.3	553/14.4
Multi-organ donation rates (% of total)	56.0	47.0	58.4
Number of utilised donors (total/per million population)	422/11.1	497/13.0	541 / 14.1
Number of donors after circulatory death - DCD[151]	0	0	0
Number of donors older than 65	8	16	18
Number of transplant centres			
Kidney	18	18	18
Liver	5	5	6
Heart	4	5	5
Lung	1	2	2
Pancreas	4	4	4
Number of deceased donor transplant procedures (total/pmp)			
Kidney	790/20.7	949/24.9	1035/27.0
Liver	224/5.9	217/5.7	282/7.4
Heart	61/1.6	79/2.1	80/2.1
Lung	11/0.3	12/0.3	15/0.4
Pancreas	20/0.5	20/0.5	34/0.9
Number of living donor transplant procedures (total/pmp)			
Kidney	20/0.5	50/1.3	40/1.0
Liver	21/0.6	20/0.5	18/0.5
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	1479	1457	1469
Liver	115	170	132
Heart	204	415	252
Lung	20	29	30
Pancreas	15	34	15
Number of mortalities while on waiting list			
Kidney	67	48	64
Liver	35	34	37
Heart	41	55	53
Lung	5	4	12
Pancreas	0	3	1

Recommendations

With regard to **Priority Action 2**, other countries could benefit from Poland sharing its experiences with quality improvements regarding the transplantation process and follow up care.

[151] Since 2009 Donation after Circulatory Death (DCD) is allowed, but no programme existed yet.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital, regional and the national level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	Poland indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that communication guidelines for informing the public exist and that periodic meetings have been organised with journalists, since the Action Plan was implemented. It is indicated that mention of organ transplantation on TV is not monitored. It is unknown to the research team if mention in newspapers is monitored.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU, but that this is intended. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action. However, the country-representative indicated that the content of this Priority Action is unclear.
Priority Action 6: Enhancing organisational models	Poland indicates that it has not been involved in any twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Poland indicates that it has agreements in place regarding common priorities and strategies for future research programmes. It is indicated that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Poland indicates that it has bilateral agreements with the Czech Republic, Slovakia, Lithuania, Latvia and other European Organ Exchange Organisations.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3 and 12 months after transplantation. It is indicated that information about graft and recipient survival is registered after 3 months and every 12 months thereafter.
Priority Action 10: Promote a common accreditation system	The country-representative indicates that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

With regard to **Priority Action 4**, other countries could benefit if Poland shares its experiences with communication guidelines for informing the public exist and organising periodic meetings with journalists. Poland could benefit from investing in monitoring how often organ donation is mentioned in newspapers or on TV.

With regard to **Priority Action 5**, the country-representative indicated that the content of this Priority Action is unclear. It could be beneficial for Poland to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Poland could benefit from investing efforts in this subject.

With regard to **Priority Action 6**, the country could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

With regard to **Priority Action 7**, other countries could benefit from Poland sharing its experiences with agreements regarding common priorities and strategies for future research programmes. It could be beneficial for Poland to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or monitoring of organ trafficking.

With regard to **Priority Action 10**, other countries could benefit from Poland sharing its experiences with these efforts. Furthermore, it could be beneficial if Poland comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action.

27. Portugal

Background information[152]

With a deceased donation rate per million population higher than 20 in 2011, Portugal's deceased donation rate is amongst the highest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population lower than 10 in 2011, the Portugal's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.
Donor organs are allocated on the regional level.

Regarding EU-funded projects, Portugal was core work package leader in EULID and ELIPSY[153] as well as partner in Alliance-O, DOPKI, ETPOD, COORENOR, MODE and ODEQUS. It is a partner in the Joint Actions ACCORD and FOEDUS.

In 2010 and 2011, the country participated in the data collection for the annual Indicators' exercises and it joined the working group on indicators[154] in 2013. Furthermore, it participated in the working group on deceased donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[155]).

A National Action Plan was presented at a Competent Authority meeting on 6-7 September 2010.

Financing of organ donation

In case of living donation, the costs and expenses are directly funded by the healthcare system.

Consent system

Since September 26th 1994 an **opting-out system** is in place. Formally, it is not mandatory an authorization from the **next-of-kin** for the purpose of organ retrieval, however in practice the next-of-kin may express objection. Normally this is accepted, unless there is an urgent or super urgent request for an organ. In these cases, legislation overrides the will of the family. Consent or refusal is **registered** in the Non Donors National Registry (RENNDA).

[152] **Sources**: ACTOR survey filled in by national Competent Authority and information additionally provided; Centro Nazionale Trapianti (2005). Alliance-O Work Package 4 INCREASE SAFETY AND QUALITY IN ORGAN TRANSPLANTATION Deliverable 4.1 STATE OF THE ART OF SAFETY PROCESSES, EXCHANGE OF BEST PRACTICES; Competent Authority Portugal. (2010). Presentation National Action Plan Portugal, 6-7 September 2010; National Statistics Institute (www.ine.pt). Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[153] For more information about EU-funded projects, see §3.1

[154] For more information about the working groups, see §3.2

[155] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	10.6	10.6	10.6
Family refusal rate (refusals/times asked)	NA	NA	NA
Actual deceased donation rate (total/per million population)	283/26.7	323/30.4	301/28.4
Multi-organ donation rates (% of total)	73.9	69.0	71.1
Number of utilised donors (total/per million population)	-	320/30.2	286/27
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	-	63	68
Number of transplant centres			
Kidney	8	8	8
Liver	3	3	3
Heart	4	4	4
Lung	1	1	1
Pancreas	1	2	2
Number of deceased donor transplant procedures (total/pmp)			
Kidney	476/44.8	522/49.1	483/45.1
Liver	200/18.8	208/19.6	193/18.2
Heart	42/4.0	50/4.7	46/4.3
Lung	4/0.4	10/0.9	18/1.7
Pancreas	14/1.3	15/1.4	25/2.3
Number of living donor transplant procedures (total/pmp)			
Kidney	51/4.8	51/4.8	47/4.4
Liver	1/0.1	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	2275	1935	1973
Liver	-	108	169
Heart	-	23	17
Lung	-	22	31
Pancreas	27	47	53
Number of mortalities while on waiting list			
Kidney	-	54	63
Liver	-	24	18
Heart	-	5	4
Lung	-	1	0
Pancreas	-	0	1

Recommendations

With regard to **Priority Actions 2 and 6**, Portugal could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local, regional and hospital with ICU facilities level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing.
Priority Action 2: Promote Quality Improvement Programmes	Portugal indicates that the government has not stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process or follow up care. There is an ongoing general quality improvement program in all hospitals; an Organ Donation Specific Quality Program is being developed.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed and undirected living donation programmes exist. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors, but that this is planned.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that periodic meetings have been organised with journalists, since the Action Plan was implemented. It is indicated that there are no communication guidelines for informing the public about organ transplantation and that mention of organ transplantation in newspapers and on TV are not monitored, but it is intended to design a communication program. In 2000 Portugal organised the European donation day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models	Portugal indicates that it has not been involved in twinning projects. Portugal participated in the Working Group on deceased donation, on the set up of a transplantation donation coordination system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Portugal indicates that there are agreements in place about transplant medicine for extra-Community patients. In the scope of the Cooperation Agreement with Spain, Portuguese patients are registered in the Spanish waiting list for lung transplantation.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, Portugal indicates that it has a bilateral agreement with Spain.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated 3 and 12 months after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

With regard to **Priority Action 3**, Portugal could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

With regard to **Priority Action 4**, other countries could benefit from Portugal sharing its experiences with organising periodic meetings with journalists. Portugal could benefit from investing in communication guidelines for informing the public about organ transplantation or monitoring mention of organ transplantation in newspapers and on TV.

With regard to **Priority Action 5**, it could be beneficial for Portugal to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Portugal could benefit from investing efforts in this subject.

With regard to **Priority Action 7**, other countries could benefit from the country sharing its experiences with agreements about transplant medicine for extra-Community patients. It could be beneficial for Portugal to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, monitoring of organ trafficking or common priorities and strategies for future research programmes.

With regard to **Priority Action 10**, other countries could benefit from Portugal sharing its experiences with these efforts. Furthermore, it could be beneficial if Portugal comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action.

28. Romania

Based on publicly available information

Background information[156]

With a deceased donation rate per million population under 10 in 2011, Romania's deceased donation rate per million population is amongst the lowest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver and heart.
With a living kidney donation rate per million population lower than 10 in 2011, Romania's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
In 2011 and 2012, important efforts by the transplant coordination were implemented to improve these donation rates, and first results seem to occur in 2013.
Donor organs are allocated on the national and the regional level.

Regarding EU-funded projects, Romania participated as a partner in ETPOD[157], COORENOR, EULID, ODEQUS and FOEDUS. It participates as a partner in the Joint Actions ACCORD and FOEDUS.

In 2011 and 2012, the country participated in the data collection launched at European level by the working group on indicators[158]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[159]).

A National Action Plan was presented at a Competent Authority meeting on 6-7 September 2010.

Financing of organ donation

In case of deceased and living donation the national transplant program is funded by the Ministry of Health.

Consent system

An **opting-in system** is in place, in which **first degree relatives** may express informed consent in writing.

[156] **Sources**: Competent Authority Romania (2010). Presentation National Action Plan Romania 6-7 September 2010; Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[157] For more information about EU funded projects, see §3.1

[158] For more information about the working groups, see §3.2

[159] For more information about CD-P-TO, see §3.3

Key Figures

- = unknown to the research team

	2008	2010	2011
Population in millions	21.0	21.2	21.4
Family refusal rate (refusals/times asked)	-	-	45/159
Actual deceased donation rate (total/per million population)	60/2.9	70/3.3	77/3.6
Multi-organ donation rates (% of total)	60	75	75.3
Number of utilised donors (total/per million population)[160]	-	-	-
Number of donors after circulatory death - DCD	1	1	-
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	5	5	3
Liver	1	1	1
Heart	2	2	2
Lung	2	0	0
Pancreas	3	1	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	115/5.5	124/5.8	144/6.7
Liver	35/1.7	42/2.0	57/2.7
Heart	6/0.3	7/0.3	7/0.3
Lung	0	0	0
Pancreas	0	0	0
Number of living donor transplant procedures (total/pmp)			
Kidney	88/4.2	112/5.3	75/3.5
Liver	9/0.4	8/0.4	8/0.4
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	2085	2418	3000
Liver	350	351	383
Heart	107	125	114
Lung	22	0	0
Pancreas	90	58	63
Number of mortalities while on waiting list			
Kidney	26	14	20
Liver	50	38	62
Heart	12	20	65
Lung	2	0	0
Pancreas	10	6	11

[160] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the regional and the national level. It is reported that these transplant donor coordinators do not receive training yet, but that it is intended.
Priority Action 2: Promote Quality Improvement Programmes	It is reported that the government has stimulated initiatives to improve the quality of the procurement process. It could be beneficial if initiatives are also stimulated to improve the identification of potential donors, the donation process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	It is reported that there are directed and undirected living donation programmes in Romania. It is reported that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is reported that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. It is unknown to the research team if efforts have been made regarding setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also unknown to the research team if there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing organisational models	Romania is involved in the twinning work package of the Joint Action ACCORD.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is reported that there are no agreements in place regarding transplant medicine for extra-Community patients. It is unknown to the research team if there are any agreements in place regarding basic rules for internal EU patient mobility and transplantation, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, it is reported that there are existing agreements between Romanian transplant centres and transplant centres from Austria, Germany and Italy concerning lung and liver transplantations.
Priority Action 9: Evaluation of post-transplant results	It is reported that post-transplant results of organ recipients are not evaluated yet, but that this is intended.
Priority Action 10: Promote a common accreditation system	It is reported that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 1**, Romania could benefit from the experiences that other countries have with this Priority Action.

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the identification of potential donors, the donation and transplantation processes and follow-up care.With regard to **Priority Actions 4, 5 and 7**, it could be beneficial for Romania to come together with countries who have taken up efforts regarding these Priority Actions to help redefine these Priority Actions and to reconsider the ways Romania could benefit from investing efforts in these subjects.

With regard to **Priority Actions 6 and 9** Romania could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

With regard to **Priority Action 10** other countries could benefit from Romania sharing its experiences with these efforts. Furthermore, it could be beneficial if Romania comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action.

29. Slovakia

Background information[161]

In Slovakia the first heart transplantation was carried out in 1968. In 1972 a kidney transplantation programme was started. In 1994 the first multi-organ procurement was performed. With a deceased donation rate per million population between 10 and 20 in 2011, Slovakia belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver and heart.
With a living kidney donation rate per million population lower than 10 in 2011, Slovakia's living kidney donation rate per million population is among the lower of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney.
Donor organs are allocated at national level.

Regarding EU-funded projects, Slovakia participated as a partner in the projects ETPOD[162], COORENOR, EFRETOS, EDD, and is a partner within FOEDUS.

In 2011 the country participated in the annual Indicators' exercise prepared by the working group on indicators[163]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[164]).

A National Action Plan was presented at a Competent Authority meeting in March 2012.

Financing of organ donation

In case of deceased and living donation, the Transplantation Program in Slovakia is completely funded by the Health Insurance companies (1 state owned/ 2 private). Principle is a flat price for each transplantation. If the transplantation cost exceeds the flat price more than 10%, expenses are enumerated individually in each transplanted patient.

Consent system

Since September 22nd 2004 an **opting-out system** is in place. **Next-of-kin** have no right to information, consent or refusal. A **registry** in which people can register refusal.

[161] **Sources**: ACTOR survey filled in by national Competent Authority.; Competent Authority the Slovakia. (2012). Presentation National Action Plan Slovakia, March 2012; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[162] For more information about EU-funded projects, see §3.1

[163] For more information about the working groups, see §3.2

[164] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	5.3	5.4	5.5
Family refusal rate (refusals/times asked)	-	7/98	9/88
Actual deceased donation rate (total/per million population)	77/14.5	91/16.8	69/12.5
Multi-organ donation rates (% of total)	48.0	54.0	58.0
Number of utilised donors (total/per million population)[165]	-	-	-
Number of donors after circulatory death - DCD	0	0	0
Number of donors older than 65	5	7	-
Number of transplant centres			
Kidney	4	4	4
Liver	2	2	2
Heart	2	1	1
Lung	0	0	0
Pancreas	0	0	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	145/27.4	162/30	116/21.1
Liver	12/2.3	33/6.1	25/4.5
Heart	26/4.9	21/3.9	19/3.5
Lung	0	0	0
Pancreas	0	0	0
Number of living donor transplant procedures (total/pmp)			
Kidney	21/4.0	7/1.3	13/2.4
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	507	388	382
Liver	12	30	30
Heart	12	22	21
Lung	-	-	0
Pancreas	-	-	0
Number of mortalities while on waiting list			
Kidney	86	101	45
Liver	0	13	14
Heart	-	5	7
Lung	-	-	0
Pancreas	-	-	0

[165] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital, regional and national level. It is indicated that these transplant donor coordinators receive training once a year.
Priority Action 2: Promote Quality Improvement Programmes	Slovakia indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, the transplantation process and follow up care. It could be beneficial if initiatives are also stimulated to improve the quality of the donation process and the procurement process. Moreover, other countries could benefit from Slovakia sharing its experiences with quality improvements regarding the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	The country-representative indicates that directed[166] living donation programmes exist and that there are no undirected living donation programmes. Furthermore, it is indicated that registers to evaluate and guarantee the health and safety of living donors are prepared to be established in 2013.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that no efforts have been made with regard to setting up communication guidelines for informing the public or organising periodic meetings with journalists. It is unknown to the research team if efforts have been made regarding monitoring mention of organ transplantation in newspapers or on TV. In addition, it is unknown to the research team if programmes have been deployed to improve knowledge and communication skills of health professionals and patient support groups.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Slovakia indicates that it has been involved in a twinning project with Italy. The country-representative indicates that the topic of this was quality management for organ transplantation, tissue and cell banking, to ensure the highest possible level of public health protection and a high standard of quality and safety for donation.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Slovakia indicates that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes. It is unknown to the research team if there are any agreements in place regarding organ trafficking.
Priority Action 8: Facilitate the interchange of organs	For the interchange of organs between national authorities, Slovakia indicates that it has a bilateral agreement with the Czech Republic, Italy, Austria and Germany.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated. It is unknown to the research team at which moments these results are evaluated.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if there are any additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the donation process and the procurement process. Moreover, other countries could benefit from Slovakia sharing its experiences with quality improvements regarding the transplantation process and follow up care.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Slovakia to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways Slovakia could benefit from investing efforts in these subjects.

[166] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

30. Slovenia

Background information[167]

With a deceased donation rate per million population between 10 and 20 in 2011, Slovenia belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart and pancreas.
In 2011 no kidney and liver transplant procedures were carried out from living donors.
Slovenia is part of Eurotransplant[168] and donor organs are allocated through Eurotransplant.

Regarding EU-funded projects Slovenia was coordinator of EDD[169] and participated as a partner in EFRETOS, EULID, and MODE. The country is core work package leader in the Joint Action FOEDUS and also participates as a partner in ACCORD.

In 2011 the country participated in the working group on indicators[170]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[171]).

A National Action Plan was presented at a Competent Authority meeting on 28 February 2010.

Financing of organ donation

In case of deceased donation, funding is covered by national health care insurance company (recipient's part) and by governmental budget (donation). In case of living donation, funding is covered by the insurance of the donor. Extra charges are covered by a public fund.

Consent system

Since January 27st 2000 an **opting-out system** is in place. The **next-of-kin** may refuse organ removal in case of explicit consent and in case of no decision by the deceased. Written consent may be officially **registered** on a person's health insurance card.

[167] **Sources**: ACTOR survey filled in by national Competent Authority; Competent Authority the Slovenia. (2010). Presentation National Action Plan Slovenia, February 2010; Eurotransplant (2009). Yearly Statistics 2008; Eurotransplant (2011a). Annual report 2010; Information provided by H. Nys, November 2012; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven; http://www.slovenija-transplant.si/index.php?id=ledvice&L=2%2527; http://www.slovenija-transplant.si/index.php?id=srce

[168] Regarding EU-funded projects, Eurotransplant was coordinator of EFRETOS, core work package leader of EDD and FOEDUS, and partner in COORENOR.

[169] For more information about EU funded projects, see §3.1

[170] For more information about the working groups, see §3.2

[171] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	2.0	2.0	2.0
Family refusal rate (refusals/times asked)[172]	23%	17%	5/36
Actual deceased donation rate (total/per million population)	37/18.3	41/20.5	31/15.5
Multi-organ donation rates (% of total)	81.1	87.8	77.4
Number of utilised donors (total/per million population)	36/18	41/20.5	-
Number of donors after circulatory death - DCD	-	0	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	-	-	1
Liver	-	-	1
Heart	-	-	1
Lung	-	-	1
Pancreas	-	-	1
Number of deceased donor transplant procedures (total/pmp)			
Kidney	52/26	61/30.5	46/23
Liver	22/11	23/11.5	20/10
Heart	6/3	19/9.5	14/7
Lung	-	-	0
Pancreas	-	1/0.5	1/0.5
Number of living donor transplant procedures (total/pmp)			
Kidney	0	0	0
Liver	0	0	0
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	72	53	68
Liver	13	8	10
Heart	17	26	34
Lung	-	0	0
Pancreas	1	-	0
Number of mortalities while on waiting list			
Kidney	4	1	1
Liver	4	5	4
Heart	2	4	8
Lung	-	0	0
Pancreas	-	-	0

Recommendations

With regard to **Priority Action 2**, Slovenia could benefit from investing efforts in improving the quality of donation process, the procurement process, the transplantation process and follow up care.

With regard to **Priority Action 3**, Slovenia could benefit from setting up registers of living donors, since it becomes mandatory with the Directive 2010/53/EU.

[172] Only percentages were given for 2008 and 2010.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital and the national level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	Slovenia indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors. It is unknown to the research team if initiatives have been stimulated to improve the quality of donation process, the procurement process, the transplantation process and follow up care. If this is not the case it could be beneficial if efforts are invested in these subjects.
Priority Action 3: Exchange of best practices on living donation	The country-representative indicates that directed living donation programmes exist and that there are no undirected living donation programmes. It is indicated that there are no registers established to evaluate and guarantee the health and safety of living donors, but that this is intended in the future.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and that there are no programmes deployed to improve knowledge and communication skills of patient support groups. Furthermore, it is indicated that communication guidelines for informing the public exist and that mention of organ transplantation in newspapers or on TV are monitored. It is indicated that there have been no periodic meetings organised with journalists, since the Action Plan was implemented. In 2008 and 2011 Slovenia organised the European Donation day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	Slovenia indicates that it has been involved in twinning projects with South-eastern Europe Health Network (SEEHN) countries. The country mentions that with Austria the subject was kidneys for young children and lung transplantations and with Italy liver transplantations for young children.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that Slovenia has no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes. It is unknown to the research team whether there are agreements in place about organ trafficking.
Priority Action 8: Facilitate the interchange of organs	For the interchange of organs between national authorities, Slovenia indicates that it is part of Eurotransplant and has bilateral agreements with Austria and Italy.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 12 months and 3 and 5 years after transplantation.
Priority Action 10: Promote a common accreditation system	It is indicated that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

With regard to **Priority Action 4**, other countries could benefit if Slovenia shares its experiences with setting up communication guidelines for informing the public and monitoring how often organ transplantation is mentioned in newspapers or on TV. Other countries could benefit if Slovenia shares its experiences with these efforts. Furthermore, it could be beneficial if Slovenia comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. On the other hand, Slovenia could benefit from investing in organising periodic meetings with journalists.

With regard to **Priority Actions 5 and 10**, other countries could benefit from Slovenia sharing its experiences with these efforts. Furthermore, it could be beneficial if Slovenia comes together with countries who have not taken up efforts on these Priority Actions to help redefine these Priority Actions.

With regard to **Priority Action 7** it could be beneficial for Slovenia to come together with countries who have taken up efforts on this Priority Action to help redefine it and to reconsider the ways Slovenia could benefit from investing efforts in this subject.

31. Spain

Background information[173]

With a deceased donation rate per million population (pmp) higher than 20 in 2011 (35.3 in 2011), Spain's deceased donation rate per million population is the highest of the countries included in this study. As in previous years, in 2011 deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung, pancreas and small bowel.
With a living kidney donation rate lower than 10 per million population (6.6 in 2011), Spain's living kidney transplantation activity is in a mid-position when compared with other countries in this study. In 2011, living donor transplant procedures were carried out regarding kidney and liver.
Donor organs are allocated at a national level.
Spain has a long history of international cooperation in the field of donation and transplantation, not only supporting other countries (MS or not) in the development of donation from the deceased but also in combating unacceptable practices in this field, as well as collecting and sharing data for transparency and continuous improvement.

Regarding EU-funded projects, Spain was coordinator of the projects DOPKI[174], ETPOD, ELIPSY, EULID, ODEQUS, and Train the Trainers, core work package leader in Alliance-O, EFRETOS, and MODE. The country is coordinator of the joint action ACCORD, and collaborating partner in the joint action FOEDUS.

In 2010, 2011 and 2012, the country participated - and was very involved and supportive - in the working group on indicators.[175] Indeed, the contribution of the Spanish National Transplant Organization (ONT) has been substantial for the indicators exercise. ONT periodically collects information on donation and transplantation activities throughout the world for the Council of Europe and the World Health Organization (WHO) through a highly consolidated network of national focal points. In order to avoid duplications in data provision, ONT centralizes the collection of the information which is then, as per agreement with the relevant competent authorities, provided to the European Commission for the aforementioned exercise. Furthermore, the country participated in the working group on deceased donation and the working group on living donation, sharing its experience in system improvements to increase performance in deceased donation and its package of initiatives and national position on live kidney donation and transplantation. In addition, it is a member of the Committee (Partial Agreement) on Organ Transplantation (CD-P-TO) of the Council of Europe, and chaired this committee for seven years, with the production of an important number of recommendations and resolutions.[176] ONT is collaborating centre of the WHO and hosts with this international organization the Global Observatory on Organ Donation and Transplantation.

Financing of organ donation

In the case of deceased donation, donation and derived transplantation are benefits of the National Health Service. There is no cost assigned to recipients, neither to donors or their family. In the case of living donation, the costs and expenses related to living donation and transplantation are directly funded by the healthcare system.

Consent system

Since October 27th 1979 an **opting-out system** is in place. By law, **next-of-kin** only have the right to be consulted, but in practice they are always asked and they hold the final veto. There is no specific **registry** in which the will with regards to donation after death is recorded, but several means are available, including Advance Directives Registry/Last Will Registry.

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[173] **Sources**: ACTOR survey filled in by national Competent Authority, as well as additional information provided; Information provided by H. Nys, November 2012; ONT statistics; Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[174] For more information about EU funded projects, see §3.1

[175] For more information about the working groups, see §3.2

[176] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	46.2	47.0	47.2
Family refusal rate (refusals/times asked)	343/1920	353/1855	319/2007
Actual deceased donation rate (total/per million population)	1577/34.2	1502/32.0	1667/35.3
Multi-organ donation rates (% of total)[177]	84.0	81.0	-
Number of utilised donors (total/per million population)	1368/29.6	1292/27.5	1451 /30.8
Number of donors after circulatory death - DCD	77	130	117
Number of donors older than 65	485	520	-
Number of transplant centres			
Kidney	44	44	44
Liver	26	25	25
Heart	18	18	18
Lung	9	7	7
Pancreas	11	13	13
Number of deceased donor transplant procedures (total/pmp)			
Kidney	2073/44.9	1985/42.2	2186/46.3
Liver*	1066/23.1	943/20.1	1103/23.4
Heart	292/6.3	243/5.2	237/5.0
Lung	192/4.2	235/5	230/4.9
Pancreas	104/2.3	94/2	111/2.4
Number of living donor transplant procedures (total/pmp)			
Kidney	156/3.4	240/5.1	312/6.6
Liver	28/0.6	20/0.4	28/0.6
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	4,301	4,434	4,493
Liver	691	772	641
Heart	90	96	98
Lung	175	173	190
Pancreas	83	163	137
Number of mortalities while on waiting list			
Kidney	-	-	-
Liver	158	140	127
Heart	29	15	18
Lung	19	16	22
Pancreas	5	2	2

- = unknown to the research team

* These figures result from subtracting living and domino liver transplants from the total number of liver transplants, as specified in the Newsletter Transplant - Council of Europe.

[177] Only donors after brain death (DBD) are taken into account.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital, regional and national level. It is indicated that these transplant donor coordinators receive initial training at the moment of appointing and regular training. This has been a key feature of the Spanish System-not created as a result of the Action Plan.
Priority Action 2: Promote Quality Improvement progr.	Spain indicates that ONT has continuously stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow-up care.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed and undirected living donation programmes exist and that a comprehensive strategy is in place for facilitating information about the option of live donation, removing technical obstacles to live transplantation and ensuring the protection of the living donor. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that there are communication guidelines for informing the public about organ transplantation, mention of organ transplantation in newspapers or on TV are monitored and periodic meetings have been organised with journalists. The communication strategy of ONT is another key feature of the so-called Spanish model. The ONT Director supports the EU Commission in the annual workshop for EU journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is indicated that additional plans or actions are undertaken regarding this Priority Action, but that the extent of this Priority Action is not clear to the country-representative.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	The country-representative indicates that it has been involved in specific twinning activities with several countries. It is indicated that Spain is acting as a supporting member state in different twinnings financed with TAIEX (Technical Assistance and Information Exchange instrument).The country-representative furthermore indicates that specific reference should also be made to the MODE project. Spain indicates that it has been supporting different Member States in developing their donation and transplantation systems with no official EU support. Lastly, the country-representative indicates that it also leads international collaborative initiatives, such as the Iberoamerican Network/Council on Donation and Transplantation. Spain was involved in the Working Group on deceased donation, on the set up of transplantation donation coordination.
Priority Action 7: Promote EU-wide agreements on aspects of tx medicine	Spain indicates that there are agreements in place about basic rules for internal EU patient mobility and transplantation, organ trafficking and common priorities and strategies for future research programmes. The country-representative indicates that it has no agreements in place regarding transplant medicine for extra-Community patients.
Priority Action 8: Facilitate the interchange of organs	For the interchange of organs between national authorities, Spain indicates that it has bilateral agreements with France, Italy and Portugal. Furthermore, Italy, France and Spain have constituted the South Alliance for transplantation. Surplus organs are exchanged with other countries on a continuous basis.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated, 3, 6 and 12 months after transplantation and at other moments depending on the specific organ recipient type.
Priority Action 10: Promote a common accreditation system	The country-representative indicates that there are common authorisation criteria for procurement organisations and transplantation centres in place, since the 80s. These criteria have just been updated by the Royal Decree 1723/2012. They also do indicate that there is a system in place for accrediting reference centres in the field of transplantation since 2006.

Recommendations

With regard to **Priority Actions 1 and 2**, other countries could benefit from Spain sharing its experiences with quality improvements regarding the donation and transplantation process and follow up care. In particular, Spain has shared with many EU and non-EU states very detailed information on its well established Quality Assurance Programme on the deceased donation process.

With regard to **Priority Action 4**, it is beneficial that Spain already supports other countries who have not taken up efforts on this Priority Action to help develop this Priority Action.

With regard to **Priority Action 5**, the country-representative indicated that the extent of this Action is not clear. It could be beneficial for Spain to come together with other countries to redefine these Priority Actions and to assess if it could benefit from investing efforts in these subjects.

With regard to **Priority Action 7**, Spain indicates that there are agreements in place about basic rules for internal EU patient mobility and transplantation, monitoring of organ trafficking and common priorities and strategies for future research programmes. Other countries could benefit from Spain sharing its experiences with these efforts. Furthermore, it is beneficial that Spain comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. Furthermore, it is desirable that this Priority Action will be defined more clearly.

Regarding **Priority Action 10**, Spain should continue its important work and continue sharing its experiences.

32. Sweden

Based on publicly available information

Background information[178]

With a deceased donation rate per million population between 10 and 20 in 2011, Sweden belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population higher than 10 in 2011, Sweden's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
Scandiatransplant[179] is an association for organ exchange between the hospitals performing organ transplantations in the Nordic countries. These hospitals are co-owners of Scandiatransplant.

Regarding EU-funded projects, Sweden representatives were work package leader in the project ELIPSY[180] and participated as a partner in ETPOD, EULID, EULOD and ODEQUS. The country is also a partner in the joint actions FOEDUS and ACCORD[181].

In 2010, 2011 and 2012, the the country was involved in the working group on indicators[182] and provided national data. Sweden left the working group in 2012. Furthermore, the country participated in the working group on deceased donation and the working group on living donation. In addition, it is a member of the Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[183]) of the Council of Europe.

Financing of organ donation

In case of living donation clinical tests and consultations before and after donation, peri-operative care and hospital stay after donation are fully covered by healthcare systems or insurances in which organ donation is free of charges for the donors.. Travel expenses before and after donation are covered. Costs of living donation are supported by the health insurance of the recipient. Payments should be completed by the donor who is then reimbursed.

Consent system

Since June 1st 1995 an **opting-out system** is in place. The **next-of-kin** may refuse organ removal if the will of the deceased is not known.

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[178] **Sources**: Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven; Scandiatransplant (2008). Transplantation and waiting lists figures 2008; Scandiatransplant (2010). Transplantation and waiting lists figures 2010; Working Group Living Donation Competent Authorities. (2010). Report on the legislation regarding donation and transplantation of organs from living donors in eleven European countries, Working group 1.

[179] Regarding EU-funded projects, Scandiatransplant participated as a partner in EFRETOS

[180] For more information about EU funded projects, see §3.1

[181] At time of publication, Sweden withdrew from this project

[182] For more information about the working groups, see §3.2

[183] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	9.2	9.4	9.4
Family refusal rate (refusals/times asked)	-	-	-
Actual deceased donation rate (total/per million population)	152/16.5	118/12.6	146/15.5
Multi-organ donation rates (% of total)	85.0	89.0	84.2
Number of utilised donors (total/per million population)[184]	-	-	-
Number of donors after circulatory death - DCD	-	-	0
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	4	4	4
Liver	3	2	2
Heart	3	2	2
Lung	2	3	2
Pancreas	3	1	3
Number of deceased donor transplant procedures (total/pmp)			
Kidney	283/30.8	202/21.5	251/26.7
Liver	140/15.2	129/13.7	149/15.9
Heart	45/4.9	56/6.0	52/5.5
Lung	52/5.7	51/5.4	60/6.4
Pancreas	10/1.1	26/2.8	35/3.7
Number of living donor transplant procedures (total/pmp)			
Kidney	136/14.8	168/17.9	184/19.6
Liver	6/0.7	8/0.9	7/0.7
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	452	415	426
Liver	46	67	43
Heart	19	29	19
Lung	11	33	27
Pancreas	24	11	13
Number of mortalities while on waiting list			
Kidney	28	2	27
Liver	12	10	4
Heart	8	7	1
Lung	4	1	5
Pancreas	1	0	0

[184] No separate information was given for the number of utilised donors.

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the local/hospital level. It is reported that these transplant donor coordinators receive initial training at the moment of appointing.
Priority Action 2: Promote Quality Improvement Programmes	It is unknown to the research team if the Swedish government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process or follow up care. Sweden collects data from all ICU's (approximately 80 ICU's) every year which is presented in a report in order to follow up and improve identification of potential donors.
Priority Action 3: Exchange of best practices on living donation	It is reported that directed[185] and undirected living donation programmes exist. It is reported that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is reported that programmes are deployed to improve knowledge and communication skills of patient support groups. It is unknown to the research team if there are programmes deployed to improve knowledge and communication skills of health professionals. It is also unknown to the research team if efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists. In 2002 Sweden organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also unknown to the research team if there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is unknown to the research team if Sweden is involved in any twinning projects. Sweden participated in the Working Group on deceased donation, which is on setting up a transplantation donation coordination system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether Sweden has any agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	The interchange of organs between transplant centres in the Nordic countries is supported by Scandiatransplant.
Priority Action 9: Evaluation of post-transplant results	It is unknown to the research team if post-transplant results of organ recipients are evaluated.
Priority Action 10: Promote a common accreditation system	It is unknown to the research team if additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Actions 2, 6 and 9**, Sweden could reconsider the importance of these Priority Actions and the ways it could benefit from investing efforts in these subjects.

With regard to **Priority Actions 4, 5, 7 and 10**, it could be beneficial for Sweden to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways it could benefit from investing efforts in these subjects.

[185] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

33. Switzerland

Background information[186]

With a deceased donation rate per million population between 10 and 20, Switzerland belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population higher than 10 in 2011, Switzerland's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.
Donor organs are allocated at national level.

Regarding EU-funded projects, Switzerland participated in the DOPKI[187] project.

In addition, it is a member of the Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[188]) of the Council of Europe and hosted several times the European Organ Donation Day (recently in 2012 for example).

Financing of organ donation

In case of deceased and living donation the costs for both organ recipients as donors are covered by the basic health insurance of the recipient. Non-reimbursed amounts are adopted by the hospital in which the transplantation was performed. No costs are charged to the family of the donor.

Consent system

Since 2007 an **opting-in system** is in place, with the possibility for the **next-of-kin** to give consent if the deceased has not consented to organ donation. Removal is not allowed if there are no next-of-kin or if they cannot be contacted. The will of the deceased in principle prevails over the will of the next-of-kin. Legislation does not provide a **register**, but instead consent is expressed by means of a personal donor card.

[186] **Sources**: ACTOR survey filled in by national Competent Authority, and information additionally provided.; Gevers, S., Janssen, A., & Friele, R. (2004). Consent Systems for Post Mortem Organ Donation in Europe. European Journal of Health Law, 11, 175-186.; Swisstransplant. (2011). Jahresbericht 2011; http://www.europeantransplantcoordinators.org/NKMData/pdf/switzerland.pdf; http://www.swisstransplant.org/l1/organspende-transplantation/organspende-transplantation-gesundheit-spender-empfaenger-altruist-lebend-glossar.php

[187] For more information about EU-funded projects, see §3.1

[188] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	7.7	7.8	8
Family refusal rate (refusals/times asked)	56/160	102/207	-
Actual deceased donation rate (total/per million population)	90/11.8	98/12.6	100/12.5
Multi-organ donation rates (% of total)	90	98	87
Number of utilised donors (total/per million population)	88/11.4	97/12.4	-
Number of donors after circulatory death - DCD	0	0	3
Number of donors older than 65	27	25	-
Number of transplant centres			
Kidney	6	6	6
Liver	3	3	3
Heart	3	3	3
Lung	2	2	2
Pancreas	2	2	3
Number of deceased donor transplant procedures (total/pmp)			
Kidney	170/22.1	180/23.1	181/22.6
Liver	83/10.8	98/12.6	100/12.5
Heart	29/3.8	35/4.5	36/4.5
Lung	40/5.2	49/6.3	54/6.8
Pancreas	17/2.2	14/1.8	28/3.5
Number of living donor transplant procedures (total/pmp)			
Kidney	116/15.1	114/14.6	101/12.6
Liver	12/1.6	2/0.3	9/1.1
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	758	780	838
Liver	108	104	125
Heart	19	31	36
Lung	46	59	49
Pancreas	16	19	51
Number of mortalities while on waiting list			
Kidney	23	26	23
Liver	25	21	24
Heart	8	7	9
Lung	7	5	5
Pancreas	2	0	0

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital level. The country-representative also indicates that on another level, there are network coordinators. It is unknown to the research team if transplant donor coordinators receive training.
Priority Action 2: Promote Quality Improvement Programmes	Switzerland indicates that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process and the procurement process.
Priority Action 3: Exchange of best practices on living donation	It is indicated that directed and undirected living donation programmes exist. It is indicated that registers are established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is indicated that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. Furthermore, it is indicated that communication guidelines for informing the public about organ transplantation have been set up. It is indicated that no efforts have been made so far regarding monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists, since the Action Plan was implemented. In 1996 and 2006 Switzerland organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models	Switzerland indicates that it has not been involved in twinning projects.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	Switzerland indicates that it has no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	For the interchange of organs between national authorities, it is indicated that the country has a bilateral agreement with France.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated 1, 6 and 12 months after transplantation. The country-representative indicates that these results are also evaluated 1 and 2 years after transplantation and so forth.
Priority Action 10: Promote a common accreditation system	It is indicated that there are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Recommendations

With regard to **Priority Action 1**, Switzerland could benefit from the experience that other countries have with training for transplant donor coordinators.

With regard to **Priority Action 2**, it could be beneficial if initiatives are also stimulated to improve the quality of the transplantation process and follow up care.

With regard to **Priority Action 4**, other countries could benefit from Switzerland sharing its experiences with setting up communication guidelines for informing the public. Furthermore it could be beneficial if Switzerland comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action with regard to this Priority Action. Switzerland could benefit from investing in efforts regarding monitoring how often organ transplantation is mentioned in newspapers or on TV or organising periodic meetings with journalists.

With regard to **Priority Actions 5, 7 and 10**, it could be beneficial for Austria to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Austria could benefit from investing efforts in this subject.

With regard to **Priority Action 6**, Switzerland could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

34. Turkey

Background information[189]

In Turkey the first heart transplantation was carried out in 1968. The first living kidney transplant was performed in 1975. The first deceased kidney transplantation was performed in 1978 and the first deceased liver transplantation was performed in 1988. With a deceased donation rate per million population under 10 in 2011, Turkey's deceased donation rate is amongst the lowest of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.
With a living kidney donation rate per million population higher than 10 in 2011, the Turkey's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.

Donor organs are allocated at national level.

Regarding EU-funded projects Turkey was an associated partner in ELIPSY[190] and also participated in ETPOD. A Turkish representative took part in the final meeting of ODEQUS, to use ODEQUS results in Turkish hospitals.

In 2011, the country took part in the annual Indicators' exercise[191]. In addition, it is a member of the Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[192]) of the Council of Europe.

A National Action Plan was presented at a Competent Authority meeting in March 2012.

Financing of organ donation

In case of deceased donation all transplant operation costs are paid by Social Security Institution of Republic of Turkey. In case of living donation all transplant operation costs are paid by Social Security Institution of Republic of Turkey and living donor costs are paid by recipient's health insurance.

Consent system

Since May 29th 1979 an **opting-in system** is in place. **Next-of-kin** are approached for consent in all cases, regardless of whether there is a registered decision of the deceased.

[189] **Sources**: ACTOR survey filled in by national Competent Authority, and information additionally provided; Bagheri, A. (2005). Organ transplantation laws in Asian countries: a comparative study. Transplant.Proc., 37, 4159-4162; Competent Authority Turkey. (2012). National Action Plan Turkey, March 2012. http://www.europeantransplantcoordinators.org/NKMData/pdf/turkey.pdf

[190] For more information about EU-funded projects, see §3.1

[191] For more information about the working groups, see §3.2

[192] For more information about CD-P-TO, see §3.3

Key figures

- = unknown to the research team

	2008	2010	2011
Population in millions	71.5	73.7	74.7
Family refusal rate (refusals/times asked)	458/720	764/1036	958/1292
Actual deceased donation rate (total/per million population)	262/3.6	272/3.6	311/4.2
Multi-organ donation rates (% of total)	96.9	-	91.0
Number of utilised donors (total/per million population)	242/3.4	246/3.3	-
Number of donors after circulatory death - DCD	3	-	-
Number of donors older than 65	1	2	-
Number of transplant centres			
Kidney	44	59	62
Liver	25	34	40
Heart	16	14	13
Lung	1	2	3
Pancreas	5	4	5
Number of deceased donor transplant procedures (total/pmp)*			
Kidney	414/5.7	395/5.2	521/7.0
Liver	212/3.0	209/2.8	281/3.8
Heart	51/0.7	86/1.1	93/1.2
Lung	1/0.0	3/0.0	5/0.1
Pancreas	10/0.1	29/0.4	26/0.3
Number of living donor transplant procedures (total/pmp)			
Kidney	1248/17.5	2107/28.6	2421/32.4
Liver	390/5.4	486/6.6	623/8.3
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	11500	16103	17390
Liver	1257	1354	1460
Heart	264	-	218
Lung	2	-	4
Pancreas	86	-	69
Number of mortalities while on waiting list			
Kidney	-	-	958
Liver	-	-	329
Heart	-	-	44
Lung	-	-	3
Pancreas	-	-	14

* Based on Transplant News Letter Council of Europe

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is indicated that transplant donor coordinators have been appointed at the local/hospital, regional and national level. Turkey indicates that these transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is indicated that the Turkish government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	The country-representative indicates that directed[193] living donation programmes exist and that there are no undirected living donation programmes. Turkey furthermore indicates that there are registers established to evaluate and guarantee the health and safety of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	Turkey indicates that programmes are deployed to improve knowledge and communication skills of patient support groups. It is indicated that there are no programs deployed to improve knowledge and communication skills of health professionals, but that these are intended in the future. It is indicated that efforts have been made regarding monitoring of mention of organ transplantation in newspaper or on TV. It is indicated that communication guidelines for informing the public about organ transplantation have not been set up and that no periodic meetings have been organised with journalists, since the Action Plan was implemented. Turkey could benefit from investing in setting up these kinds of guidelines. In 2005 Turkey organised the European Donation Day.
Priority Action 5: Facilitate the identification of organ donors across Europe	The country-representative indicates that it does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU, but it is intended. It also indicates that there are no additional plans or actions undertaken regarding this Priority Action
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	With regard to twinning projects, Turkey indicates that it has taken part in Mediterranean Transplant Network (MTE), Black Sea Area Transplant Project and European Training Program on Organ Donation (ETPOD), all of which aim at cooperation and collaboration among participating countries.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is indicated that Turkey has agreements in place regarding organ trafficking. It is indicated that there are no agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.
Priority Action 8: Facilitate the interchange of organs between national authorities	Turkey indicates that it is not part of a fixed collaboration with other countries for the interchange of organs between national authorities, but that these kinds of collaborations are intended with Spain, Italy, UK and the Mediterranean Transplant Network.
Priority Action 9: Evaluation of post-transplant results	It is indicated that post-transplant results of organ recipients are evaluated in one week.
Priority Action 10: Promote a common accreditation system	The country-representative indicates that additional plans regarding the promotion of a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 2**, other countries could benefit from Turkey sharing its experiences with quality improvements regarding the transplantation process and follow-up care.

