Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member States

FACTOR Study

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In this study NIVEL reports on the uptake and impact of the EU Action Plan on organ donation and transplantation (2009 – 2015). The study was undertaken in 2016-2017 and has been performed in close cooperation with representatives from the European Commission, DG SANTE. Throughout the study, National Competent Authorities in charge of organ donation and transplantation were regularly consulted and asked for input. The authors thank both the representatives of DG SANTE and the Competent Authorities for their kind cooperation and input. Five peer reviewers were asked to comment on this study: Eurotransplant: Undine Samuel (Eurotransplant), Bernadette Haase-Kromwijk (NL/NTS), Beatriz Dominguez-Gil (ES/ONT), Triona Norman (UK/ NHSBT) and Alessandro Nanni Costa (IT/CNT-ISS).
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Utrecht, November 2017

EXECUTIVE SUMMARY

Background

Organ donation and transplantation has become an established practice, bringing considerable benefits to thousands of patients in Europe and worldwide every year.

The availability of donor organs is often a question of life and death for patients requiring a transplant, and shortage of organs is one of the main factors limiting the number of transplants. This shortage is observed in the EU, albeit to varying degrees, in each individual Member State, and has been the main challenge to address in organ transplantation.

In 2008, the European Commission therefore brought forward the EU Action Plan on Organ Donation and Transplantation 2009-2015: Strengthened Cooperation between Member States (hereinafter referred to as the "Action Plan")[1].

This Action Plan is a non-binding instrument that is complementary to the organ-specific legislation that was presented in parallel and adopted since (Directive 2010/53/EU, and implementing legislation 2012/25/EU). The Action Plan aims to help the Member States to address three challenges, i.e.

(1) to increase organ availability,

(2) to enhance efficiency and accessibility of transplant systems and

(3) to improve quality and safety.

To this end, ten Priority Actions (PA) were defined, aiming to focus strengthening of cooperation among the Member States along these three challenges (see Figure 1).

To increase organ availability, the Action Plan advocates: appointing of transplant donor coordinators (PA1) and promoting quality improvement programmes in hospitals (PA2) hence optimizing deceased organ donation; exchanging best practice on donation from living donors (PA3); strengthening communication skills of professionals and patient support groups (PA4) and facilitating identification of donor across Europe and cross-border donation (PA5) in order to increase public awareness.

To enhance *efficiency and accessibility of transplant systems*, the Plan emphasizes: a need to enhance organisational models (PA6) in the Member States; establish EU-wide agreements (PA7) and facilitate organ exchange between countries (PA8).

Finally, to improve *quality and safety*, which is also the main objective of the legislation, the Plan proposes: the evaluation of post-transplant results (PA9) and an accreditation system for organ donation, procurement and transplant programmes (PA10).

[1] Action Plan on Organ Donation and Transplantation (2009-2015): "Strengthened Cooperation between Member States". http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:sp0007