With regard to **Priority Action 4**, other countries could benefit from Turkey sharing its experiences with monitoring the mentioning of organ transplantation in newspaper or on TV. Furthermore, it could be beneficial if Turkey comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. Turkey could benefit from investing in setting up communication guidelines for informing the public about organ transplantation organising periodic meetings with journalists.

[193] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

With regard to **Priority Action 5**, it could be beneficial for Turkey to come together with countries who have taken up efforts on this Priority Action to help redefine this Priority Action and to reconsider the ways Turkey could benefit from investing efforts in this subject.

With regard to **Priority Action 7**, other countries could benefit from Turkey sharing its experiences with agreements in place regarding monitoring of organ trafficking. Furthermore, it could be beneficial if Turkey comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action. It could be beneficial for Turkey to further look into setting up agreements regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients or common priorities and strategies for future research programmes.

With regard to **Priority Action 10**, other countries could benefit from Turkey sharing its experiences with these efforts. Furthermore, it could be beneficial if Turkey comes together with countries who have not taken up efforts on this Priority Action to help redefine this Priority Action.

35. United Kingdom

Based on publicly available information

Background information[194]

In the United Kingdom, the first living kidney transplantation was performed in 1960 and the first heart and liver transplantations were performed in 1968. In 1983 the first combined heart and lung transplantation was carried out. With a deceased donation rate per million population between 10 and 20 in 2011, the United Kingdom belongs to the majority of the countries included in this study. In 2011, deceased donor transplant procedures were carried out regarding kidney, liver, heart, lung and pancreas.

With a living kidney donation rate per million population higher than 10 in 2011, the United Kingdom's living kidney donation rate per million population is among the higher of the countries included in this study. In 2011 living donor transplant procedures were carried out regarding kidney and liver.

Donor organs are allocated at national level.

Regarding EU-funded projects the United Kingdom was core work package leader in EFRETOS[195] and EULID and participated in Alliance-O, DOPKI and ODEQUS. The country is core work package leader in the Joint Action ACCORD (work package on links with intensive care units) and also participates in the FOEDUS Joint Action.

The country participates as a full member in the working group on indicators[196] and participated in the annual data collection exercises. Furthermore, the country participated in the working group on deceased donation and living donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[197]).

A National Action Plan was presented at a Competent Authority meeting on 28 February 2011.

Consent system

Since 2006, an **opting-in system** is in place**. Next-of-kin** have no legal right to veto or overturn a decision, but they do have the right to give consent if no decision has been taken. Consent or refusal is **registered** in the NHS Organ Donor Register.

[194] **Sources**: Competent Authority United Kingdom. (2011). Presentation National Action Plan United Kingdom, 28 February 2011; Competent Authority United Kingdom. (2011). Third meeting of the Competent Authorities for organ donation and transplantation, September 2011; NHS Blood and Transplant. (2011). Transplant activity in the UK. Activity Report 2010/11; Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven.

[195] For more information about EU-funded projects, see §3.1

[196] For more information about the working groups, see §3.2

[197] For more information about CD-P-TO, see §3.3

Key figures

	2008	2010	2011
Population in millions	60.2	61.9	62.3
Family refusal rate (refusals/times asked)	591/1551	1009/2348	1104/2542
Actual deceased donation rate (total/per million population)	885/14.7	1015/16.4	1056/17
Multi-organ donation rates (% of total)	77.2	72.3	70.9
Number of utilised donors (total/per million population)	-	-	-
Number of donors after circulatory death - DCD	264	373	405
Number of donors older than 65	-	-	-
Number of transplant centres			
Kidney	24	27	26
Liver	8	7	7
Heart	7	7	7
Lung	5	6	6
Pancreas	8	10	11
Number of deceased donor transplant procedures (total/pmp)			
Kidney	1382/23.0	1698/27.4	1726/27.7
Liver	683/11.3	688/11.1	722/11.6
Heart	127/2.1	124/2.0	148/2.4
Lung	139/2.3	162/2.6	191/3.1
Pancreas	216/3.6	195/3.2	236/3.8
Number of living donor transplant procedures (total/pmp)			
Kidney	920/15.3	1026/16.6	1026/16.5
Liver	36/0.6	24/0.4	37/0.6
Number of patients awaiting for a transplant (only active candidates) on 31/12			
Kidney	9498	7013	6721
Liver	356	472	523
Heart	115	139	170
Lung	243	250	223
Pancreas	459	313	262
Number of mortalities while on waiting list			
Kidney	277	290	308
Liver	88	115	98
Heart	23	24	23
Lung	56	48	61
Pancreas	15	14	30

- = unknown to the research team

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	It is reported that transplant donor coordinators have been appointed at the local/hospital level. It is reported that these transplant donor coordinators receive initial training at the moment of appointing and regular training.
Priority Action 2: Promote Quality Improvement Programmes	It is reported that the government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, the transplantation process and follow up care.
Priority Action 3: Exchange of best practices on living donation	It is reported that directed and undirected living donation programmes exist. It is furthermore reported that registers are established to evaluate and guarantee the health and safety of living donors. The country is involved in the working group on living donation, in which a manual/toolbox on experiences with living donation is developed.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	It is reported that programmes are deployed to improve knowledge and communication skills of health professionals and patient support groups. It is unknown to the research team if efforts have been made with regard to setting up communication guidelines for informing the public, monitoring mention of organ transplantation in newspapers or on TV or organising periodic meetings with journalists.
Priority Action 5: Facilitate the identification of organ donors across Europe	It is unknown to the research team if the country provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. It is also unknown to the research team if there are additional plans or actions undertaken regarding this Priority Action.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	It is unknown to the research team if the United Kingdom has been involved in any twinning projects. The country did participate in a Working Group on deceased donation, which is on setting up a system for transplantation donation coordination.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	It is unknown to the research team whether the United Kingdom has any agreements in place regarding basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, organ trafficking or common priorities and strategies for future research programmes
Priority Action 8: Facilitate the interchange of organs between national authorities	It is unknown to the research team if the United Kingdom is part of a fixed collaboration for the interchange of organs between national authorities.
Priority Action 9: Evaluation of post-transplant results	It is reported that post-transplant results of organ recipients are evaluated. It is unknown to the research team at which moments these results are measured.
Priority Action 10: Promote a common accreditation system	It is reported that additional plans regarding promoting a common accreditation system for organ donation/procurement and transplantation programmes are undertaken.

Recommendations

With regard to **Priority Action 2**, other countries could benefit from the United Kingdom sharing its experiences with quality improvements regarding the transplantation process and follow up care.
With regard to Priority Action 4, it could be beneficial for the United Kingdom to come together with countries who have taken up efforts regarding public awareness to help redefine this Priority Action and to reconsider the ways the United Kingdom could benefit from investing efforts in this subject.

With regard to **Priority Actions 5, 7 and 10**, it could be beneficial for the United Kingdom to come together with countries who have taken up efforts on these Priority Actions to help redefine these Priority Actions and to reconsider the ways the United Kingdom could benefit from investing efforts in these subjects.

With regard to **Priority Action 6**, the United Kingdom could reconsider the importance of this Priority Action and the ways it could benefit from investing efforts in this subject.

With regard to **Priority Action 8**, the country could benefit from the experience that other countries have with this Priority Action.

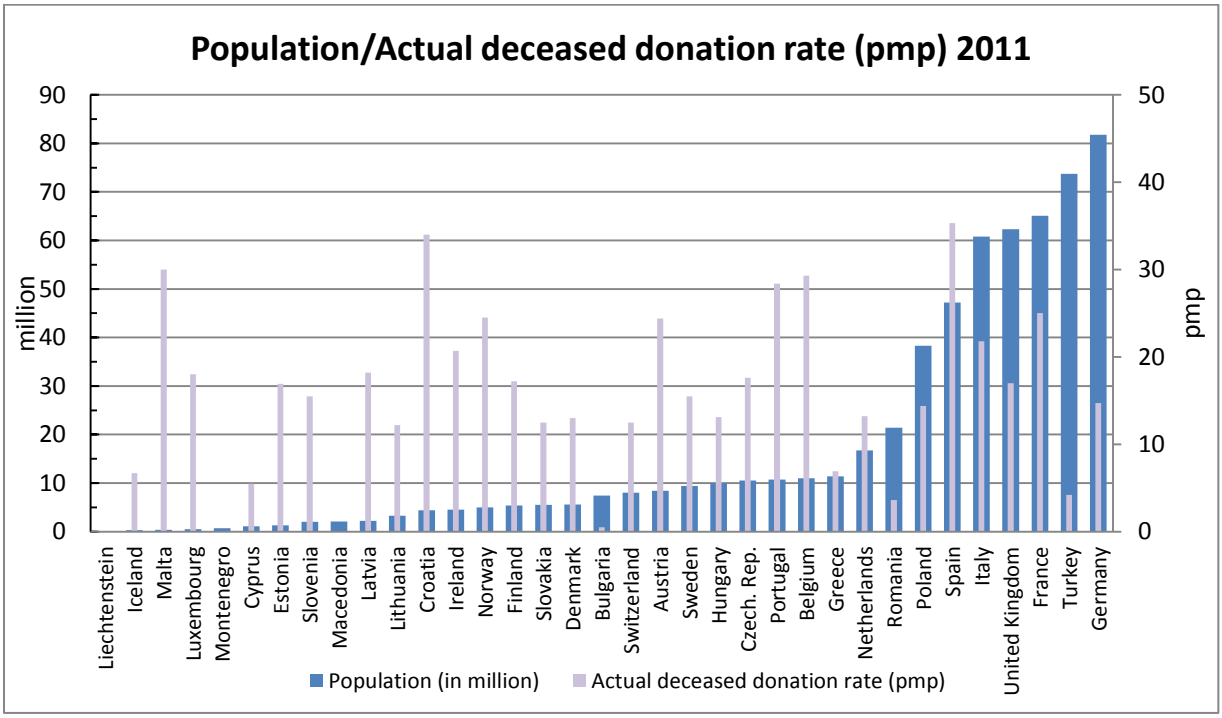
Differences between countries

As the data presented in the country sheets show, there is a great diversity between countries. Key issues chosen by the research team are the differences in donation rates, waiting lists and the relevance of deceased and living donation in each country. Extra analyses were conducted examining whether significant differences existed between countries based on 3 criteria, namely: deceased donation rates (lower than 10 versus higher than 10), population size (smaller than 10 million, between 10 and 50 million and larger than 50 million) and EU membership status (being an EU Member State or non EU country). In addition correlations were assessed between the key indicators of every Priority Action. Using the appropriate statistics[198] no significant relationships were found, implying that there is no relationship between the uptake of priority actions on the one hand and deceased donation rates, population size, EU membership status on the other hand. Nor was the uptake of Priority Actions statistically related.

In figure 2.27, the **population size** is set off against actual **deceased donation rates** per million population (pmp). It seems that the size of the country is not a predictor for the rate of organ donors per million population.

Figure 2.27. The relationship between population size and deceased donation rate (pmp) 2011

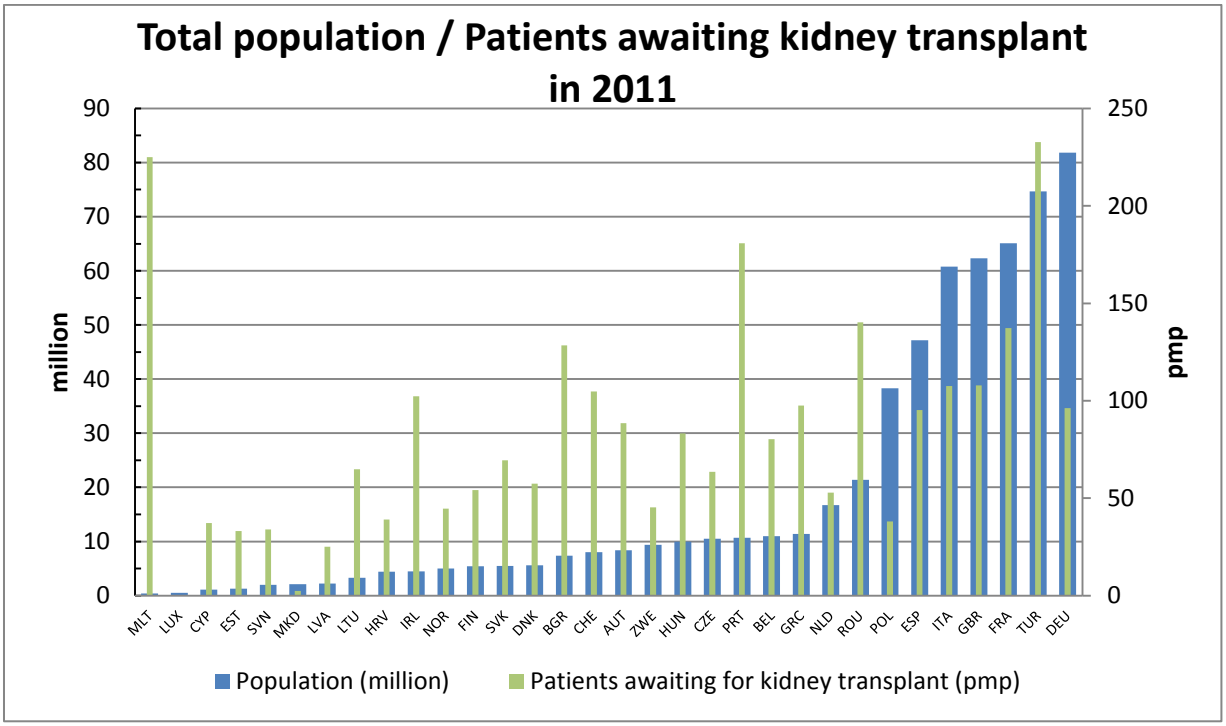
Source: Council of Europe (2012). Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2011 Strasbourg: Council of Europe.



[198] Fisher's exact test for differences and Cronbach's Alpha for correlations

Figure 2.28. The relationship between population size and waiting list in 2011

Source: Council of Europe (2012). Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2011 Strasbourg: Council of Europe.

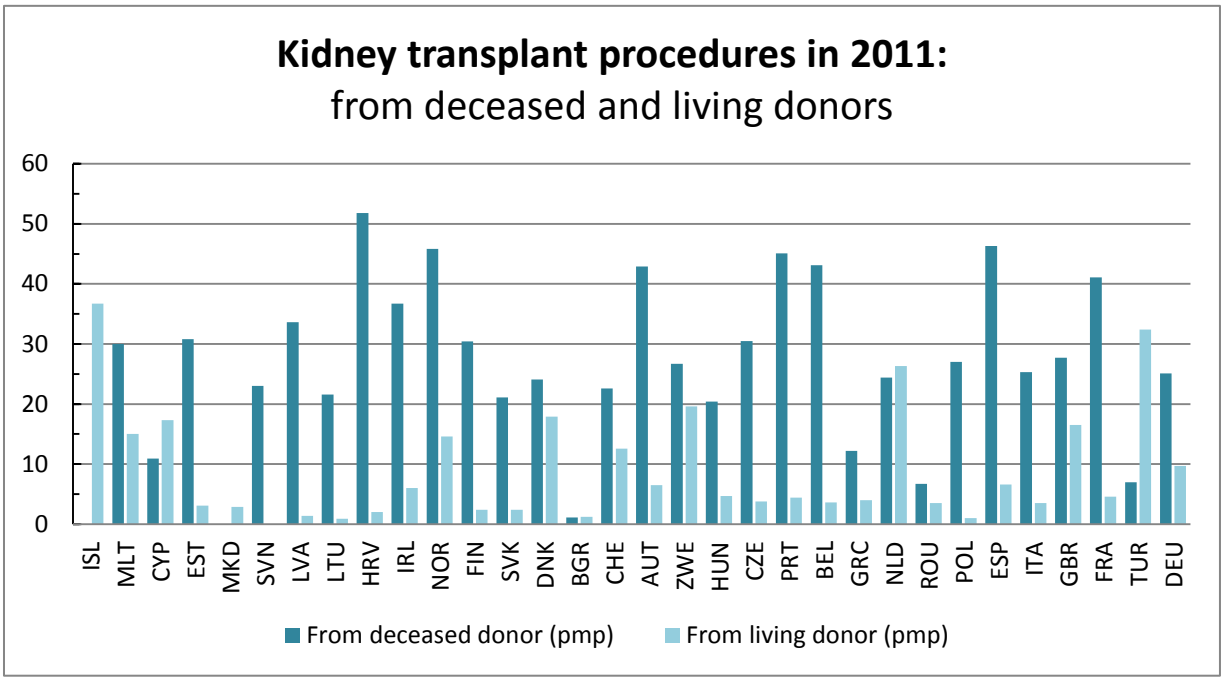


When considering (figure 2.28) the **number of patients awaiting a kidney transplantation** (only active candidates on 31/12/2011) compared to the **total population of the country**, it appears that among both smaller and larger countries there are countries with relatively low and high numbers of patients awaiting kidney transplantation.

On the other hand, as figure 2.28 is focused only on kidney transplant and as in smaller countries kidney transplant is the first (if not often unique) transplant procedures organised, there might be a higher "specialisation in kidney transplantation" in these countries (for example in Cyprus, Malta, Iceland), whereas other relatively small countries involved in European Organ Exchanges Organisations (EOEOs) such as Scandiatransplant and Eurotransplant might not such a huge "specialisation need" (for example in Luxemburg, Slovenia, Croatia).

Living donation is possible for kidney transplants and liver transplants (more recently also for lung transplants, but still very marginally). Figure 2.29 focuses on kidney transplants only as it is the most common, and therefore the most relevant to compare deceased and living donation. It shows that there are considerable country differences with regard to the number of kidney transplantations from deceased donors on the one hand and living donors on the other hand. Nearly all countries report that living donor kidney transplantations are executed and in several countries living donor kidney transplantations significantly contribute to the total number of donations. But only in Turkey, the Netherlands and Iceland the numbers of transplants from living donors exceed the numbers of transplants from deceased donors.

Figure 2.29. Kidney transplant procedures (pmp) from deceased donors and from living donors in 2011 Source: Council of Europe (2012). Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2011 Strasbourg: Council of Europe.



To conclude on these **differences between countries, beyond the kidney cases**: all countries have kidney transplant programmes in place, but not all countries have programmes in place to transplant all types of organs, to implement transplant procedures for combined organs or to transplant children or specific patients (highly immunised, difficult-to-treat…). When considering other types of transplants at the European level, the pictures will therefore be different from the "kidney pictures", but still diverse.

However, based on the Transplant Newsletters data and maps, it seems also possible to draw some (obvious) **general conclusions** regarding the size of the country and the types of transplant proposed: so far mainly countries with a large population, and therefore a large healthcare sector, are in the capacity/have the resources to ensure transplantation for "rare organs" (or complicated cases).

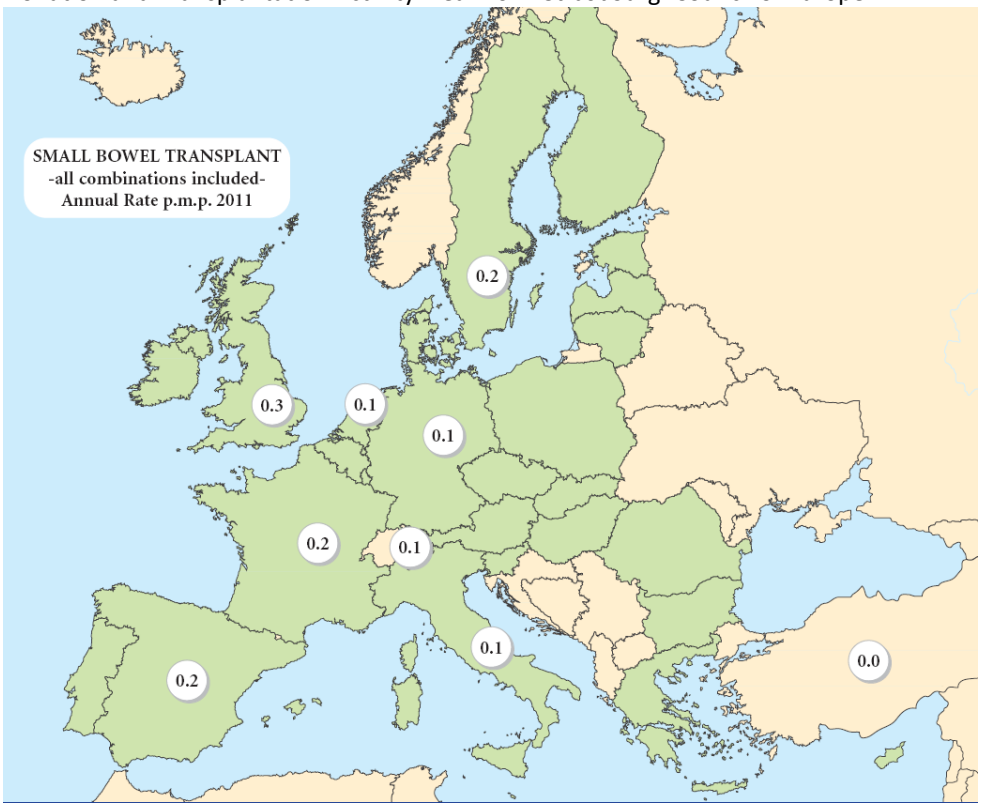
For example, in 2011 only the following nine (large) countries have had transplant procedures for small bowel: France, Germany, Italy, the Netherlands, Spain, Sweden, the United Kingdom, Switzerland and Turkey (See Map 1).

Regarding pancreas transplantation in 2011(see Map 2), the situation is less acute but still similar, with the following 22 countries having these capacities: Austria, Belgium, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden, U.K., Croatia, Norway, Switzerland, Turkey (and only 13 of these countries had more than 20 transplants in that year 2011).

But it should also be said that these figures do not automatically imply that there are no bilateral or multilateral agreements in place with competent authorities from other countries to treat their nationals.

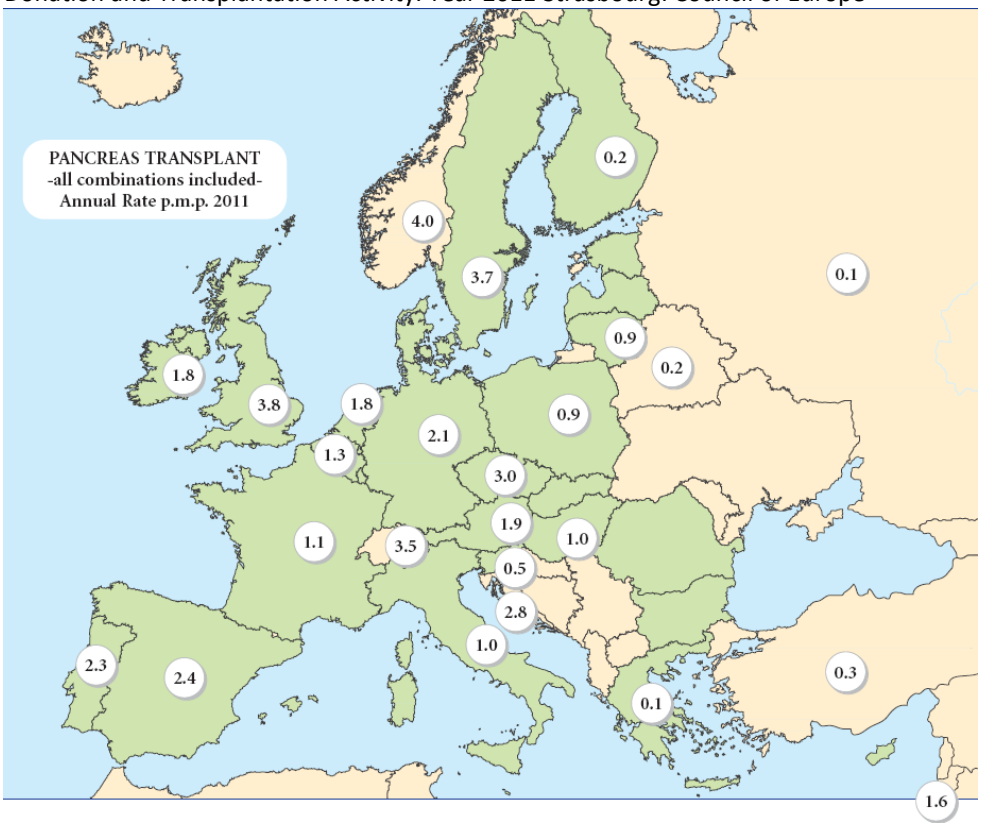
Map 1: Small bowel transplant per million population in 2011

Source: Council of Europe (2012). Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2011 Strasbourg: Council of Europe



Map 2: Pancreas transplant per million population in 2011

Source: Council of Europe (2012). Transplant Newsletter. International Figures on Organ Donation and Transplantation Activity. Year 2011 Strasbourg: Council of Europe



2.3 The implementation of the Action Plan in Europe (WP2)

In this sub-chapter, the aggregate results of the assessment of the Action Plan implementation at national level are presented. First results on each individual Priority Action are presented. Second, conclusions for each Priority Action are proposed. Whenever possible, the results of the ACTOR-study are compared to the results of a survey conducted among Competent Authorities in 2009 by Commission services.[199]

2.3.1 Challenge 1: Increasing Organ Availability

OBJECTIVE 1: MEMBER STATES SHOULD REACH THE FULL POTENTIAL OF DECEASED DONATIONS

Priority Action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Design indicators to monitor this action.

Action 1.1 Incorporate in the Set of National Priority Actions the objective of gradually appointing transplant donor coordinators in hospitals. Design indicators to monitor this action.

Action 1.2 Promote the establishment of internationally recognised standards for transplant donor coordinator programmes.

Action 1.3 Promote the implementation of effective training programmes for transplant donor coordinators.

Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators.

According to the Action Plan, the organisation of the organ donation process can play an important role in increasing organ availability. The plan furthermore mentions that combining an efficient system for organ donor identification, detection and procurement has been identified as one of the key ways to increase deceased organ donation.[200] In particular it names the presence of a key donation person at hospital level (transplant donor coordinator), whose main responsibility it is to develop a proactive donor detection programme as the first important step towards optimising organ donation and improving donor detection rates.[201] More specifically, it is said that Member States should aim to gradually appoint transplant donor coordinators in all hospitals in which there is potential for organ donation.

Results

Transplant donor coordinators have been appointed in almost all countries and some remaining countries plan to do so (Figure 2.2). When further examining the level on which these transplant donor coordinators have been appointed (Figure 2.3), the local/hospital level is mentioned most often, followed by the national level and in third place the regional/interregional level. A few CAs indicate that there are transplant donor coordinators on other levels such as clinical level or transplant centre level. Furthermore, it differs between countries whether transplant donor coordinators are appointed on one or on several levels. The results of the 2009 survey show that at that time 23 representatives out of 27 indicated that transplant donor coordinators were appointed,

[199] The questions asked in the 2009 survey of can be found in Annex 3

[200] Communication From The Commission Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States SEC(2008) 2956; SEC(2008) 2957

[201] Council of Europe Recommendations (Rec (2005)11) on the role and training of professionals responsible for organ donation.

and 2 were planning to appoint them. Most coordinators worked on hospital level. About half of the country-representatives indicated that the coordinators worked on the regional level and/or the national level.

Information from 32 national representatives was acquired on the **tasks of transplant donor coordinators**. On the whole there is great similarity amongst countries in the tasks described. On a hospital/local level concrete steps in the organ donation and transplantation process are most often mentioned, e.g. the identification and preparation of potential donors and communication with the family (including asking for consent). Transplant donor coordinators on a regional/interregional or national level in general operate at different aspects of the process, e.g. functioning as a contact person, keeping up registers/data and waiting lists, allocating organs, training personnel and promoting organ donation in general.

With regard to **professional training**, a large majority of the representatives indicate that transplant donor coordinators receive specific training (Figure 2.4). There are differences, however, in when and how regular these coordinators receive training. In almost one third of the countries transplant donor coordinators receive both initial training at their appointment and regular training. In the remaining countries transplant donor coordinators receive one type of training, it being either initial training at their appointment, regular training or another form of training. In 2009, about two third of the 27 representatives indicated that coordinators received initial training at the moment of appointing, 15 indicated regular training, and 8 representatives indicated both. With regard to the content of the training a number of aspects are frequently mentioned, namely legislation, donor identification, criteria for (brain) death, organ procurement/preservation and communication with the family. A number of representatives explicitly refer to Transplant Procurement Management (TPM) courses. In total, 615 transplant donor coordinators received specific professional training in 2011. Whether the training that transplant donor coordinators receive has been tested for effectiveness differs between countries. According to the results, 8 out of 27 representatives report that trainings have been tested for effectiveness. In 14 countries out of 27, no such testing has been done (yet).

Figure 2.2

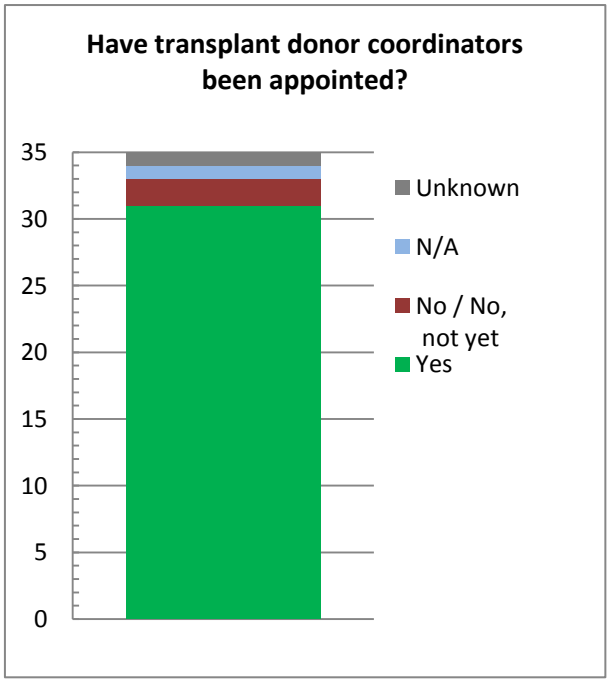
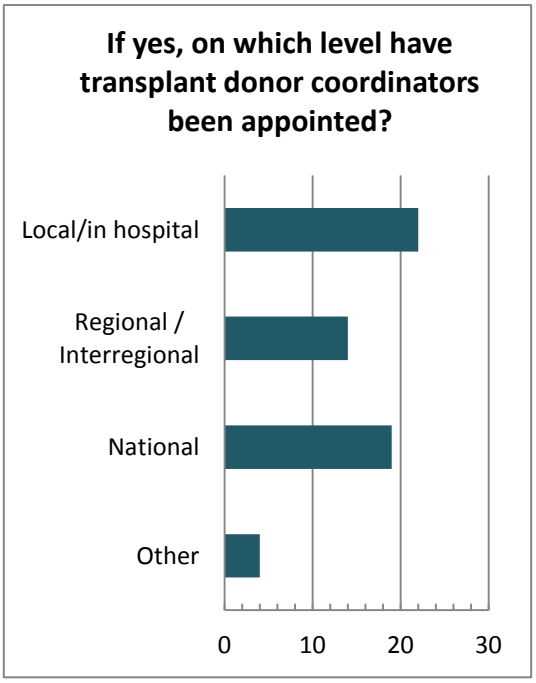
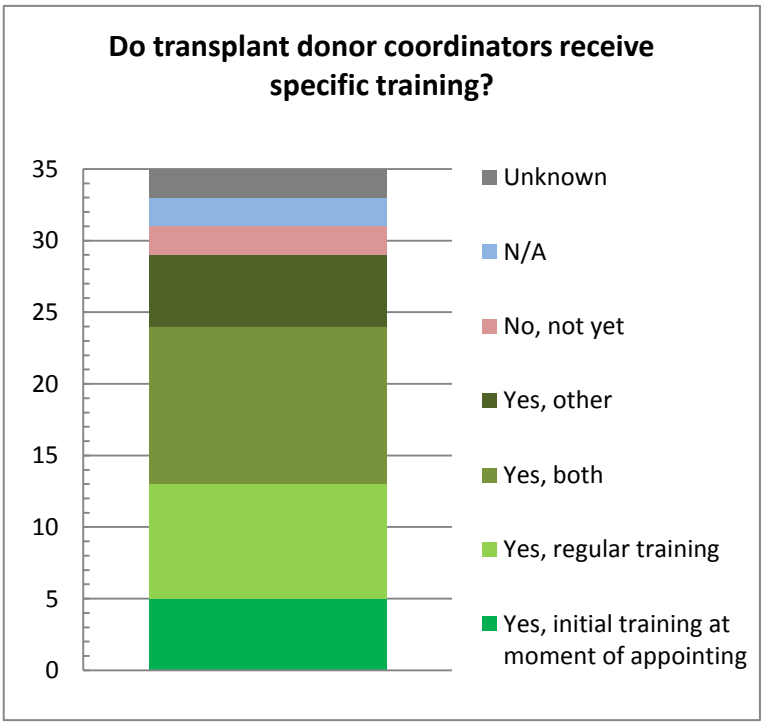


Figure 2.3



Regarding **accreditation**, 8 out of 29 representatives say that they use a national or international accreditation scheme to qualify transplant donor coordinators, whereas 19 out of 29 representatives indicate that they do not. Schemes that were listed were national accreditation schemes, some established by law, UEMS Certification for European Transplant Coordinators, advanced courses, medical courses, and approval of the hospital director or another organization. As to what accreditation system is used in the countries, the information reported differs, ranging from courses to national accreditation schemes.

Figure 2.4



In the almost all countries, transplant donor coordinators are appointed, and this number seems to have slightly increased since 2009. Although all coordinators receive training, these trainings are not often evaluated. This can be improved. Furthermore, it may be valuable to develop a common accreditation scheme.

Priority Action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.

Action 2.1 Incorporate in the Set of National Priority Actions the objective of gradually putting in place Quality Improvement Programmes in hospitals. Design indicators to monitor this action.

Action 2.2 Promote accessibility to and training on a specific methodology on Quality Improvement Programmes.

The Action Plan identifies the promotion of Quality Improvement Programmes for organ donation as another important way of optimising the organisation of the organ donation process. According to the Action Plan, Quality Improvement Programmes are primarily for self-evaluation within the hospital, in accordance with characteristics of the hospital and the health system.[202] CA

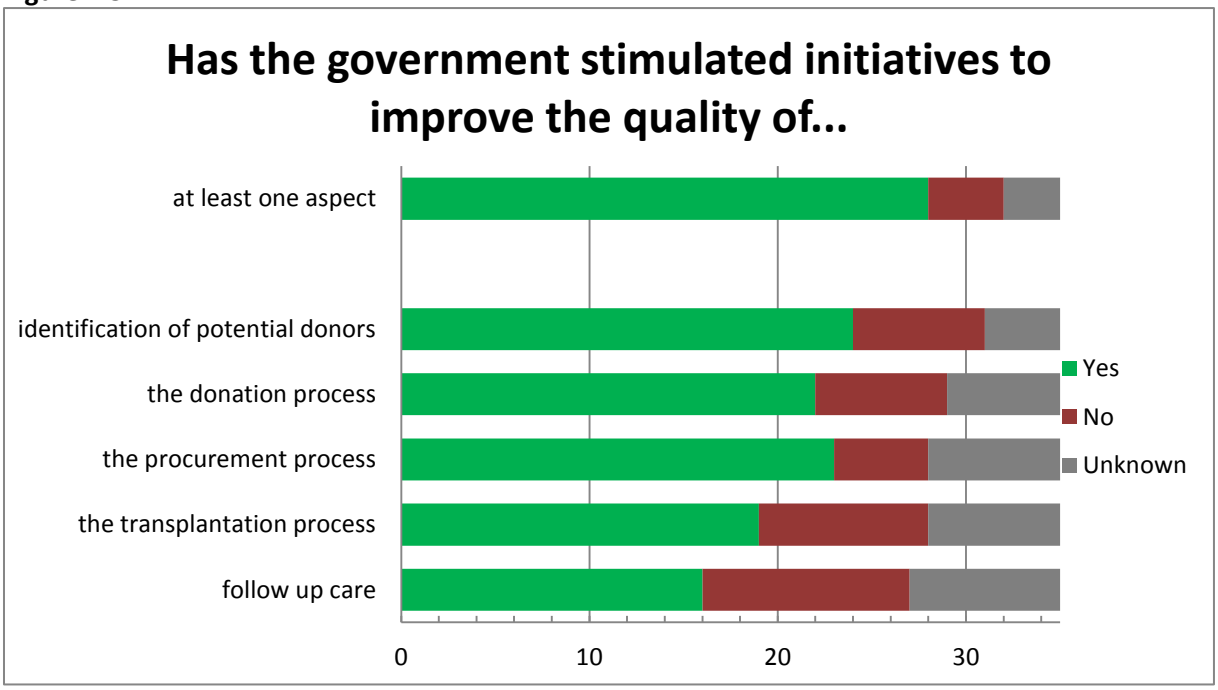
[202] Council of Europe Recommendation (Rec (2006)16) on quality improvement programmes for organ donation.

representatives were asked whether the (local) government has stimulated or introduced initiatives to improve the quality of five aspects in individual hospitals: identification of potential donors, donation process, procurement process, transplantation process and follow-up care.

Results

As it can be seen in Figure 2.5, the results show that in most countries the government has stimulated initiatives to improve the quality of at least one aspect of the organ donation process. Mentioned most often are initiatives to improve the quality of the identification of potential donors, whereas follow-up care is mentioned least often.

Figure 2.5



The following remarks further illustrate how this Priority Action is implemented. The Spanish CA reported: “One essential component of the Spanish Model is the Quality Assurance Programme in the deceased donation process, as a tool to define and monitor the potential of deceased organ donation, evaluate areas where improvement is possible, evaluate and monitor overall performance and study those demographic, hospital factors and even practices which have an impact on the previously mentioned areas. Data collection and analysis of these data allow identifying also benchmarks and best practices. In place since the year 1998, Transplant donation coordinators have been essential in the design of this programme and the continuous data collection for the internal evaluation phase is their task. This data collection, initially performed in paper forms, is now carried out electronically through a specifically designed web-based application. An important part of the programme is the External evaluation phase, where external observers make an evaluation of the process of deceased organ donation. These external evaluators are also donation coordinators with a high level of training and knowledge and already participating in the internal evaluation phase.”

The Turkish CA reported: “The Ministry of Health of Turkey has organised a training programme for intensivists to improve these processes. In total a number of 1780 intensivists, neurologists and nurses who are working at intensive care unit from all around Turkey have taken this course in 2012.”

In 2009, about one third of the CA representatives indicated that their countries use Quality Improvement Programmes, about the same number indicated they do not, and the other third were planning to utilise it. Compared to the 2012 results, there seems to be an increase in the uptake of

this action. What exactly a Quality Improvement Programme entails is however not clear from the description in the 2009 survey. This was one of the reasons why this item was reformulated. Representatives who indicated that they utilised these programmes also indicated that the programmes could be both voluntary or mandatory.

As can be seen, in most countries some actions are undertaken to improve quality of the different steps around organ donation and transplantation. However, not all aspects are taken up, so this could be improved. It seems that extra efforts are needed especially in the follow-up care.

OBJECTIVE 2: MEMBER STATES SHOULD PROMOTE LIVING DONATION PROGRAMMES FOLLOWING BEST PRACTICES.

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.

Action 3.1 Incorporate in the Set of National Priority Actions the promotion of altruistic donation programmes for living donors, with safeguards built in concerning the protection of living donors and the prevention of organ trafficking.

Action 3.2 Promote the development of registers for living donors to evaluate and guarantee their health and safety.

The Action Plan encourages the promotion of living donation programmes to improve the availability of organs for transplantation, since living donation could be a significant alternative complementing deceased donation, at least for kidney and maybe also for liver transplantation. Furthermore, the plan mentions that registers of living donors should be set up to assess and guarantee the safety of these donors. This principle now became an obligation with the adoption in 2010 and transposition in 2012 of Directive 2010/53/EU, in particular with its article 15 on "quality and safety of living donation".

Results

The results indicate that almost all countries have living donation programmes with related donors (Figure 2.6). [203] On the other hand, a much smaller number of CA representatives (less than half) report that living donation programmes are in place with unrelated donors. In 2009, 25 out of 27 CAs indicated that living donation programmes were in place in their countries.

Based on the information of 27 countries on living donation with related donors and 17 countries on living donation with unrelated donors, it can be concluded that there are differences between countries in what these programmes entail. Country differences are primarily based on legal definitions and exist in whether or not a legal or genetic relationship is required for donation, whether living donation is prohibited and whether living liver donation occurs (or only kidney living donation). In addition, some representatives mention that there are differences between what is stated in the law and what happens in practice. Living donation with an unknown recipient may for example be legal, but not well accepted in practice, and therefore rarely implemented.

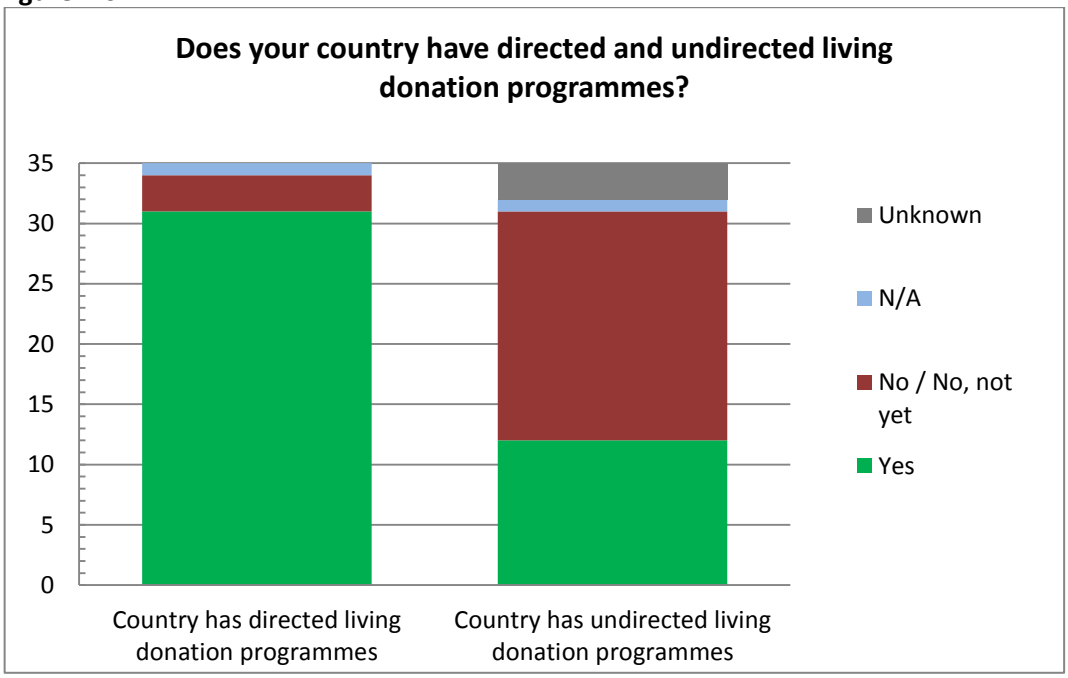
With respect to the protection of living donors, results show that in 22 out of 33 countries independent bodies exist that evaluate living donors. In 2009, 19 of 27 representatives indicated that there is a public body that evaluates the living donor. Concerning organ trafficking, almost all representatives (27 out of 31) report that this is prohibited by law. Consequently, 1 country reports that organ trafficking is not prohibited and 2 CA representatives indicate that organ trafficking is not

[203] Directed living donation refers to living donation with donors that are relatives or friends. Undirected living donation refers to living donation with unrelated donors.

yet prohibited, but that it is intended to be in the future. Out of these 3 countries, 2 are non EU Member States.