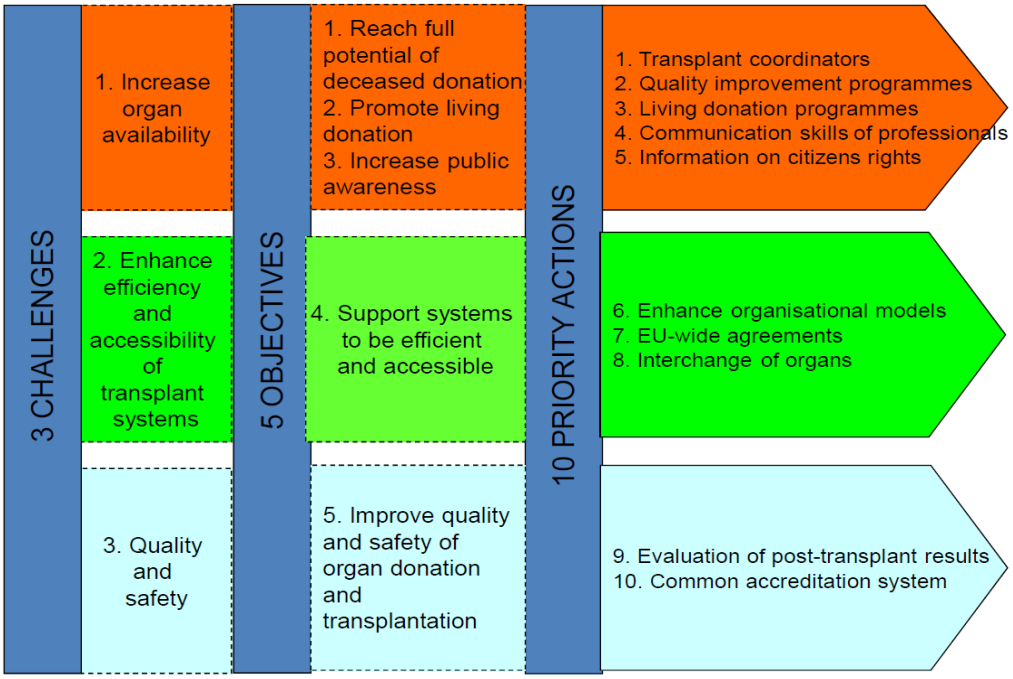

Figure 1: Overview of the Action Plan

During the period of the Action Plan, i.e. from 2009 to 2015, efforts have been made to develop and implement those Priority Actions, both at the national and the European level.

This study therefore aims to assess the uptake and impact of the Action Plan in the Member States, and presents a final review of the Action Plan (hereafter "the FACTOR study"). It provides an overview of the efforts made during the period of the Action Plan and its state of implementation at national level[2] as well as at EU level.

This study presents some key figures on organ donation and transplantation (Chapter 2), an assessment of the implementation of the Action Plan at national level (Chapter 3), a description of EU support to implement these Priority Actions (Chapter 4), success factors and key lessons learned (Chapter 5) and suggestions for potential future actions (Chapter 6).

To conduct this study, an external contractor[3] was funded by the European Commission in 2015.

Key figures on organ donation and transplantation

Since the adoption of the Action Plan, the total number of ***organ donors*** at the EU level has considerably **increased, i.e.** from 12.3 thousand in 2008 to 14.9 thousand in 2015. This accounts to a 21% **increase** over the period. This overall increase includes an increase in living organ donors of 29.5% and increase in deceased organ donors of 12%.

[2] The study focuses on the EU Member States. However, a total of 36 countries participated in the study i.e. 28 EU Member States, the European Economic Area (EEA) countries (Iceland, Liechtenstein, Norway and Switzerland) and candidate/associated countries (the Former Yugoslav Republic of Macedonia, Montenegro, Serbia, and Turkey).

[3] NIVEL, Netherlands Institute for Health Services Research.

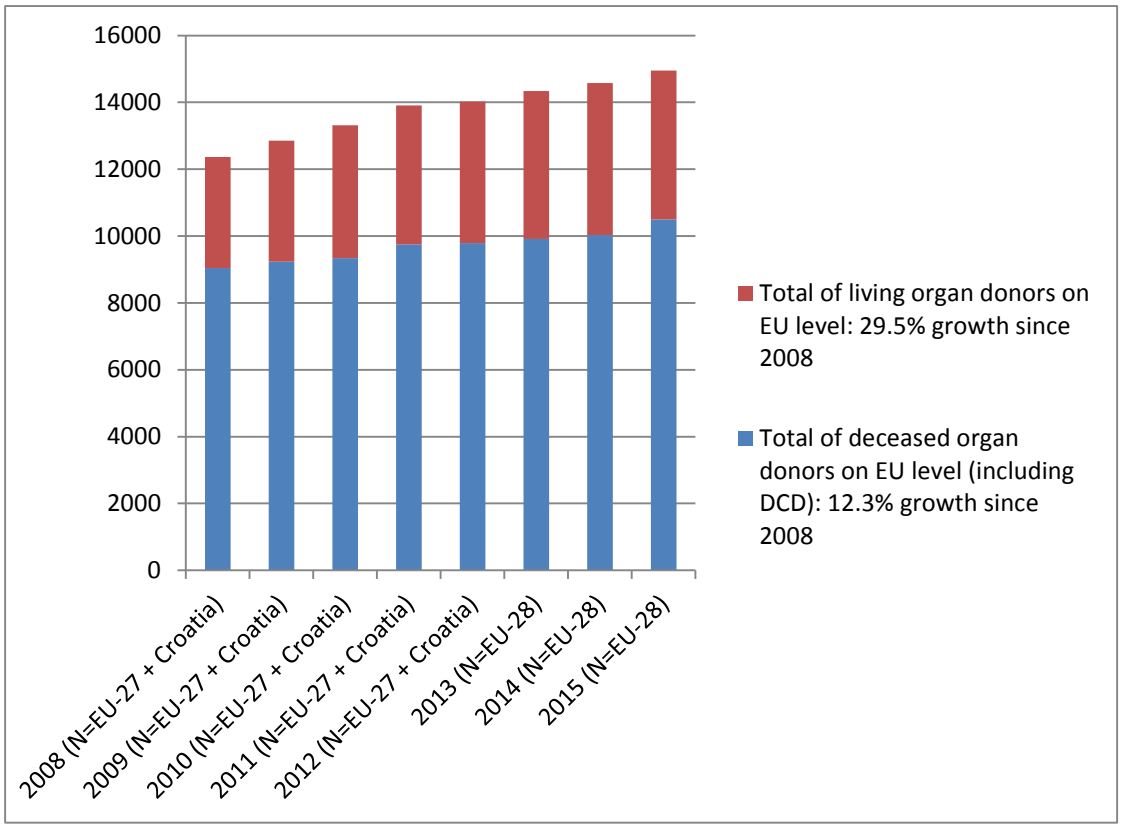

Figure 2: Number of organ donors in the EU in 2008-2015

Significant differences in (growth of) donation rates can be observed between countries. For instance, the average deceased donation rates varied from 1.3 PMP (Bulgaria) to 34.3 PMP (Spain) at beginning of the Action Plan (2008-2009). To compare, at the end of the Action Plan, in 2014-2015, deceased donation rates varied from 4 PMP (Greece) to 38 PMP (Spain).

Whereas most countries have demonstrated a steady increase in donation rates since the adoption of the Action Plan, some countries also have reported a fluctuation or fall-back. Poorer transplant rates can be noted in several countries that were hit by the economic crisis like Cyprus, Greece, Ireland, Portugal and Estonia. As organ transplantation builds on the entire health system, these poor transplant results might be a reflection of the overall impact of the economic crisis on the national healthcare systems.

Important to note is the backdrop of more than 20% in transplant numbers in Germany during the same period. Without Germany, the other EU-27 Member States have grown almost 25%. One reason lies probably in the 2011 scandal on manipulation of waiting lists, which had an impact on willingness to donate, but also other organisational issues are to be looked at.

For living donation (mainly for kidney transplants, but also possible for liver and lung transplants), average rates varied from 1.1 PMP (Poland) to 33.8 PMP (Cyprus) in 2008-2009. To compare, in 2014-2015 living donation rates varied from 0 PMP (Slovenia) to 31.3 PMP (the Netherlands).

An encouraging trend was observed in the number of ***transplants*** over the period of the Action Plan. Overall, there was an increase with 4.641 transplants, from 28.066 transplants in 2008 to 32.707 in 2015. This accounts to a ***17% increase*** over the period. The number of transplants was increasing for all types organs over the period of the Action Plan, except for small bowel transplants. There was a 16% increase in kidney transplants (the most transplanted organ), and liver transplants increased by

16%, heart transplants by 10%, pancreas transplants by 7% and lung transplants even by 41%.