Last, the results of this study show that in 16 out of 31 countries "registers" (or "records") have been established to evaluate and guarantee the health and safety of living donors. These registers may contain general and medical information about the donor, the relationship with the recipient and recipient follow-up. It should be noted that having a register does not necessarily mean that it is filled with long-term follow-up data.[204] Out of 27 representatives, 16 indicated in 2009 that they follow up living donors with national registers, 5 representatives reported that it was planned for 2010 or 2011.

Figure 2.6



Most countries perform living donation, and slightly more countries than in 2009 have an independent body to evaluate the living donors. In 2012, about the same number of countries as in 2009 uses registers to follow up on living donors. This should be improved. More can be done to make living donation a growing, successful and safe practice.

[204] Registers are now a requirement in the Directive 2010/53/EU. In the Joint Action ACCORD Member States are supported in their efforts to set-up these registers.

OBJECTIVE 3: INCREASE PUBLIC AWARENESS OF ORGAN DONATION

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.

Action 4.1 Incorporate in the Set of National Priority Actions the recognition of the important role of the mass media and the need to improve the level of information to the public on these topics.

Action 4.2 Promote training programmes geared towards health professionals and patient support groups on organ transplantation communication skills.

Action 4.3 Organise periodic meetings at national level (competent authorities) with journalists and opinion leaders and manage adverse publicity.

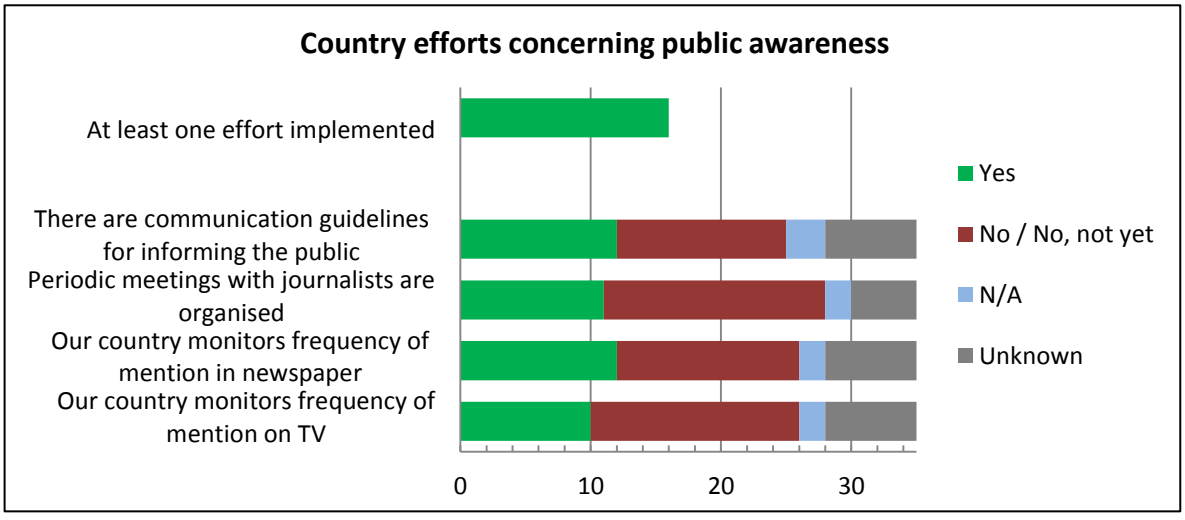
In addition to optimising the organ donation process, the Action Plan also mentions that increasing public awareness of organ donation can be an important factor in increasing organ donation rates. Representatives of the countries were asked whether there are country efforts regarding four aspects of public awareness: (1) having communication guidelines for informing the public, (2) organising periodic meetings with journalists, (3) monitoring the mention of organ transplantation in newspapers and (4) monitoring the mention of organ transplantation on television.

Results

The results in Figure 2.7 show that in slightly less than half of the countries at least one effort has been undertaken regarding public awareness.[205] There is little difference in how often the different efforts have been implemented by countries. When looking at the number of efforts implemented by countries, there are differences in the number of efforts that countries have implemented, with 6 countries having implemented all four efforts and 3 countries one effort (Figure 2.8).

With regard to **who is responsible for the deployment of communication guidelines for informing the public about organ transplantation**, most of the 17 responding CAs mention the Ministry of Health or national transplant centres. Concerning periodic meetings with journalists, the number of meetings reported by representatives ranges from 1 to 12 in 2011. In 2009, 16 of 27 representatives indicated that periodic meetings were organised with journalists.

Figure 2.7



[205] For the indicator regarding the implementation of at least one effort, it was not possible to adequately distinguish between the answers No / No, not yet, N/A and Unknown, therefore only the number of countries with at least one effort implemented are presented.

Figure 2.8

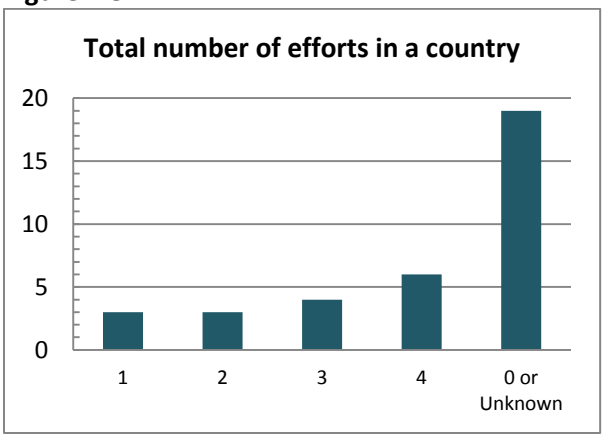


Figure 2.9

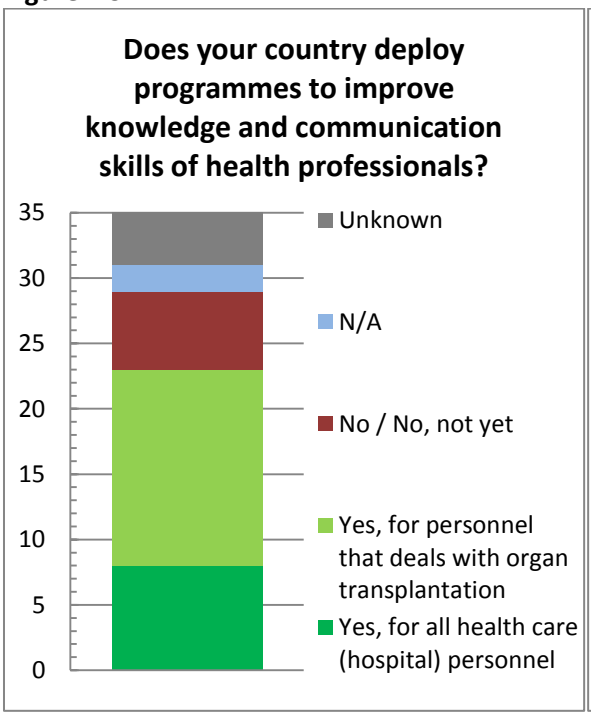


Figure 2.10

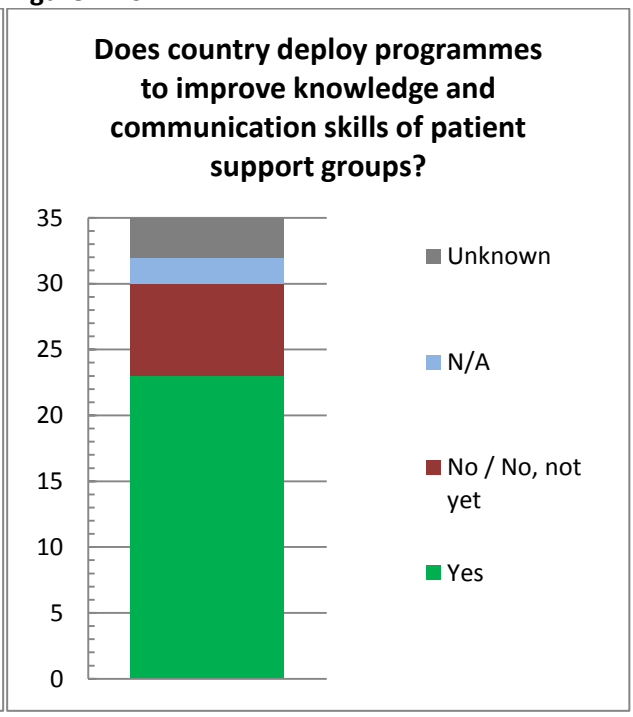
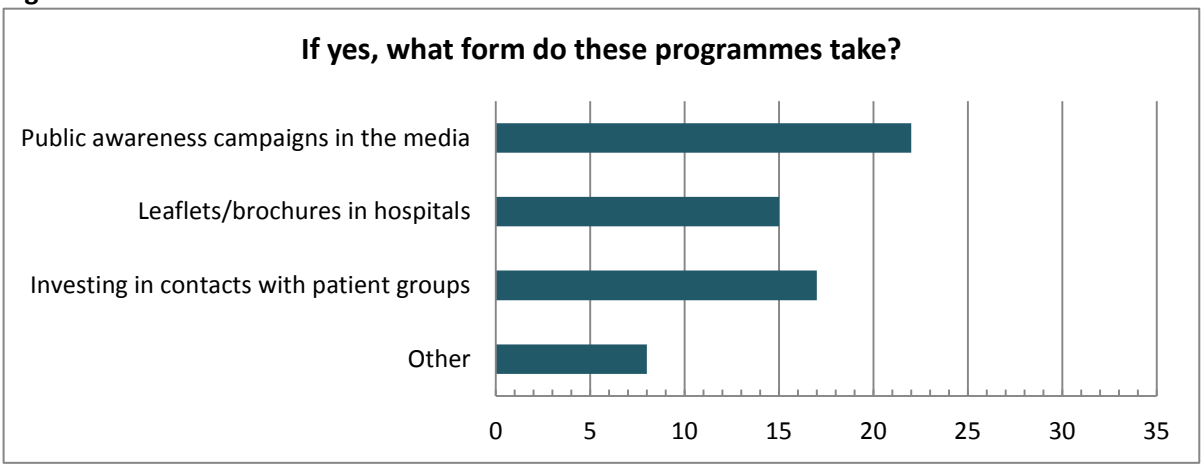


Figure 2.11



Next to informing the public directly, the Action Plan refers to the need to **improve the knowledge and communication skills of health professionals and patient support groups**. As it can be seen in Figure 2.9, in about two-thirds of the countries where data is available, programmes are deployed for health professionals to improve these skills. In most cases, these entail programmes for personnel dealing with organ transplantation and to a lesser extent these entail programmes for all (hospital) health care personnel. In 2009, 24 of 27 representatives indicated that programmes are deployed in order to improve the knowledge and communication skills of health professionals, mainly consisting of trainings and to a lesser extent the use of media officers in hospitals. The results of 2012 furthermore indicate that in about two-thirds of the countries programmes are deployed to improve knowledge and communication skills of patient support groups (Figure 2.10). Of these, public awareness campaigns in the media are most often used, followed by investing in contacts with patient groups and leaflets/brochures in hospitals (Figure 2.11). A number of representatives indicate that these programmes take another form or that they have extra activities. An example mentioned is a 24 hour telephone line available for consultation in Spain. The internet is mentioned by several representatives. In Belgium, there was a campaign in cooperation with Facebook launched in September 2012 and a campaign at each local voting office for local elections in October 2012. Similar initiatives were also done in other EU countries. For example in Italy, each year in January and May meetings with journalists were organised since the Action Plan was adopted. In France besides monitoring organ donation on TV and in newspapers, radio and internet are monitored as well. In the Netherlands monitoring the social media is added to this. In 2009, 18 of 27 representatives reported that programmes for patient support groups were deployed, mainly consisting of leaflets or brochures in hospitals, public awareness campaigns in the media, and investing in contacts with patient groups.

Since 2009, numbers on this action have not changed much, although there are differences between the different aspects to creating and monitoring public awareness. The data presented clearly demonstrates that there is ample room for improvement on this Priority Action.

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.

Action 5.1 Collect and disseminate information about citizen's rights concerning organ donation across the EU.

Action 5.2 Develop mechanisms to facilitate the identification of cross-border donors.

Due to the mobility of citizens, and therefore of patients and donors in the EU, the Action Plan highlights the need to collect and disseminate information about citizen's rights concerning organ donation across Europe and to facilitate identification of cross-border donation in Europe. The management of waiting lists and the definition of allocation criteria of organs are mainly national tasks. However, via the Action Plan Member States have the opportunity to share information and expertise.

Results

With regard to the **legal criteria for permitting the donation of organs after death**, the results in Figure 2.12 show that most countries have regulations on the possibility for non-residents or non-nationals of a country to become donors in this country. Of the countries responding, a majority allows non-residents and residents with a foreign nationality to donate organs after death. There is less consensus, however, on whether or not illegal persons who die in a country can be donors. Of the countries for which data is available, in less than half of the countries illegal persons can legally be donors. In 2009, 22 CAs indicated that persons with a foreign nationality can be donor, in 20 countries, non-residents can be a donor, and in 7 countries, illegal persons can be a donor.

Concerning **criteria for admittance to waiting lists**, there is also variation between countries. Residency in the country or being signed up with local social security or health care insurance are criteria in a majority of the countries for which data is available (Figure 2.13). Local nationality, on the other hand, is required in about half of the countries. Representatives were also asked to indicate what percentage of their transplanted patients are either local residents, foreign residents or non-residents. Regarding local residents the percentages mentioned ranged from 82 to 100, for foreign residents from 0 to 15 and for non-residents from 0 to 18.

Concerning the dis**semination of information about citizen's rights concerning organ donation across the EU** (of countries for which data is available), only a minority of 12 countries were said to provide easily accessible information to citizens about their legal position as a possible donor in other EU countries (Table 2.14). In 2009, 10 of the 24 CAs indicated that information was available about transplantation abroad.

Figure 2.12

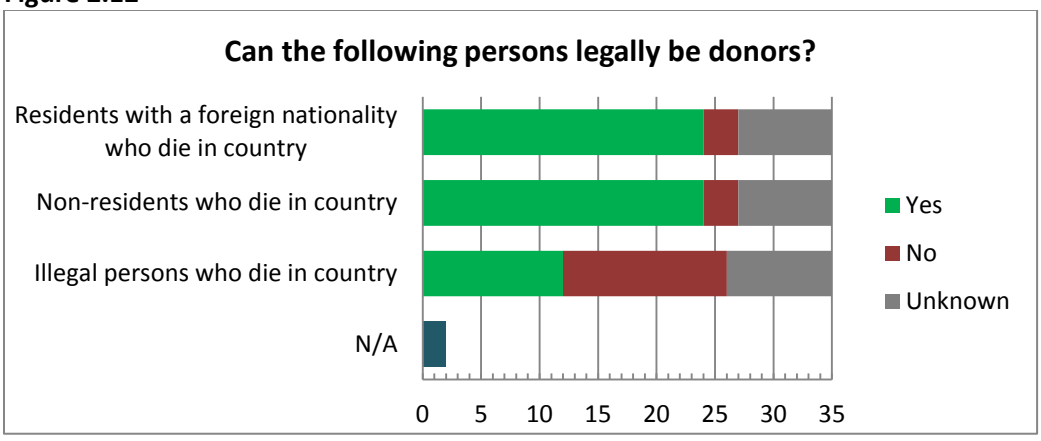


Figure 2.13

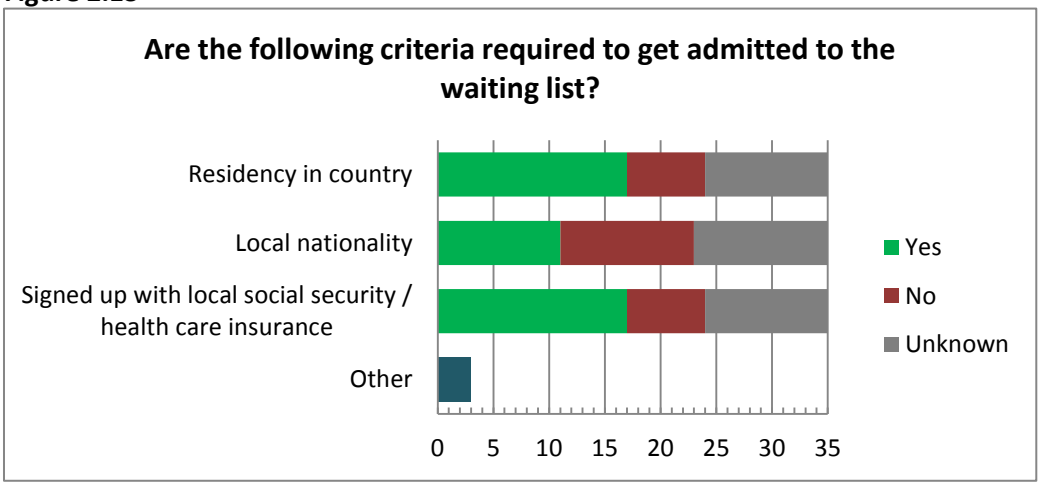
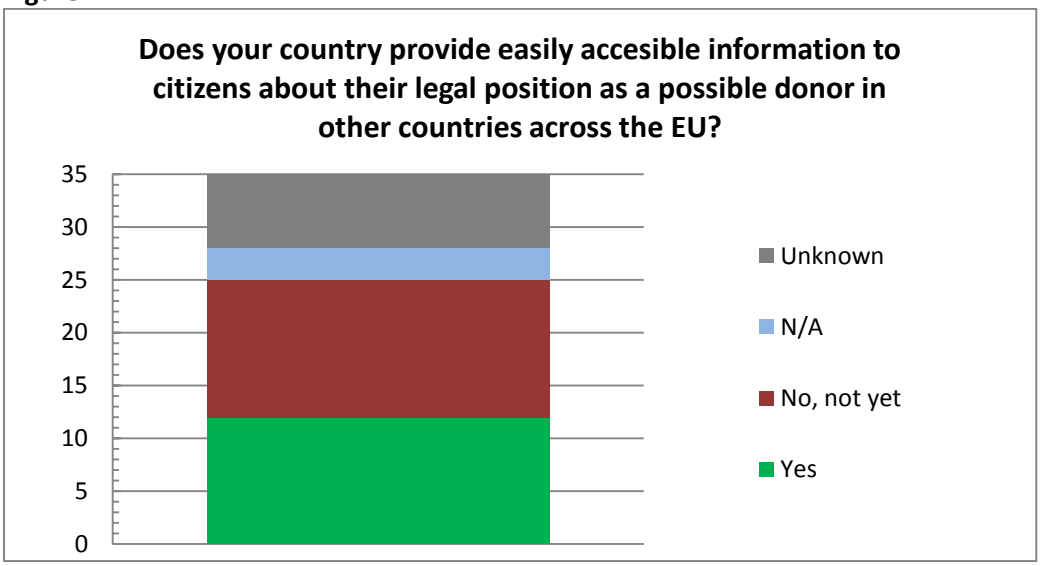


Figure 2.14



On this action, not much change, compared to 2009, is reported. It is positive that most countries at least have regulations in the area of organ donation abroad and across Europe, but the level of provision of information to the public can be improved further.

2.3.2 *Challenge 2: Enhancing The Efficiency And Accessibility Of Transplant Systems*

OBJECTIVE 4: SUPPORT AND GUIDE TRANSPLANT SYSTEMS TO BE MORE EFFICIENT AND ACCESSIBLE

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

Action 6.1 Include in the Set of National Priority Actions ad hoc recommendations of the committee of experts to the Member States by way of regular reporting.

Action 6.2 Promote twinning projects and peer reviews.

Action 6.3 Assess the use of structural funds and other Community instruments for the development of transplantation systems.

Action 6.4 Promote networks of centres of reference.

The formulation of the Action Plan suggests that even among EU countries with well-developed health and organ transplant services, there may always be room for improvement. Hence, the Action Plan aims to promote initiatives to enhance the organisational models of organ donation and transplantation, sharing experiences and promoting best practices. These initiatives include twinning projects, peer reviews or similar projects, assessing the use of structural funds and other community instruments and promoting networks of centres of reference. It is to be noted that in twinning activities and peer reviews, there are for countries two ways to be involved: as supporting country and as supported country. Depending on their capacities, some countries might be involved in different projects both as supporting and supported parts. And "supporting activities" might also bring some learning to the supporting country, via a reflection on its own organisation.

Results

The results in Figure 2.15 show that little more than half of the countries for which data is available have been involved in **twinning projects, peer reviews or similar projects**. Moreover, out of these representatives about half indicate that these projects have led to changes (Figure 2.16). In addition, in 5 countries, results of these projects have been documented. In 2009, 12 of 27 CAs had already been involved in twinning projects, while 13 had not. Only 10 had been involved in peer reviews, while 15 indicated that they had not.

Another alternative to **enhance organisational models** is the use of **structural funds**[206] or other **community instruments**.[207] The use of such funds will not always be known to the CAs, so on this topic existing initiatives may have not been fully captured in the present study. Only few representatives explicitly reported the use of these funds and/or instruments (Figure 2.17). A number of respondents indicate that their country is not eligible for structural funds or that they are uninformed about them. On the other hand, out of 21 respondents, 9 indicate that they do not use these funds, but are interested in the possibilities. An example of usage of structural funds mentioned is the appointment of in-house (hospital) donor coordinators (Czech Republic). In 2009, 7 countries already used structural funds against 13 that did not.

Networks of centres of reference are specialized medical centres networks. They can be established at the national level, and may also be European in the future. Such networks do not really officially exist in the field of organ donation and transplantation at European level. However, such a wording is used in another EU, health-related legislation: following the adoption in March 2011 of Directive 2011/24/EU on patients' rights to cross border healthcare (transposition by 25 October 2013) and in accordance with its Article 12 (4), the European Commission is currently working, together with EU Member States, on the preparation ("implementation measures") of a list of criteria and conditions for European Reference Networks (ERNs) and healthcare providers wishing to join such networks as Centres of Expertise. The Commission is still in the drafting stage of the implementing measures and discussions are still on going on several of the issues. At this stage, it is therefore not possible to foresee the clinical areas wherein ERNs may be established in the future. However the field of organ donation and transplantation might be one such area. The Action Plan also proposed the participation in "networks of centres of reference" regarding organ transplantation. The results show that less than a third of the countries for which data is available have transplantation centres or hospitals that participate in these kinds of networks (Figure 2.18). An example mentioned of specialities of networks of centres of reference is paediatric kidney, liver and heart transplantation (Spain). Other examples that were given were: lung transplantation, cystic fibrosis, live donor liver transplantation, heart-lung transplantation, pancreas transplantation, and small bowel transplantation. In 2009, 5 out of 20 countries participated in networks of centres of reference.

[206] The Structural Funds and the Cohesion Fund are the financial instruments of European Union (EU) regional policy, which is intended to narrow the development disparities among regions and Member States. The Funds participate fully, therefore, in pursuing the goal of economic, social and territorial cohesion. Structural funds were defined in the questionnaire as funds intended to facilitate structural adjustments of specific sectors, regions, or combinations of both (not specifically – but can – be dedicated to Health systems). For more information: http://europa.eu/legislation_summaries/glossary/structural_cohesion_fund_en.htm

[207] Other community instruments were defined in the questionnaire as other projects funded by other programmes from the European Union such as the Framework Research Programmes, or Pre-Accession Aids for Candidate Countries, Technical Assistance and Information Exchange (TAEIX) support from EU Delegations.

Figure 2.15

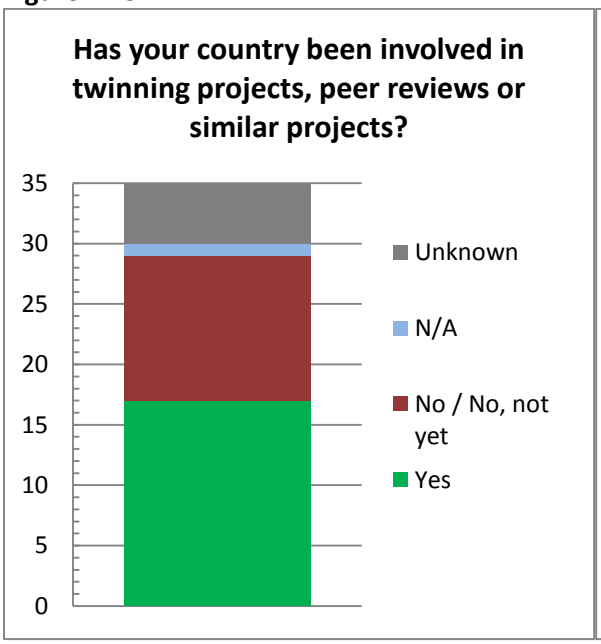


Figure 2.16

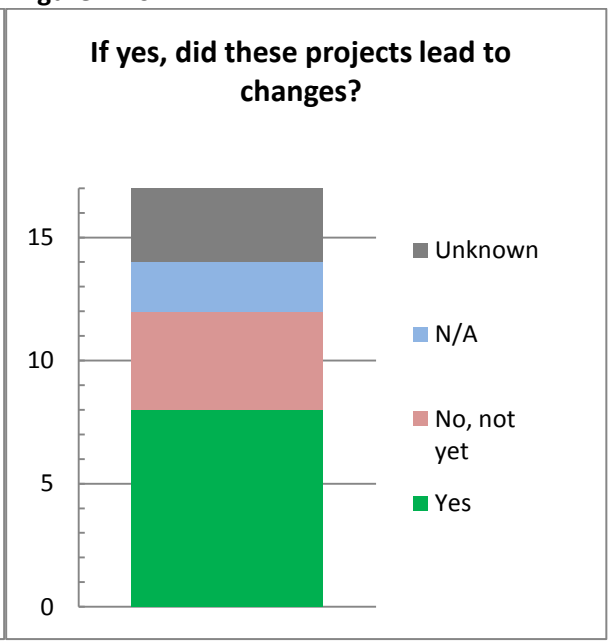


Figure 2.17

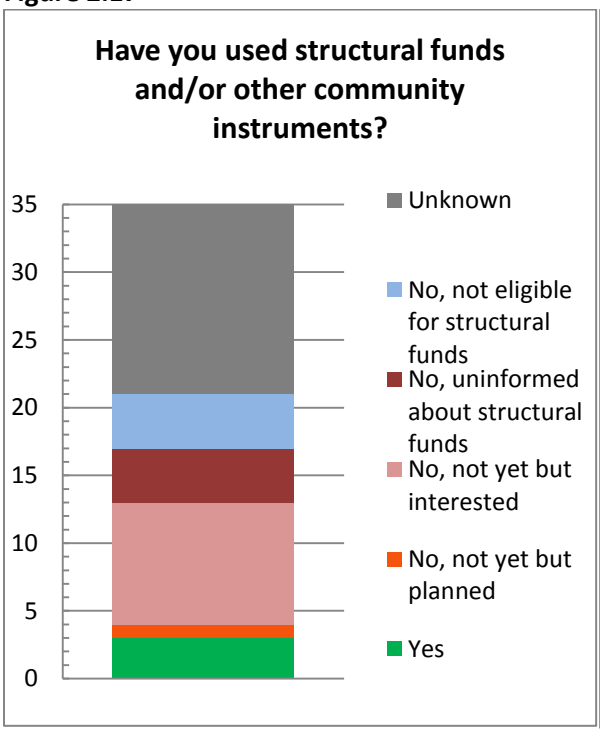
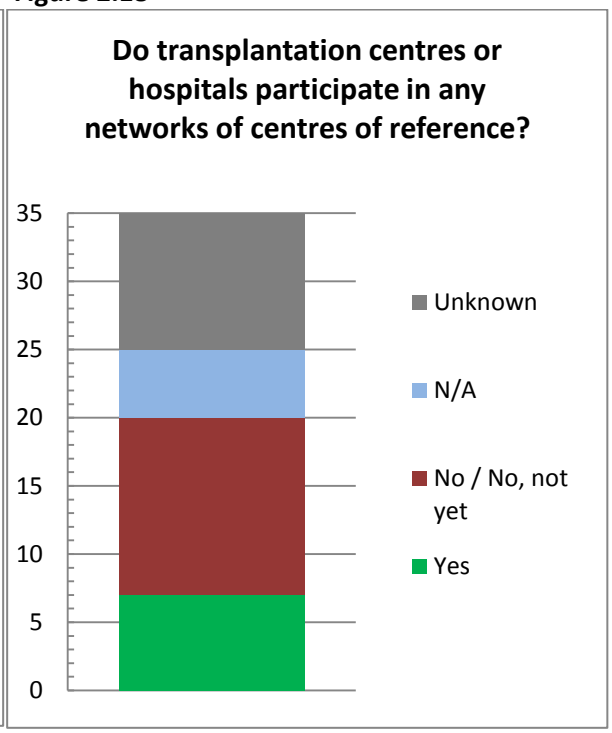


Figure 2.18



The number of countries that has been involved in twinning projects or peer reviews has evolved since 2009, however numbers are not very comparable. Twinning activities can be an efficient way to exchange best practices, so it could be stimulated further. Also the structural funds might be an opportunity, since a number of representatives are interested in the usage of these. Still not many respondents indicated that hospitals or transplantation centres participate in networks of centres of reference.

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

Action 7.1 EU-wide agreement on basic rules for internal EU patient mobility and transplantation, in compliance with Community law.

Action 7.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patients.

Action 7.3 EU-wide agreement on monitoring organ trafficking.

Action 7.4 EU-wide agreement on common priorities and strategies for future research programmes.

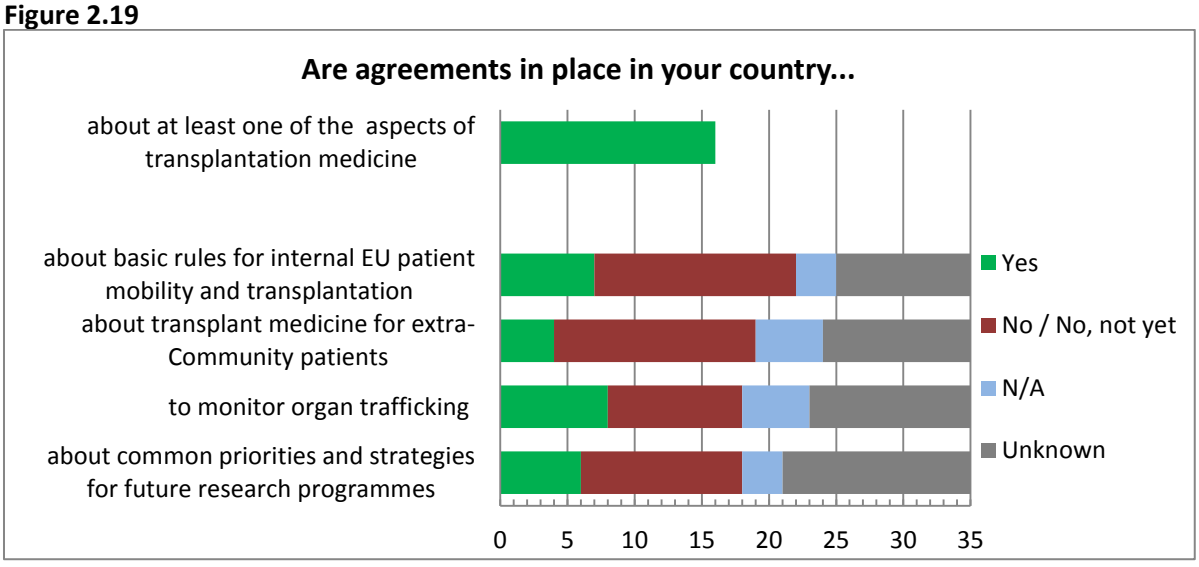
The Action Plan proposes that EU-wide agreements are reached on various aspects of transplantation medicine to enhance a so called cooperation method. Respondents were asked if agreements were in place concerning four topics, namely (1) basic rules for internal EU patient mobility and transplantation, (2) transplant medicine for extra-Community patients, (3) tracking organ trafficking and (4) common priorities and strategies for future research programmes.

Results

Results show that little less than half of the representatives report that they have at least one agreement in place (Figure 2.19).[208] A limited number of representatives indicate that they have agreements in place regarding any one of the 4 topics. In 2009, 19 of 24 responding CAs were interested in developing EU-wide agreements on patient mobility in the EU, 12 in agreements on patient mobility from outside the EU, 16 in agreements on organ trafficking, 19 in agreements on future research programmes, and 16 in agreements on European transplant research network.

On the topic of organ trafficking, out of 24 responding representatives, more than half indicate that they do not see organ trafficking as a possible threat in their country (Table 2.2).Three representatives indicate that they see organ trafficking as a threat in their country for all types of organs. The kidney was most often mentioned as an organ that poses a risk for trafficking (7 representatives), probably because living donation is possible for kidney transplants.
The other organs were mentioned by a few representatives.

Figure 2.19



[208] For the indicator regarding the implementation of at least one effort, it was not possible to adequately distinguish between the answers No / No, not yet, N/A and Unknown, therefore only the number of countries that have at least implemented one effort are presented.

Table 2.2

For which organs is organ trafficking a possible threat in country?	Number of countries = 24
All organs	3
Liver	4
Kidney	**7**
Heart	2
Lung	1
Other, being pancreas, pancreas islets, intestine	1
None	**15**

With regard to **future research**, CA representatives (who might not have a direct influence on the agenda-setting for research at national level) were asked to indicate which subjects they feel future research should focus on. Subjects mentioned were among other things Donation after Circulatory (Cardiac) Death (DCD), statistics and analysis of software parameters and the monitoring of donation potential.

Last, CA representatives were asked about which topics **EU-wide agreements** should be made on in their view. Examples of topics mentioned include extended donor criteria, patient mobility within the EU and organ trafficking.
The results from the 2009 assessment cannot exactly be compared with the results of this assessment. However, as the greater part of representatives were interested in developing EU-wide agreements in 2009 on several aspects of organ donation and transplantation, and in 2012 still little agreements have been reached, it might be worth to investigate what the views are of the Competent Authorities on this Priority Action.

Priority Action 8: Facilitate the interchange of organs between national authorities.

Action 8.1 Evaluate procedures for offering surplus organs to other countries.

Action 8.2 Put procedures in place for the exchange of organs for urgent and difficult-to-treat patients.

Action 8.3 Design IT tools in support of the previous actions.

Another action proposed within the Action Plan is to have in place **system(s) or structure(s) for the exchange of organs between Member States**, especially in the **case of urgent and difficult-to-treat patients**. The Action Plan moreover specifies that an IT-tool could support the exchange of organs between Member States.

Results

Results presented in Figure 2.20 show that almost all countries are part of at least one fixed collaboration with other countries and use these to exchange organs. A number of countries are part of Eurotransplant (Austria, Belgium, Croatia, Germany, Luxembourg, the Netherlands, Slovenia – and Hungary in a preliminary stage) or Scandiatransplant (Denmark, Finland, Iceland, Norway, Sweden), but more representatives indicate that they have bilateral agreements with one or more other countries. A new initiative is the Southern Europe Transplant Alliance, signed on 1 October 2012 between Spain, France and Italy. These countries want to exchange organs for special groups of

patients. In 2009, besides the (at that time) 6 countries participating in Eurotransplant and 5 in Scandiatransplant, 11 CAs indicated to be part of a multilateral collaboration, and 12 of a bilateral collaboration. Three were not, and 2 CAs were planning to take part of a collaboration in 2010. Mostly these collaborations involved all types of patients, or patients with urgent needs for transplantation and to a lesser extent paediatric patients (children) or patients with a rare HLA-pattern. In most cases, the liver was involved, followed by lung, kidney and heart.

Regarding **patient categories** that are considered within fixed collaborations with other countries in 2012, out of 28 representatives, about half say that all kinds of patients are taken into account (Table 2.3). In addition, more than half of the representatives indicate that patients with urgent needs are included in fixed collaborations and about a third indicates that paediatric patients are. Finally, a few representatives indicate older patients, patients with rare HLA-patterns or other special patients are included. When asked which organs are involved in such collaborations, out of 28 representatives, a majority answer the liver, as well as the lungs (Table 2.4). To a lesser extent, this is also the case for kidney, heart, pancreas, pancreas islets and intestines. The number of organs mentioned by representatives that came from abroad in 2010 ranges from 1 to 149 and the number of organs that left the country in the same year ranged from 1 to 114. Information on the change over time has not been collected and therefore cannot be reported.

Figure 2.20

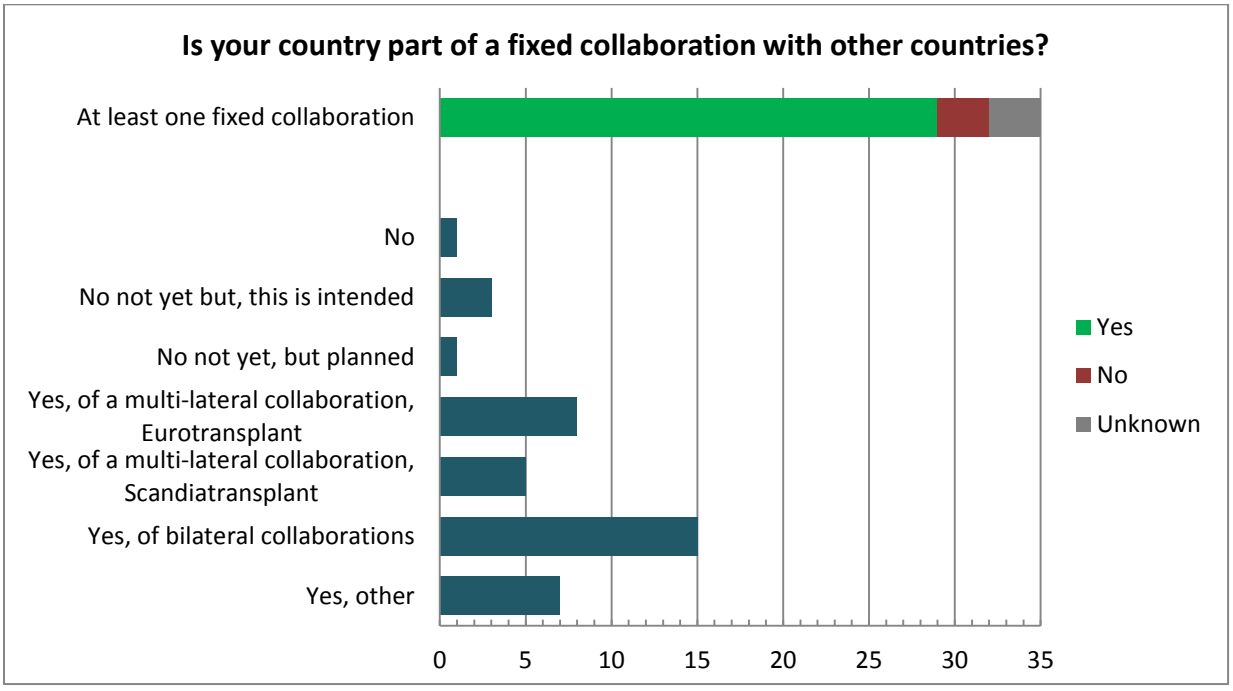


Table 2.3

Which patient groups are involved in a fixed collaboration with other countries?	Number of countries = 28
All patients	15
Patients with urgent needs	16
Paediatric patients	10
Older patients	1
Patients with rare HLA-patterns	2
Other	4

Table 2.4

Which organs are involved in a fixed collaboration with other countries?	Number of countries = 28
Liver	24
Kidney	18
Heart	17
Lung	21
Other, being pancreas, pancreas islets, intestine	14
Other	1

Table 2.5

Which non-allocated organs were offered to other countries?	Number of countries = 26
Liver	13
Kidney	12
Heart	13
Lung	13
Other, being pancreas, pancreas islets, intestine	6

Regarding whether or not **organs non-allocated in the country were offered to other countries**, results indicate that out of 25 countries, 16 have offered organs. Out of the 9 representatives that report not having offered any organs to other countries, 7 stated they did not have any non-allocated organs (meaning probably that potentially "non-allocated" organs were not procured). Regarding the type of organs involved, of the 26 representatives with data, about half indicate either liver, kidney, heart or lung (Table 2.5). The number of organs non-allocated locally and consequently offered to other countries ranges from 1 to 47 per country. Representatives were furthermore asked to indicate whether their country evaluates procedures for offering non-allocated organs to other countries. Out of 25 representatives, 6 representatives report that they do and 12 representatives report that they do not. These results highlight a potential to offer more (so far) non-allocated organs.

Representatives were asked to report if there are **procedures in place for the exchange of urgent and difficult-to-treat-patients**. More than half of the representatives with data, report that these kinds of procedures are in place (Figure 2.21). In addition, out of 18 representatives, almost all indicate that livers are involved in these procedures and a majority of the representatives report that kidney, heart or lung are involved (Table 2.6). A third of the representatives mention the pancreas, pancreas islets or intestines in this context.

Figure 2.21

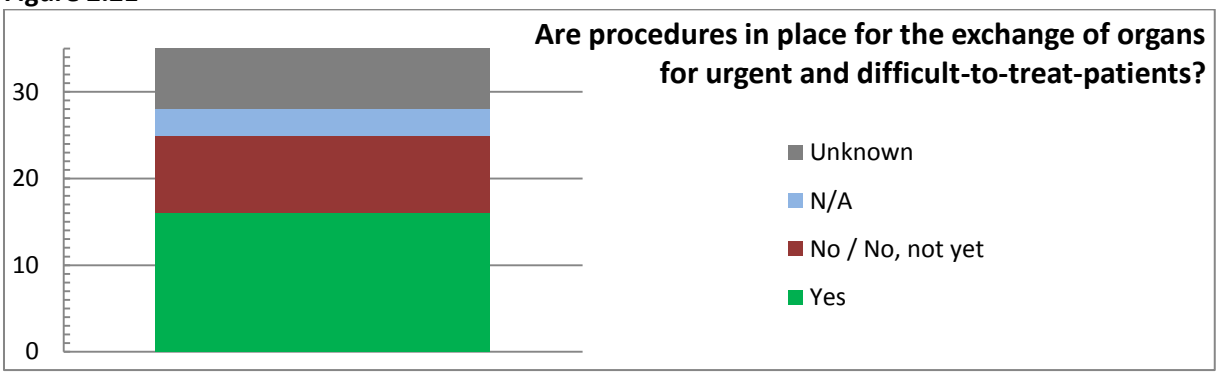
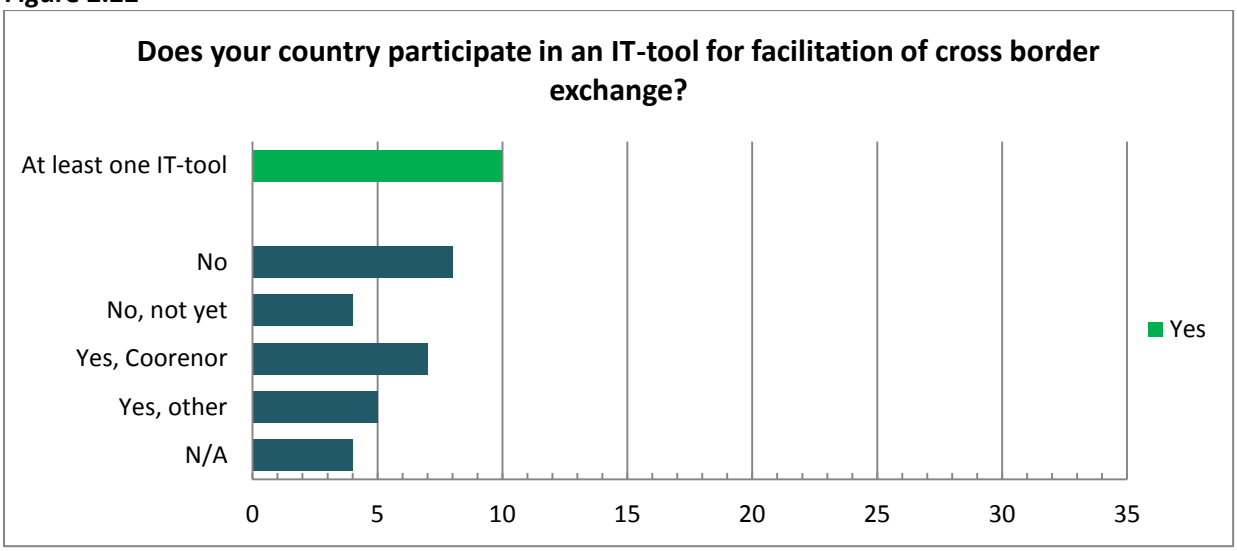


Table 2.6

Which organs were involved in procedures for the exchange of organs of urgent and difficult-to-treat patients?	Number of countries = 16
Liver	15
Kidney	11
Heart	13
Lung	13
Other, being pancreas, pancreas islets, intestine	6

With regard to **participation in an IT-tool**, results show that of the countries with data, less than a third participates in at least one IT-tool for the facilitation of cross border exchange (Figure 2.22). Out of these representatives, 7 mention the IT-tool developed by the EU-funded COORENOR project and 5 indicate that they participate in another IT-tool, for instance systems in Eurotransplant or Scandiatransplant, or the European Children List (ECL) for heart, lung and small bowel. The reason for their non-participation was the current unavailability of an IT-tool to them.
Also the IT-tool developed by the COORENOR project was not yet available to all countries: it was first available to countries who participated in the COORENOR project (which finished in December 2012). The Joint Action FOEDUS which will start mid 2013 will give the opportunity for other countries to join and use this IT-tool. Finally some representatives indicate that the exchange of non-allocated organs is an issue which they are planning to take up in the future.

Figure 2.22



It is not possible to exactly compare the number of collaborations with the 2009 data, but results suggest that this action is taken up by an increasing amount of countries. Still, much room for improvement exists, especially on the actual and effective exchange of non-allocated donor organs.

2.3.3 *Challenge 3: Improving Quality And Safety*

OBJECTIVE 5: IMPROVE THE QUALITY AND SAFETY OF ORGAN DONATION AND TRANSPLANTATION

Priority Action 9: Evaluation of post-transplant results.

Action 9.1 Develop common definitions of terms and methodology to evaluate the results of transplantation.

Action 9.2 Develop a register or network of registers to follow up organ recipients.

Action 9.3 Promote common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors**.**

Action 9.4 Develop and promote good medical practices on organ donation and transplantation on the basis of results, including the use of expanded donors.

To improve the quality and safety of organ donation and transplantation, the Action Plan aims to support the **evaluation of post-transplant results**, via common definitions, the use of registers as well as the development and promotion of medical practices, for example around the quality and safety conditions for the use of expanded donors (donors with medical difficulties, such as elderly donors or donors with difficult health conditions).

In this area, the Action Plan is **complementary to the Directive 2010/53/EU on the quality and safety** of human organs intended for transplantation. "The collection of relevant post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation", as stated in Recital 24 of the Directive: the quality and safety of organs should be evaluated by the relevant competent authorities "throughout patients' recovery and during the subsequent follow-up". However, this principle was not made mandatory within the Directive.

Results

A majority of the CA representatives states that in their country post-transplant results are systematically collected in a database/register (Figure 2.23).

Figure 2.23

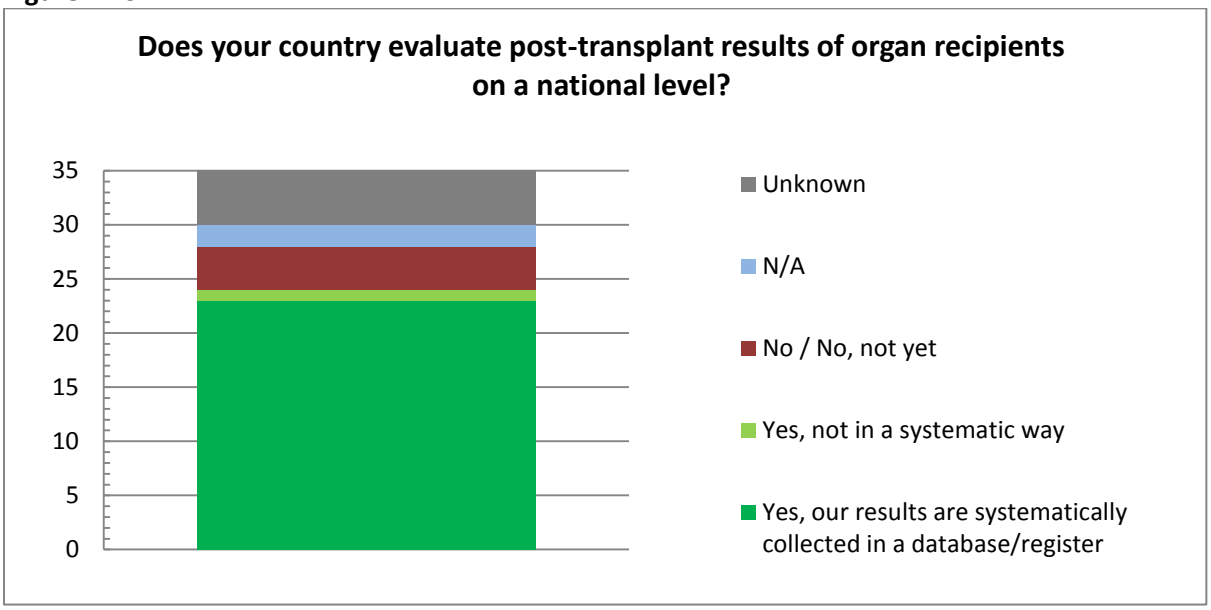
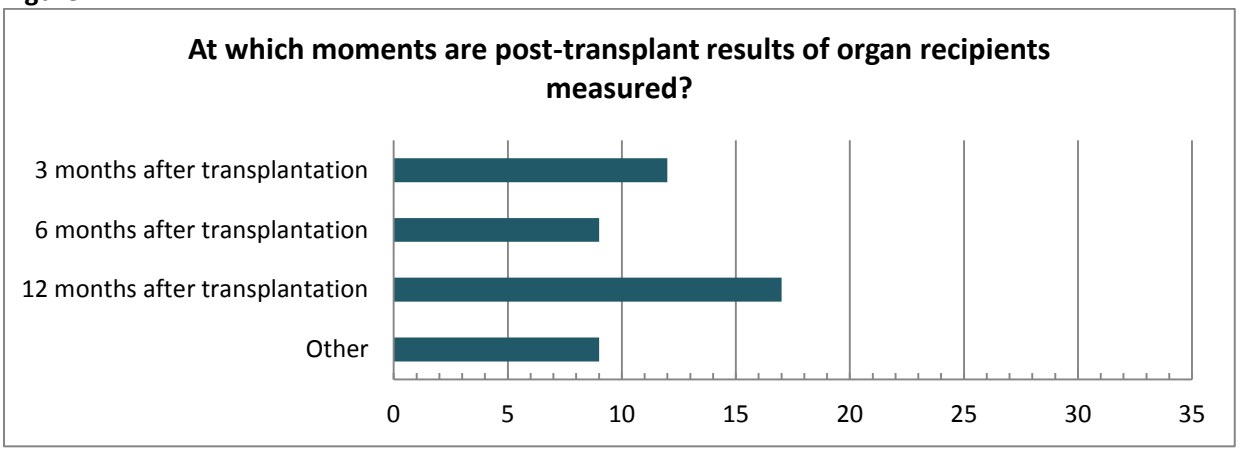


Figure 2.24

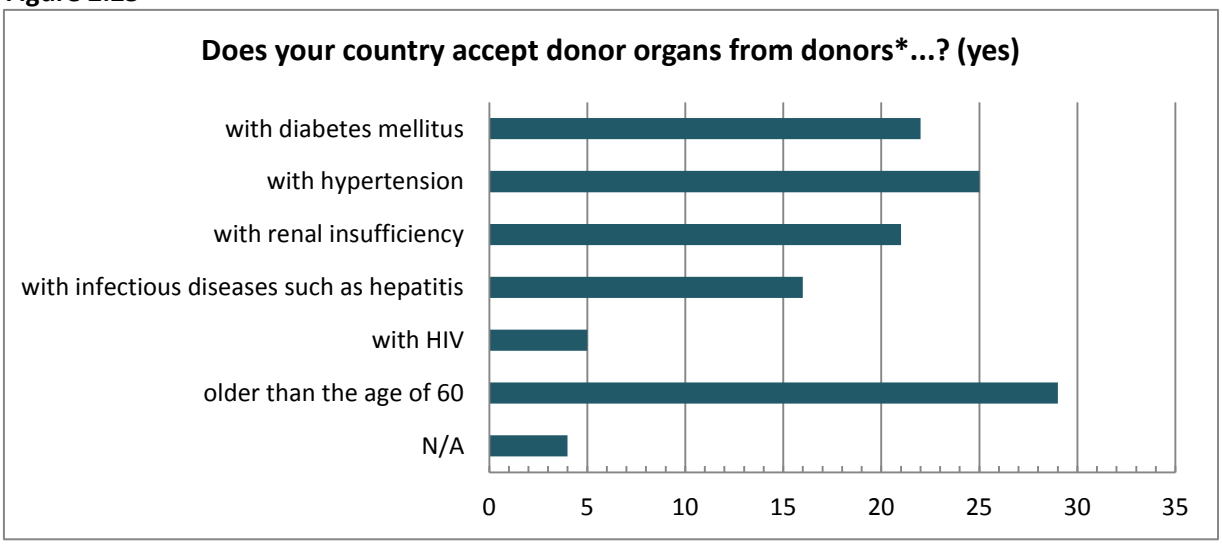


The following examples may help to get a clear picture of the type of activities under this action. The Polish CA reported that they operate a web-based transplant registry that connects all transplant centres and Poltransplant. Every transplantation is registered immediately after operation. Information about graft and recipient survival is registered after 3 months and every 12 months thereafter. The French CA reports on the analysis that are based on their registration of medical follow-up data, such as funnel plots, which shows treatment effect sizes, to evaluate centres according to their post-transplant results, global and period comparative survival curves, annual reporting and estimation of graft survivors data, specific studies on risk factor on factors that affect post-transplant results and the evaluation of centre specific performance by cumulative sum (Cusum) method (foreseen in 2012-2013).

In 2009, 17 out of 27 CAs indicated that transplant results were systematically evaluated via a database or register, and 6 indicated they did but not in a systematic way. These evaluations were mostly organised at national level or at the level of transplant centres.

When asked at which moments post-transplant results of organ recipients are measured, representatives most often mention a period of 12 months after transplantation (Figure 2.24). Other time periods (e.g. 3 or 6 months after transplantation) are also mentioned by a number of representatives.

Figure 2.25



* NOTE: Regardless of the type of organs and conditions of recipient

With regard to the **use of expanded donors**, a majority of the representatives say that they accept donor organs from donors older than the age of 60 (Figure 2.25). In addition donors with diabetes mellitus, hypertension or renal insufficiency are known to be accepted in a substantial number of countries. To a lesser extent, donors with infectious diseases such as hepatitis are accepted. Last, a few representatives indicate that donors with HIV are accepted.

Since 2009, more countries started evaluating organ donors systematically, which is positive. In 2012, it has not been asked how often donors are evaluated over a longer period of time, but it might be worth to pay more attention to this. The use of expanded donors is important in the context of an ageing society. Possibilities to evolve and stimulate the use of these types of donors could be explored further.

Priority Action 10: Promote a common accreditation system for organ donation / procurement and transplantation programmes.

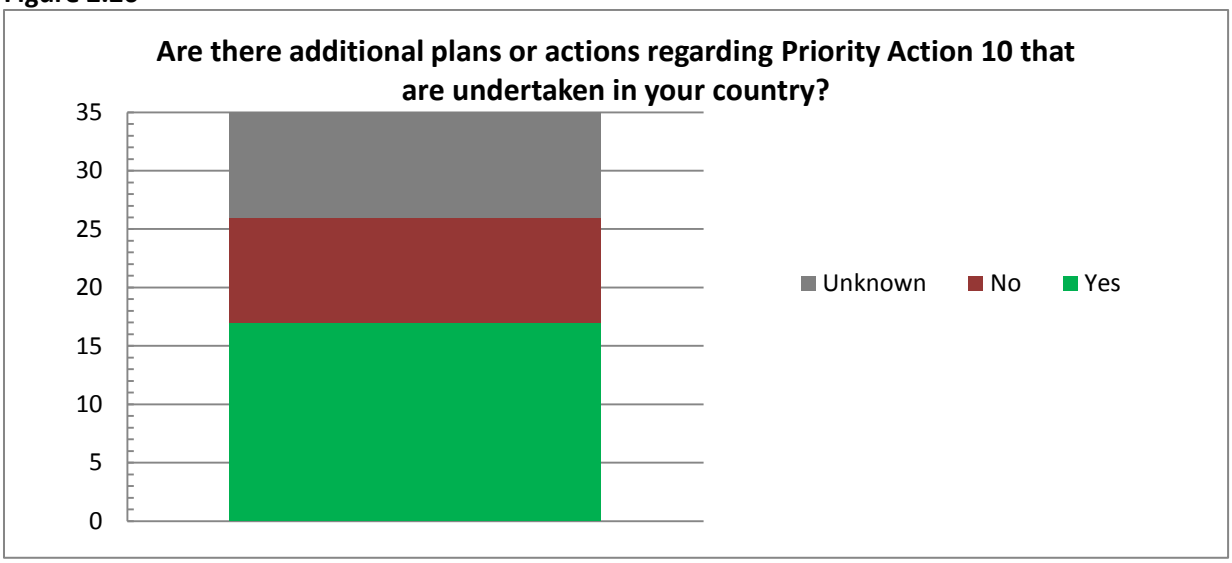
Concerning the last Priority Action, the Action Plan proposes a general wording: the objective is to "promote a common accreditation system for organ donation / procurement and transplantation programmes", without specifying any concrete sub-actions as it was done for other Priority Actions.

CA representatives were asked if there are plans or actions regarding the promotion of a common accreditation system that are undertaken in their country. An accreditation scheme may refer to medical capabilities recognised by professional societies, educational systems, via training programmes and/or also through administrative procedures to authorise activities in a hospital.

Results

From the 26 countries with data, more than half indicate that plans or actions have been undertaken to promote a common accreditation system for organ donation/procurement and transplantation programmes (Figure 2.26).

Figure 2.26



Several CAs reported more in detail on these systems. These reports indicate that differences between countries are noteworthy.

For example the Cypriot CA reported that the policy regarding accreditation is established in law.

The French CA describes a wide scope of issues to be audited, based on the ODEQUS project:

- Organization and administration (personnel and direction),
- Quality of the structure (Technical features of the structure-Equipment),
- Quality of the processes (updating and operational suitability),
- Management of the waiting list,
- Transplant activity,
- Quality of the outcomes – Results,
- Sample data check (medical records of patients in waiting list, medical records of transplanted patients),
- Donations, retrievals and transplants in the area,
- Other parameters chosen by the Audit Commission and the National Competent Authority.

The German CA reports that the qualification requirements of procurement teams are laid down in the guidelines of the German medical association. Accreditation relates to several issues such as qualification of procurement teams, tissue typing, blood tests, preservation, packing and transport.

The Hungarian CA reports that the first joint institutional accreditation was done by UEMS (European Union of Medical Specialists) Section of Surgery & European Board of Surgery, Division of Transplant Surgery on 1st of October, 2010.

The Italian CA states that in addition to evaluation of post-transplant outcomes, there is an audit program for local coordinating units and for kidney, liver, heart and lung centres. A national methodology has been established.

The CA for the Netherlands states that a formal accreditation system is available:

- All hospitals are considered to be (potential) donor hospitals,
- The Dutch Ministry of Health provides licences for transplantation programmes,
- An accreditation system for retrieval surgery was developed (Dutch Association for Surgery),
- Also a model protocol organ and tissue donation was developed by relevant parties,
- The Netherlands have available guidelines, protocols, legislation, background information, including brain death protocol.

The Polish CA states that accreditation for organ, tissues and cells transplantation, organ and tissue preservation, organ, tissue and cells recover from living donors is required to get permission from the Minister of Health. This is granted for 5 years.

In Portugal and Romania, accreditation is based on cooperation with all European countries adopting the rules in Directive2010/53/EU.

In Slovakia, documents are in preparation.

In Slovenia, minimal standards of quality and safety are defined (majority done), a system was set up to assure safety of patients and living donors as well as certification for human resources.

In Spain, there is a system in place for accrediting reference centres in the field of donation and transplantation since 2006.

In Turkey, transplant centres have been authorised since the year 2000. Authorised centres develop their transplantation programme and this programme is approved by the Ministry of Health of Turkey. The National Action Plan states that these centres and programmes have been audited.

The United Kingdom reported several accreditation activities related to transplant centres, procurement organisations (for living and deceased donation) and transportation. Inspections of all licenced establishments are foreseen for October 2012 and March 2014. A proposal is made to inspect all licensed establishments.

In 2012, only half of the countries have established accreditation schemes at national level. There might be opportunities to increase this number. However, it was found that the operationalisation of this concept varies greatly between countries. This suggests the need for further clarification of the exact meaning of this Priority Action, clarification which may now be facilitated by the existence of Directive 2010/53/EU which did not exist when the Action Plan was adopted.

2.4 Conclusions on the Priority Actions: aggregated results from the national results

1. **Transplant donor coordinators**
   Almost all countries have installed donor coordinators, and the number has slightly increased since 2009. Differences exist in how this was done. Some countries appointed donor coordinators at a national level, others at the level of hospitals. The Action Plan recommends the appointment of coordinators on hospital level. Also the tasks of these coordinators differ per country, from a predominantly administrative role to the identification of potential donors. Almost all coordinators receive training, however these trainings are not often evaluated. This can be improved. Furthermore, it might be valuable if a common accreditation scheme could, or would be developed. Countries with less developed plan, could learn from the experience of other countries. Developed in the Working group for deceased donation under the Action Plan, the manual on how to set-up such a coordination system might help in this regard, as it is based on several national experiences. Also some room for improvement exists for several countries in terms of accreditation of transplant donor coordinators. No clear evidence exists on the optimal level of organisation of these coordinators, be it on a hospital or on a local level. A critical appraisal of the most effective way to assign coordinators should be in place, also regarding a possible role of donor coordinators in the process of living donation.

2. **Quality Improvement Programmes**
   Regarding initiatives to improve quality of the organ donation process, most countries have taken up at least one initiative. But, not all initiatives have been taken up in similar ways. Lagging behind are initiatives to stimulate the quality of follow-up care and the transplantation process. These should be taken up more actively. Initiatives regarding the identification of potential donors, the donation and procurement process are taken up by more than half of the countries. Quality improvement should not be limited to the primary process of organ procurement, but should cover the full cycle of procurement, transplantation and evaluation.

3. **Living donation**
   Living donation is a possibility in almost all countries. Yet, the number of countries taking up living donation has not changed much since 2009. Most of the countries have installed (a) separate body(ies) to evaluate living donors and this number has slightly increased since 2009, but still not all countries have such a body. Only half of the countries have established registers to evaluate and guarantee the health and safety of living donors. Since so many countries have taken up living donation, this is becoming an important next step. Those countries that have not yet done so, should set up registers and start monitoring the health and safety of the living donors over a longer period of time. This is also required by the EU legislation since August 2012.

4. **Knowledge and communication skills of health professionals and patient support groups**
   Several representatives report a variety of strategies to communicate about organ donation to increase awareness among their populations. This seems somewhat at odds with the formal answers on specific activities from the Action Plan, that indicate a far lesser degree of activity. Apparently activities on this topic have been taken up by many countries, but perhaps not all in a very systematic way. A possible strategy to make progress on this Action may be to start developing national communication plans on organ donation. Such plans may benefit from the experience of countries with successful communication activities and from the expertise developed in the context of the European Donation Day. These plans could for instance allow for ad-hoc actions and could contain strategies on how to react on 'bad publicity'. Making such plans would also be a strategy to allocate a specific national budget to such actions and therefore contribute to the sustainability of the communication efforts. The Work package of the FOEDUS Joint Action focusing on these aspects will help in this regard.

5. **Organ donors across Europe**
   In many countries, regulations are in place to clarify the legal position of non-residents as potential donors. Differences exist between countries regarding who can be a donor. Lagging behind is the provision of clear information on this topic to European citizens, and this has not improved much since 2009. Because of the potential impact of such decisions and because of the differences between countries in the role of the next-of-kin, investing more in clear information on this topic is needed. Here again, the Work package of the FOEDUS Joint Action focusing on these aspects will help in this regard.

6. **Enhance organisational systems**
   The potential for learning from other countries is underused. Many, but not all, countries participated in twinning projects in 2012, which is more than in 2009. The majority of countries reported positive results; now or expected in the future. Learning from each other is a potentially strong strategy to improve the process of organ donation, especially considering the rich diversity in the EU. Furthermore, a knowledge gap seems to exist among CAs on the possible use of structural funds or other community instruments. Whether this is compensated through other channels is unknown. Members States can and should explore more possibilities to access structural funds for organising transplant programmes and activities. Also, only few countries indicate that their hospitals participate in networks of centres of reference.

7. **EU-wide agreements**
   Only few countries have indicated that EU-wide agreements on aspects of transplantation medicine are in place. But still, in 2009, many representatives indicated they were interested in developing these agreements. Exactly what is meant by 'EU-wide' agreements remains unclear, however. Are these agreements between individual countries, e.g. neighbouring countries, or are these agreements that are shared by many or all EU countries? Also to what purpose should there be such agreements? Should they be seen as a first step towards implementation in a directive, or should they been seen as useful instruments only? Although this action refers to fundamental issues, the scope and definition of this action should be reconsidered, in particular as the adoption of EU legislation (Directives 2010/53/EU and 2012/25/EU) might have brought new elements in the European transplantation landscape.

8. **Interchange of organs**
   Almost all countries are involved in at least one type of collaboration on cross-border exchange with other countries, sometimes bilateral, sometimes of a larger scale. The numbers seem to be in motion since 2009. Depending on the needs, ot all of these collaborations concern all types of patients and all kinds of organs, several are restricted to specific patient groups or organs. Also not all countries have actually offered to other countries organs non-allocated at national level.

Within the COORENOR project, an IT-Tool to support the exchange of donor organs was set up, which will be made available to more countries. Exchange of organs for difficult-to-treat patient groups or non-allocated organs is of vital importance. Whatever can be done to stimulate this process should be considered: broadening the scope of collaborations to more patient groups and organs, stimulate the effective exchange of organs and support the process of making an IT-tool available to all countries.

9. Evaluating post-transplant results

Systematically collecting and analysing post-transplant results helps to improve the quality and safety of the donation and transplantation. Since 2009, more countries started doing this. In 2012, the relevance of collecting data is shared by nearly all countries, most of them indicate they do analyse post-transplant results. It is not clear whether results from different countries can be compared. The fact that not all countries share the same period after which they measure post-transplant results suggests variability in the structure and type of data. This would make it difficult to compare these data. For mutual learning it is essential to agree upon shared definitions and procedures for collecting and reporting such data. Given the shortage of organs, a good understanding of outcome and best use is essential. It would therefore be strongly recommended for all Member States to work towards a shared data-model and subsequently to implement it, so country data can be compared in a valid way. It is vital to pay more attention to the evaluation of post-transplant results on a longer term. The use of expanded donors is important with regard to an ageing society. Possibilities to evolve and stimulate the use of these types of donors may be further explored.

10 Accreditation schemes

More than half of the representatives indicate that plans or actions have been undertaken to promote a common accreditation system for organ donation/procurement and transplantation programmes. A closer look at these plans or accreditation systems suggests a great degree of variability in topics, thoroughness and whether or not accreditation is evaluated. It would seem that the accreditation systems are far from being a common accreditation scheme. For those countries in the process of developing an accreditation system it might be valuable to learn from others. It would also be advisable to more clearly define what exactly is meant by such broad concepts as 'accreditation schemes'. For those countries with a more developed accreditation system it might be worthwhile to share and compare their experiences with others and to invite other countries to participate in the role of auditor.

In general

The state of uptake and implementation of the specific Priority Actions differs between countries. Activities related to **Priority Actions 1, 3 and 8 are increasingly being taken up by almost all countries**. EU-funded projects reflect the state of these Actions: many countries are involved and efforts go further than providing insight and sharing knowledge, they aim at implementation. This means that these Priority Actions have a great potential for actual and EU-wide implementation.

Priority Actions 2, 6 and 9 have been taken up by most countries. This means that for these Priority Actions there is a great potential for mutual learning through an exchange of experiences. The uptake of these Priority Actions seems to have increased as compared to an assessment in 2009.

Fewer countries have taken up activities in relation to Priority Actions 4, 5, 7 and 10. Their meaning was not always clear to all CAs. It would therefore be beneficial to have further discussions on each of them in order to come to a shared, more precise and common understanding.

One may consider defining a logical order in pursuing Priority Actions. Some activities need to be taken up before others, only after which next steps can be taken. An analysis of this logical order can lead to the construction of a roadmap, suggesting countries to start with the primary activities needed for organ donation and subsequently improve the organisation, quality and effectiveness of the process.

3 Efforts at the European level supporting the Action Plan on Organ Donation and Transplantation (WP3)

This chapter deals with three different ways in which the European Union (EU) is involved in the realisation of the Action Plan. It should be noted that the European Union here primarily means European actors such as the European Commission (EC) - which adopted the Action Plan, finances projects and contracted the present study - but also national experts, often representatives of CAs, involved in EU projects and activities.
Firstly, the funding as well as the working of projects is discussed. Through its funding instrument the EC co-determines the project agenda[209] and therewith influences the contributions projects can make on the various Priority Actions.
Secondly, direct actions are described. These were listed and expounded on by EC representatives. Diplomatic activities are not described as these remained outside the scope of this study.
Finally, the role and actions of several organisations and collaborating initiatives is described. These can play a supportive role in achieving the aims as laid down in the Action Plan.

3.1 EU-funded projects

By funding projects or activities, the EU may support the advancement of some of the Priority Actions in the Action Plan. This chapter mainly focuses on the EU Health Programme, because it provides the main available tools. Also projects funded through the Research Programme are mentioned, as the first projects related to the Action Plan, Alliance-O and DOPKI[210], were funded through the EU Research Framework Programmes (FP 6 and FP7).[211] Other instruments will be referred to when relevant. The current EU Health Programme funds projects and actions from 2008 to 2013. This programme is the main instrument used by the European Commission to implement the EU Health Strategy and to support EU Member States in the common objectives of their health policies at EU level. By nature, the programme is more focused on public health and on direct implementation than on research, which is funded via the Research programmes. The annual objectives are stated in the Health Strategies[212] adopted by the Commission in 2007 "Together for Health: A Strategic Approach for the EU 2008-2013", and later on in the "Europe 2020 Strategy: investing in health and addressing the issue of the ageing society". After examination of applications (also based on the evaluation of external experts), the Committee of the Health Programme - where contributing countries are represented - decides upon the definitive work plan and upon projects to be funded.

The Executive Agency for Health and Consumers (EAHC) is entrusted by the European Commission to implement the EU Health Programme, mainly through the financing of five types of different activities: projects (after call for proposals), conferences, Joint Actions, tenders and operating grants (as well as a direct grant to the Council of Europe for activities in the field of "substances of human origin": blood, tissues and cells, organ transplantation).
A list of projects relevant for the field of organ donation and transplantation was provided by the EC and EAHC in the tender specifications prior to the launch of the ACTOR study. Archival studies and internet searches lead to the same projects. Projects were included when their stated goals showed resemblance to the established goals in the Action Plan. The study of projects was performed in June 2012. An overview of the included projects and their types of financing is given in Table 3.1.

[209] Topics for projects can also be proposed by applicants who therefore also play a role in this agenda-setting, http://ec.europa.eu/eahc/health/projects.html

[210] All acronyms are explained in Annex 1

[211] http://ec.europa.eu/research/fp7

[212] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007DC0630:EN:NOT and http://ec.europa.eu/europe2020

Table 3.1 Types of financing for the activities under the European Action Plan on Organ Donation and Transplantation, in chronological order [213]

Project Acronym	Project	Joint Action	Confe-rence	Tender
Alliance-O (European Group for Coordination of Research Programmes on Organ Donation and Transplantation)	x[214]			
DOPKI (Improving the Knowledge and Practice of Organ Donation)	x[215]			
ETPOD (European Training Program on Organ Donation)				x
EULID (Euro Living Donor)	x			
EDD (European Donation Day)	x			
ELPAT platform (Ethical, Legal and Psychosocial Aspects of organ Transplantation) (conferences funded in 1010 and 2013)			x	
EFRETOS (European Framework for the Evaluation of Organ Transplants)	x			
ELIPSY (Euro Living Donor Psychosocial Follow Up)	x			
COORENOR (COORdinating a European initiative among National organizations for ORgan transplantation)	x			
EULOD[216] (Living Organ Donation in Europe)	x			
ODEQUS (Organ Donation European Quality System)	x			
European Training Course in Transplant Donor Coordination ("Train the trainers")				x
MODE (Mutual Organ Donation and transplantation Exchanges: Improving and developing cadaveric organ donation and transplantation programs)		X		
ACCORD (Achieving Comprehensive Coordination in ORgan Donation throughout the European Union)		X		
ACTOR (Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015))				x
FOEDUS (Facilitating Exchange of Organs Donated in EU MS)		x		
Also (regularly renewed): Direct **Grant to the Council of Europe** for activities in the field of blood transfusion, tissues&cells and organ transplantation				
For direct links to several project websites see: http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20121009_contact_points.pdf For project databases: (Public) Health Programmes: http://ec.europa.eu/eahc/projects/database.html Research Programmes: http://cordis.europa.eu/search				

[213] Operating grants are not included in this overview because so far no operating grant was given in this field

[214] Funded by DG Research

[215] Funded by DG Research

[216] Funded by DG Research

Impact of EU-funded projects on Action Plan

This section will start with a general overview of the above mentioned projects and their contributions to the Action Plan. Then, two projects that had already started before the adoption of the Action Plan will be described. These earlier projects finished before the adoption of the Action Plan, but may nonetheless be considered to have contributed to the Action Plan "avant la lettre" and may have paved the way for the adoption of a voluntary Action Plan and of a flexible Directive. This is followed by a description of the projects per Priority Action. Because some projects are continuations of previous projects, the results will be described in chronological order as much as possible.

For the general overview, four different functions of project activities are distinguished:

1. *Knowledge acquisition*: activities that give insight in the current state of affairs;
2. *Development of tools*: activities with the aim to develop instruments, guidelines, toolkits, recommendations etc.;
3. *Exchange of knowledge*: activities with the aim to (actively) exchange knowledge and best practices (courses, trainings, congresses etc.);
4. *Change*: activities that intervene with or change actual practice.

This classification into four different types of activities indicates the nature of the contribution to a Priority Action. Important to note is that this description does not entail an evaluation of the individual projects. Their contribution to the Priority Actions is described based on information from the project documentation that was publicly available and made available for the purpose of the present study by the Executive Agency for Health and Consumers (EAHC). In case of recently started (or future) projects, this description is solely based on the stated project goals (or work plans of the Health Programme stating objectives set for Joint Actions). For other projects, progress reports, final reports and in some instances project evaluations are used.

General results

Projects are not evenly distributed over the Priority Actions (table 3.2), with some Priority Actions, for instance Priority Action 9, which seems to receive more project attention than others. This does not necessarily mean that more progress is made when more projects address the general subject of a Priority Action (as it can tackle different sub-actions, and maybe not all of them). For instance, on Priority Action 8, much is achieved by only two projects. Furthermore, the research team noticed that it was not always clear from the project documentation whether projects complement and build upon other (previous) projects and to what degree there is overlap. Finally, during the timespan of this study many projects were still ongoing. This means that in many cases project results were not yet available.

Table 3.2 Overview of projects' contribution to Priority Actions, projects placed in chronological order

Projects	Priority Actions											Deceased (D) Living (L) donation	Funding
	General	1	2	3	4	5	6	7	8	9	10		
ALLIANCE-O (2004 – 2007)	x											D/L	**EU fund**ing via Research Framework Programme (FP)**: €1.999.999**
DOPKI (2006 -2009)			x									D	**EU finding via FP: €1.584.430**
ETPOD (2007- 2009)		x	x		x							D	60% EU funding via EU Health Programme (HP), total budget €1.304.388,85
EULID (2007-2009)				x						x		L	60% EU funding (HP), total budget €879.720
EDD (2009-2011)					x							D/L	55% EU funding (HP), total budget €273.324; 20 months
ELPAT (conferences 2010, 2013)					x	x						D/L	2010 conference: 36% funding (HP), total budget €209.505. 2013 conference: max. €100.000 EU funding
EFRETOS (2009-2011)										x		D (L)	60 % EU funding (HP), total budget €1.250.000,00
ELIPSY (2009-2012)				x	x					x		L	60% EU funding (HP), total budget €273.324,00
COORENOR (2010-2012)			x	x	x	x	x		x	x	x	D/L	56% EU funding (HP), total budget €1.424.215,95
EULOD (2010-2012)				x		x		x				L	90% EU funding (FP): **€1.099.657** Total budget: **€1 220 621**
ODEQUS (2010-2012)		x	x		x		x				x	D/L	60% EU funding (HP), total budget €999.942,82
Train the trainers (2011)		x			x							D (L)	EU funding (HP) for €270.757 (tender)
MODE (2011-2012)			x				x			x		D/L	49% EU funding (HP), total budget €577.477,90
ACCORD (2012-15)		x					x			x	x	D/L	60% EU funding (HP) total budget €2.435.122,91
FOEDUS (2013-2016)									x	x		D	70% EU funding (HP), max.EU funding €1.150.000,
Number of projects	**1**	**4**	**5**	**4**	**6**	**2**	**4**	**1**	**2**	**7**	**3**		

Table 3.3 (below) shows the different functions of the activities in the various projects. Based upon the project information for each project, the activities were classified according to the earlier mentioned classification into four types of activities: knowledge acquisition, the development of tools, exchange of knowledge and change. Projects that could be linked to the aims as stated in the Priority Actions mostly aim at acquiring knowledge, at tool development, and at the exchange of

knowledge and best practices by providing training programmes and organising congresses. It was found that for two Priority Actions activities are performed that intervene or change actual practice: PA 8 regarding the "facilitation of the interchange of organs between national authorities" and PA 6 about "enhancing organisational models of organ donation and transplantation", , while other PAs also partially classifies as potentially (or as a result) creating change, for example when the development of a tool or exchange of knowledge is directly applied. On PA 8, this reflects an advanced state of implementation. COORENOR and FOEDUS have contributed and will continue to do so, by developing an IT-tool for the interchange of donor organs. Although these projects also acquire and share knowledge and develop a tool, they definitely aim at promoting the actual exchange of donor organs. As said, this was unique. Most projects focus on knowledge gathering and on the exchange and development of tools, whereby actual changes in the donation process are not on the projects' agenda. Implementation can however still occur when results are implemented, but this is outside of the direct scope of these first projects funded under the Action Plan (this could come now with the new sort of projects funded thanks to the adoption of the legislation: the "joint actions", which are still on-going (ACCORD) or just started (FOEDUS).
In addition, this limited number of projects that bring direct change can be expected, following the limited legal mandate of the Commission at EU level. The concrete organisation of transplant activities falls under the responsibility and mandate of the individual Member States.

Table 3.3 Activities of projects classified into different types

	Priority Actions									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Knowledge acquisition	**x**	**x**	**x**	**x**	**x**	**x**	**X**	**X**	**x**	**x**
Development of tools	**x**	**x**	**x**	**x**		**x**	**-**	**X**	**x**	**x**
Exchange of knowledge	**x**	**x**	**x**	**x**	**x**	**x**	**-**	**X**	**x**	**x**
Change						**x**		**X**		

Table 3.4 (at the end of this paragraph) shows the chronologically ordered involvement of all separate countries in EU-funded projects. It shows that with time, the number of countries participating in these projects has increased, also thanks to the new types of project funded, the "joint actions", which are supposed to involve as many countries as possible, and among these countries the (public/competent) authorities in charge of organ donation and transplantation. Furthermore, it shows that participation by countries varies greatly. This may be explained by the fact that some countries joined the EU only in 2004. On the type of projects funded, another development that could be noticed is that funding has shifted from "simple projects" to "joint actions".

Projects that started before the Action Plan was adopted

The **Alliance-O**[217] and **DOPKI** projects started before the Action Plan was adopted (respectively in 2004 and 2006), were both funded through the Research Framework programme (DG Research of the European Commission) and prepared the way for future projects under the EU Health Programme. These projects were coordinated by institutions that later became Competent Authorities.

The **Alliance-O** project (**European group for coordination of national research programmes on organ donation and transplantation**) was coordinated by the French (future) "Competent authority" Agence de la Biomédecine (ABM) and built on an already existing collaboration between France and Germany. It lasted from October 2004 until October 2007.. During the Symposium of Frankfurt in 2003, a joint declaration of governments and procurements organisations from France, Germany,

[217] All acronyms are explained in Annex 1

Hungary, Italy, Portugal, Spain and the United Kingdom was formulated and resulted in the Alliance-O[218] ERA-NET[219] coordination action. The ERA-NET scheme was a new instrument which aimed at promoting collaboration and the coordination of research activities undertaken in Member States and associated countries. Alliance-O focused on the coordination of research efforts on organ transplantation within countries. The most important subjects of research were:

- the donor pool (for instance on heart-beating donors (now called DCD: donors after circulatory death) and non-heart-beating donors (DBD, donors after brain death) and on living donors),
- allocation rules,
- the safety and quality of organ transplantation,
- evaluation methodology,
- fundamental research,
- the coordination of ethical and legal issues

The objectives of the **Alliance-O project** were to identify, compare and coordinate all efforts of countries concerning organ donation and transplantation, their methodologies (aims, organisation, evaluation, funding, benchmarking) and their results. These different benchmarking analyses resulted in relevant recommendations and position papers. The project furthermore resulted in proposals for future actions. The proposals concerned all steps of activity for heart beating and non-heart-beating and living donors. Many proposals recommended better collaborations between Member States, the development of common definitions of terms and common approaches, and the avoidance of duplicating work. Some of these tools already existed, but had to be translated and disseminated. A final report was published summarising all the project's actions and a workshop was organised where the work of the projects was presented to Competent Authorities, research representatives, transplant professionals and journalists. Furthermore, the participating partners decided to continue the efforts of the Alliance-O project (Alliance-O, 2007). Alliance-O finished before the adoption of the Action Plan, however the activities can be linked to the aims as stated in the Priority Actions. As living donation is addressed, these activities relate to Priority Action 3. Furthermore, it seems that efforts were made for what later became Priority Action 6, on enhancing organisational models and on Priority Action 2 on Quality Improvement Programmes. Furthermore, the project worked on future collaborations, which can be linked to Priority Action 8, and future research priorities also mentioned in Priority Action 7.

The **DOPKI**[220] project (Improving the Knowledge and Practices in Organ Donation) lasted from January 2006 until March 2009. It was coordinated by the (future) Spanish "Competent authority" ONT and funded through the Research Framework programme. DOPKI aimed to improve knowledge and to develop applicable actions that help to improve organ donation rates. Specific objectives were to design and validate statistic methods to explore relations between mortality rates, social and demographic data, health systems and donation and transplantation rates. Besides Eurotransplant, 10 countries participated (DOPKI, 2007). Donation processes in hospitals were monitored and

[218] http://ec.europa.eu/research/fp7/pdf/era-net/publishable_summaries/fp6/alliance-o_publishable_executive_summary_en.pdf

[219] http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ_RCN=7468153 http://ec.europa.eu/research/fp7/index_en.cfm?pg=eranet-projects, http://www.cordis.europa.eu/coordination/era-net.htm ERA-NET Scheme (European Research Area – Networking): The objective of the ERA-NET scheme is to step up the cooperation and coordination of research activities carried out at national or regional level in the Member States and Associated States through: the networking of research activities conducted at national or regional level, and the mutual opening of national and regional research programmes. The scheme should contribute to making a reality of the European Research Area by improving the coherence and coordination across Europe of such research programmes. The scheme also enabled national systems to take on tasks collectively that they would not have been able to tackle independently.

[220] http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ_RCN=8324583 http://www.ist-world.org/ProjectDetails.aspx?ProjectId=6f283c82639e4619a8a289d126b2f448&-SourceDatabaseId=7cff9226e582440894200b751bab883f , Retrieved on 21-08-2012

evaluated in order to implement corrective measures in the process. Information on the outcome of recipients of expanded criteria donors was shared between countries. Finally, the results of the projects were disseminated in cooperation with the WHO (DOPKI, 2007).The DOPKI project resulted in a number of documents, publicly available on the DOPKI website, and in a guide with the recommendation to build up a quality assurance programme (DOPKI, 2009a). Although the Action Plan was introduced after the DOPKI-project, it nevertheless relates closely to the aim of Priority Action 2, which focuses on Quality Improvement Programmes in hospitals (DOPKI, 2009b). Many projects were a continuation of the efforts of the DOPKI project.

Results of the EU funded projects related to the Action Plan, per Priority Action

The activities of the projects that relate to a specific Priority Action will be described below. The activities of all selected projects will be described arranged per Priority Action. In addition, activities will be categorised into one of the four types of activities, making use of the project descriptions, websites, presentations, minutes, inception reports and evaluation reports.

Priority Action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Design indicators to monitor this action.

Four EU-funded projects are directly related to Priority Action 1: **ETPOD, "Train The Trainers", ODEQUS and ACCORD**.

One early project which promoted the role of the Transplant Donor Coordinator is the **ETPOD** project (European Training Program on Organ Donation), and still is a"multiplicator" within and outside of the European Union. ETPOD was funded under the EU Health Programme and was coordinated by a consortium led by a Spanish institution. Organisations and Competent Authorities of 16 European countries[221] participated in the organisation of the original ETPOD project (ETPOD, 2006). The project ended in 2009, and was set up to develop and provide training programmes on various subjects, aimed at health professionals and transplant donor coordinators in European countries. The project also included a 'Train the trainers' programme, aimed at training key donation personnel as multipliers of the training actions, providing them with the skills required to replicate other training programmes. These activities specifically contributed to sub action 1.3 of the European Action Plan, which is on promoting the implementation of effective training programmes for transplant donor coordinators. Other training programmes were aimed at medical professionals. One of the training programmes reached over 3000 participants from 15 of the EU Member States and 2 candidate countries. Furthermore, non-partner countries have shown interest in the developed similar training courses (ETPOD, 2009a). The impact of the ETPOD project on donation rates was evaluated. The conducted surveys showed that the number of procured brain death donors in the 25 hospitals in which the participants worked showed a significant increase of 27,8% (ETPOD, 2009a).[222] The ETPOD activities can be classified as type 3 actions, because knowledge is actively shared through providing training. And the evaluation shows that results of the project, once applied, created changes in practices and in donation rates.

After ETPOD, another training programme was funded in 2010 (implemented in 2011) via the EU Health Programme, namely the **European Training Course in Transplant donor coordination** (called "**Train the Trainers**" course), organised by the consortium ONT and IAVANTE (Spain). The course was meant for experienced transplant donor coordinators at hospital, regional and national level. The ultimate goal is that these coordinators selected by their CAs obtain additional tools and are

[221] Please find participation of countries in EC-funded projects in table 3.4

[222] The increase was statistically significant (p=0,01)

therefore "consolidated" as (or become) national/regional/local trainers in charge of the professional training for other coordinators at national/regional/local/hospital level in the Member States. The course can be linked to the ACCORD project, which is also led by ONT.[223] A total of 79 coordinators of 25 Member States participated in the training. Overall, all students expressed that the training was very useful to improve training activities in their country (Dominguez-Gil et al., 2012; European Transplant Coordinators, 2012). A positive aspect of the course was the attention for implementation through the design of an implementation plan, and the fact that CAs were strongly and repeatedly "encouraged", during CA meeting in Brussels, to make a "good use" of these trainers in their country - but it remains unclear, at national level, what efforts will be made to encourage the participants of the course to actually implement what they learned, and which resources CAs can/did put at their disposal to do so. With regard to the Action Plan, the Train the Trainers course contributes to Priority Action 1 on promoting the role of transplant donor coordinators and in particular to sub-action 1.3 on the implementation of effective training programmes for transplant donor coordinators. Because knowledge and best practices are actively exchanged in the Train the Trainers course, it can be considered a type 3 activity.

The **ODEQUS project** (Organ Donation European Quality System) is also related to Priority Action 1. It was coordinated by a Spanish institution, was funded under the Health Programme and lasted from 2010 to 2013 (finalisation for September 2013). Hospitals and authorities from 11 European countries participate in ODEQUS (ODEQUS, 2009). One main objective of the project is to identify the best organisational models and give recommendations to improve donation rates, by providing quality criteria and quality indicators to use at hospital level (and tested in the participating hospitals). These actions can be classified as type 1 actions (ODEQUS, 2009).[224] Since the project has not finished yet and no interim or evaluation reports are available at the time of drafting, the impact of the project on the European Action Plan cannot be determined yet. However, the preliminary results communicated as well as some CAs from the countries of which hospitals were involved (Spain, Sweden, Portugal for example) both indicate that ODEQUS' results will help them to put in place the "quality and safety framework" (including appropriate training and measures foreseen for the staff involved in organ donation and transplantation) - foreseen under Directive 2010/10/53, even though ODEQUS application and selection in 2009 come before the adoption of the Directive in 2010.

One objective of the **ACCORD project** (Joint action funded under the Health Programme) is to improve cooperation between Intensive Care Units (ICUs) and transplant donor coordinators (a specific work package led by the United Kingdom is dedicated to this topic). A close cooperation between ICUs and transplant donor coordinators could improve deceased donation rates, as more possible donors can become actual donors and donation could be better integrated in the end-of-life care (ACCORD, 2012). The project aims to provide a practical toolkit (rapid improvement tool) with recommendations about different approaches for end-of-life care. This project has started in June 2012, 23 European countries participate in ACCORD (ACCORD, 2012). These activities within ACCORD, and specifically this work package, are classified as type 2 actions: the development of tools.

The project activities related to Priority Action 1 mainly consist of knowledge acquisition, the development of tools, and the exchange of knowledge.

[223] http://health-med-news.com/health/spain-will-train-european-transplant-coordinators/, Retrieved on 21-08-2012

[224] http://www.odequs.eu/index.html, Retrieved on 21-08-2012

Priority Action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.

Four EU-funded projects can be directly related to Priority Action 2: **COORENOR, ETPOD, MODE and ODEQUS.**

COORENOR contributes to Priority Action 2, since one of its objectives is to make an overview of existing quality assurance programmes in EU Member States. Organisations and Competent Authorities of 11 European countries participate. Legal aspects, organisational aspects (i.e. an overview of medical centres accredited to organ donation, healthcare professional training and existing quality assurance programmes) and critical steps related to procedures of deceased donation are analysed. The results can be used in the realisation of a specific methodology on Quality Improvement Programmes (Priority Action 2.2) (Costa, 2012a). COORENOR's activities can be classified into type 1, because they provide insight into the current state of affairs.

One of the training programmes of **ETPOD** is also related to sub-action 2.2 on promoting accessibility to and training on a specific methodology on Quality Improvement Programmes, because it involved the management of a transplant procurement office concerning the quality indicators of the organ donation process (ETPOD, 2009a). Training on quality indicators could contribute to promoting self-evaluation by hospitals, and can be seen as a type 3 action.

In addition, the Joint Action **MODE** makes a contribution to Priority Action 2. Organisations and Competent Authorities of 8 European countries take part in MODE. MODE's main objective is the exchange of best practices in the field of organ donation and transplantation by organising bilateral contacts between Member States. Because knowledge is actively shared, the activities of MODE are classified as type 3 actions.

Last, one main objective of **ODEQUS** is to make recommendations about Quality Improvement Programmes at hospital level, i.e. practically to propose, formulate, test and agree on key quality criteria and quality indicators. More specific objectives are to train health care professionals in the creation and implementation of quality criteria and indicators, to identify standards of best practices and to define quality indicators and to finally implement these indicators in selected hospitals. The best practices will be identified through experts' opinions, literature review and research for evidence and a survey sent to all European countries to get insight in the current use of Quality Improvement Programmes at hospital level (ODEQUS, 2009).[225] The activities of ODEQUS are type 1, 2 and 3 actions because insight will be given in the current use of Quality Improvement Programmes, recommendations will be made and trainings are provided to health care professionals. And as highlighted for ODEQUS under PA 1, the preliminary results communicated as well as some CAs from the countries of which hospitals were involved (Spain, Sweden, Portugal for example) both indicate that ODEQUS' results will directly and concretely help them to put in place the "quality and safety framework" foreseen under Directive 2010/10/53. ODEQUS' results will be presented to the whole group of CAs in September, thus enabling their dissemination in non-participating countries and for participating countries in the whole country via the national CAs.

The activities of the projects related to Priority Action 2 consist of knowledge acquisition, development of tools, and exchange of knowledge.

[225] http://www.odequs.eu/index.html, Retrieved on 21-08-2012

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.

Five projects are related to this Priority Action: **EULID, ELIPSY, EULOD, COORENOR, and ACCORD.** One might consider that the **ELPAT Conferences** (co-funded in 2010 and 2013) also contributed to this Priority Action, as well as **ODEQUS**, already mentioned under the two previous Priority Actions, which developed specific quality criteria and five quality indicators for living donation.

The **EULID** project, which finished in 2009, has analysed and compared ethical, cultural and legal aspects of living donation. Organisations and Competent Authorities of 11 European countries participated (EULID, 2007). The main outcomes of the project were that consensus was achieved on legislation, ethical aspects and protection of the living donor, and recommendations were formulated. Examples of recommendations are that all costs related to living donation should be reimbursed and that minors should be prohibited from becoming living donors. EULID provided the preparatory actions for the possible development of a European register of registers to follow-up living donors or for a good interconnection between existing registers. The evaluators of the project did however state that the geographical representation of the countries that participated was not optimal (Delmonico, 2009; Medina-Pestana, 2009), which is logical since the project was funded on the basis of a simple "call for proposal", at the beginning of the Action Plan, before the adoption of the legislation (no "joint action" with a large geographical coverage was possible at that stage). According to the evaluators, significant information was gathered and the final legal directives, ethical recommendations and recommendations for protecting the living donor have the potential to be internationally applied. However, economic and cultural disparities could be an obstacle for complete international adaptation (Medina-Pestana, 2009). The activities of EULID can be classified as type 1 and 2 actions.

Another project regarding living donation is **ELIPSY** which ran from 2009 until 2012 (ELIPSY, 2008) and built upon the results of EULID, also as many participants took part in both projects. Organisations and Competent Authorities of 7 European countries participated. The ELIPSY project has designed living donor follow-up tools and methodologies as well as a recipient follow-up methodology. These were tested through an EU-wide prospective and retrospective study, assessing the short-term and the long-term impact of living donation.[226] Problems that were encountered during the project were problems with meeting deadlines and difficulties with the statistical data analysis (ELIPSY, 2011a). ELIPSY can be seen as a follow-up of EULID, and contributes to Priority Action 3.2: the development of registers for living donors to evaluate and guarantee their health and safety. The project's activities can be considered as type 2 actions (development of tools). Depending on the degree of dissemination of the follow-up methodology – and of its integration into ACCORD's work package on living donors registries, actual practice could be changed.

EULOD (2010-2012) especially focused on new EU Member States. Here, the need for organ transplantation is as high as in many other countries, but resources and experience with living donation are relatively limited.[227] EULOD was funded through the Research Framework program and draws upon the support, knowledge and network of the the European Society for Organ Transplantation (ESOT) and of **European platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT)**, which was also funded twice by the EU Health Programme via grants for conferences: 2010 and 2013 ELPAT congresses. Organisations and Competent Authorities of 8 European countries participated in EULOD (and representatives from even more countries in the ELPAT conferences). A description of living donation practices is provided by EULOD, since the

[226] http://www.eulivingdonor.eu/elipsy/what-is-elipsy.html, Retrieved on 21-08-2012

[227] http://www.eulod.org/?section=aboutEulod&item=8, Retrieved on 21-08-2012

project's aim was to establish an inventory and to promote the exchange of best practices and organisational models for living donation in Europe together with its ethical, legal and psychosocial aspects.[228] EULOD activities are directly related to Priority Action 3, on exchanging best practices on living donation. However, implementation of best practices depends on whether results of the project are disseminated. Also, it has to be investigated in what way this project complements other projects that have worked on living donation. EULOD's activities can be considered type 3 actions, because knowledge is actively exchanged.

One part of **COORENOR** also aims to develop a common strategy on living donation procedures, based on an analysis of existing procedures in the participating countries. The COORENOR project takes into account the results of the EULID project (COORENOR, 2010), but it is unclear if the results of the EULOD project are taken into account (this is actually not sure, as these two projects partially ran in parallel, as they were coordinated by two different consortiums who applied for two different funding mechanisms: Public Health Programme for COORENOR and EULID and Research Programme for EULOD. But at least, results of allprojects were presented to the whole network of National Competent authorities in Brussels). Parts of the planned activities on living donation are the design and production of a short information brochure on living kidney donation. The brochures is addressed to potential donors and shall be distributed in dialysis centres and out-patient clinics across Europe (COORENOR, 2011b). The final report of the results and the common strategy was not yet available at the time of writing (COORENOR, 2011a). The production of an information brochure on living kidney donation is related to sub-action 3.1, the promotion of altruistic donation programmes in individual countries. It is classified as a type 2 activity, because it can be seen as a tool.

Last to come in time, the **Joint Action ACCORD** (2012-2015) has a work package focused on registers to follow-up living donors (clearly linked to article 15 of Directive 2010/53/EU). It will provide recommendations for the development of a European living donor registry, or connected living donor registries, and a methodology for supranational data sharing. This requires a comprehensive description of existing registries, for which a survey will be developed. Discussions between experts will form the basis for the recommendations (ACCORD, 2012). ACCORD has started in June 2012, so no final results are available yet. However, it is known that ELIPSY and ACCORD closely work together so that ELIPSY results can be used within ACCORD. The fact that ACCORD involves CAs is of special significance as CAs have the means and authority to establish registers. The development of registries for living donors in Member States, which is set down in the Action Plan and now also in the EU (and therefore also national) legislation(s), is necessary to build up evidence about the consequences of donating an organ during lifetime. The recommendations produced by the ACCORD project relate to Priority Action 3 and its sub actions, and can be considered as type 2 actions.

The project activities related to Priority Action 3 mainly consist of knowledge acquisition, development of tools, and exchange of knowledge.

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.

Seven projects can be linked to this Priority Action: **EDD, COORENOR, FOEDUS, ELPAT, ETPOD, "Train the Trainers"** and **ODEQUS**.

One EU-funded project which fully focused on this objective is shortly called "**EDD**". It was led by Slovenia and inspired from the Council of Europe, the initiator of "European Organ Donation Days", hosted every year in a different country (member of the Council of Europe), and held in 2008 in

[228] http://www.eulod.org/?section=WorkingPackages&item=13, Retrieved on 21-08-2012

Slovenia. Organisations and Competent Authorities from 5 European countries participated (EDD, 2009). The main objective of the project was to develop and disseminate the guidelines for the organisation of European Donation Days (using the Slovenian experience of the European Organ Donation Day 2008), through the consultation of experts. The impact of this specific 2008 EODD on public awareness in Slovenia was measured (EDD, 2009). The public received more information about organ donation, and awareness about EDD increased. Knowledge levels of the public did not increase significantly however, and no effects were measured on general opinion, personal opinion or declaration of the decision. Nevertheless, it seemed that in all participating countries the public wanted more information about organ donation and transplantation after the EDD (Avsec, 2011; EDD, 2011a). Since raising public awareness is a complex and ongoing activity, the EDD project may be useful and valuable for increasing public awareness (EDD, 2011b).

The development of guidelines about the organisation of an EDD can be considered as type 2 actions (development of tools).

Part of the analyses of the **COORENOR** project is focused on public awareness campaigns and their impact, more specifically regarding deceased donation. The aim was to provide an overview of existing campaigns in European countries and an analysis of the data by the consortium partners was expected to provide insight into the impact of these efforts on organ donation. A successful analysis of best practices in campaign strategies may make a contribution to this Priority Action and its overarching objective. However, it seems important that the best practices are disseminated towards professionals involved in public campaigns.

Building upon the results of the EDD projects and national experiences, the **FOEDUS Joint Action** (starting in May 2013) focuses mainly on cross-border exchanges in the field of organ transplantation, but has also a work package, led by Slovenia and Germany, which will focus on public awareness. 22 European countries and 1 international organisation will participate (FOEDUS SOHO TEAM, 2011). The issue of cross-border agreements and organ exchanges requires a special communications and public awareness approach. One aim of the FOEDUS Joint Action is therefore to develop a best practice strategy to approach media and public, and to answer to their expectations. Earlier experiences, such as the organisation of the European Donation Days, will be valuable for the development of a strategy that will help all Member States willing to tackle this issue (Costa, 2012b). As FOEDUS is a Joint Action, partners involved are often CAs themselves, i.e. public authorities. Special attention will be given to social media, cooperation between Member States, understanding of possibilities in the own country and other Member States and proactive communication approaches for National Authorities towards public/media strategies (FOEDUS SOHO TEAM, 2011). The development of a strategy for communication, public awareness and to address adverse publicity can be considered as a type 2 activity (development of tools).

Another project which may, at least in an indirect way, contribute to public awareness is **ELPAT**. It also contributes to the aspect of promoting training programmes for health care professionals on communication skills. ELPAT is a European platform that brings continuity, progress and dissemination in European research and dialogue on Ethical, Legal and Psychosocial Aspects of organ Transplantation. The first ELPAT congress took place in 2007 and was funded by the EU, as well as the 2010 and 2013 editions (Health Programme). Since February 2008, ELPAT is an official section of the European Society for Organ Transplantation (ESOT). It aims to integrate and structure this field of science by bringing together European professionals from different fields, such as ethicists, lawyers, physicians, policy makers and criminologists. ELPAT currently consists of over 160 experts from more than 25 European countries and makes a special effort to involve new EU countries, candidates and

East-European Countries.[229] The ELPAT congress can be considered a type 3 action, because knowledge and best practices are actively shared. The EU financially contributes again to an ELPAT conference in April 2013, therefore dissemination impact is still expected.

Furthermore, **all EU-funded projects** also (have to and do) pay attention to **dissemination of their results** which may contribute to public awareness. For instance, the results of the ELIPSY project are disseminated on scientific congresses and one abstract coming forth of the ELIPSY project has been selected as a Silver Award in the 12th Congress of the Asian Society of Transplantation for best abstracts (CAST 2011).[230]

Another aspect of Priority Action 4 is the **promotion of training programmes geared towards health professionals and patient support groups** on organ transplantation communication skills. Three projects, ETPOD, Train the Trainers[231] and ODEQUS, contribute to this by providing training programmes to healthcare professionals, or guidelines on what to train. The training programmes of the ETPOD projects aim at different involvement levels in order to contribute to an increase in organ donation knowledge, to maximise the impact in the growth of the organ donation rates and to disseminate reliable information to the community in order to raise donation consciousness and to encourage positive attitudes. The training programmes are based on a study of the training needs of healthcare professionals involved in the organ donation process (ETPOD, 2009b).ODEQUS also provides training programmes for healthcare professionals, focused on the creation and implementation of quality criteria and indicators, on identifying standards of best practices, on defining quality indicators and finally on implementing these indicators in selected hospitals. This project is not yet finished (ODEQUS, 2011). The training programmes of ETPOD, Train the trainers, and ODEQUS can be classified into type 3 actions, because knowledge and practices are actively exchanged.

The activities on of the projects related to Priority Action 4 consist of knowledge acquisition, development of tools, and exchange of knowledge.

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.

Five projects directly contribute to the collection of information about citizens' rights concerning organ donation: **EULID, EULOD, ELPAT, COORENOR and FOEDUS**.

In relation to this Priority Action, recently, the Commission Implementing Directive 2012/25/EU was adopted on 9 October 2012, laying down information procedures for the exchange of human organs intended for transplantation between Member States. The deadline for EU Member States to transpose this Directive into national laws is April 2014. It should be noted that this technical directive will support the exchange of information when organs are exchanged between countries, but it will not directly facilitate the identification of organ donors.

A comparative analysis of national transplant laws/regulations regarding living organ donation was provided by the **EULOD** project. With the help of legal experts across Europe, including experts from ELPAT, transplant laws from all European countries were collected. The project report describes these laws and reconsiders all legal requirements for living organ donation in different European countries. In addition, it emphasises the donor-recipient relationship and procedural safeguards (Weimar &

[229] http://www.esot.org/Elpat/Content.aspx?item=10, Retrieved on 21-08-2012

[230] http://groupware.eulivingdonor.eu/grup_4/mod_news/?option=view&listcategory=8&entry=30, Retrieved on 21-08-2012

[231] http://health-med-news.com/health/spain-will-train-european-transplant-coordinators/, Retrieved on 21-08-2012

Ambagtsheer, 2012; Lopp, 2012). The main objective of the **EULID** project was to analyse the European situation regarding legal, ethical, protection and registration practices concerning living organ donation. The activities of these two projects provide insight into current practices concerning citizen's rights, and are therefore considered type 1 actions. Furthermore, the **ELPAT congresses** also cover legal aspects of organ donation and transplantations (ELPAT, 2011). Since knowledge is actively shared at congresses, this can be classified as a type 3 action.

A continuation and development (with more partners) of the efforts made in the **COORENOR project** is the **Joint Action FOEDUS**. On the basis of the mapping of legal aspects in COORENOR, the partners will collect and analyse all active bilateral and multilateral agreements between national or international organisations taking also into account consent systems (opting in/out) and definitions used for donation (e.g. brain death, non-heart-beating donors, extended criteria) (FOEDUS SOHO TEAM, 2011). FOEDUS' other work package on communication and information should also contribute to the identification of organ donors across Europe and cross-border donation, as it will provide guidelines on how to better inform citizens. More information about the FOEDUS Joint Action will be given when Priority Action 8 is discussed, since the activities of FOEDUS are also (more) relevant for that Priority Action. The activities of COORENOR and FOEDUS are a great step towards fulfilling the objectives of Priority Action 5 and its sub-actions. These activities are considered type 1 activities, because they give an overview of the current state of affairs.

The project activities related to Priority Action 5 mainly consist of knowledge acquisition, and the exchange of this knowledge.

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

Tackling a core issue within the Action Plan ("organisational models"), Priority Action 6 is broadly formulated, with four sub-actions, which is certainly why various projects can be related to this action: in particular **Alliance-O, COORENOR, ODEQUS, MODE and ACCORD** (but also **ETPOD, Train the trainers, DOPKI**… already explained under Priority Actions 1 and 2, as well as **TAIEX grants** awarded to candidate countries for twinning activities in the field of organ donation & transplantation).

The focus of one work package of **COORENOR** lies on the analysis of existing transplant programmes. This part of the project builds on the outcomes of the Alliance-O project and the overview to be produced will also help to map the progress that has been made in the seven Alliance-O countries (Costa, 2012a). The investigation of the content of existing organisational models of individual countries is considered a type 1 activity.

The main objective of the **ODEQUS** project is to identify the best organisational models and practices for deceased donation, living donation and transplantation and to provide recommendations and tools for the implementation of transplant donor coordination and Quality Improvement Programmes. More specific objectives are to train health care professionals in the creation and implementation of quality criteria and indicators, to identify standards of best practices and to define quality criteria and indicators and to finally implement, and therefore test, these indicators in selected hospitals (ODEQUS, 2009)[232], to make them available for the whole transplant community afterwards. This project started in 2010 and is finishing in 2013. The activities of ODEQUS can be classified as type 1, type 2 and also type 3 activities, because the project will give insight in the current state of affairs and provides tools and trainings.

[232] http://www.odequs.eu/index.html, Retrieved on 21-08-2012

The **MODE** project also contributes to Priority Action 6, since its main objective is the exchange of best practices in the field of organ donation and transplantation through twinning projects. The main topics on which the project focuses are existing donation and transplantation laws and how they influence transplant activities, procedures for brain death diagnosis and quality programs for donation, approaches to the traceability from donation to transplantation, distribution of essential structures, organisational networks and quality programmes for transplantation (MODE, 2011d). The countries with established systems organised host visits, and countries currently developing their systems got the chance to have up to five exchange visits on different topics. The visits have identified training needs for health care professionals and Competent Authorities (MODE, 2011a). ONT (Spain) was in charge of organisation of the courses, which took place in May 2012. The topics chosen are:

- Reporting on adverse events and reactions
- Quality assurance programme of the donation process in Spain
- Quality assurance of the transplantation process (MODE, 2011b)

Hosting countries were Spain, Italy, Slovenia, Portugal, and Czech Republic.
After the visits, the possibility for the implementation of best practices was assessed by the partner countries. Most countries were very positive about the possible implementation of the various best practices, but implementation proved difficult in some countries because of differences such as organisational or legislative systems. According to the reports of the visits, it is important to point out that the visits are only meant to be a starting point of a longer relationship between countries for the real transfer of best practices. It is up to the individual countries to discuss and agree upon further bi- or multilateral contacts and cooperation (MODE, 2011e). These activities may contribute to enhancing organisational models, and because of the bi- and multilateral contacts, they also contribute to sub action 6.2 on twinning projects and peer reviews. The activities performed in the MODE project are considered type 3 activities, because knowledge is actively exchanged. Depending on the actual implementation of best practices in the participating countries in the future, the MODE activities could also be characterised as type 4 activities.

Building upon COORENOR's and MODE's experience, another project that involves twinning activities is the **ACCORD Joint Action**, which started in June 2012, with a special work package led by France focusing on twinning. The countries involved in the twinning activities are France with Bulgaria, Italy with Cyprus, Czech Republic, Lithuania and Malta, and finally the Netherlands with Hungary (ACCORD, 2012). Through these activities, knowledge and best practices will be exchanged between countries, and they can therefore be considered type 3 activities. The ACCORD project will also result in a set of general recommendations for other future twinning projects, which are type 2 activities.

Finally, it should also be noted that several candidate/neighbouring countries such as Moldova, Serbia, Turkey… applied for grants to support twinning/knowledge sharing/capacity building activities in the field of organ donation and transplantation, and receiving EU funding for these activities.

The project activities related to Priority Action 6 mainly consist of knowledge acquisition, development of tools, exchange of knowledge and implementation.

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

Activities of organisations such the two "European Organ Exchange Organisations" **Eurotransplant** (8 member countries) and **Scandiatransplant** (5 member countries), and of the **European Society for Organ Transplantation** (ESOT), as well as initiatives like the **EULOD** project, the **ELPAT conferences** (EU-funded in 2010 and 2013) can be related to this Priority Action, as well as ESOT's **Conferences on Donation after Circulatory Death** (DCD).

Priority Action 7 is about achieving EU-wide agreements on several aspects of transplantation medicine. This Action is formulated in a very broad way, and many activities may somehow help to promote certain agreements. This makes it difficult to exactly assess what projects should be considered under this heading and what projects should not be considered. It should certainly be mentioned that those activities which focus upon the cooperation between countries in the projects in general and activities such as the organisation of scientific congresses in which new EU countries, candidates and other East-European Countries are also involved (ELPAT, ESOT conferences such as on DCD). In February 2013, the last ESOT's conference on DCD took place in Paris and was co-funded by the Competent authorities charge of organ donation & transplantation from France, the Netherlands, the United Kingdom and Spain. Furthermore, the Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation addresses the whole EU context and set-up for organ donation and transplantation (in particular quality and safety), and therefore several issues related to Priority Action 7. The EU actors such as the European Commission and CAs from the EU Member States work together with the WHO (World Health Organisation) and Council of Europe, among others on topics such as organ trafficking, living donation, scientific guides for the quality and safety of organs, tissues & cells intended for transplantation. This cooperation will be addressed in chapter 3.3. Finally, the topic of cross-border exchange was addressed in the recently adopted Directive 2012/25/EU. One of the objectives of EULOD is linked to Priority Action 7, namely to gain insight in organ trafficking in Europe which is a type 1 action for sub-action 7.3 on agreements about organ trafficking. Several activities are undertaken to support this Priority Action. These mainly consist of cooperation and knowledge exchange between countries on various topics.

Finally, it should be noted that several EU-funded projects, in the field of Research or of Public Health, tackle "aspects of transplantation medicine" which could lead, in the future, to "EU-wide agreements". It was and is for example the case with

- **Alliance-O,**
- **COORENOR** (for example on brain death and on living donation) and
- **FOEDUS** (to find a scientific consensus on the organ and donor characterisation),

as well as with research projects funded under the 7th Framework programme[233] which started end of 2012 or early 2013:

- **BIO-DrIM** (personalised minimisation of immunosuppression after solid organ transplantation by biomarker-driven stratification of patients to improve long-term outcome and health-economic data of transplantation),
- **COPE** (Consortium on Organ Preservation in Europe – for kidney and liver transplantation),
- **EUROSTAM** (a Europe-wide strategy to enhance transplantation of highly sensitized patients on basis of acceptable HLA mismatches – for kidney transplantation),
- **STELLAR** (Stem cell based therapy for kidney repair),
- **HepaMAb** (human monoclonal antibody therapy to prevent Hepatitis C virus reinfection of liver transplants: advancing lead monoclonal antibodies into clinical trial).

Some of these recent Research projects build upon results of previous Research projects such as **RISET**, **Xenome** and **The ONE study**. Their results will progressively contribute to reach scientific consensus on many aspects of the transplantation medicine within Europe.

[233] All the projects are presented in the Cordis database for EU Research projects: http://cordis.europa.eu/projects/

Priority Action 8: Facilitate the interchange of organs between national authorities.

Two projects are directly related to this Priority Action: **COORENOR** and **FOEDUS**.

Since Priority Action 8 is related to sub-action 5.2 ('Develop mechanisms to facilitate the identification of cross-border donors'), the same projects that were relevant to sub-action 5.2 are also partially relevant to Priority Action 8, even if in one case the focus is put on identifying donors and in the other case on exchanging organs.
It is also important to mention the directive adopted on a related topic (but more for procedural aspects) in October 1012: Directive 2012/25/EU laying down information procedures for the exchange, between MS, of human organs intended for transplantation (to be transposed by April 2014).[234]

As mentioned before, **COORENOR** provides an analysis and overview of existing national legislations on organ exchanges and deceased and living donation. The project also aimed to set up an IT-portal for cross-border exchanges of organs to speed up communication on requests and offers of organs, IT-portal which was tested during COORENOR and will now be further developed and expanded within FOEDUS. The system includes email notifications and an SMS gate for national coordinators (Costa, 2012a). In its design, special attention is paid to individual national legislations providing conditions for organ exchange, import and export, financial, organisational, logistical and other related issues (COORENOR, 2011b). The functioning of the IT-portal was tested among the consortium countries for six months, from June 2012 (Costa, 2012a).[235] Results from this were not yet available at time of writing, but the IT-tool was used several times to support the actual exchange of organs between countries thanks to the IT-tool, and patients transplanted. COORENOR was very positively assessed by an evaluation committee who wrote that it should be disseminated and further discussed by national authorities (COORENOR, 2011a). Results were presented to the CAs in March 2013 and are further developed and used within the Joint Action FOEDUS. COORENOR makes a major contribution to sub action 8.3. Even if the IT-tool is not yet fully operational, COORENOR activities can be considered types 2 and 3 activities, with possibly type 4 impact.

As was earlier discussed, a continuation of the efforts made in the COORENOR project is the Joint Action FOEDUS. The actions of FOEDUS can be classified as type 4 activities, but, from our perspective, it depends on the scope of implementation of the IT-tool. Important to note is that a substantial number of countries (22 + Eurotransplant) participate in the Joint Action, which will be important for the implementation of the actual interchange of organs between countries.

The project activities related to Priority Action 8 consist of knowledge acquisition, development of tools, and exchange of knowledge. In addition to this, several activities may influence daily practice to a certain degree already and possibly even more so in the future.

Priority Action 9: Evaluation of post-transplant results

Four projects directly focus on the evaluation of post-transplant results: **EFRETOS, COORENOR, FOEDUS and MODE** (and marginally **EUROCET**). Furthermore, the **Council of Europe** (supported by the EU via a Direct Grant) pays attention to this subject, by developing the Guides to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells (addressed in Chapter 3.3),

[234] http://ec.europa.eu/health/blood_tissues_organs/docs/organs_impl_directive_2012_en.pdf, Retrieved on 25-01-2013
[235] http://www.eulod.org/?section=WorkingPackages&item=12, Retrieved on 21-08-2012

which also reflect and build upon EU legislation and EU-funded projects.

The main project to address post-transplant results was **EFRETOS**, and it made a major contribution on this topic. Eleven countries participated in this project. The main objective of EFRETOS was to provide a detailed specification of the data requirements for a European Registry for the follow-up of transplanted patients and to describe the appropriate functional framework, a feasible technical approach and the organisational and legal prerequisites for realising a pan-European registry. These activities are considered type 2 actions, because tools are developed which are preparatory for the development of an actual registry. This could result in a better possibility to evaluate the results of organ transplantation in Europe, more insight into the long term effects of organ transplantation and an improved health care system with respect to organ transplantation in terms of safety and efficiency. The ultimate goal of EFRETOS is that all European countries would feel the need to participate in the registry even though the post-transplant follow-up was - after discussions between countries – in the end not formulated as mandatory in Directive 2010/53/EU. The registry could also be used for bench-marking purposes (EFRETOS, 2008). In terms of the Action Plan, the EFRETOS project has made a start with the achievement of Priority Action 9 on the evaluation of post-transplant results. Such efforts may need to be continued, also in the future, preferably with more participating countries.

COORENOR made an analysis of the current status of deceased donation practices in European Member States starting from the outcomes of the Alliance-O and DOPKI projects. The main issues of analysis are cerebral death assessment and several critical and successive steps, relating to procurement, safety, quality, allocation, and outcomes (COORENOR, 2011b).The aim is to re-evaluate steps in the procedure of donation, expanding the analysis to more recently acceding countries and those which have not yet been explored. In order to do so, several questionnaires have been agreed upon and circulated among the consortium parties.[236] COORENOR finished in December 2012, final deliverables were just delivered in February 2013. The analysis and forthcoming recommendations concerning the current status and best practices in deceased donation and their transferability to other countries are expected to contribute to Priority Action 9.3, which is about the development and promotion of good medical practices on organ donation and transplantation on the basis of results. These activities are considered type 1 actions, because they will give insight into current practices.

The **FOEDUS Joint Action** will support sub-action 9.3, with a work package promoting common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors. The project addresses the development of common terms and definitions on expanded donor criteria (FOEDUS SOHO TEAM, 2011), which can be considered as activities of types 1 and 2.

In addition, the **MODE Joint Action** also addressed post-transplant results. As described earlier (under twinning activities, Priority Action 6), onsite visits were organised for the purpose of exchanging best practices. The stronger countries organised host visits, and weaker countries got the change to have up to five exchange visits on different topics. The visits have identified training needs for health care professionals and Competent Authorities. ONT (Spain) was in charge of organising the courses in May 2012. One of the topics the course reported on was adverse events and reactions (MODE, 2011b). The training course on reporting adverse events and reactions is most closely related to Priority Action 9, since this involves registration of post-transplant results with regard to quality and safety. The training can be considered as a type 3 activity, because knowledge is actively exchanged.

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Finally, the EUROCET project started in 2005.[237] Through the EUROCET project, a common registry for the collection of data on organ, tissue and cell donation and transplantation was set up and is still monitored by Italian CA in collaboration with WHO. Countries that participated were Czech Republic, Estonia, France, Hungary, Italy, Netherlands, Poland, Slovakia, Slovenia, Spain, and the United Kingdom. One ultimate goal of the registry was to improve patient care by expanding the services available to medical professionals. The Action Plan was introduced after the EUROCET-project, but the activities of EUROCET can be, in a way, related to Priority Action 9, on the evaluation of post-transplant results. However, EUORCET in practice focus more on Tissues&Cells activities.

The activities on of the projects related to Priority Action 9 mainly consist of knowledge acquisition, development of tools, and exchange of knowledge.

Priority Action 10: Promote a common accreditation system for organ donation procurement and transplantation programmes.

The wording of this Priority Action is very open, and it is the only Priority Action where no sub-action was defined. The focus will be on four projects that can be more or less directly related to Priority Action 10: **COORENOR, ODEQUS, ACCORD and MODE** (but one might consider that other projects also relate to this PA).

COORENOR can be related to this Priority Action because the projects provides an overview of medical centres that are accredited to organ donation (Costa, 2012a).

In the case of **ODEQUS**, it seems clearer: the main objective of the project is to define a methodology to assess the performance of organ procurement and organ transplantation at hospital level by identifying organisational models and best practices, focussing on the legal framework, accreditation and certification, organisation, human and material resources, education and research. More specific objectives are to train health care professionals in the definition and implementation of quality criteria and indicators, to identify standards of best practices and to define quality indicators and finally implement these indicators in selected hospitals (ODEQUS, 2009).[238] The activities of ODEQUS are type 1, 2 and 3 actions. Insight is provided into current practices (type 1), a manual is being developed (type 2), and trainings (type 3) were provided in the implementation of quality criteria in hospitals which ultimately would result in the development of an audit system.

In the **ACCORD and MODE Joint Actions**, twinning activities between countries are organised. In each project, one of the twinning activities is focused on the development of an accreditation system (ACCORD, 2012; MODE, 2011c).

Last but not least, it should be noted that the **Directive 2010/53/EU**, adopted in July 2010 after the Action Plan (December 2008), now provides a new instrument to monitor accreditation models, linked in many countries to authorisation schemes: under the Directive procurement organisation and transplant centres have to be authorised, and the European Commission or any other Member State can ask to "provide information on the national requirements for the authorisation of procurement organisations and transplantation centres" (article 5 on procurement organisations and article 9 on transplantation centres).

The activities on of the projects related to Priority Action 10 mainly consist of knowledge acquisition, development of tools, and exchange of knowledge.

[237] http://www.eurocet.org, Retrieved on 21-08-2012

[238] http://www.odequs.eu/index.html, Retrieved on 21-08-2012

Final remarks regarding the projects

Many projects have contributed to the Action Plan in diverse ways, and many projects are still contributing. Projects may serve as the 'bottom-up' strategy of the European Commission to support the Action Plan. All of these projects are developed and led by representatives of different European countries (whether Competent authorities themselves, or hospitals/universities/other institutions, and sometimes both types). Projects mobilise experts and expertise in Europe towards achieving the Action Plan's goals. A closer look at the projects suggests an evolutionary development in the functions of the projects. Early projects seem to focus more on the issue of information gathering, followed by the development of tools and expertise, whereas the later projects are more focused on the exchange of knowledge and expertise. Implementation is a function of some of the projects. The Commission through its funding seems to primarily take up a supportive role, leaving the final realisation of the Action Plan to the individual States, which is in line with Commission's legal mandate and with the Action Plan which focuses on "strengthened cooperation between Member States". It is not always clear how projects build upon each other's results, over time and among projects, in particular if the funding mechanisms are different, in particular for projects not funded under the (Public) Health Programmes which coordinators might therefore "less naturally" report to CAs in charge of organ donation & transplantation.

Sometimes, there also seems to be some overlap between the activities of projects. For projects to be more effective new projects should be required to explicitly explain how they build upon the achievements of other projects and goals attained within the Action Plan. Such strategies should be facilitated by the new kind of projects now available thanks to the adoption of the EU Organs' legislation: Joint Actions. Promising examples are indeed the Joint Actions ACCORD and FOEDUS which respectively builds upon the legacy of ELIPSY, and COORENOR, which again were respectively based on the outcomes of EULID, Alliance-O and DOPKI.

Another observation is that some new EU Member States seem to participate to a lesser extent in some projects. In some project evaluations it was stressed that results of the project cannot be projected onto for instance newer EU countries because of cultural and economic differences, or that only some "more enthusiastic" countries with well-established transplant programmes and registries are involved (probably because more resources are available in these countries, keeping the enthusiasm alive). If widespread implementation of the results of a project is an objective of the project, it might be beneficial to stimulate the involvement of new EU countries, candidate countries and East-European countries. In the recent projects, a greater number of countries seem to be involved compared to the earlier projects – again thanks to the new kind of projects: Joint Actions. This is a positive phenomenon. However, as can be seen in table 3.4, efforts could still be made to involve all countries.

Table 3.4: Overview involvement of countries in EU-funded projects[239],[240]

Project Country	Alliance-O	DOPKI	ETPOD	EULID	EDD	ELPAT	EFRETOS	ELIPSY	COORENOR	EULOD	ODEQUS	Train the trainers	MODE	ACCORD	FOEDUS	Total per country
Year started	2004	2006	2007	2007	2008	2008	2009	2009	2010	2010	2010	2010	2011	2012	2013	
Austria			MUW								MUW	x				3
Belgium										KUL		x			MOH	2
Bulgaria			**BEAT**							BCB		x		**BEAT**	**BEAT**	**5**
Cyprus			PSTC	PSTC				PSTC	PSTC			x		MOH	**MOH**	7
Croatia		**MOH**			DCC						**MOH**			**MOH**	**MOH**	**5**
Czech R.		**KST**			KEM; **KST**		CTS		**KST**			x	**KST**	**KST**	**KST**	**8**
Denmark															MOH	1
Estonia			TUH							TUH		x	TUH	TUH	**MSA**	6
Finland												x				1
France	**ABM**	**ABM**	**ABM**	APHP			**ABM**	HN	**ABM**		**ABM**	x		**ABM**	**ABM**	**11**
Germany		**DSO**	**DSO**				**DSO**	SUB		Univ. Munster	**DSO**	x		**DSO**	**DSO**	**9**
Greece			**EOM**				**EOM**							**EOM**	**EOM**	**4**
Hungary	HT	HT							HNBTS			x	OVSZ	HNBTS	OVSZ	7
Iceland															**MOH**	1
Italy	**CNT**	**CNT**	FITOT; **ISS**	**ISS**			**CNT;** Univ Padua		**CNT**		FITOT	x	**ISS**	**CNT**	**ISS-CNT**	**11**
Ireland												x		HSE		1
Latvia									PSCUH			x		PSCUH		3
Liechtenstein																0

[239] A list of abbreviations and acronyms of EU-funded projects and of the various institutions involved can be found in annex 1

[240] **Bold** = Competent Authority (as identified in 2012 for this study; with the Directive 2010/53/EU being transposed in national laws in 2012, the national set-up are evolving, a transposition check will be done by Commission in 2013)

Project Country	**Alliance-O**	**DOPKI**	**ETPOD**	**EULID**	**EDD**	**ELPAT**	**EFRETOS**	**ELIPSY**	**COORENOR**	**EULOD**	**ODEQUS**	**Train the trainers**	**MODE**	**ACCORD**	**FOEDUS**	**Total per country**
Lithuania			**NBT**						**NBT**			x	**NBT**	**NBT**	**NBT**	**6**
Luxembourg																0
Malta												x		MOH	**MOH**	2
Macedonia																0
Montenegro																0
Netherlands							NTS; UMCG			Erasmus MC		x		**NTS**		4
Norway				Rikshospitalet										**HDIR**	**HDIR**	**3**
Poland			**PT;** MUW	**PT**					**PT**; MUW	**PT**	**PT**	x		**PT**		**7**
Portugal	**OPT**	**OPT**	**ASST**	HGSA EPE				HGSA EPE CHP	**ASST**		**ASST**	x	**ASST**	**ASST**	DGS	**11**
Romania			UTM	**NAT**					FCI	SACRI	FPT	x		**NAT**	MOH	**7**
Slovak Republic			**UNM**		**UNM**		DUH		**UNM**			x			SMU	6
Slovenia		**ST**		**ST**	**ST**		**ST**					**x**	**ST**	**ST**	**ST**	**8**
Spain	**ONT**	**ONT**	IL3, IMAS	FBG, HCB			**ONT**	HCB			IL3; DTI; FIB	x, **ONT**; Iavante	**ONT**	**ONT**		**11**
Sweden			MUH	SUH				SUH		Univ. Gothenb.	KI	x		**NBH**	**NBH**	**8**
Switzerland		SwT														1
Turkey			AUTC					MPAHC								2
UK	**NHSBT**	**NHSBT**		**NHSBT**			**NHSBT**				**NHSBT**	x		**NHSBT**	**NHSBT**	**8**
Europe/ International		ET			ET; CoE	ESOT	ET, SKT ESOT,		ET	ESOT				ET	ET	
Total*	6	10	16	11	5	-	11	7	11	8	11	25 **	8	23	22	

* total number of countries involved (without international organisations)

** participants from 25 countries (2 Spanish coordinators + Spanish participants = 1 country represented)

3.2 Efforts directly managed by the European Commission under the European Action Plan on Organ Donation and Transplantation

In this chapter, the efforts of the European Commission (EC) for the EU Action Plan are described. Important to note is that this chapter is limited to a description of the activities that are directly managed by the EC, but still with the active involvement of experts from the Member States, excluding the funding of projects (described in Chapter 3.1). The results are described per Priority Action and are based on internal documents of the EC found on the CIRCA platform (collaborative workspace for partners of European institutions) and a questionnaire filled in by EC representatives of the European Commission.

For the different Priority Actions of the Action Plan, EC policy might differ, depending whether the EC has a legal mandate or not. This determines the EC actions. This legal mandate is primarily based on article 168 of the Treaty on the Functioning of the European Union (TFUE)[241], which states:

> "***1. A high level of human health protection shall be ensured*** *in the definition and implementation of all Union policies and activities.*
> ***Union action, which shall complement national policies, shall be directed towards improving public health […].***
> ***2. The Union shall encourage cooperation between the Member*** *States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas […].*
> ***4.*** *By way of derogation […], the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions,* ***shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: (a) 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.[…]."*

EC actions are anchored and activated via different instruments:

1. **Legal/official instruments**:

- The "**Action Plan on organ donation and transplantation (2009-2015)**: **Strengthened Cooperation between Member States**" prepared after the same public consultations, as an incentive, voluntary initiative, adopted as a **Communication from the Commission**, in December 2008.
- **The Directive 2010/53/EU** on standards of quality and safety of human organs intended for transplantation **prepared by the Commission**, after a public consultation, in 2008/2009 and **adopted by the European Parliament and the Council** on 7 July 2010. It formally established, via its article 19, the network of national Competent Authorities meeting and exchanging twice a year in Brussels, and also involved in EU-funded projects.
- **Commission implementing directive 2012/25/EU of 9 October 2012** laying down information procedures for the exchange, between Member States, of human organs intended for transplantation (technical Directive, to be transposed by April 2014).

[241] EN C 83/122 Official Journal of the European Union 30.3.2010

The paragraph 4 (a) of article 168 TFEU is the legal basis which allowed Parliament and Council to adopt Directive 2010/53/EU. Since the Directive was adopted in July 2010 (and transposed for August 2012), therefore after the adoption of the Action Plan in December 2008, this Action Plan, in its first year, was/is also a tool to improve "quality and safety" and to cover what was afterwards taken over in the legislation.

2**. Financial/practical tools as a coordination mechanism**:

- In addition to **Research programmes** and other **Community funding**, the **(Public) Health Programme**s finance projects in the field of "substances of human origin" ("SoHO", i.e. Blood, Tissues & Cells and Organs). The projects are administratively monitored with the support of the Executive Agency for Health and Consumers (EAHC) in Luxembourg, Commission's Directorate-General for Health & Consumers (SANCO) is proposing policy lines, identifying the key issues to propose to the Programme Board where all Member States are represented and co-draft the Annual work programme for the Health Programmes (2000-2007, 2008-2013 and 2014-2020).[242] External evaluators are also involved in the selection of projects to be funded, before
- **Meetings**: "Action Plan meetings" for all Member States were held. Since the adoption of the Directive, they are called "**meetings of national Competent Authorities**", as such a network is foreseen under article 19. Also meetings of working groups established after the adoption of the Action Plan are financed on EC budget: working groups on deceased donation, on indicators and on living donation.
- Finally, EC internal budget is used to organise **specific events** such as the **Journalist Workshops on organ donation & transplantation** (2010, 2011 and 2012 editions – Communication budget).

Results: Efforts directly coordinated by the EC for the Action Plan on Organ Donation and Transplantation

The EC applies different instruments to contribute to the Action Plan. A valuable instrument is the organisation of a biannual meeting of Competent Authorities. These meetings serve as a platform to exchange views and knowledge and discuss the progress and strategies regarding the Action Plan and projects funded to support the Action Plan. Two or three national Competent Authorities also present their national actions relating to the Action Plan at each CA meeting.
Furthermore, there are three working groups under the Action Plan, namely for Deceased Donation, Indicators and Living Donation and they are directly managed by the Commission and financed by internal funds (not via the Health Programme). For the working groups, content, work, invitations and reimbursement of national experts are directly monitored, coordinated and organised by the EC, but of course the active involvement of national representatives is key.

General monitoring of Priority Actions by the EC: Working Group on Indicators
The main objective of the working group on indicators is to strengthen, via annual exercises, knowledge-sharing between MS and to build common knowledge based on basic indicators on key aspects of the transplantation chain, namely donation, allocation, waiting lists, transplantation, health outcomes, health resources (also with data collected through ONT (Spain) for the Council of Europe Newsletter). When this working group was created in 2009-10, it was decided to follow that

[242] http://ec.europa.eu/eahc/health/index.html, Retrieved on 28-08-2012

whole chain from donation to transplantation, outcomes and resources, and not to specifically focus on each of the Priority Actions.

ONT usually collects mainly quantitative data such as the numbers of donations and transplantation proceedings per country, also presented in the annual Transplant Newsletters of the Council of Europe. The same numbers are also be used by the working group on indicators, but are presented in different ways (charts and not maps) and combined with qualitative data collected by the EC. The end-product is presented for discussion and improvement to the whole group of CAs. The qualitative data additionally collected involved more and more countries every year. In 2010, 20 countries participated in the working group and in 2011, 24 countries (Van der Spiegel & Le Borgne, 2012).

The working group on indicators demonstrates that there are still many discrepancies in the use of indicators and room to improve data collection, data completeness and data quality. However, the working group is helping to improve the quality of data to make countries aware of where rogans could be made available/exchanged. In 2012 and 2013, the working group continues its annual exercise and the objective is to collect data on more countries and improve data quality to make data more useable.

Results per Priority Action

In the next section the EC's actions are described per specific Priority Action of the Action Plan.
With regard to several Priority Actions, the EC has no direct legal mandate. The EC generally contributes to these Actions by enabling sharing of best practices through the coordination mechanism, for which CAs meetings and project funding are of vital importance.

Priority Action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Design indicators to monitor this action.

Harmonising numbers on transplant coordinators is said to be difficult, as figures are mainly based on part-time jobs and cover different national realities and organisations in the health systems. The **working group on deceased donation**, the first to be set up, also directly contributed to this Priority Action. In the working group, the role of the transplant donor coordinator was identified as a key success factor for donation from deceased persons. This working group also produced a manual on how to set up a system for transplant donor coordination, with several national examples. Belgium, France, Italy, Portugal, Spain, Sweden and the United Kingdom volunteered to share their national experiences. The manual is about key requirements in the donation process and the roles and skills of donor transplant coordinators and key donation personnel. In 2011, the final version was submitted. In 2012 this final version was translated into the languages requested by the CAs and was posted on the Circa platform (Le Borgne, 2012a). The working group has also made first steps in establishing internationally recognised standards for transplant donor coordinator programmes (sub action 1.2). The next step would be to assess whether the manual is useful for all Member States, and whether the manual is adopted by other (non-member) countries.
In addition, in another activity which is related to Priority Action 1, EC representatives invited a transplant coordinator (from Belgium) to speak to journalists to explain his tasks, during the Journalist workshops in 2010, 2011 and 2012.

EC representatives concluded on Priority Action 1 that the EC and CA group have a basis to show, justify and explain the concept of transplant donor coordinators and the way to implement/put in place a transplant donor coordination/key donation personel. Now, more is to be done to monitor how Member States have picked this up and see whether this can be enforced or incentivised. EU-funded projects are normally not presented in this chapter, however as a "tender" is a special

instrument through which the EC can "command" a service, ETPOD and "train the trainers" should be mentioned here as they directly contributed to PA1, based on EC willingness.

Priority Action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.
For this Priority Action too, the Commission can do most through its coordination mechanism. Next to the EU-funded projects like ODEQUS, MODE, FOEDUS (work package on ICUs), the EC promotes Quality Improvement programmes through disseminating and sharing the results of projects and working groups within the CA meetings. More specifically, the manual developed within the working group on Deceased Donation also relates to Quality Improvement Programmes. Furthermore, projects like EULID, ELIPSY and the toolbox foreseen in the working group on living donation – even if they focus more specifically on living donation – provides tools to address quality improvement (this last working group is more related to Priority Action 3, so it will be discussed more elaborately later).

According to the EC representatives, the activities on Priority Action 2 could be more successful if the uptake of this action was monitored and efforts were strengthened. As written down in the 2009 Action Plan, several Member States consider this Priority Action (2) to be more of a national issue and to a lesser extent a matter for the EU – but here again the EU Action Plan may serve as a tool for Member States to exchange national best practices. ODEQUS results will be available, and presented in the CA meeting in September 2013, which might create for CAs the encouragement to use the quality criteria and quality indicators agreed upon for hospital level, within the national framework for quality and safety to be implemented at national level due to adoption of Directive 2010/53/EU.

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.
The EC also coordinated a working group on living donation. The objectives of this group were first discussed with the CAs in 2011 and the first physical meeting took place in February 2012. The objective of the working group on living donation is to provide a manual/toolbox on experiences of Member States on living donation. The manual should contain information about legal aspects, ethical principles, donor evaluation, selection and protection, donor registration, psychological aspects, financial and economic aspects of living donation programs and optimising living donations (European Commission, 2012b). A final version of the manual/toolbox is not yet available, but will be available in 2013 on the Circa platform when finished. The following countries participate in the working group: Belgium, France, Germany, Italy, the Netherlands, Norway, Spain, and the United Kingdom (European Commission, 2012b).

Secondly, it should be said that regarding both deceased and living donation, the EU legislation (Directive 2010/53/EU) requires donation to be voluntary and unpaid. The legislation also makes it mandatory for Member States to build a register of living donors (article 15). This means that the EC now has possibilities through a legal mandate and a coordination mechanism for this Priority Action. The monitoring of the implementation of living donor registers by Member States is planned in the transposition check of the Directive 2010/53/EU (2013). If Member States have not fully implemented article 15 of the Directive, some measures will be taken to accompany them, as is already the case with the work package on living donation registers within the Joint Action ACCORD, which can build upon results from the EULID and ELIPSY projects. If there is no improvement, an infringement procedure can be put in place. As the national, ethical and legal framework for living donation will continue to differ from one EU country to another, efforts should be maintained to know about the different systems and share best practices.

The EU generally promotes Priority Action 3 through the coordination mechanism with international organisations and through funding of the Council of Europe. The Council of Europe together with ONT (Spain) monitors the number of living donors through the Transplant Newsletter.

Aspects related to organ trafficking were mainly dealt with at the Council of Europe level. In June 2011, a joint meeting with the EC, Council of Europe and the EAHC was organised to avoid duplication of efforts. DG SANCO followed up at EC level with the continuous integration of the concept of "trafficking for the purpose of removal or organs" into the new EU strategy and legislation around trafficking in human beings (the Directive 2011/36/EU - whose deadline for transposition is 6 April 2013)[243], led by DG Home Affairs, as well as in projects funded by this DG, such as the HOTT project. DG SANCO informed the CAs who could propose an expert in Tissues, Cells and Organ trafficking for the Third EU Group of Experts on trafficking in Human Beings. The subject of organ trafficking is also related to Priority Action 7. More about the work of the Council of Europe can be found in Chapter 3.3.

As stated by the EC representatives, living donation complements deceased donation. The work on living donation also started later than the work on deceased donation. Furthermore, living donation was put on the political agenda, for example through the Cypriot Presidency of the European Union (second half 2012) and consequently in the Council Conclusions[244] on organ donation and transplantation adopted by Health Ministers in December 2012. Since living donation is a relatively recent development in many countries there still is much to be gained in this area.

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.

The EC contributes to this Priority Action through the coordination mechanism. As mentioned by the EC representatives, it is important to note that public awareness is very difficult to measure, but adverse publicity is more visible and could impact organ donation, therefore the EC wants to reflect and act on this.

It has been considered that integrated coordination with personnel who are willing and trained to engage with and support the media (sub-action 4.2), is a successful strategy which seems to yield good results with a moderate budget. Therefore training activities such as ETPOD and "Train the trainers" include communication in their actions. Good relations with the media are an important parallel strategy to increase public awareness, next to efficient structures and organisational change (DG Health and Consumer (SANCO) - Organ Donation and Transplantation, 2010).

Besides EU-funded projects such as ETPOD and "Train the Trainers", the EC organises centrally journalist workshops to make journalists aware of their key role on this issue, of the complexity of the issue and of the added-value to work of the EU level, and generally indirectly to increase public awareness at least by creating a positive culture around organ donation. The organisation of journalist workshops corresponds with the objective of the Action Plan to increase public awareness of organ donation and Priority Action 4 and its sub-actions. Several CAs and national experts and patients were invited to present their experience and work (coordinator, surgeon, living donor, relative of deceased donor…). The exchange of best practices on these strategies between health experts, media and the EC contributes to this Priority Action. The workshops will also help in recognising the important role of the mass media and the need to improve the level of information of the public (sub-action 4.1), because from these workshops, it can be assumed that when public

[243] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:101:0001:0011:EN:PDF

[244] http://ec.europa.eu/health/blood_tissues_organs/docs/organs_council_ccl_2012_en.pdf

trust is increased, donation rates might also increase, and vice-versa. And above, all steps from donation to transplantation, including ethical aspects, are tackled and explained in their complexity, thus providing for a transparent discussion.

Journalist Workshops are organised by DG SANCO in the context of the campaign 'Europe for patients', a communication campaign to inform citizens about EU healthcare policies and actions. Health experts, media and personnel of the EU exchange best practices of effective and non-effective strategies to improve public awareness (DG Health and Consumer (SANCO) - Organ Donation and Transplantation, 2010). After the workshops, seven articles were published in national newspapers. The articles authorised by authors and editors were translated and published on the website of the European Commission.[245] In October 2011 and October 2102, a second and third journalist workshop was organised.[246] Some other actions or events followed the journalist workshops, directly linked to them, such as a Testimony of the Dutch donor & recipient on the website of the Dutch "association of kidney patients" (Nierpatiënten Vereniging Nederland), and an event on organ transplantation organised by the European Kidney Health Alliance (EKHA) for the 2012 World Kidney Day at the European Parliament.

Other activities related to Priority Action 4 are the presentation of projects concerning organ donation at the Public Health programmes Conference organised by DG SANCO in May 2012.[247] Furthermore, during the CA meeting in March 2012, it was agreed to create a new slot in the CA meeting agendas, focusing on Communication issues. This was implemented in September 2012, March 2013 and will be further implemented.

To be able to assess and evaluate the aforementioned strategies a clear objective is needed. Such a clear goal is lacking. On this topic a more explicit goal formulation may help, also in the development of a more comprehensive communications strategy.

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.

Until now, several activities have contributed to Priority Action 5. Firstly, the issue of the identification of cross-border donors was put on the political agenda by the Cypriot presidency in 2012, where two topics were discussed for organ donation and transplantation: living donation and cross-border exchanges of organs and patients. Furthermore, during the CA meeting in September 2012 there was a legal discussion on the status of "visiting (i.e. foreign) retrieval teams" who retrieve organs for cross-border donations, under the acknowledgment of both CAs. The EC representatives stated that the Council of Europe discussions on "double-listing" (on waiting lists) and "listing of non-residents" should probably not be repeated in CA meetings, but should nonetheless be followed carefully. Lastly, the EC has close collaboration with exchange organisations such as Eurotransplant and Scandiatransplant. The cooperation with these organisations is explained in Chapter 3.3.

The identification of donors falls outside the legal mandate at EU level, however for the Commission it is important to provide to CAs tools for such an identification and donation. Therefore the EC propose to include such a topic for the EU-funded Joint Action FOEDUS starting mid 2013.

[245] http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm#fragment1, Retrieved on 28-08-2012

[246] http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm

[247] http://ec.europa.eu/health-eu/newsletter/89/newsletter_en.htm, Retrieved on 28-08-2012

http://ec.europa.eu/health/programme/events/ev_20120503_presentations_en.htm, Retrieved on 28-08-2012

http://ec.europa.eu/health/programme/docs/success_stories_hp_2008-2013_en.pdf, Retrieved on 28-08-2012

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

Besides **funding projects** such as **ODEQUS, COORENOR, MODE, ACCORD**, the EC contributes to this action by the work in the **working groups for deceased donation** (manual on how to set-up coordination systems) **and living donation** ("toolbox"), as well as by **asking CAs to present** during the biannual meetings how organisational models are implemented within their Member State, allowing for feedback and peer review. The EC also ensures organisational models are regularly subject of projects or Joint Actions funded by the Health Programme, including through twinning.

In addition, **structural funds** can be directly allocated to countries and regions in need, for structural development, and countries then decide on which topics this funding is allocated at their local level. This is a source of budget that DG SANCO has tried to explore to support Member States, but this is primarily in countries' hands. Other Community instruments are for example funds from the **Research Programmes** (6^{th} and 7^{th} framework programmes). Therefore, it was possible to propose organ transplantation and tissue and cells related topics several times as one of the Health topics. In the past, DOKPI and Alliance-O were funded through the Research funds. Currently, EULOD, which is on living donation, is finishing. In 2011, DG SANCO has again proposed the subject of organ transplantation resulting in this topic being included in a call for proposals on Health and in many projects funded (COPE, HepaMab… see part 3.1, Priority Action 7).

The sub-actions for this action are about twinning projects, peer reviews, the use of structural funds and networks of centres of reference. **TAIEX (Technical Assistance and Information Exchange)** is an EU instrument, available at the level of the EU Delegations in non EU country, that helps countries become acquainted with, apply and enforce EU legislation, and which monitors their progress in doing so. It funds short-term peer-to-peer technical assistance, advice and training, provided mainly in 3 ways:

- Workshops attended by officials from beneficiaries' administrations,
- Expert missions that provide in-depth advice to beneficiaries' administrations,
- Study visits to EU countries' administrations.[248]

When applicants ask for funding in the field of organ donation and transplantation, DG SANCO is regularly asked by EU delegations (for example in the Black-Sea area: Moldova, Montenegro, Turkey) to provide an opinion about the use of funds for organ transplantation, to help building up capacity mainly through TAIEX Workshops, where national experts from the EU go for specific training sessions. The same applied earlier for Croatia.

Several activities on organ donation and transplantation were for example recently funded via TAIEX:

- 28 May 2012 (Podgorica - Montenegro): Expert Mission on Drafting Legislation on Organ Donation and Transplantation[249]
- 21 May 2012 (Barcelona - Spain): Study Visit on Tissues and Organ Transplant[250]
- 07 March 2011 (Madrid - Spain): Study Visit on the provisions of the Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation[251]
- 22 February 2011 (Zagreb - Croatia): Workshop on Organ Donation and Transplantation Medicine Collaboration in South Eastern Europe[252]

[248] http://ec.europa.eu/enlargement/tenders/taiex/index_en.htm, Retrieved on 28-08-2012

[249] http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=48625, Retrieved on 28-08-2012

[250] http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=47700, Retrieved on 28-08-2012

[251] http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=43847, Retrieved on 28-08-2012

[252] http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=42609, Retrieved on 28-08-2012

Other grants were awarded prior to and after these examples (on-going process, depending on applications received). This TAIEX funding constitutes one of the EU "Community instruments" available.

In addition to developing national programmes to ensure self-sufficiency, it might be important, when not all (transplant) therapies are available in a country, to develop cross-border agreements where exchanges are regulated and foreseen. In addition, through this mechanism, patients can be looked after when back home, as the follow-up is a very important aspect of organ transplantation.

According to the EC representatives, several countries or regions can benefit from twinning activities, via TAIEX grants (non EU countries) or via structural funds (EU countries) - but it is their decision to apply for specific topics, depending on their needs. Structural funds can be explored further, it may provide more opportunities in the future.

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.
The EC representatives stated that Priority Action 7 is a very complex one, since it lies within the competence of Member States themselves. This especially applies for agreements on sensitive topics such as waiting lists and allocation criteria concerning extra-Community patients. The sub-actions of Priority Action 7 are about patient mobility, issues on extra-Community patients, organ trafficking and future research. There are some activities, besides the funding of projects by the EC which might contribute to this action.

Firstly, the EC aims to **understand MS practices** through their annual indicators exercises, and the **National Priority Actions** which are presented and discussed during CA meetings. Within the Commission**, organ trafficking** falls in the mandate of DG HOME AFFAIRS, but DG SANCO is associated and monitors the integration of the concept of "trafficking for the purpose of removal or organs" into the new EU strategy and legislation (**EU legislation on trafficking in human beings**, namely the Directive 2011/36/EU[253] - whose deadline for transposition is 6 April 2013, and EU-funded project HOTT[254]). DG SANCO informed the CAs about this and proposed an expert for Tissues, Cells and Organ trafficking for the Third EU Group of Experts on trafficking in Human Beings.

As said earlier, aspects relating to organ trafficking are mainly dealt with at the **Council of Europe** (CoE) level and CoE draft recommendations were formulated and adopted by Ministers for CoE countries in 2004 and more recently. According to the EC representatives, there is no need to duplicate these activities since the Council of Europe has a wider geographical scope. But EC and CoE ensure to inform their group of representatives on each other's activities. The EC work is grounded on principles such as formulated in the WHO Guiding principles on human cell, tissues and organ transplantation endorsed in May 2010.

The strategies for **future research programmes** (see also funding of research under Priority Action 6), are proposed by the Commission before being adopted by the European Parliament and Council, hence DG SANCO has no direct impact on them, but regularly proposes the topic of organ transplantation for annual Health calls and it is also regularly retained (see 2011 calls, part 3.1), also because it is in line with the objectives of the Research programmes.

[253] http://ec.europa.eu/anti-trafficking/, Retrieved on 28-08-2012
[254] http://ec.europa.eu/anti-trafficking/entity.action;jsessionid=wMZPRvkGHKNL1jQRLlXfLX6WBC0tZvqv4h5GsRFPsny3nXTwy6vb!1142670905?path=EU+Projects%2FHOME_2011_ISEC_AG_THB_4000002186

Priority Action 8: Facilitate the interchange of organs between national authorities.
The sub-actions of Priority Action 8 are about evaluating procedures to offer "surplus organs"[255] (which can not be allocated in the country of procurement) to other countries, the exchange of organs (in particular for urgent and difficult-to-treat patients) and IT-tools to support this.

The EC has a growing legal mandate in facilitating this interchange. The Implementing Directive discussed in 2011/2012 with Member States was adopted on 9 October 2012 (transposition deadline: 10 April 2014). It proposes a more detailed framework "where organs are exchanged between Member States" (article 29 of Mother Directive), as it lays down "detailed rules for the uniform implementation of this Directive […]" on the following:

- Procedures for the transmission of information on organ and donor characterisation as specified in the Annex in accordance with Article 7(6)
- Procedures for the transmission of the necessary information to ensure the traceability of organs in accordance with Article 10(4),
- Procedures for ensuring the reporting of serious adverse events and reactions in accordance with Article 11(4).

The new piece of legislation, following the Mother Directive, will complement the voluntary work done so far. The EC has coordinated the discussion and has put in place a "Committee on organ transplantation" as stated in article 30 of the Mother directive. This Committee met in March and in April 2012. The new Implementing Directive was also object of an "intra-service consultation" within the Commission.

In adddition, the EC can stimulate processes through the usual coordination mechanisms. Besides **funding projects such as COORENOR and FOEDUS** (which clearly focus on cross-border organ exchange, via an IT-tool, common scientific consensus as well as bi- and multilateral agreements), the activities and results of projects on this Priority Action were addressed on a political level during the Cypriot Presidency in July 2012 and are addressed and discussed during the CA meetings.
One needs to take account of the concept of "self-sufficiency" and on the need to build "domestic systems" as formulated in the WHO Guiding principles on human cell, tissues and organ transplantation endorsed in May 2010. The EC representatives stressed that the EC always respects Member States' different views and positions as it is in the interest of all EU countries to reach consensus.

Differences between countries exist in the degree to which they participate in the exchange of donor organs. Coordination activities therefore have to take these differences into account. Some countries will benefit from progress, whereas other countries are already involved in exchange programmes.

Priority Action 9: Evaluation of post-transplant results.
The main contribution for PA 9 was the funding of the project **EFRETOS**, as one sub-action of PA 9 is about the development of a register to follow-up organ recipients: EFRETOS provided for a common "blue print" agreed upon amongst transplantation experts from different European countries.

Another of the sub-actions of Priority Action 9 is on the development of definitions of terms and methodology to evaluate transplantation results. The EC does not have the mandate nor the resources to develop common definitions of terms and methodology on organ donation, therefore contributions of national experts, scientists and surgeons are needed and gathered via **projects like**

[255] The original wording of the Action Plan "surplus organs" reflects the terminology commonly used in 2008 when the Action Plan was adopted. However in the current context of organ shortage, it should now be avoided, therefore the wording "organs not allocated nationally/locally/otherwise" would be preferred.

EFRETOS, COORENOR, ODEQUS… and via **professional societies like ESOT** (for example DCD conferences focusing on Donation after Circulatory Death and its results, depending on the type of organ transplanted).

The third sub-action is focuses on **expanded donors**, meaning that in a global situation of an ageing population, the criteria for donors are expanded and that for example older donors, donors with high blood pressure or donors with a disease might also be accepted, once risks for recipients have been evaluated. This is regularly discussed in CA meetings, as well as within the working group on Indicators (Donation part: questions on donor ages and medical contra-indications).

The fourth sub-action refers to **good medical practices** on organ donation and transplantation. The EC representatives indicated that common work on good medical practices on organ donation and transplantation is developed within the **Council of Europe Guide on Quality and Safety of Organ transplantation**, together with national experts from EU countries and with the support of the EC. During discussions with the Council of Europe about a good synergy of efforts, clarity towards Member States and avoiding double efforts, the efforts of the Council of Europe regarding medical and scientific good practice were acknowledged, in particular as the main writers of the Guides are national experts from EU countries. Moreover, it was agreed to add information on EU-funded projects and EU legislation in the Council of Europe Guide when relevant. One way through which the EU funds the Council of Europe is through a direct grant for these guides.

On this Priority Action, there is always room for improvement. The evaluation of post-transplant results, comparisons of differences between countries and learning from best practices are fruitful strategies to improve the process of organ donation in Europe.

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.

With regard to Priority Action 10, the EC representatives state that this is a difficult action, because of the very general wording and therefore both technically and politically. There is no legal mandate for the EC on this subject and the coordination mechanism has not really been applicable here so far, both regarding educational schemes and health systems. Although one might consider that **training efforts** (ETPOD, Train the Trainers EU-funded projects) might be linked to this Priority Action, the CA group has not yet recognised this subject as a priority for the EC and the subject is left primarily to the doctors and the **scientific community**, for example via the **professional societies**. As accreditation covers many professional realities (nurses, transplant surgeons, intensivists, neurologists, nephrologists) in different countries with different health systems and training systems, the scope for an area without exclusive EU mandate might be a too broad to reach consensus. On the other hand, with the transposition of **Directive 2010/53/EU** which foresees that procurement centres and transplantation centre are **authorised by CAs**, an opportunity could be to look at the national transposition laws and determine how authorisation schemes function in every country, also by exchange of experience in the group of CAs.

In 2005, the Council of Europe adopted recommendations on the role and training of professionals responsible for organ donation (transplant “donor coordinators”).[256] New discussions were on-going in 2011 but were finally abandoned, because no consensus was reached for a vote. The EC also relies on (private) organisations/associations for which it is a "more natural field" such as the Council of Europe and ETCO which will propose a certification course in Croatia in October 2012.

[256] https://webgate.ec.europa.eu/sanco/heidi/index.php/Heidi/Healthcare/Tissue,_cell_and_organ_transplants-#Council_of_Europe, Retrieved on 28-08-2012

The EC representatives furthermore proposed that a clear, common and shared definition of what would be elements for "accreditation systems for organ donation/procurement and transplantation systems" would be helpful. It is obvious that as long as this Priority Action lacks a clear operational definition, progress will be hard to make.

Final Remarks

This analysis clearly shows that the EC takes up an **active role concerning the Action Plan**. Apart from the **funding of projects and actions**, the EC primarily uses its **coordination mechanism**. The EC brings together expertise and authorities from all relevant Member States and involves them in the Action Plan. For this the EC employs a **wide array of strategies**, not only the meetings of the Competent Authorities, but also expert meetings, working groups,, the development of manuals or toolbox journalists workshops, participation in Conferences. The EC relies on volunteers within the CA group and national experts. An obstacle for some Priority Actions is the applicability of Priority Actions because of differences in national realities and the lack of resources and staff.

Another important EC instrument is to **facilitate research on organ donation and transplantation**. This research has been supported in successive EU Framework Programmes for research and innovation. Most recently, the Health programme of the Seventh Framework Programme for Research and Technological Development (FP7, 2007-2013) launched a specific call for proposals entitled 'Innovative approaches to solid organ transplantation' (HEALTH.2012.1.4-1). As a direct result, five research projects on topics such as widening the donor pool, improving outcome of organ transplantation and preventing infection are now in the start-up phase and will receive a total EU financial contribution of around EUR 26.6 million. Other projects relating to transplant activities are also funded. The Commission proposal for "Horizon 2020", the Framework Programme for Research and Innovation (2014-2020) envisages further support to the organ transplantation research field.[257]

Means within the EU and of countries however are not infinite. For all Priority Actions, initiatives were found that contribute. But for most Priority Actions it was impossible to determine whether or not enough was done and whether or not the goals that are set will eventually be reached. In order to make more effective use of the EC instruments, it would be worthwhile to formulate more pronounced priorities, so that EC activities can be better channelled to those priorities. Of course this will be a near-impossible task, because of the diversity between priorities of individual Member States and their autonomy. Nevertheless, it would be a great help if some priorities could be formulated.

[257] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0811:FIN:en:PDF

3.3 Organisations and collaborating initiatives in the field of organ donation and transplantation

In this chapter, important organisations and collaborating initiatives in the field of organ donation and transplantation are described. The selection of organisations and collaborating initiatives is based on the tender specifications as formulated by the Commission (end 2011), therefore cooperation fields should be described, but other, more recent initiatives might also be missing.

The Council of Europe

The Council of Europe was founded in 1949 by ten countries. Nowadays it covers the entire European continent, with 47 member countries. The Council of Europe seeks to develop common and democratic principles in order to protect the individual. More specifically, its objective is to protect human rights, democracy and the rule of law, promote awareness, find solutions for European societal problems, and consolidate democratic stability.[258] One of the subjects the Council of Europe addresses is organ donation and transplantation with regard to human rights and prevention of commercialisation of organs. In this field, the Council of Europe adopted the first Resolution in 1978 aimed at establishing legislation for a better protection of donators and recipients while encouraging progresses in science and medical therapy.

In 1987, the Council of Europe set up the Select Committee of Experts on organisational aspects of cooperation between countries on organ transplantation (SP-CTO), which seeks to prepare recommendations for the Committee of Ministers. This Expert Group is now called Council of Europe Committee (Partial Agreement) on Organ Transplantation (**CD-P-TO**) and works under the European Directorate for the Quality of Medicines & Healthcare (EDQM). The CD-P-TO continues its work on ethical and organisational aspects.[259] One important activity of the CD-P-TO is the publication of the Transplant Newsletters, in collaboration with the Spanish CA (Organización Nacional de Trasplantes, ONT), which gives international numbers and figures on organ donation and transplantation (Council of Europe, 2011).

In 1997, the Council of Europe adopted the **Oviedo Convention**, aimed at protecting the human being in his dignity and identity and to guarantee anybody without discrimination the respect of his integrity and other fundamental rights and liberties concerning the application of biology and medicine. The Convention has an **additional protocol on organ donation and transplantation**, which bans any financial aspect. In addition, the Council of Europe has organised the **European Organ Donation Day (EODD)** since 1998, hosted every year in a different European countries. Since then, many Donation Days were organised, also resulting in an EU-funded project formulating guidelines for the organisation of Donation Days, including statistical methods to measure its awareness-raising potential and examples of activities to organise (Avsec, 2011).[260]

The Council of Europe is deeply involved in the development of policies concerning organ donation and transplantation in countries of the **Black Sea Area**[261] (Armenia, Azerbaijan, Bulgaria, Georgia, Moldova, Romania, Russian Federation, Turkey and Ukraine – some of them being also EU countries or EU neighbouring/candidate countries). Furthermore, the Council of Europe made a recommendation to Member States on **Organ Trafficking**, adopted by the Committee of Ministers on

[258] http://www.coe.int/aboutCoe/index.asp?page=nosObjectifs&l=en, Retrieved on 18-07-2012

[259] http://www.edqm.eu/en/organ-transplantation-work-programme-72.html, Retrieved on 18-07-2012

[260] http://ec.europa.eu/health-eu/newsletter/80/newsletter_en.htm#8, Retrieved on 18-07-2012

[261] http://www.edqm.eu/en/organ-transplantation-projects-1452.html, Retrieved on 18-07-2012

19 May 2004 at the 884th meeting of the Ministers' Deputies, and another recommendation in 2005 about the **role of transplant donor coordinators**.[262] [263] [264]

The collaboration between the Council of Europe and the European Commission is strong and consists of **mutual presence at key events and joint development of projects**. According to Commission Implementing Decision 2011/C358/06, the Council of Europe receives annually from the European Commission for a direct grant for activities in the field of "Substances of Human Origin", including organ donation and transplantation, but also blood transfusion and tissues&cells transplantation. The work of the Council of Europe does not correspond to a specific Priority Action in particular, however it can be linked to objectives in Priority Action 4 (EODD), 5 (listing of non-residents on waiting lists), 7 (organ trafficking), 9 (Guides, expanded donors) and 10 (CoE reflection about qualification and training).

The World Health Organization (WHO)

The WHO works within the United Nations system since 1948 and it coordinates, directs and provides leadership on global health matters. More specifically, it helps setting the research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring health trends. In the field of organ donation and transplantation, the WHO focuses on **ethical aspects**, aiming at condemning the sale and purchase of organs.

In 1991, the WHO adopted a resolution (WHA 44.25) which consists of **Guiding Principles with regard to organs and tissues**. The Guiding Principles address voluntary donation, non-commercialisation, the preference for using deceased organs over organs of living donors, and the preference for genetically related over non-related donors. The Guiding Principles have a great influence on professional codes and legislation, but do not directly focus on safety concerns.[265] In 2004, the WHO adopted a resolution aimed at collecting and examining data on practices, safety, quality, efficacy, epidemiology and ethical issues of organ donation and transplantation, in order to update the Guiding Principles. Several initiatives were taken up in response; several experts and representatives of health authorities and scientific and professional societies were consulted by organising a working group. Furthermore, the Global Knowledge base on Transplantation (GKT)[266] was launched in 2006 as a tool to monitor activities and practices in transplantation and to encourage transparency at a global level (Alliance-O, 2007). The World Health Assembly (the decision-making body of the WHO) urged Member States to take measures to protect the poor and vulnerable from **transplant tourism** and to address the wider problem of **international trafficking of human organs and tissues**. In response to this, concerned by the problems the WHA addressed, representatives from different societies in the field organised a meeting in 2006. During the meeting the idea of developing a formal Declaration was conceived, aimed at inspiring and uniting countries engaged in fighting unethical practices in organ transplantation. A Steering Committee was convened which laid the basis for the 2008 Istanbul Summit. The Summit goals were to draft a final Declaration defining organ trafficking, transplant tourism and commercialism, and to achieve consensus on principles of practice and recommended alternatives to address the shortage of organs.

[262] https://webgate.ec.europa.eu/sanco/heidi/index.php/Heidi/Healthcare/Tissue,_cell_and_organ_transplants#Council_of_Europe, Retrieved on 18-07-2012

[263] All recommendations of the Council of Europe can be found at: https://webgate.ec.europa.eu/sanco/heidi/index.php/Heidi/Healthcare/Tissue,_cell_and_organ_transplants#Council_of_Europe.

[264] http://www.edqm.eu/en/organ-transplantation-reports-73.html, Retrieved on 18-07-2012

[265] http://www.who.int/ethics/topics/human_transplant/en/, Retrieved on 18-07-2012

[266] http://www.who.int/transplantation/knowledgebase/en/, Retrieved on 18-07-2012

In 2008, more than 150 representatives of scientific and medical bodies from 78 countries around the world, came together to agree and work on the draft of the **Declaration of Istanbul**. Working groups were assigned to develop the various components of the Declaration and the results of their meetings were presented at plenary sessions for approval. The Declaration of Istanbul was published on the 5th July, 2008 in the Lancet. After that, it has been published in various medical journals and was translated into many languages.[267]

In 2010, a meeting with 140 representatives of international scientific and medical bodies, government officials and ethicists was organised by the World Health Organization, The Transplantation Society (TTS), and the Spanish National Transplant Organization ONT (Organización Nacional de Trasplantes), and supported by the European Commission. The purpose of this Third Global Consultation was to call for a worldwide mission to satisfy organ donation and transplantation needs, based on resources within countries and regulated by ethical, regional, or international cooperation, when needed. The Guiding Principles of the WHO and the Declaration of Istanbul were leading during the consultation. As a result, the **Madrid Resolution** was adopted, which expresses both an assertion to progress in satisfying organ donation and transplantation needs, and a roadmap of how this may be achieved.[268]

In 2010, the **NOTIFY project** (Exploring vigilance notification for organs, tissues and cells) was initiated by the WHO and the Italian CA in charge of Organs, but also Tissues&Cells transplantation (National Transplant Centre, CNT) as a joint venture. The **SOHO V&S project** (Vigilance and Surveillance of Substances of Human Origin), which is co-funded by the EU, participated in the NOTIFY project. The project was aimed at providing a global interface for the vigilance and surveillance of substances of human origin (tissues and cells for transplantation and for assisted reproduction). More than 100 experts gathered documented cases of adverse reactions and events which were used to develop guidance for treating physicians on detection and confirmation of adverse reactions and events. This resulted in a database with vigilance information, which will be made publicly available on the NOTIFY website (under development at the time of this study). It will be updated and provide a reference to types of adverse reactions and events and their causes, and is intended to stimulate collaboration for institutions and organizations on vigilance and surveillance. The database also resulted in a number of didactic papers, addressing infections, malignancy, errors, genetic transmission and more. In 2011, a meeting with experts from 36 countries, including non-European countries, was organised to seek agreement on priorities and continuation of the development of global vigilance and surveillance for organs, tissues and cells.[269] In 2012, the EC took part in a meeting organised by CNT for the NOTIFY initiative, thus ensuring a consistent approach on this global issue.

Another project launched by the WHO is the **SONG project**, in collaboration with the International Council for Commonality in Blood Banking Automation (ICCBBA). The SONG project is aimed at providing a nomenclature for organ transplant products in order to provide a framework and coding system to describe organ transplants and to improve traceability, vigilance, surveillance and activity reporting. The nomenclature is developed during meetings between experts, who agree on relevant categories, important characteristics of different organs, and structuring all the information. The first meeting took place in 2011. The framework created during the meeting, is proposed to stimulate a

[267] http://www.declarationofistanbul.org/index.php, Retrieved on 18-07-2012

[268] http://www.tts.org/index.php?option=com_content&view=article&id=746:the-madrid-resolution-on-organ-donation-and-transplantation&catid=67:august-2010-newsletter&Itemid=565, Retrieved on 18-07-2012

[269] http://www.declarationofistanbul.org/index.php, Retrieved on 18-07-2012

discussion within the organ donation and transplantation community.[270]

According to the EC representatives, collaboration between the WHO and the European Commission in the field of transplantation is regular but limited for the moment. WHO representative are always invited to CA meetings to inform and be informed on on-going initiatives. The most important topics addressed are organ trafficking, the WHO South-Eastern European Health Network[271] (SEEHN - which has a strengthened cooperation in the field of organ donation a transplantation), tissues and cells as well as organs transplantation. The WHO is a partner in several projects on organ donation and transplantation funded under the Health programme. The work of the WHO is broad generally speaking, but not so broad when related to organ transplantation. It can be linked to P.A.7, especially regarding the topic of organ trafficking.

ESOT: European Society for Organ Transplantation

The European Society for Organ Transplantation (ESOT) was founded in 1982.[272] [273] ESOT aims to become the professional society and umbrella organisation under which all European transplant activities are dealt with. ESOT is a scientific and not-for-profit society with the objective to exchange knowledge about organ donation and transplantation, and to improve the health and well-being of patients suffering from (end-stage) organ diseases. ESOT cooperates with many transplant organisations to tackle these transplant activities in Europe, from a scientific perspective. Furthermore, it provides education programmes and develops best practice guidelines in the field of organ transplantation, made possible by the work of voluntary specialised professionals. ESOT is registered as a charity ("Algemeen Nut Beogende Instelling": ANBI) in the Netherlands.

ESOT is divided into **six sections:**

- ELITA for liver and intestines,
- EPITA for pancreas and islets,
- The Thoracic Committee in conjunction with the ESHLT on heart and lungs,
- ELPAT for ethical, legal and psychosocial aspects of organ transplantation (joined in 2008),
- The Kidney Committee for kidney transplantation,
- The European Donation Committee/European Transplant Coordinators Organisation (ETCO; joined in 2011) is the Society's donation and procurement section.[274]

ELITA, EPITA, the Thoracic Committee and the Kidney Committee all focus on providing a scientific forum with the aim to exchange information on the specific subject they focus on.

The **European Transplant Coordinators Organisation (ETCO)** was set up in 1983 with the goal to represent transplant donor coordinators around the world and to promote organ and tissue donation in all member countries. ETCO also provides a forum in which skills, experience, work and research can be shared.[275] Every two years ETCO organises the European Organ Donation Congress, in which scientific research is disseminated. Furthermore, ETCO continuously provides trainings and education such as workshops and symposia (Maio, 2011). ETCO also has an official journal, named

[270] http://www.who.int/transplantation/tra_song/en/index.html, Retrieved on 18-07-2012

[271] http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/public-health-services/south-eastern-europe-health-network-seehn, Retrieved on 18-04-2013

[272] http://www.esot.org/Content.aspx?item=65, Retrieved on 18-07-2012

[273] http://www.esot.org/Content.aspx?item=66, Retrieved on 18-07-2012

[274] http://www.esot.org/Content.aspx?item=12, Retrieved on 18-07-2012

[275] http://www.europeantransplantcoordinators.org/, Retrieved on 18-07-2012

'Organs, Tissues & Cells'.[276] ETCO merged with ESOT Donation Committee in September 2011.[277]

According to the EC representatives, the direct collaboration between ESOT and the European Commission as such is limited but it might be strengthened if ESOT applies for and obtains Conference grants via the EU Health Programme (like for the DCD Congress organised in February 2013 in Paris, ESOT expressed the wish to apply for a grant for the next Conference in 2014 or 2015). So far this cooperation mainly consists of (ESOT) experts' input in EU-funded projects (therefore managed by the projects' coordinators) regarding for example topics such as alternative donors or ethical/legal/psychosocial aspects (ESOT's ELPAT Conferences where funded twice via the EU Health Programme). ESOT is well represented among national representatives of CAs or in the board of Eurotransplant, therefore collaboration goes practically through official channels (CA meetings) and projects such as Train the Trainers or ELPAT Conferences.

ESOT and its sections contribute to Action Plan in many ways. First of all, with their dissemination of research and promotion of organ and tissue donation, they contribute to Priority Action 4, on improving the knowledge of health professionals and patient support groups. Besides, it also contributes to improving the level of information for the public (sub-action 4.1). Furthermore, ESOT provides numerous trainings and courses for health professionals, which contribute to sub-action 4.2. By providing certificates and diplomas for these trainings and courses, it also contributes to promoting a common accreditation scheme for organ donation and procurement, and transplantation programmes (Priority Action 10). ESOT's donation and procurement section (marged with ETCO), which is mainly focused on transplant donor coordinators, directly contributes to Priority Action 1, which is focused on promoting the role of transplant donor coordinators. ETCO also put effort into promoting the establishment of internationally recognised standards for transplant donor coordinators (sub-action 1.2), training programmes for transplant donor coordinators (sub-action 1.3), and providing certificates and diplomas for the establishment of international accreditation schemes for transplant donor coordinators (sub-action 1.4). The latter also relates to Priority Action 10, which deals with the promotion of a common accreditation scheme for organ donation/ procurement, and transplantation systems.

Eurotransplant

As a service-provider entrusted by the relevant national Ministries of Health, Eurotransplant International Foundation is a non-profit service organisation responsible for the allocation of donor organs in seven European countries (soon eight): Austria, Belgium, Croatia, Germany, Luxembourg, the Netherlands and Slovenia, covering over 124 million inhabitants (and from Mid 2013 probably also Hungary which joined for a test phase in 2012).[278] [279] It was founded in 1967.[280] The main target of Eurotransplant (ET) is to ensure an optimal use of available donor organs. More specific goals are to reduce the loss of donor organs, to obtain better outcomes of transplantation by matching donor tissue characteristics, to help in cases of high urgency and to provide solutions for special groups such as children, elderly patients and highly immunised patients. The allocation system is based upon medical and ethical criteria. All transplantation centres within ET countries have access to a central computer database. In this database, the transplantation centres enter the general and medical

[276] http://www.organsandtissues.net/, Retrieved on 18-07-2012

[277] http://www.esot.org/Content.aspx?item=319, Retrieved on 18-07-2012

[278] http://www.eurotransplant.org/cms/index.php?page=about_brief, Retrieved on 18-07-2012

[279] http://www.efretos.org/Partners.aspx, Retrieved on 18-07-2012

[280] http://www.eurotransplant.org/cms/index.php?page=about_brief, Retrieved on 18-07-2012

information of their recipients along with the recipient profile and the donor profile. Accordingly to principles agreed by type of organ within specialised sections, these profiles can be used to make the best possible match between donor and recipient. Through conducting and facilitating scientific research, Eurotransplant aims at a constant improvement of transplant outcomes.[281] Eurotransplant participates in several EU-funded projects, such as EFRETOS (main coordinator) and FOEDUS (coordinator of the work package on bi- and multilateral agreements) and is continuously developing new projects. As the existence of such an "European Organ Exchange Organisation" (EOEO) is now foreseen under the Organs' Directive (article 21), and as ET was entrusted by some Member countries to fulfil some of the tasks of a Competent authority, the collaboration with the European Commission is frequent and good. It mainly consists in the participation in CA meetings, working groups and EU-funded projects as well as in input at these meetings, projects, policies and legal developments. This is required as several MS views are linked with ET. The following topics are addressed: implementing legislation on cross-border exchange of organs, Joint Action on cross-border exchange (FOEDUS, 2012), follow-up recipients post-transplant (EFRETOS and other), WG indicators (Questionnaire EC).

Eurotransplant as an exchange organisation directly contributes to Priority Actions 5, 7 and 8, which are about the identification of organ donors across Europe and cross-border donation in Europe (5), EU-wide agreements of transplantation medicine (7) and the interchange of organs between national authorities (8). Within its geographical scope and through its involvement in EU-funded projects, it also contributes a.o. in the discussions in/with input for Priority Actions 9 (evaluation of post-transplant results), 10 (accreditation system), 2 (quality improvement programmes). It should be noted that Eurotransplant works primarily in the field of deceased donation.

Scandiatransplant

Scandiatransplant (SKT) is a Nordic organ exchange organisation founded in 1969, which covers a population of 24.5 million inhabitants in five countries, namely Denmark, Finland, Iceland, Norway and Sweden. At the time of this study, Scandiatransplant includes a cooperation of all 12 Nordic transplant centres in addition to eight immunology laboratories. It aims to facilitate and improve the exchange of organs and tissue between the transplant centres within the participating countries, to control a central database, to contribute to promoting the provision of human organs and tissue for transplantation, and to support scientific activities (Höckerstedt, 2012).[282] Scandiatransplant participates in several EU-funded projects, such as EFRETOS or ACCORD. According to the EC representatives, the collaboration with the European Commission is good and consists in the participation in CA meetings and working groups and in inputs into meetings, projects, policies and legal developments, required as several MS views are linked with Scandiatransplant. The following topics are addressed: implementing legislation on cross-border exchange of organs, living donation, WG indicators.[283]

Scandiatransplant is comparable to Eurotransplant as an exchange organisation, and also directly contributes to Priority Actions 5, 7 and 8, which are about the identification of organ donors across Europe and cross-border donation in Europe (5), EU-wide agreements of transplantation medicine (7) and the interchange of organs between national authorities (8). Within its geographical scope and through its involvement in EU-funded projects, it also contributes a.o. in the discussions in/with input

[281] http://www.eurotransplant.org/cms/index.php?page=aims, Retrieved on 18-07-2012

[282] http://www.scandiatransplant.org/history.htm, Retrieved on 18-07-2012

[283] ACTOR questionnaire EC representatives

for Priority Actions 3 (living donation), 9 (evaluation of post-transplant results), 10 (accreditation system), 2 (quality improvement programmes). As Scandinavian countries are very developed regarding living donation, it should be noted that Scandiatransplant is involved in the field of deceased donation and living donation (both are captured in Scandiatransplant IT-tool).

Southern European Transplant Alliance

A new initiative is the Southern European Transplant Alliance (SAT), which was signed on 1st October 2012 between Spain, France and Italy (official cooperation between the three CAs, also open in the future to other countries). In the CA meeting of March 2013 in Brussels, SAT asked for, and obtained the same status than Eurotransplant and Scandiatranplant. The objective is to develop common strategies and practical solutions for difficult-to-treat patients and specific/specialised programmes.

Some others organisations cooperating with the Commission/CAs at EU level can also be mentioned, even if there is no direct, systematic cooperation, but merely an ad-hoc mutual exchange of information, depending on the agenda of the CA meetings

Donor Action

Another organisation active at European level in the field of organ transplantation is Donor Action. Donor Action is a foundation founded in 1998, it is based in Belgium, with a satellite office in Switzerland. Donor Action provides the Donor Action Program, a quality management program designed to increase the identification of organ donors and to maximise a hospital's donation potential. It aims to indicate where and when in the process of organ donation potential donors are missed; to highlight problem areas and staff training needs; and to provide remedial measures that can be adapted to local hospital conditions.[284] Donor Action took part in the "stakeholders meetings" organised by the European Commission for consultation before the adoption of the Action Plan, and regularly sends the Donor Action Newsletter (Questionnaire EC).

European Kidney Health Alliance

The European Kidney Health Alliance (EKHA) is an alliance of not-for-profit organisations who represent key stakeholders in kidney health issues in Europe (different professional societies, nephrologists, transplant surgeons, but also nurses' associations and patients' associations). EKHA takes a multidisciplinary approach involving patients and their families, doctors and nurses, researchers and other healthcare professionals who work cooperatively with the aim to decrease the prevalence and incidence kidney disease and its consequences.[285] The EKHA promotes epidemiological research and public health initiatives, access to the best possible treatment for patients, appropriate education and social support for patients, and state-of-the-art clinical investigation and basic research related to kidney diseases.[286] The EKHA approached the EC officers in charge of organ transplantation in 2011 and, based on their proposal, assisted in finding a living donor and a recipient to give a testimony during the 2011 Journalist Workshop on Organ Donation and Transplantation. Afterwards, EKHA organised in March 2012 at the European Parliament an event linked to the World Kidney Day and focused on kidney transplantation, with patients' testimonies too (Questionnaire EC). EKHA, regularly invited to the European Parliament thanks to the "Group for kidney health" chaired by a Member of the European Parliament (MEP), keeps the Commission informed of its activities.

[284] http://www.donoraction.org, Retrieved on 18-07-2012

[285] http://www.ekha.eu/index.php, Retrieved on 18-07-2012

[286] http://www.ekha.eu/htmldocs/ekha/4-16/ekha/kidney_health_disease.html, Retrieved on 18-07-2012

European Association for the Study of the Liver

The European Association for the Study of the Liver (EASL) is an organisation focusing in science and educational programmes of the liver. It organises the International Liver Congress, encourages initiatives to organise conferences, provides a forum for basic and clinical education of young professionals, coordinates the generation of clinical guidelines, and tries to place liver diseases and research on political policy agendas (for example events organised at the European Parliament).[287]

Final Remarks

Activities of many other European and national associations or (professional) societies could have been mentioned here, as they are in a way contributing/complementary to the Action Plan. However, they focus more on research than on public health and are mainly active via national channels; in addition there are no direct or systematic interaction with the groups of CAs or the Commission, therefore they were not described here.

On the institutions described here: the activities of the **Council of Europe and the WHO** provide an important context and general frame for the Action Plan. They provide a common ground of norms and principles regarding organ donation that is shared by many countries, such as the Oviedo Convention, stressing the ethics and fundamental rights of all people and the 'Guiding Principles', stressing issues like the voluntary character of donation and non-commercialisation. As main European society in this field, **ESOT** plays a central role in the process of acquiring, disseminating and applying knowledge on organ donation. Within ESOT and other organisations, the professional societies play a central role in developing and sharing scientific knowledge, at European level but also via national channels. **Eurotransplant** and **Scandiatransplant** play a central role in the exchange of donor organs, but also as a source of expertise, representing the participating countries, and **SAT** as a new actor complement the European map.

3.4 Conclusion

The Action Plan, as a voluntary tool, is well embedded and supported by a **rich and diverse network of actors** that provide ethical frameworks and legal principles, projects, actions, expertise and experts. With the EU instruments on funding, initiatives from professionals, experts and policy makers can be supported. This instrument has been used widely, with initiatives ranging from acquiring the necessary knowledge base to initiatives that focus much more on knowledge sharing. A new element that has been put on this agenda is how to make these projects work for the new EU Member States. The EC undertakes a wide variety of more direct actions through their coordinating instrument. However, Member States differ in how the process of organ donation is organised and in the issues they have to tackle. These differences are in some cases rather large: some countries have a tightly monitored and well developed system of organ donation and still they are faced with a wide gap between the demand for donor organs and their supply. In other countries a system for organ donation is still being set up. These countries also face the discrepancy between the need for donor organs and their availability. The practical problems they face, however, are different and in many cases quite unique.

This diversity can serve as a **rich source for mutual learning**. This source is used extensively: twinning projects are organised and knowledge and practical solutions are shared. This diversity may also have led to the rather open formulation of the Priority Actions. This open formulation allows for the diversity and at the same time also provides a focus. Now that the Action Plan is at its mid-term, a reconsideration of the Priority Actions aiming at defining more precise priorities, may where possible help in focussing the energy and means on those issues that are considered to be most important. The challenge both for the EU and for the countries will be to find a suitable answer to the diversity issue, through projects and supportive actions that take these differences into account.

[287] http://www.easl.eu/_about-easl/vision-and-mission, Retrieved on 19-03-2013

4 Conclusions and recommendations

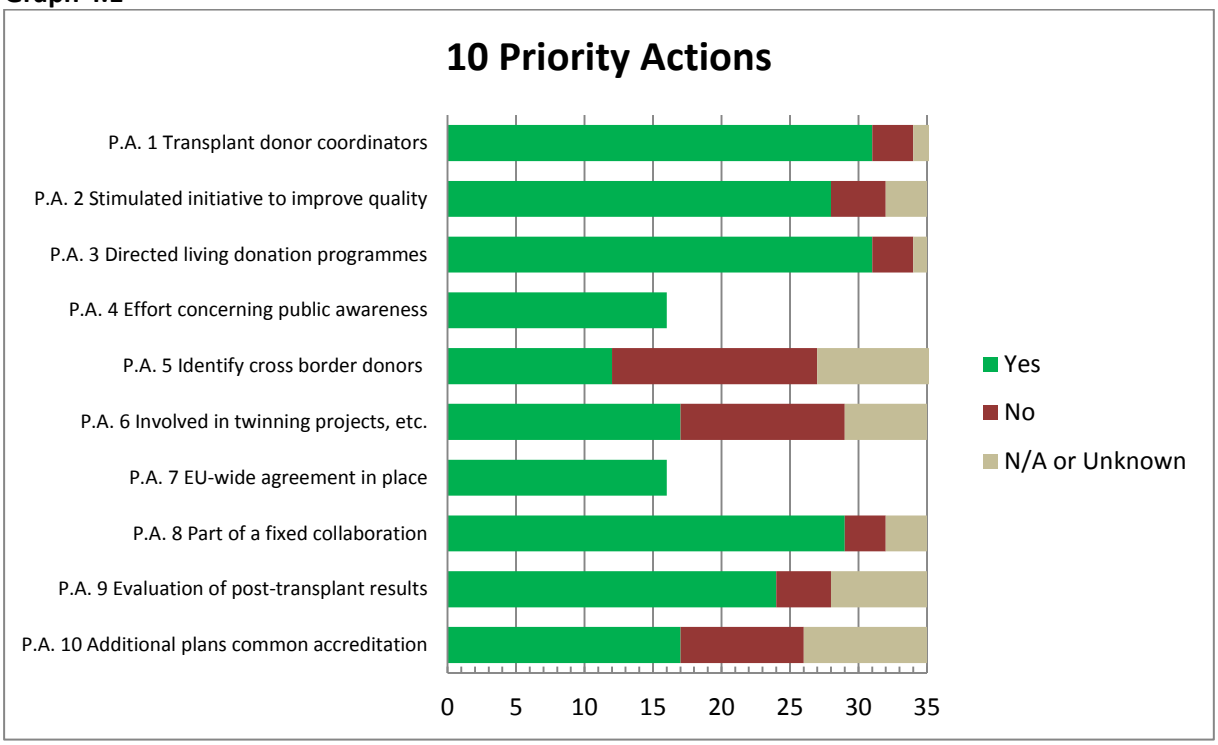
4.1 Introduction

The ACTOR study aims to provide the European Commission, the national Competent authorities (CAs) and the European Transplant Community, with an overview of efforts that have been made during the first-half period of the "*Action Plan on Organ Donation and Transplantation* (2009-2015): *Strengthened Cooperation between Member States*". This Action plan was set up as a non-binding instrument, complementary to the EU legislation adopted in July 2010 and established in accordance with article 168, §2 of the Treaty on the functioning of the European Union (TFEU). The Action Plan is a tool to address the shortage of organs, to support transplant systems and to improve quality and safety. In this study, it is analysed to what extent activities related to the various Priority Actions in the Action Plan have been carried out. This has been done for 35 countries (all EU Member States as well as Iceland, Norway, Croatia, Macedonia (fYRoM), Switzerland, Turkey, Liechtenstein and Montenegro) and at the European level. In this chapter all findings are summarised. In addition, recommendations are made for further implementation during the second half-period of the Action Plan.

4.2 Country activities related to Priority Action: conclusions and recommendations for each Priority Action

A difference exists in the degree to which countries have undertaken activities related to the various Priority Actions, as can be seen below. For the ten Priority Actions it was assessed whether individual countries undertook at least some activities. These are indicated with the green bars in Graph 4.1.

Graph 4.1[288]



[288] For the key indicators for P.A. 4 and 7 it was not possible to adequately distinguish between the answers No / No, not yet, N/A and Unknown, therefore only the number of countries that have at least implemented one effort are presented.

Activities that have been taken up <u>by almost all countries</u> (29 or more out of 35)
Activities related to Priority Actions 1 (transplant coordinators), 3 (living donation) and 8 (exchange of organs) have been taken up, be it in different ways, by almost all countries. This does not mean that these countries have no more work to do on these issues. Almost all countries have taken up certain activities, but for each of the Priority Actions more progress can be made. Bringing these actions one step further is therefore likely to be welcomed by many countries. EU-funded projects reflect the state of these Actions: many countries are involved and efforts go further than providing insight and sharing knowledge, they aim at implementation.

Priority Action 1 is about promoting the role of transplant donor coordinators in every hospital where there is potential for organ donation. On the whole, data show that almost all countries appoint transplant donor coordinators. Not all countries have transplant donor coordinators installed at hospital level however, as is encouraged by the Action Plan. Also countries differ in the professional background of their transplant donor coordinators. A large majority of the Competent Authorities (CAs) report that there is specific training for transplant donor coordinators, but a smaller number of CAs indicate that these trainings have been tested for effectiveness. Last, a minority of the CAs say that they use a national or international accreditation scheme to qualify transplant donor coordinators. These are Germany, Spain, United Kingdom, Greece, Montenegro, Norway, Portugal and Slovenia. Other countries may benefit from their experience in this field. Some CAs stated not to have appointed transplant coordinators. These are Hungary and Macedonia. They may benefit from the experience of other countries. CAs participating in the focus group discussion[289] stressed the importance of precisely defining the role of transplant donor coordinators and profile in each country, together with the need for continuous training and education. The EC might consider further support of these training courses, as was suggested by some member states. In addition, the need for more quantitative data was stressed.
Several EU-funded projects (a.o. ETPOD, Train the Trainers) have been active that support this Action, they aim or aimed at providing training, sharing of knowledge, implementation, development of tools and at identifying the best organisational models. Direct efforts from the EC on this Priority Action are limited to funding, communication and coordination. Within the Working group on Deceased donation, a manual with guidelines on how to set-up a transplant donor coordination system was prepared by volunteering Member States: Belgium, France, Italy, Portugal, Spain, Sweden and the United Kingdom. This manual may help to further this Priority Action. It is subsequently up to the individual countries to take inspiration from those examples that best fit their own national realities.

Priority Action 3 deals with the exchange of best practices on living donation programmes among EU Member States. Virtually all CAs indicate that they have living donation programmes with related donors, with the exception of Bulgaria, Latvia and Montenegro. For some countries living donation is almost as important as deceased donation (only for the Netherlands living donation is more important than deceased donation). Substantially fewer CAs report that they have living donation programmes with unrelated donors. A small majority of the CAs say that independent bodies that evaluate living donors exist in their country. These are Belgium, Switzerland, Czech Republic, Germany, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Italy, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Turkey and Sweden. In addition, organ trafficking is said to be prohibited in almost all countries. Finally, in about half of the countries registers to evaluate and guarantee the health and safety of living donors are known to have been established. Living donation always involves a certain degree of risk for the donor. It is therefore vital that all countries start setting up registers and start monitoring the health and safety of the living

[289] A web based focus group discussion was held with CAs based on a first presentation of the results of this study, 11 CAs participated

donors over a longer period. This need has been translated into Directive 2010/53/EU, which states that "Member States shall ensure that a register or record of the living donors is kept, in accordance with Union and national provisions on the protection of the personal data and statistical confidentiality". Based on outcomes of previous EU-funded projects such as EULID and ELIPSY, in the ACCORD project Member States will be further supported in their efforts to set-up and fill in registers. The importance to protect and care for the living donor was also stressed by several of CAs who participated in the focus group discussion. EU-funded projects (EULID, ELIPSY, but also COORENOR, EULOD and ELPAT conferences) have helped to provide the necessary background, legal and ethical, to be able to draw up the directive on the Action, make preparations for a living donor register, knowledge exchange and information for potential donors. All different aspects are brought together in one document by the Working Group on Living Donation. It is noticed that the setup of registries is not only an obligation of Member States, but also a potential instrument to build up an evidence base about the consequences of organ donating during lifetime.

Priority Action 8 aims to facilitate the interchange of organs between National Authorities. A large majority of the CAs report they are part of at least one fixed collaboration with other countries. Eight EU countries are member of Eurotransplant, which centrally allocates organs that become available, and five Scandinavian countries allocate organs with the support of Scandiatransplant. In addition, a new Alliance (SAT) among three Southern European countries for similar purposes. Overall, more than half of these CAs indicate that patients with urgent needs are included in fixed collaborations. About one third indicate that paediatric patients are involved and a few CAs mention that they include older patients, patients with rare HLA-patterns or other special patient groups. Not all of these collaborations concern all types of patients and all kinds of organs, several are restricted to specific patient groups or organs. Exchange of organs for difficult-to-treat patient groups or non-allocated organs is of vital importance. Whatever can be done to stimulate this process should be considered: broadening the scope of collaborations to more patient groups and organs would be one of these. Less than half of the countries are known to have offered non allocated organs to other countries. Subsequently a limited number of CAs report that their country evaluates procedures for offering non allocated organs to other countries. Last, less than one third of the CAs report participation in at least one IT-tool for the facilitation of cross-border organ exchange. Regarding the effectuation of organ exchange it seems that some steps still have to be taken. The first thing would be to support those countries that do not yet have such a supporting IT-system in place and make such a tool available to them. Such initiatives are on their way and should be stimulated. An IT-tool was developed in the context of the COORENOR project. The follow-up of this project, FOEDUS, aims (among other things) to make this tool available to other countries and to test it for effectiveness. FOEDUS is a Joint Action in which many countries (23) will participate, which makes this a project with high expectations, regarding the IT-tool to exchange organs, but also the three other core work packages: bi- and multilateral agreements, scientific consensus on the information to be exchanged with the organ, and communication aspects for donation from nationals and non-nationals. For this Action, the EU has a legal mandate limited to cross-border exchange of organs, however with the adoption of Directive 2012/25/EU in October 2012 harmonised rules are being established to exchange information about these organs (deadline for transposition into national laws: April 2014). This technical Directive will not directly help to have more organs harvested or exchanged, but should facilitate the exchange of information when organs are exchanged.

Actions that have been taken up <u>by most countries</u> (17 to 28 out of 35 countries)

Priority Actions 2 (quality improvement programmes), 6 (organisational models) and 9 (post-transplant results) have been taken up by most countries. This means that for these Priority Actions there is a great potential for mutual learning through an exchange of experiences. For these Priority Actions, twinning activities may be of special relevance, since many countries have experience with these actions, and several others do not. In the focus group discussion, the importance and impact of

twinning activities were stressed. Also the need for a solid organisation of the donation process within individual countries was stressed. This may also imply the allocation of enough time and facilities to those involved professionals. EU-funded projects focus mainly on providing insight and sharing knowledge and not on implementation, except ODEQUS which will provide in September 2013 quality criteria and quality indicators designed for and tested at hospital level. These ODEQUS tools will therefore be timely available to support the implementation of the "quality and safety framework" explicitly foreseen in the Organs' Directive 2010/53/EU.

Priority Action 2 is about the promotion of Quality Improvement Programmes in every hospital where there is potential for organ donation. A majority of the CAs report that their government has stimulated initiatives to improve the quality of at least one aspect of the organ donation process. The majority of countries also stimulated initiatives for Quality Improvement Programs for the identification of potential donors and the donation and procurement processes. However, fewer CAs report such initiatives on the transplantation process and follow-up care. A large minority of countries reported to have taken up initiatives on all of these issues. These are Cyprus, Czech Republic, Germany, Spain, France, United Kingdom, Greece, Italy, Lithuania, Montenegro, The Netherlands, Norway, Poland and Turkey. Thus it would seem that the next step should be to stimulate other countries to also take up these topics. EU-funded projects have supported this Priority Action by providing insight in the current state of affairs, by training on quality indicators and by knowledge sharing, and, for the countries involved in the ODEQUS project described above, by testing and implementing quality criteria and indicators defined at hospital level. It should be considered that how individual countries implement quality improvement programmes is their responsibility, in function of their local organisation of medical care. But, it seems that more benefits might be obtained when countries that have experience with quality improvement of the transplantation process and follow-up care would be enabled to share these experiences with others. Twinning projects and large scale Joint Actions might be beneficial. The direct EC mandate for this Priority Action is limited (however it is linked to the "quality and safety framework" foreseen in the legislation) and initiatives through the coordinating mechanism have been taken up. But it seems that several States consider this Priority Action more of a national issue than an EU one, which is correct since the organisation of health systems remain under national responsibilities. However, instruments developed within the ODEQUS project will be soon, in the CA meeting in September 2013, made available to all countries, involved those not involved in the project.

Priority Action 6 is about enhancing the organisational models of organ donation and transplantation in the EU Member States (here again, typically a domain of national responsibility, however exchanges of best practices is always possible and encouraged). Just over half of the CAs indicates that their country has been involved in twinning projects, peer reviews or similar projects. Furthermore, a small number of countries reported to have used structural funds and/or other Community instruments. A minority of CAs report that their country has transplantation centres or hospitals that participate in networks of centres of reference. The potential of learning from other countries for this Priority Action is therefore underused. Many countries participated in twinning projects, peer reviews or similar projects. These are Austria, Bulgaria, Cyprus, Czech Republic, Spain, Estonia, France, Croatia, Hungary, Ireland, Italy, Lithuania, Malta, The Netherlands, Slovakia, Slovenia and Turkey. The majority reported positive results, now or expected in the future. Learning from each other is a potentially strong strategy to improve the process of organ donation, especially considering the rich diversity in the EU. EU-funded projects (COORENOR, MODE, ACCORD, TAIEX grants) contribute to this Priority Action primarily through providing insight and sharing knowledge. The EU provides support through twinning projects, peer reviews and the use of structural funds. A knowledge gap seems to exist among CAs on the possible use of structural funds or other community instruments such as the EU Research Framework Programmes (FP6 and FP7), which are primarily used by Universities and Research consortiums, not necessarily involving – for the moment – the CAs,

Public Health authorities. Whether this is compensated through other channels is unknown, but it would be useful to fill this knowledge gap so more countries could use these instruments for the benefit of organ donation.

Priority Action 9 aims at the evaluation of post-transplant results. Systematically collecting and analysing post-transplant results will help to improve the quality of the donation and transplantation process. Collecting data is seen as relevant by nearly all countries as most of them indicate that they do analyse post-transplant results. These are Austria, Belgium, Bulgaria, Switzerland, Czech Republic, Germany, Spain, Estonia, Finland, France, United Kingdom, Greece, Croatia, Italy, Lithuania, Macedonia, Montenegro, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia and Turkey. It is however not clear whether results from different countries can be compared at European level (and maybe also at national levels: among regions or transplant centres).
A majority of the countries try to systematically collect post-transplant results in a database/register. With regard to the use of expanded donors, a majority of the countries accept donor organs from donors older than 60 and a substantial number of countries accept donors with diabetes mellitus, hypertension or renal insufficiency. Fewer countries accept donors with infectious diseases such as hepatitis and a few countries accept donors with HIV. These differentiated practices should be further compared and explored, keeping in mind quality and safety requirements.
The fact that not all countries use the same timeframe for the measurement of post-transplant results suggests variability in the structure and type of available data. This makes comparison difficult. For mutual learning it is essential to agree upon shared definitions and procedures for collecting and reporting such data. It would be advisable to work towards a shared data-model and subsequently to implement it, so country data can be compared in a valid way. This was the objective of the EU-funded EFRETOS project.
This Priority Action seems to have received considerable attention in EU-funded projects, implying that much effort is paid to get progress on this Action: much knowledge has been gathered and information has been shared. For this Priority Action, the stage is now set for the final phase: implementation and adoption by as many countries as possible. Still, EU representatives are aware of the sensitivity of this Priority Action and point to complex ethical issues and the issue of ownership of data.

Activities that have been taken up <u>by fewer countries</u> (from 10-17 out of 35 countries)
From graph 4.1 it becomes clear that fewer countries have taken up activities in relation to Priority Actions 4 (awareness-raising), 5 (cross-border donation), 7 (EU-wide agreements) and 10 (common accreditation system). This requires reflection. It appears that these Priority Actions have a shared characteristic. From the interactions with the CAs, it became apparent that for each of these Priority Actions the exact meaning was not always clear. General advice would therefore be to have a thorough discussion on each of these Priority Actions in order to come to better shared and more precise definitions of these Priority Actions. In order to work Priority Actions should be clear, based on a shared understanding of their relevance and their contribution to the main objectives of the Action Plan.

Priority Action 4 aims to improve public awareness and the knowledge and communication skills of health professionals and patient support groups on organ transplantation. With regard to efforts concerning public awareness, less than half of the CAs indicate that their country has undertaken one or more out of four efforts (communication guidelines for informing the public, periodic meetings with journalists, monitoring of mention in newspapers, monitoring of mention on TV). These are Belgium, Switzerland, Czech Republic, Spain, Finland, France, Greece, Croatia, Hungary, Italy, Lithuania, The Netherlands, Poland, Portugal, Slovenia and Turkey. Many countries, however, report

a variety of strategies to communicate about organ donation to increase awareness among their populations. Also, many CAs report that activities have been carried out with regard to improving knowledge and communication skills of health professionals, since about two-thirds of the CAs report that programmes are deployed for health professionals to improve these skills. Similarly two thirds of the CAs report that programmes are deployed to improve these skills of patient support groups. These two findings seem to contradict each other.

Apparently activities on this topic have been taken up by many countries, but perhaps not all in a very systematic way. A possible strategy to make progress on this Action may be to start developing national communication plans on organ donation. Such plans may benefit from the experience of countries with successful communication activities and from the expertise developed in the context of the European Donation Days and EU-funded EDD project. They may for example allow for ad-hoc actions and could contain strategies on how to react on 'bad publicity'. The EU-funded Joint Action FOEDUS which started in May 2013 has a specific work package focused on these aspects and will support national efforts in this direction.

Ample knowledge and experience to make such plans is available. Countries with a rich repertoire of communication activities might be able to come up with good strategies, allowing for creativity and local initiatives. Several projects have been funded to bring this Action further, also the organisation of European Donation Days, guided by the Council of Europe, should be mentioned. Different media should be used and the message should be brought with great care. It was said that such actions require investments that are scarce. Positive references were made to the FOEDUS project, which will as said have a Work Package dedicated to communication. It was also noticed that professionals may have different views on how to create public awareness. It is suggested that the participation of organisations of transplanted patients may help. Also DG SANCO organised journalist workshops directly leading to exposure in national newspapers and enabling to share experiences at the European level. This Priority Action is not one that can be finalised with a legal document or a quality system. It requires constant attention and creativity - also depending of the national context and culture - to use new media and come up with ideas to better reach the general public.

In conclusion, this Priority Action may benefit from a reconsideration of priorities. It might be considered to agree upon the development of national communication plans. Such plans may help to move this action into a more professional and effective direction.

Priority Action 5 aims at facilitating the identification of organ donors across Europe and cross-border donation in Europe. In many countries regulations are in place to clarify the legal position of non-residents as potential donors. Differences exist between countries regarding who can be a donor. A majority allows non-residents and residents with a foreign nationality to be donors, but fewer countries permit organ donation from illegal persons. Regarding criteria for admittance to waiting lists, a majority of the countries require residency in the country or being signed up with local social security or health care insurance, whereas local nationality is required in fewer countries. A majority of the CAs indicate that criteria for sending and receiving organs to and from other countries have been established and a majority of the CAs report that they identify potential cross-border donors when no suitable match can be found in their own country.
Lagging behind is the provision of clear information on this topic to European citizens. A minority of countries, Belgium, Cyprus, Czech Republic, France, Germany, Greece, Croatia, Hungary, Lithuania, Montenegro, the Netherlands and Slovenia, reported to provide easily accessible information to citizens about their legal position as a possible donor of non-national residents. Because of the potential impact of such decisions and because of the differences between countries in the role of the next-of-kin, investing more in the provision of clear information on this topic is advisable. FOEDUS work package on communication and cross-border donation will also tackle this issue.

Priority Action 7 is about promoting EU-wide agreements on aspects of transplantation medicine.
Little less than half of the countries indicate having at least one agreement in place. These are Bulgaria, Czech Republic, Germany, Spain, Estonia, France, Croatia, Italy, Liechtenstein, Lithuania, Montenegro, the Netherlands, Norway, Poland, Portugal and Turkey. Regarding any of the four topics (basic rules for internal EU patient mobility and transplantation, transplant medicine for extra-Community patients, monitoring organ trafficking and common priorities and strategies for future research programmes), a limited number of countries have agreements in place. However, what exactly is meant by 'EU-wide' agreements remains unclear. Are these agreements between individual countries, e.g. neighbouring countries, or are these agreements that are shared by many or all EU countries. Also to what purpose should there be such agreements? Should they be seen as a first step towards implementation in a directive, or should they been seen as useful instruments only? Although this action refers to fundamental issues, the scope and wording of this action should be reconsidered. In its current state the Priority Action hardly provides a direction. The EU-funded projects have not paid much specific attention to this Action.

Priority Action 10 is about promoting a common accreditation system for organ donation/ procurement and transplantation programmes. More than half of the CAs indicate that additional plans or actions have been undertaken to promote a common accreditation system for organ donation/procurement and transplantation programmes. These are Austria, Belgium, Cyprus, Czech Republic, Germany, Estonia, France, United Kingdom, Greece, Croatia, Hungary, The Netherlands, Poland, Portugal, Romania, Slovenia and Turkey.
A closer look at the plans or accreditation systems suggests a great deal of variety in topics, thoroughness and whether or not accreditation is evaluated. It would seem that the accreditation systems are far from being a common accreditation scheme. For those countries in the process of developing an accreditation system it might be valuable to learn from others. It would also be advisable to more clearly define what exactly is meant by such broad concepts as 'Quality Improvement Programmes'. For those countries with a more developed accreditation system it might be worthwhile to share their experiences with others and to invite other countries to participate in the role of auditor. In the focus group discussion it was mentioned that to be able to reach common accreditation systems much more work is required, like a quality analysis of current systems leading to improvements in each of these systems. EU-funded projects have dealt with this Priority Action only in rather general terms. If this Priority Action is taken seriously and tangible results are expected at the end of the four year period, a thorough discussion of this Priority Action is required and a new, more concrete, course of action should be determined.
Now with the Directive 2010/53/EU transposed, in 2012, into national laws of EU Member States, a new tool is also available: EU Member States (and the European Commission) can ask each other to "provide information on the national requirements for the authorisation of procurement organisations" and "transplant centres" (articles 5 and 9). As authorisation and accreditation can be, and are often, closely linked, this dimension and possibility, which was not available at the moment of adoption of the Action Plan, can now be explored.

4.3 The role of the European Commission (EC)

The Action Plan is well embedded and supported by a rich and diverse network of actors that provide ethical frameworks and legal principles, projects, actions, expertise and experts. In this study two EC instruments that support the Action Plan have been discussed. First, the instrument of funding of projects and actions and second, the direct actions[290] of the EC.

[290] Diplomatic activities of the EC are beyond the scope of this study.

EU-funded projects

Many projects have contributed to the Action Plan in diverse ways and many projects are still contributing. Their role in the promotion and implementation of the different Priority Actions has been described in detail in chapter 3. Projects may support initiatives from experts, professionals and policy makers in the different countries. Projects are not evenly distributed over the Priority Actions with some Priority Actions receiving more projects' attention than others, but not necessarily meaning that more progress is made when more projects are tied to one Priority Action. At the time of this assessment, many projects were not yet finished and results of these projects are not yet (fully) available. In addition, it is not always clear whether projects complement and build upon other, previous projects.

Projects mobilise experts and expertise towards achieving the Action Plan's priorities. A closer look at the projects suggests an evolutionary development in the functions of the projects. Early projects seem to focus more on the issue of information gathering, followed by the development of tools and expertise, whereas the later projects are more directed towards the exchange of knowledge and expertise. Implementation is hardly a function of the projects. The Commission through its funding seems to primarily take up a supportive role, leaving the final realisation of the Action Plan to the individual States. This is in line with the division of competences, leaving the responsibility of organising transplant systems to the Member States. At the beginning of the Action Plan, most projects were funded after a simple "call for proposals" where applicants had to come up with a topic commonly chosen and build a consortium willing to work together on this topic. Thus, for the ease of feasibility in these early stages, these consortiums rarely gathered more than 15/20 partners. But on the other hand, several projects could be funded, which explains the diversity of topics tackled. Since the Directive 2010/53/EU was adopted a new instrument of the Health Programme became more accessible, namely the Joint Actions. MODE, ACCORD, but also FOEDUS are such Joint Actions, involving each at least 23 countries and at country level firstly the CAs, thus demonstrating their potential. For these Joint Actions, the Commission proposed, the annual work plans of the Health programme, the topics to be tackled within the project, topics to be then further defined and fine-tuned by the consortium of partners. And these Joint Action - or at least one of their main work package - have a clear link with the legislation, for example ACCORD with the work package on living donation register (article 15 Directive 2010/53/EU).

Another observation is that new EU Members seem to participate to a lesser extent in the projects, at least in the early stage of the Action Plan. It seems that in many cases the initiative for a project is taken up by one of the older EU Member States, leading to the observation that a more active involvement of new EU Member States is needed for the Action Plan to have an overall impact.

In the focus group with CAs, it was mentioned that the EC has been found to increase efforts to encourage complementarity between projects. Also it was mentioned that the design of the projects is improving. This development is highly supported and as it relies mainly on projects' proposals formulated by national experts and CAs, this should be feasible. CAs furthermore mention the need for projects to be practical, to focus upon the reasons why systems fail and to remedy these. Also the need to limit bureaucratic work is expressed. CAs indicate the importance of these projects for their work, especially the function these projects have in terms of exchanging experiences and expertise. More could be done to effectively disseminate the results of projects, including a more active involvement of CAs themselves, which are the key actors to disseminate the results in their respective countries, via national channels and means.

Other EC activities, with special reference to the CA meetings

The EC takes up an active role concerning the Action Plan. Apart from the funding of projects and actions, the EC primarily uses their coordination mechanism. The EC brings together expertise and

authorities from all relevant countries and involves them in the furthering of the Action Plan. For this the EC employs a wide array of strategies, not only the meetings of the CAs, but also expert meetings, workshops and the dissemination of manuals and projects' results.

Opportunities are seen within the exploration of structural funds. An obstacle for some Priority Actions is the applicability of specific Priority Actions because of differences in national realities and the lack of resources and staff. At times it remains unclear whether Member States would allow and appreciate more efforts by the EC on a specific Priority Action.

In the focus group with CAs the importance of the biannual meetings of the CAs was underlined. A feeling that several CAs expressed is the need for more focus. They asked for documents to be circulated at an earlier moment, they asked to limit the number of topics allowing more time for a lengthier discussion that goes beyond the initial statements. The meetings are found to be important as an instrument to share knowledge. The CIRCA platform is said to be helpful. Some suggestions to increase the effectiveness of these meeting were also made. It was for instance suggested to include a reception to facilitate interaction. Also instruments that work for one CA should be made available to other CAs – which basically means that CAs should actively share such tools with other CAs, using CIRCA platform. It was furthermore suggested that not all discussions would need face-to-face communication, but that social media and IT tools may help in the interaction, also in between the CA meetings. CAs could also be more involved in the drafting of the agenda. Finally, the importance of the contribution of people (experts) that are really knowledgeable in the field of organ donation is highly valued.

4.4 Final remarks and main recommendations

This study could not have been performed without the input and contribution of many CAs and the EC representatives. They have been extremely cooperative. Also, their shared and strong wish to try to bridge the gap between the demand for donor organs and the availability of organs became very clear. This shared goal nevertheless contrasts with the diversity between countries. In addition to geographical, human, economical, educational, cultural… differences, countries differ in how the process of organ donation and transplantation is organised and in the issues they have to tackle. These differences can be rather substantial: some countries have a tightly monitored and well developed system of organ donation but still face a wide gap between the demand for donor organs and their supply. In other countries a system for organ donation is just being set up. The number and type of actors involved in organ donation and transplantation, as well as the practical problems these countries face are different and often unique. Countries have different legal systems, the role of next-of-kin differs, and whereas in some countries living donation is vital in other countries it may be (almost) absent. The challenge within the EU will be to find a suitable answer to this diversity (and even to make a good use of it), through projects and supportive actions that take these differences into account, based on the shared understanding of the need to bridge the gap between demand and availability of donor organs, to make transplant systems more efficient and transparent, as well as to improve quality and safety aspects.

This study leads to the following recommendations.

1. **Three Priority Actions**, those on **transplant donor coordinators (1) , living donation (3) and the interchange of organs between national authorities (8)**, received attention of almost all countries and are recognised as being **very important**. It is recommended to **build upon** this advantage and to invest energy in bringing these actions further.
    a. Regarding **transplant donor coordinators**, the importance of precisely defining their role and profile in each country was highlighted, together with the need for

continuous training and education. However, these definitions should take into account and accommodate differences between countries. Here, the EC may play a role. Also it was mentioned that more quantitative data would be welcome.

b. Regarding **living donors**, it was remarked that the importance of living donors is increasing. The importance to protect and care for the living donor was stressed by several representatives. Further development of guidance documents and follow-up registers are instrumental in this area.

2. **Knowledge exchange, twinning projects and expertise sharing are highly valued**. Efforts to further develop the process of organ donation should **incorporate these strategies to a maximum**. The new instrument of Joint Actions that became available with the Directive could prove to be a valuable instrument. Priority Actions that have already been taken up by many countries, but not by all, may especially benefit from this strategy, especially the **promotion of quality improvement programmes in hospitals with potential for donors (2), the evaluation and learning of post-transplant results (9)**. Also in the field of increasing public awareness the exchange of knowledge, ideas and experiences could be beneficial.

3. **Four Priority Actions**, those on **public awareness (4), facilitating the identification of organ donors across Europe (5), EU-wide agreements (7) and common accreditation systems (10), should be carefully re-examined**. A minority of countries have taken up activities regarding these topics. Also what exactly these Priority Actions really aim at is not always clear to CAs. Therefore it is advisable to re-examine the meaning of these Priority Actions and to provide them with an additional focus that has meaning and is useful. It might be that the ambiguity of these Priority Actions stems from the political sensitivity of issues they relate to. This should be made clear. If no common basis for an unambiguously phrased Priority Action can be found, these should be deprioritised.

4. One may consider defining a **logical order in pursuing Priority Actions**. Some activities need to be taken up before others, only after which next steps can be taken. An analysis of this logical order can lead to the construction of a roadmap, suggesting countries to start with the primary activities needed for organ donation and subsequently improve the organisation, quality and effectiveness of the process.

5. Efforts to **increase the complementarity of EU-funded projects and actions** are welcomed and should be **continued**.

6. **Newer Member States need special attention** as they are often in the process of building up their system for organ donation and transplantation, though not always in the same way. Their needs will, in many cases, differ from the older Member States. Also it seems that they participate to a lesser degree in different projects. Extra efforts should be made to get a clearer picture of the needs and the agenda of these new Member States. These needs may be met through the exchange of knowledge, but also through specific projects and actions or the tailoring of existing efforts.

7. The **meetings of the CAs are essential for the progress of the Action Plan**. Steps might be taken to further increase the effectiveness of these meetings. One may think of an experiment of using an IT-tool to support online discussions in advance of a meeting, in order to better prepare a topic in advance of a CA meetings. In this study such a tool, an internet focus group, was used. Sixteen countries participated in this focus group. It provided valuable information without the need for physical. Also the possibility of allocating time for a more informal get together could be considered.

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National organisations

Croatia: Donor Network of Croatia
Czech Republic: Czech Transplantation Coordinating Centre (KST)
Estonia: Tartu Hospital University
France: Agence de la biomédecine
Germany: Deutsche Stiftung Organtransplantation (DSO)
Greece: Hellenic National Transplant Organization
Hungary: HungaroTransplant
Italy: Centro Nazionale Trapianti (CNT)
Lithuania: Lithuanian Bureau on Organ Transplantation

Netherlands: Nederlandse Transplantatie Vereniging
Norway: Rikshospitalet / Radium Hospitalet
Poland: Poltransplant
Portugal: Autoridade Para Services de Sangue e Transplantacáo (ASST)
Romania: National Transplant Agency
Slovakia: Slovak Centre on Organ Transplantation
Slovenia: Institute of the Republic of Slovenia for the Transplant of Organs and Tissues: Slovenija Transplant
Spain: Organización Nacional de Trasplantes (ONT)
Sweden: Swedish Council for Organ and Tissue Donation
Switzerland: Swiss National Foundation for Organ Donation and Transplantation. Foundation Swiss Blood Stem
United Kingdom: UKTransplant Austria: Austrotransplant

Websites and webpages of European institutions

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http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:056:0036:0062:EN:PDF

EU Directives in the field of organ donation and transplantation
Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation [291]:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF
Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:275:0027:0032:EN:PDF

[291] The original number "2010/45/EU" was wrongly attributed and consequently corrected; "2010/53/EU" is the right number.

Database for projects funded under EU Health Programme
http://ec.europa.eu/eahc/health/index.html
http://ec.europa.eu/eahc/projects/database.html

DG Research
http://cordis.europa.eu/home_en.html

Other
http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&-project_ref=ETEN-517417
https://webgate.ec.europa.eu/sanco/heidi/index.php/Heidi/Healthcare/Tissue,_cell_and_organ_transplants#Council_of_Europe
https://webgate.ec.europa.eu/sanco/heidi/index.php/Heidi/Healthcare/Tissue,_cell_and_organ_transplants#Council_of_Europe
http://ec.europa.eu/anti-trafficking/
http://ec.europa.eu/enlargement/tenders/taiex/index_en.htm
http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=48625
http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=47700
http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=43847
http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=42609
http://ec.europa.eu/health/blood_tissues_organs/events/ev_20111018_en.htm
http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm

EU-funded project websites
ACCORD: http://www.accord-ja.eu/
ALLIANCE-O: http://ec.europa.eu/research/fp7/pdf/era-net/publishable_summaries/fp6/alliance-o_publishable_executive_summary_en.pdf
COPE: http://www.cope-eu.org/
http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ_RCN=13430950
DOPKI: http://www.ist-world.org/ProjectDetails.aspx?ProjectId=6f283c82639e4619a8a289d126b2f448&-SourceDatabaseId=7cff9226e582440894200b751bab883f
EFRETOS: http://www.efretos.org/
ELIPSY: http://www.eulivingdonor.eu/elipsy/
ELPAT: http://www.esot.org/Elpat/Content.aspx?item=10
http://www.edqm.eu/en/organ-transplantation-projects-1452.html
European Training Course in Transplant Donor Coordination ("Train the Trainers"):
http://www.etc.iavante.es/
EULID: http://www.eulivingdonor.eu/elipsy/what-is-elipsy.html
http://www.eulivingdonor.eu/media/upload/pdf//elipsy_poster_catalana_editora_132_3.pdf
http://groupware.eulivingdonor.eu/grup_4/mod_news/?option=view&listcategory=8&entry=30
EULOD: http://www.eulod.org/?section=aboutEulod&item=8

http://www.eulod.org/?section=WorkingPackages&item=13
http://www.eulod.org/?section=WorkingPackages&item=12
FOEDUS: http://ec.europa.eu/eahc/news/news232.html
HEPAMAB: http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ_RCN=13463381
MODE: http://www.mode-ja.org/
ODEQUS: http://www.odequs.eu/index.html

Links to other institutions and associations

Council of Europe:
http://www.coe.int/aboutCoe/index.asp?page=nosObjectifs&l=en
http://www.edqm.eu/en/organ-transplantation-work-programme-72.html
http://www.edqm.eu/en/organ-transplantation-reports-73.html

Eurotransplant:
http://www.eurotransplant.org/cms/mediaobject.php?file=year_20083.pdf
http://www.eurotransplant.org/cms/mediaobject.php?file=year_2010.pdf
http://statistics.eurotransplant.org/

ESOT:
http://www.esot.org/Content.aspx?item=12

WHO:
http://www.who.int/transplantation/tra_song/en/index.html
http://www.who.int/ethics/topics/human_transplant/en/

Other:
http://health-med-news.com/health/spain-will-train-european-transplant-coordinators/
http://www.declarationofistanbul.org/index.php
http://www.tts.org/index.php?option=com_content&view=article&id=746:the-madrid-resolution-on-organ-donation-and-transplantation&catid=67:august-2010-newsletter&Itemid=565
http://www.declarationofistanbul.org/index.php
http://www.europeantransplantcoordinators.org
http://www.organsandtissues.net
http://www.ekha.eu/,http://www.ekha.eu/htmldocs/ekha/4-16/ekha/kidney_health_disease.html
http://www.edtnaerca.org/
http://www.donoraction.org
http://www.easl.eu/

ANNEXES

Annex 1: List of abbreviations and acronyms of organisations and (EU-funded) projects used in this study

A	
ABM	Agence de la Biomédecine, France
ACCORD	Achieving Comprehensive Coordination in ORgan Donation throughout the European Union (EU-funded project)
ACTOR	Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) (EU-funded project, present study)
Alliance-O	European Group for Coordination of Research Programmes on Organ Donation and Transplantation (EU-funded project)
ANBI	Algemeen Nut Beogende Instellingen, Dutch non-profit institution
APHP	Assistance publique - Hôpitaux de Paris, France
ASST	Autoridade para os Serviços de Sangue e da Transplantaçao, Portugal
AUT	Austria
AUTC	Akdeniz University Transplant Center, Turkey
B	
BCB	Bulgarian Center for Bioethics, Bulgaria
BEAT	Bulgarian Executive Agency for Transplantation
BEL	Belgium
BGR	Bulgary
C	
CA(s)	(National) Competent Authority(ies) in charge of organ donation and transplantation in EU Member States under Directive 2010/53/EU
CD-P-TO	European Committee on Organ Transplantation of the Council of Europe (Partial Agreement)
CEU	Central European University (Közép-Európai Egyetem), Hungary
CHE	Switzerland
CHP	Centro Hospitalar do Porto, Portugal
CNT	Centro Nazionale Trapianti, Italy
CoE	Council of Europe
COORENOR	COORdinating a European initiative among National organizations for ORgan transplantation (EU-funded project)
COPE	Consortium on Organ Preservation in Europe (EU-funded project)
CTS	Czech transplant Society
CYP	Cyprus
CUB	Charité Universitätsmedizin Berlin, Germany
CZE	Czech Republic
D	
DBD	Donation after Brain Death, previously called Heart-Beating (HB) donation
DCD	Donation after Circulatory (Cardiac) Death, previously called Non-Heart Beating (NHB) donation
DCC	Donor Coordination Croatia
DEU	Germany
DG	General Directorates (of the European Commission)
DGS	Direçao Gèral de Salude, Portugal

DG SANCO	Directorate-General for Health and Consumers ("Santé et Consommation") of the European Commission
DNK	Denmark
DOPKI	Improving the Knowledge and Practice of Organ Donation ((EU-funded project)
DSO	Deutsche Stiftung Organtransplantation, Foundation for Organ transplantation, Germany
DTI	Donation Transplantation Institute, Barcelona, Spain (organiser of TPM courses)
DUH	Derer University Hospital, Slovak Republic
E	
EAHC	Executive Agency for Health and Consumers, agency of the European Commission executing the (Public) Health Programme(s)
EASL	European Association for the Study of the Liver
EC	European Commission
ECDC	European Centre for Disease Prevention and Control (EU agency linked to European Commission, DG Health & Consumers)
ECL	European Children List
EDC	ESOT's European Donation Committee which merged with ETCO in 2011 to become the Society's donation and procurement section
EDD	European Donation Day (EU-funded project)
EODD	European Organ Donation Day, Council of Europe initiative
EDQM	European Directorate for Quality of Medicines & Health Care, Council of Europe
EEA	European Economic Area (EU countries + Iceland, Liechtenstein and Norway)
EFRETOS	European Framework for the Evaluation of Organ Transplants (EU-funded project)
EKHA	European Kidney Health Alliance
ELIPSY	Euro Living Donor Psychosocial Follow-up (EU-funded project)
ELITA	ESOT's section for liver and intestines transplantation
ELPAT	Ethical, Legal and Psychosocial Aspects of organ Transplantation, ESOT's plateform since 2008 - 2010 and 2013 Conferences
EMA	European Medicines Agency (EU agency linked to European Commission, DG Health & Consumers)
EPITA	ESOT's section for pancreas and islets transplantation
EOEO(s)	European Organ Exchange Organisation(s)
EOM	Hellenic Transplant Organisation, Greece
ERA-NET	European Research Area – NETworking (EU Research mechanism)
ESHLT	European Society for Heart and Lung Transplantation, working with ESOT's Thoracic Committee
ESOT	European Society for Organ Transplantation
ESP	Spain
EST	Estonia
ET	Eurotransplant International Foundation
ETCO	European Transplant Coordinators Organisation (merged with ESOT in 2011)
ETPOD	European Training Program on Organ Donation (EU-funded project)
EU	European Union
EULID	Euro Living Donor (EU-funded project)
EULOD	Living Organ Donation in Europe (EU-funded project)
EUROCET	European Registry of Competent Authorities for Tissues and Cells (EU-funded project)
F	
FBG	Fundacio Bosch I Gimpera, Barcelona, Spain
FCI	Fundeni Clinical Institute, Romania

FIB	Fundación para la Investigación Biomédica del Hospital Gregorio Marañón, Spain
FIN	Finland
FITOT	Fondazione per l'Incremento dei Trapianti d'Organo e di Tessuti O.n.l.u.s., Italy
FOEDUS	Facilitating collaboration on organ donation between national authorities in the European Union (EU-funded project)
FP (6 and 7)	6th and 7th (Research) Framework Programme(s): EU-funding in the Research field
FPT	Fundatia Petnru Transplant -National Agency for Transplantation, Romania
FRA	France
G	
GBR	United Kingdom
GKBT	Global Knowledge Base on Transplantation
GRC	Greece
H	
HBD	Heart Beating Donor/Donation (now called DBD, donation after brain death)
HCB	Hospital Clinic de Barcelona, Spain
HDIR	Norwegian Directorate of Health
HEPAMAB	Human monoclonal antibody therapy to prevent hepatitis C virus reinfection of liver transplants: advancing lead monoclonal antibodies into clinical trial (EU-funded Research project)
HGSA EPE	Hospital Geral de Santo Antonio EPE, Portugal
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
HOME	Directorate-General for Home Affairs (DG HOME) of the European Commission, in charge of Freedom, Security and Justice,
HN	Université René Descartes-Hôpital Necker, Hospital Necker, France
HNBTS	Hungarian National Blood Transfusion Service, Hungary
HRV	Croatia
HSE	Health Service Executive, Ireland
HT	Hungaro-transplant
HUN	Hungary
HP	(EU) (Public) Health Programme run by the Executive Agency for Health & Consumers for the European Commission
I	
ICCBBA	International Council for Commonality in Blood Banking Automation
ICU(s)	Intensive Care Unit(s)
IL3	Fundació IL3-Universitat de Barcelona, Spain
IMAS	Institut Municipal d'Assistència Sanitària, Barcelona Spain
IRL	Ireland
ISHLT	International Society for Heart and Lung Transplantation
ISL	Iceland
ISS	Instituto Superiore di Sanità, Italy
ITA	Italy
K	
KDP	Key Donation Professionals
KI	Karolinska Institut, Sweden
KEM	Klinicke experimentalni mediciny, Czech Republic
KST	Koordinační strědisko transplantací, Czech Republic
KUL	Catholic University Leuven, Belgium

L

LIE	Liechtenstein
LTU	Lithuania
LUX	Luxembourg
LVA	Latvia

M

MPAHC	Medical Park Antalya Hospital Complex, Turkey
MKD	Macedonia
MLT	Malta
MNE	Montenegro
MODE	Mutual Organ Donation and transplantation Exchanges: Improving and developing cadaveric organ donation and transplantation programs (EU-funded project)
MOH	Ministry of Health
MS	Member States, meaning Member States of the European Union
MSA	Ministry of social affairs
MUH	Malmoe University Hospital, Sweden
MUW	Medical University of Vienna, Austria

N

NAT	National agency of transplantation, Romania
NBH	National board of Health, Sweden
NBT	Nacionalinis Transplantacijos Biuras, Lithuania
NHBD	Non-Heart-Beating Donor/-ation (now called Donation after Circulatory Death, DCD)
NHSBT	National Health Service Blood and Transplant, United Kingdom
NLD	The Netherlands
NOR	Norway
NOTIFY	Exploring Vigilance Notification for organs tissues and cells
NTS	Nederlandse Transplantatiestichting, the Netherlands

O

ODEQUS	Organ Donation European Quality System (EU-funded project)
ONT	Organización Nacional de Trasplantes, Spain
OPT	Organizaçao Portuguesa de Transplantaçao, Portugal
OVSZ	Országoa Vérellátó Szolgálat, Hungary

P

PA(s)	Priority Action(s) of the Action Plan
Pmp	Per million population (used to presente donation and transplantation rates)
POL	Poland
PRT	Portugal
PSCUH	Paula Stradina Dliniska Universitates Slimnica, Pauls Stradins Clinical University Hospital (PSCUH), Latvia
PSTC	Paraskevidion Surgical and Transplant Center of Cyprus
PT	Poltransplant, Poland

R

ROU	Romania

S

SACRI	Academic Society for the Research of Religions and Ideologies, Romania
SANCO	Directorate-General for Health and Consumers ("Santé et Consommation") of the European Commission
SAT	Southern European Transplant Alliance

SEEHN	South-Eastern European Health Network (WHO initiative)
SKT	Scandiatransplant
SMU	Slovak Medical University
SOHO V&S	Vigilance and Surveillance of Substances of Human Origin (EU-funded project)
SONG	Standardization of Organ Nomenclature Globally (WHO project)
SP-CTO	Select Committee of Experts on Organizational Aspects of Cooperation between countries on Organ Transplantation (former Council of Europe Committee)
ST	Slovenija – Transplant
SUH	Sahlgrenska Universitetssjukhuset - Sahlarenske University Hospital, Sweden
SVK	Slovakia
SVN	Slovenia
SwT	Swiss-Transplant
T	
TAIEX	Technical Assistance and Information Exchange (EU-funding)
TFEU	Treaty on the functioning of the European Union
TPM	Transplant Procurement Management (courses organised by DTI)
TTS	The Transplantation Society
TUH	Tartu University Hospital (Sihtasutus Tartu Uelikooli Kliinikum, TUH), Estonia
TUR	Turkey
U	
UEMS	European Union of Medical Specialists
UMCG	Universitair Medisch Centrum Groningen, University Medical Center Groningen, the Netherlands
UNM	Universitna Nemocnica Martin, Jessenius Faculty Hopsital of Medicine in Martin, Slovak republic
UNOS	United Network for Organ Sharing, United States of America
UTM	University of Medicine and Pharmacy of Targu-Mures, Romania
W	
WHA	World Health Assembly (decision-making body of WHO**)**
WHO	World Health Organisation
Z	
ZWE	Sweden

Annex 2: The "Action Plan on Organ donation & transplantation (2009-2015): Strengthened Cooperation between Member States" (Communication from the European Commission)

Priority Action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Design indicators to monitor this action.

Action 1.1 Incorporate in the Set of National Priority Actions the objective of gradually appointing transplant donor coordinators in hospitals. Design indicators to monitor this action.
Action 1.2 Promote the establishment of internationally recognised standards for transplant donor coordinator programmes.
Action 1.3 Promote the implementation of effective training programmes for transplant donor coordinators.
Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators.

Priority Action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.

Action 2.1 Incorporate in the Set of National Priority Actions the objective of gradually putting in place Quality Improvement Programmes in hospitals. Design indicators to monitor this action.
Action 2.2 Promote accessibility to and training on a specific methodology on Quality Improvement Programmes.

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.

Action 3.1 Incorporate in the Set of National Priority Actions the promotion of altruistic donation programmes for living donors, with safeguards built in concerning the protection of living donors and the prevention of organ trafficking.
Action 3.2 Promote the development of registers for living donors to evaluate and guarantee their health and safety.

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.

Action 4.1 Incorporate in the Set of National Priority Actions the recognition of the important role of the mass media and the need to improve the level of information to the public on these topics.
Action 4.2 Promote training programmes geared towards health professionals and patient support groups on organ transplantation communication skills.
Action 4.3 Organise periodic meetings at national level (competent authorities) with journalists and opinion leaders and manage adverse publicity.

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.

Action 5.1 Collect and disseminate information about citizen's rights concerning organ donation across the EU.
Action 5.2 Develop mechanisms to facilitate the identification of cross-border donors.

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

Action 6.1 Include in the Set of National Priority Actions ad hoc recommendations of the committee of experts to the Member States by way of regular reporting.
Action 6.2 Promote twinning projects and peer reviews.
Action 6.3 Assess the use of structural funds and other Community instruments for the development of transplantation systems.
Action 6.4 Promote networks of centres of reference.

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

Action 7.1 EU-wide agreement on basic rules for internal EU patient mobility and transplantation, in compliance with Community law.
Action 7.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patient.
Action 7.3 EU-wide agreement on monitoring organ trafficking.
Action 7.4 EU-wide agreement on common priorities and strategies for future research programmes.

Priority Action 8: Facilitate the interchange of organs between national authorities.

Action 8.1 Evaluate procedures for offering surplus organs to other countries.
Action 8.2 Put procedures in place for the exchange of organs for urgent and difficult-to-treat patients.
Action 8.3 Design IT tools in support of the previous actions.

Priority Action 9: Evaluation of post-transplant results.

Action 9.1 Develop common definitions of terms and methodology to evaluate the results of transplantation.
Action 9.2 Develop a register or network of registers to follow up organ recipients.
Action 9.3 Promote common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors.
Action 9.4 Develop and promote good medical practices on organ donation and transplantation on the basis of results, including the use of expanded donors.

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.

Annex 3: Questions of the 2009 Survey, conducted by European Commission services among (future) Competent Authorities in charge of organ donation and transplantation

Priority Action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation.

For the purposes of this document transplant "donor coordinators" shall be understood as health professional directly responsible and involved in the organ donation process [1]

1. Does your Member State already appoint transplant donor coordinators?
a. Yes
b. No
c. Not yet, but planned
d. N/A

2. How many transplant donor coordinators do you have today in total in your country? . . . . .(total number); this being:
a. a full time job
b. an additional task
c. both

3. On which level are they active?
a. Hospital
b. Regional
c. National
d. Other

4. Do transplant donor coordinators receive training?
a. Initial training at moment of appointing
b. Regular training
c. Both
d. None

5. How are the activities of transplant coordinators funded?
a. Funding is made available by?
National body
Regional body
Other
Mix
b. The hospital receives…
… a fixed amount for being a place of procurement
… an amount in function of the number of donors
… an amount in function of the number of organs procured
… Mix
c. The transplant donor coordinators are funded…
… directly by the central funding body
… indirectly through the hospital
... Mix

d. The transplant donor coordinators receive…
… a fixed amount (salary) for being a coordinator
… an amount in function of the number of donors
… an amount in function of the number of organs procured
… Mix

6. Do you plan to further develop the concept of transplant donor coordinators in 2010?
a. Appoint a larger number of transplant donor coordinators, up to …….. (number)
a. Appoint a larger number of transplant donor coordinators
b. Develop the training program
c. Others
d. None, but plans for 2011

Comment box:

Priority Action 2: Promote Quality Improvement Programmes (QIP) in every hospital where there is potential for organ donation.

For the purposes of this document "quality improvement programmes (QIP)" shall be understood broadly.
QIP's are primarily (self-)evaluations of the whole process of organ donation according to the characteristics of the hospital. These will make it possible to compare results and thus to pinpoint areas for improvement.

1. Do you utilise QIP?
a. Yes
b. No
c. Not yet
d. N/A
c. Not yet, but planned by . . . . (year)

2. If yes, are these:
a. Voluntary
b. Mandatory
c. N/A

3. If yes, how many hospitals have a QIP . . . (number) out of the . . . .(total number) of donor hospitals?

number of hospitals having a QIP
total number of donor hospitals
Hospitals having a QIP in function of the number of donor hospitals
0-24%
25-49%
50-74%
75-99%
100%

4. If yes, what is the precise scope of the QIP's?
a. the donation process
b. the procurement process
c. the transplantation process
d. N/A

5. If yes, what do QIP's include?
a. An external audit/ quality control system
b. Specific feedback
c. General guidelines
d. Other

6. Do you plan to further develop QIP's in 2010
a. Yes
b. No
c. Not yet
d. N/A
c. Not yet, but planned by . . . . (year)

Comment box:

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.

1. Are the relevant national legal provisions in place in your country?
a. Yes, they allow living donation
b. Yes, but living donation is explicitly not allowed
c. Yes, living donation is allowed under certain conditions, being,
i. Blood-related family only
ii. Not blood-related
iii. Other
d. Not yet, but legal changes foreseen
e. No legal provisions are planned

2. Do you have living donation programmes?
a. Yes
b. No

3. If yes, how many living donations did you have in the last year? . . . .

4. Is there a public body (i.e. ethical committee, judge, state attorney) that evaluates the living donor?
a. Yes
b. No

5. Do you follow-up on living donors with national registers?
a. Yes
b. No
c. Not yet, but planned by 2010-2011

i. For how many years is the follow- up done?. . . . .

6. Do you plan to further develop the living donation programmes in 2010?
a. Not in 2010
b. Yes, by creating more information/education to the public
c. Yes, by creating more information/education to the professionals
d. Other

Comment box:

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation

1. Do you deploy programmes in order to improve knowledge and communication skills of health professionals?
a. Yes
b. No
c. Not yet, but planned by 2010

2. If yes, what form do they take?
a. Training of health professionals, i.e. family approach
b. In-hospital media officers, trained for topics on donation/tx
c. Other

3. Do you deploy programmes in order to improve knowledge and communication skills of patient support groups?
a. Yes
b. No
c. Not yet, but planned

4. If yes, what form do they take?
a. Public awareness campaigns in the media
b. Leaflets/brochures in hospitals
c. Investing in contacts with patient groups
d. Other

5. Do you organise periodic meetings with the journalists?
a. Yes
b. No
c. Not yet, but planned

Comment box:

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe

1. Can the following people legally be donors in your country?
a. Persons with a foreign nationality that die in your country?
b. Non-residents that die in your country (e.g. dying on holiday)?

c. Illegal persons that die in your country?
d. No
e. N/A

2. Are the following criteria required in order to get admitted to the waiting list in your country?
a. Residency in the country: Y/N
b. Local nationality: Y/N
c. Signed up with local social security: Y/N
d. Others, please explain…

3. What percentage of your transplanted patients are:
a. Residents in your country with the local nationality: …%
b. Residents in your country, with a foreign nationality: …%
c. Non-residents: …%

4. Are there citizens in your country who went abroad for organ transplants? Y/N
a. Do they first get an approval from your local social security?
b. Is specific information available on transplantation abroad?

5. Is the follow-up of your citizens transplanted abroad covered by the national health insurance system?
a. Yes
b. No
c. N/A

Comment box:

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

For the purposes of this document "twinning projects" shall be understood as any initiative where one Member State aims to help a beneficiary Member State in the development of their transplantation system; this could include the creation of modern and ef
1. Have you already used twinning projects?
a. Yes
b. No
c. Not yet, but planned
d. N/A

For the purposes of this document "peer reviews" shall be understood as an appraisal in broad terms. Peer review requires a community of experts in a given (and often narrowly defined) field, who are qualified and able to perform impartial review.
2. Have you already used peer reviews?
a. Yes
b. No
c. Not yet, but planned by 2010
d. N/A

As explained in the previous Action Plan meeting structural funds are a set of Community funds supporting Member States in developing their infrastructures
(http://ec.europa.eu/regional_policy/funds/prord/sf_en.htm)
Other Community instruments should be understood broadly and can e.g. include: TAIEX (http://taiex.ec.europa.eu/) or the 7th Framework Programme (http://cordis.europa.eu/fp7/)

3. Have you already used structural funds and other Community instruments?

a. Yes
b. No
c. Not yet, but interested
d. Not yet, but planned by 2010

For the purposes of this document "centres of reference" shall be understood as hospitals and/or highly specialised multi-field competence units, which have a role of expertise and which advise the doctors, the patients and their families. These Reference

4. Do you participate in any networks of centres of reference?

a. Yes
b. No
c. Not yet, but planned by 2010-2011

Comment box:

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

1. Are you interested in any of the following aspects for developing EU-wide agreements

a. Patient mobility within the EU
b. Patient mobility from outside the EU
c. Organ trafficking
d. Future research programmes on organ donation and transplantation
e. European transplant research network
f. Others

2. Which one would you like to focus on in 2010

g. a-b-c-d-e-f

a. Patient mobility within the EU
b. Patient mobility from outside the EU
c. Organ trafficking
d. Future research programmes on organ donation and transplantation
e. European transplant research network
f. Others

Comment box:

Priority Action 8: Facilitate the interchange of organs between national authorities.

1. Are you already part of a fixed collaboration with other countries?

a. Yes, of a multi-lateral collaboration
a1. Eurotransplant
a2. Scandiatransplant
b. Yes, bilateral collaborations

c. No
d. Not yet, but planned by 2010
a. With next countries: ……, ……, ……..,

2. Which patient groups are involved?
a. All patients
b. Urgent needs for transplantation
c. Paediatric patients
d. Rare HLA-patterns
e. Other

3. Which organs are involved?
a. Liver
b. Kidney
c. Heart
d. Lung
e. Other, being pancreas, pancreas islets, intestine
e. Other, being……

4. Do you have data available for:
a. How many organs came from abroad last year? . . . . .
b. How many organs left your country last year? . . . . .

Comment box:

Priority Action 9: Evaluation of post-transplant results.

1. Do you evaluate post-transplant results?
a. Yes, results are systematically collected in a database/register
b. Ye, not in a systematic way
c. No
d. Not yet, but planned by 2010
e. N/A

2. If yes, do you have an established method of evaluation?
a. Yes
b. No
c. N/A

3. On which level do you organise these evaluations?
a. Per transplant centre
b. Per region
c. National

Comment box:

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.

The following questions are on purpose phrased broadly; the aim is see how Member States perceive a potential common accreditation system; this could include accreditation, designation etc

1. Common accreditation system for donation/procurement programmes

a. What would be the main benefits? . . . .

b. How far is standardisation feasible? . . . .

2. Common accreditation system for transplantation programmes

c. What would be the main benefits? . . . .

d. How far is standardisation feasible? . . . .

3. How could the EU best support centres of excellence? . . . .

Comment box:

[1] According to Recommendation Rec(2005)11 of the Committee of Ministers to member states on the role and training of professionals responsible for organ donation (transplant "donor co-ordinators") of the Council of Europe

Annex 4: Survey Questions ACTOR project

Projects:

	My country was involved in this project/ organisation in the past	My country is involved in this project/organisation at this moment	My country will be involved in this project/organisation in the future	If so, in which specific topic/work package are you more specifically interested in/involved?
- DOPKI				
- Alliance-O				
- ETPOD				
- ELIPSY				
- EULID				
- EULOD				
- EDD				
- EFRETOS				
- COORENOR				
- ODEQUS				
- ELPAT				
- MODE (Joint Action 2010)				
- ACCORD (Joint Action 2011)				
- Train the Trainers in Donor transplant coordination				
- FOEDUS (Future Joint Action foreseen to be financed under the 2012 Public Health Programme)				
Council of Europe activities in the field of organ donation and transplantation				
Other projects/activities				
- Working group on Deceased donation under the Action Plan				

- Working group on Indicators under the Action Plan				
- Working group on Living donation under the Action Plan				
- Journalist Workshop on Organ donation and transplantation (organised by European Commission in Nov. 2010 and October 2011)				
- EUROCET				
- SOHO V&S				
- NOTIFY				
- ETCO				
- ESOT				
- ECOT				

Background:

1. Population (million inhabitants)

2008….
2010…

2. What is the legislative framework concerning organ donation and transplantation in your country? . . . .(Opting in/out?, Registers? Role relatives?)

3. On which level are organs allocated in your country? More than 1 answer possible.
   a. On hospital level
   b. On transplant center level
   c. On national level
   d. On the level of Eurotransplant/Scandiatransplant/other organisation, namely……
   e. Other, namely . . . .

4. How is health care for organ donors and recipients financed in your country in case of deceased donation?

5. How is health care for organ donors and recipients financed in your country in case of living donation?

6. Actual deceased donation rate 2008 and 2010 (total&PMP)*

2008: …total …PMP
2010: …total …PMP

O Number is not registered in my country

7. National number of utilized donors 2008 and 2010 (number of donors used for a transplant) (total&PMP)*

*An actual donor (HBD and NHBD) is a deceased person from whom at least one organ has been recovered for the purpose of solid organ transplantation, in contrast to a utilised donor, who is an actual donor from whom at least one solid organ has been transplanted. The number of utilised donors is therefore lower than the number of actual donors (Council of Europe, 2011).

2008: …total …PMP
2010: …total …PMP

O Number is not registered in my country

8. Number nonheartbeating donors 2008 and 2010 (total)

2008: …total
2010: …total

O Number is not registered in my country

9. Number of donors older than 65 in 2008 and 2010 (total)

2008: …total
2010: …total

O Number is not registered in my country

10. Multi-organ donation rates 2008 and 2010 (% of Total)*
    * Multiorgan donor: An actual donor from whom at least two different types of organs have been recovered for the purpose of transplantation (Council of Europe, 2011).

2008: …% of total
2010: …% of total

O Number is not registered in my country

11. Family refusal rates 2008 and 2010 (total)

2008: … number refusals out of….
2010: … number refusals out of….

O Number is not registered in my country

12. National number of deceased donor transplant procedures 2008 and 2010 (total)

2008
Kidney:
Liver:
Heart:
Lung:
Pancreas:

2010
Kidney:
Liver:
Heart:
Lung:
Pancreas:

O Number is not registered in my country

13. National number of living donor transplant procedures 2008 & 2010 (total)

2008
Kidney:
Liver:

2010
Kidney:
Liver:

O Number is not registered in my country

14. National survival rates (total number of transplants, deceased and living (2008 & 2010)):

2008:
Kidney deceased:...
Heart deceased:...

2010:
Kidney deceased:...
Heart deceased:...

O Number is not registered in my country

15. Numbers of adverse events related to organ quality 2008 & 2010:

2008:
infections (total number of patients)…
transmission of malignant diseases (total number of patients)…
organ damage (total number of patients)…

2010:
infections (total number of patients)…
transmission of malignant diseases (total number of patients)…
organ damage (total number of patients)…

O Number is not registered in my country

16. Number of people on waiting lists in 2008 & 2010 (per organ, total number of patients active on the WL during 2010/2008 /patients awaiting for a transplant (only active candidates) on 31/12/2008 and 31/12/2010)

2008:
Kidney: …/…
Liver: …/…
Heart: …/…
Lung: …/…
Pancreas: …/…

2010:
Kidney: …/…
Liver: …/…
Heart: …/…
Lung: …/…
Pancreas: …/…

O Number is not registered in my country

17. Mortality while on waiting list in 2008 & 2010 (Total number, per organ)

2008:
Kidney:…
Liver:…
Heart:…
Lung:…
Pancreas:…

2010:
Kidney:…
Liver:…
Heart:…
Lung:…
Pancreas:…

O Number is not registered in my country

18. For which organs does your country have protocols to indicate admission of patients to the waiting list? If possible, can you please upload? (More than 1 answer possible)
    a. None (Yes/No)
    b. Kidney (Yes/No)
    c. Liver (Yes/No)
    d. Heart (Yes/No)
    e. Lung (Yes/No)
    f. Pancreas (Yes/No)
19.

O Number is not registered in my country

CHALLENGE 1: INCREASING ORGAN AVAILABILITY
OBJECTIVE 1: MEMBER STATES SHOULD REACH THE FULL POTENTIAL OF DECEASED DONATIONS

Priority Action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Design indicators to monitor this action.

20. Have transplant donor coordinators been appointed in your country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by……(year)
    d. Yes
    e. N/A

21. On which level? Can you indicate the total number of transplant donor coordinators per level? (More than 1 answer possible)
    a. Local/in hospital, total number: ...
    b. Regional, total number ….
    c. National, total number ….
    d. Interregional, total number ….
    e. Other, namely ….

22. Can you indicate the main task of the transplant donor coordinator per level (if applicable)? (More than 1 answer possible)
    a. The main task of the local/in hospital transplant donor coordinator is:…
    b. The main task of the regional transplant donor coordinator is:…
    c. The main task national transplant donor coordinator is: …
    d. The main task of the interregional transplant donor coordinator is: …
    e. Other, namely …. with the main task to: …

23. Total number of (national) transplant centers? …

24. Total number of transplant procurement hospitals? ....

25. Do transplant donor coordinators receive specific training?
    a. No
    b. No not yet, but this is intended
    c. No, not yet, but planned by ……. (year)
    d. Yes, initial training at moment of appointing
    e. Yes, regular training
    f. Yes, both
    g. Yes, other, namely.....
    h. N/A

26. What does this training entail? . . . .

27. How many transplant donor coordinators participated in 2011?

(total number . . . .)

28. Have the trainings for transplant donor coordinators been tested for effectiveness?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . .year)
    d. Yes >>> Can you please upload relevant documents?
    e. N/A

29. Does your country use national or international accreditation schemes to qualify transplant donor coordinators?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . .(year)
    d. Yes
    e. N/A

30. Which accreditation scheme does your country use? . . . .

31. How many transplant donor coordinators have received accreditation in 2010?

. . . .Transplant donor coordinators

32. Are there additional plans or actions regarding transplant donor coordinators?
    a. No
    b. Yes > Please document?

33. Has the European Action Plan influenced your national policy on transplant donor coordinators?
    a. No, the European Action Plan has not influenced our national policy on transplant donor coordinators
    b. Yes, our national policy on transplant donor coordinators is/ will be influenced by the European Action Plan
    c. Other, namely . . . .
    d. N/A

34. If yes, can you explain in what way your national policy is changed since the introduction of the European Action Plan on transplant donor coordinators? . . . .

Priority Action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.

35. Does the government stimulate or has the government introduced initiatives to improve the quality of different aspects of the organ donation and transplantation process in individual hospitals? Please specify for the following domains of the organ donation and transplantation process:
    a. Identification of potential donors (Yes/No)
    b. The donation process (Yes/No)
    c. The procurement process (Yes/No)
    d. The transplantation process (Yes/No)
    e. Follow up care (Yes/No)

36. Has the European Action Plan influenced your national policy on Quality Improvement Programmes?
    a. No, the European Action Plan has not influenced our national policy on Quality Improvement Programmes
    b. Yes, our national policy on Quality Improvement Programmes is/ will be influenced by the European Action Plan
    c. Other, namely . . ..
    d. N/A

37. If yes, can you explain in what way your national policy is changed since the introduction of the European Action Plan regarding Quality Improvement Programmes?

OBJECTIVE 2: MEMBER STATES SHOULD PROMOTE LIVING DONATION PROGRAMMES FOLLOWING BEST PRACTICES.

38. Has the European Action Plan influenced your national policy on living donation programmes?
    a. No, the European Action Plan has not influenced our national policy on living donation programmes
    b. Yes, our national policy on living donation programmes is/ will be influenced by the European Action Plan

c. Other, namely . . . .
d. N/A

39. If yes, can you explain in what way your national policy is changed since the introduction of the European Action Plan regarding living donation programmes?

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.

40. Does your country have directed* living donation programmes?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

* Directed living donation means living donations to relatives or friends

41. If yes, what do these programmes entail? . . . .>>> Could you please upload relevant document?

42. Does your country have undirected* living donation programmes?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

* Undirected living donation (or altruistic living donation) means living donation to strangers

43. If yes, what do these programmes entail? . . . . >>> Could you please upload relevant documents?

44. If yes, how many hospitals have a living donation program (both directed and undirected)?
    . . . .(number) out of the . . . .(total number) of donor hospitals?

45. If yes, how many living donations did you have in 2011 (directed & undirected)?

    Directed:
    Kidney: . . . . (total)
    Liver: . . . . (total)

    O Number is not registered in my country

    Undirected:
Kidney: . . . . (total)
Liver: . . . . (total)
O Number is not registered in my country

Total number of living donations:
Kidney: . . . . (total)
Liver: . . . . (total)

46. Is there an independent body that evaluates the living donor?
    a. No
    b. No not yet, but this is intended

c. No not yet, but it is planned by . . . . (year)
d. Yes
e. N/A

47. Is organ trafficking prohibited by law?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes >>>> Can you specify the legal framework? . . . .
    e. N/A

48. Are registers established to evaluate and guarantee the health and safety of living donors?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

49. If yes, what information is registered? . . . .

50. Are there additional plans or actions regarding Priority Action 3 that are undertaken in your country?
    a. No
    b. Yes > Please document?

OBJECTIVE 3: INCREASE PUBLIC AWARENESS OF ORGAN DONATION

51. Has the European Action Plan influenced your national policy on public awareness of organ donation?
    a. No, the European Action Plan has not influenced our national policy on public awareness of organ donation
    b. Yes, our national policy on public awareness of organ donation is/ will be influenced by the European Action Plan
    c. Other, namely . . . .
    d. N/A

52. If yes, can you explain in what way your national policy is changed since the introduction of the European Action Plan regarding public awareness of organ donation?

Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.

53. Are there communication guidelines for informing the public about organ transplantation in your country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

54. Who is responsible for the deployment of these guidelines? . . . .

55. Does your country monitor the frequency of organ transplantation mention in newspapers?
    a. No

b. Yes >>> How many times? . . . .
c. N/A

56. Does your country monitor the frequency of organ transplantation mention on TV?
    a. No
    b. Yes >>> How many times? . . . .
    c. N/A

57. Does your country deploy programmes in order to improve knowledge and communication skills of health professionals on organ transplantation?
    a. No
    b. No not yet, but this is intended
    c. Not yet, but planned by . . . . (year)
    d. Yes, for personnel that deals with organ transplantation
    e. Yes, for all health care (hospital) personnel
    f. Other, namely . . . .
    g. N/A

58. Does your country deploy programmes in order to improve knowledge and communication skills of patient support groups on organ transplantation?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

59. If yes, what form do these programmes take? (More than 1 answer possible)
    a. Public awareness campaigns in the media
    b. Leaflets/brochures in hospitals
    c. Investing in contacts with patient groups
    d. Other, namely . . . .

60. Did you organise periodic meetings with journalists since the European Action Plan was implemented?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

61. If yes, how many meetings have there been in 2011?
    . . . .meetings

62. How often has this resulted in press clippings in 2011?
    . . . . times

63. Are there additional plans or actions regarding Priority Action 4 that are undertaken in your country?
    a. No
    b. Yes > Please document?

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.

64. Does your country provide easily accessible information to your citizens about their legal position as a possible donor in other countries across the EU?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes >>>> Can you specify how inform your citizens? . . . .
    e. N/A

65. Can the following people legally be donors in your country?
    a. Residents with a foreign nationality who die in your country? (Yes/No)
    b. Non-residents who die in your country (e.g. dying on holiday)? (Yes/No)
    c. Illegal persons who die in your country? (Yes/No)
    d. N/A

66. Are the following criteria required in order to get admitted to the waiting list in your country?
    a. Residency in the country: (Yes/No)
    b. Local nationality: (Yes/No)
    c. Signed up with local social security or health care insurance: (Yes/No)
    d. Other, namely . . . .

67. Does your country identify potential cross border donors, when no suitable match can be found in your own country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but planned by . . . . (year)
    d. Yes through Eurotransplant
    e. Yes through Scandiatransplant
    f. Yes through . . . ..
    g. N/A

68. Does your country have criteria for sending/receiving organs to/from other countries?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

69. If yes, which criteria?
    For sending organs to other countries . . . .
    For receiving organs from other countries . . . .

70. What % of your transplanted patients are:
    a. local residents? . . . .%
    b. foreign residents? . . . .%
    c. non-residents? . . . .%

71. Are there additional plans or actions regarding Priority Action 5 that are undertaken in your country?
    a. No
    b. Yes > Please document?

CHALLENGE 2: ENHANCING THE EFFICIENCY AND ACCESSIBILITY OF TRANSPLANT SYSTEMS

OBJECTIVE 4: SUPPORT AND GUIDE TRANSPLANT SYSTEMS TO BE MORE EFFICIENT AND ACCESSIBLE

72. Has the European Action Plan influenced your national policy on efficiency and accessibility of transplant systems?
    a. No, the European Action Plan has not influenced our national policy on the efficiency and accessibility of transplant systems
    b. Yes, our national policy on efficiency and accessibility of transplant systems is/ will be influenced by the European Action Plan
    c. Other, namely . . . .
    d. N/A

73. If yes, can you explain in what way your national policy is changed since the introduction of the European Action Plan regarding efficiency and accessibility of transplant systems? ……

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

74. Has your country been involved in twinning projects, peer reviews?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

75. If yes, can you indicate the topics and size of these projects (number of participants)? . . . .

76. From which countries were the participants? . . . .

77. Did these projects lead to changes?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes >>>> What changes? . . . .
    e. N/A

78. Do you have documented results of these projects?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes >>> document?
    e. N/A

79. Have you already used structural funds* and/or other community instruments* for the purpose of the development of transplantation systems?
    a. Yes
    b. No, not egilible for structural funds
    c. No, uninformed about structural funds
    c. No, not yet, but interested
    d. No not yet, but planned by . . . . (year)

    * Structural and Cohesions funds are funds intended to facilitate structural adjustment of specific

sectors, regions, or combinations of both (not specifically - but can - dedicated to Health systems).
* Other "Community instruments" can be other Projects funded by other programmes from the European Union such as the Framework Research Programmes, or Pre-Accession Aids for Candidate Countries, TAEIX support from EU Delegations.

80. Please specify usage of these funds: . . . .

81. Do transplantation centers or hospitals in your country participate in any networks of centres of reference?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

82. Which specialities do the participating centres of reference have?

83. Are there additional plans or actions regarding Priority Action 6 that are undertaken in your country?
    a. No
    b. Yes > Please document?

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

84. Are agreements in place about basic rules for internal EU patient mobility and transplantation in your country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

85. Are agreements in place about transplant medicine for extra-Community patients in your country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

86. Are agreements in place to monitor organ trafficking in your country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

87. For which organs do you see organ trafficking as a possible threat in your country? (More than 1 answer possible)
    a. Liver
    b. Kidney
    c. Heart
    d. Lung
    e. Other, being pancreas, pancreas islets, intestine
    f. Other, being . . . .

g. All organs
h. None

88. On which topics do you think EU-wide agreements should be made? . . . .

89. Are agreements in place about common priorities and strategies for future research programmes in your country?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

90. Which subjects do you think future research programmes should focus on? . . . .

Priority Action 8: Facilitate the interchange of organs between national authorities.

91. Are you part of a fixed collaboration with other countries? (More than 1 answer possible)
    a. No
    b. No not yet, but this is intended
    c. No not yet, but planned by . . . . (year), ...With next countries: . . . ., ..., ...,
    d. Yes, of a multi-lateral collaboration, namely Eurotransplant
    e. Yes, of a multi-lateral collaboration, namely Scandiatransplant
    f. Yes, of bilateral collaborations, With next countries . . . ., ..., ...,
    g. Yes, other namely . . . .

92. Which patient groups are involved? (More than 1 answer possible)
    a. All patients
    b. Patients with urgent needs for transplantation
    c. Paediatric patients
    d. Older patients
    e. Patients with rare HLA-patterns
    f. Other, namely . . . .

93. Which organs are involved? (More than 1 answer possible)
    a. Liver
    b. Kidney
    c. Heart
    d. Lung
    e. Other, being pancreas, pancreas islets, intestine
    f. Other, being . . . .

94. How many organs came from abroad in 2010, and how many organs left your country in 2010?
    a. Organs from abroad . . . .Organs left country . . . .
    b. No data available
    c. N/A

95. Has your country offered non allocated organs to other countries in 2010?
    a. No, there were no non allocated organs
    b. No, because . . . .
    c. Yes

96. If yes, how many in 2010?

97. Which organs were involved? (More than 1 answer possible)
    a. Liver
    b. Kidney
    c. Heart
    d. Lung
    e. Other, being pancreas, pancreas islets, intestine
    f. Other, being . . .

98. Does your country evaluate procedures for offering non allocated organs to other countries?
    a. No
    b. Not yet, but planned by . . . . (year)
    c. Yes >>> Can you please upload documents?
    d. N/A

99. Are procedures in place for the exchange of organs of urgent and difficult-to-treat patients?
    a. No
    b. No not yet, but this is intended
    c. No not yet, but it is planned by . . . . (year)
    d. Yes
    e. N/A

100. Which organs are involved? (More than 1 answer possible)
    a. Liver
    b. Kidney
    c. Heart
    d. Lung
    e. Other, being pancreas, pancreas islets, intestine
    f. Other, being . . . .

101. Total number of organs for difficult to treat patients exchanged across borders in 2010: …….

102. Does your country participate in an IT-tool for the facilitation of cross border exchange? (More than 1 answer possible)
    a. No
    b. No not yet, but this is intended
    c. No not yet, but planned by . . . . (year)
    d. Yes, Coorenor
    e. Yes, other namely . . . .
    f. N/A

103. If no, why not? . . . .

104. Are there additional plans or actions regarding Priority Action 8 that are undertaken in your country?
    a. No
    b. Yes > Please document?

CHALLENGE 3: IMPROVING QUALITY AND SAFETY

OBJECTIVE 5: IMPROVE THE QUALITY AND SAFETY OF ORGAN DONATION AND TRANSPLANTATION

105. Has the European Action Plan influenced your national policy on quality and safety?
   a. No, the European Action Plan has not influenced our national policy on quality and safety
   b. Yes, our national policy on quality and safety is/ will be influenced by the European Action Plan
   c. Other, namely . . . .
106. If yes, can you explain in what way your national policy is changed since the introduction of the European Action Plan on quality and safety? . . . .

Priority Action 9: Evaluation of post-transplant results.

107. Does your country evaluate post-transplant results of organ recipients on a national level?
   a. No
   b. No not yet, but this is intended
   c. No not yet, but planned by . . . . (year)
   d. Yes, results are systematically collected in a database/register
   e. Yes, not in a systematic way . . . .
   f. Yes, but only at a regional or local level
   g. N/A

108. At which moments does your country measure post transplant results of organ recipients? (More than 1 answer possible)
   a. 3 months after transplantation
   b. 6 months after transplantation
   c. 12 months after transplantation
   d. Other, namely . . . ..

109. Does your country accept donor organs from: (regardless of the type of organs and conditions of recipient) (More than 1 answer possible)
   a. donors with diabetes mellitus?
   b. donors with hypertension
   c. donors with renal insufficiency
   d. donors with infectious diseases such as hepatitis
   e. donors with HIV
   f. donors older than the age of 60
   g. N/A

110. Are there additional plans or actions regarding Priority Action 9 that are undertaken in your country?
   a. No
   b. Yes > Could you please upload relevant document?

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.

111. Are there additional plans or actions regarding Priority Action 10 that are undertaken in your country?
   a. No
   b. Yes > Please document?