Again, a significant variation is observed between Member States, in the numbers of organs transplanted in the countries.

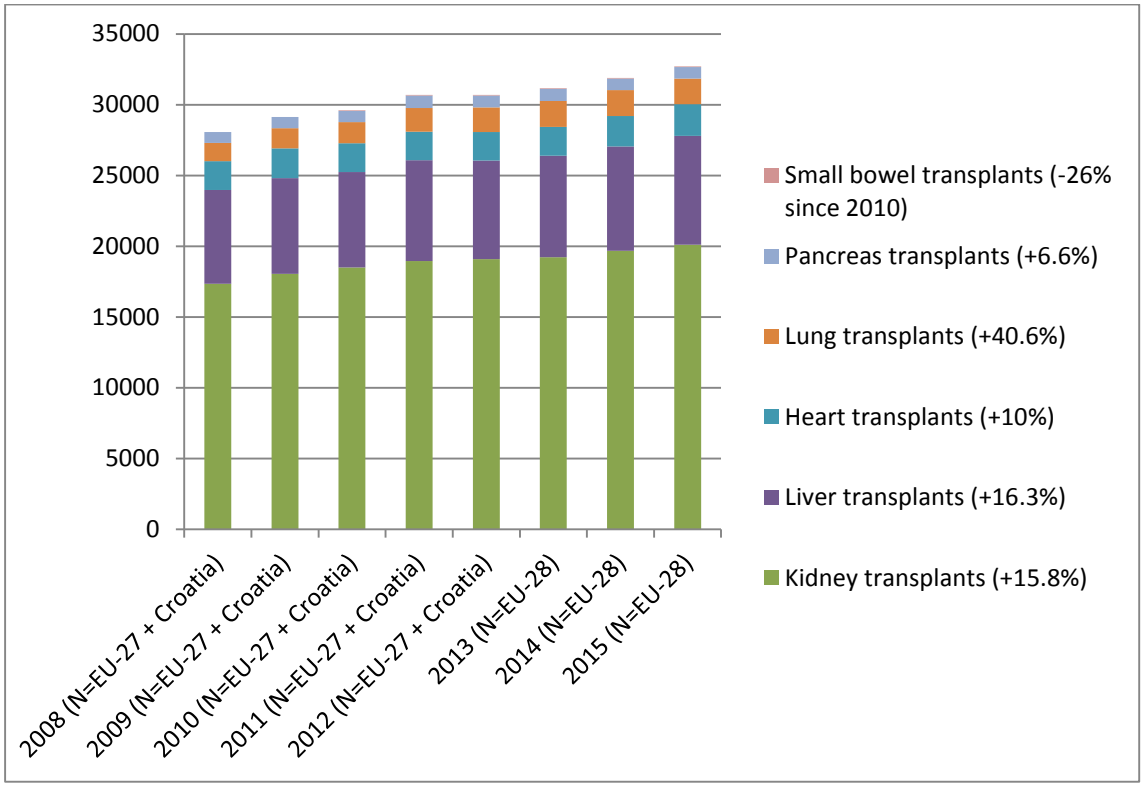

Figure 3: Organ transplants in the EU in 2008-2015

The Action Plan also reveals that ***cross-border exchange of organs plays an important role*** to optimise use of the limited number of available organs. The majority of cross-border exchange takes place within European Organ Exchange Organisations (EOEO). Three European such organisations exist, i.e. *Eurotransplant, Scandiatransplant and SAT* (Southern Alliance on Transplantation), and many Member States participate in it[4].

[4] Eurotransplant (AT, BE, DE, HR, HU, LU, NL, SI).
Scandiatransplant (DK, FI, IS, NO, SE).
the South Alliance for Transplantation (SAT) (ES, FR, IT, PT, CH, CZ).

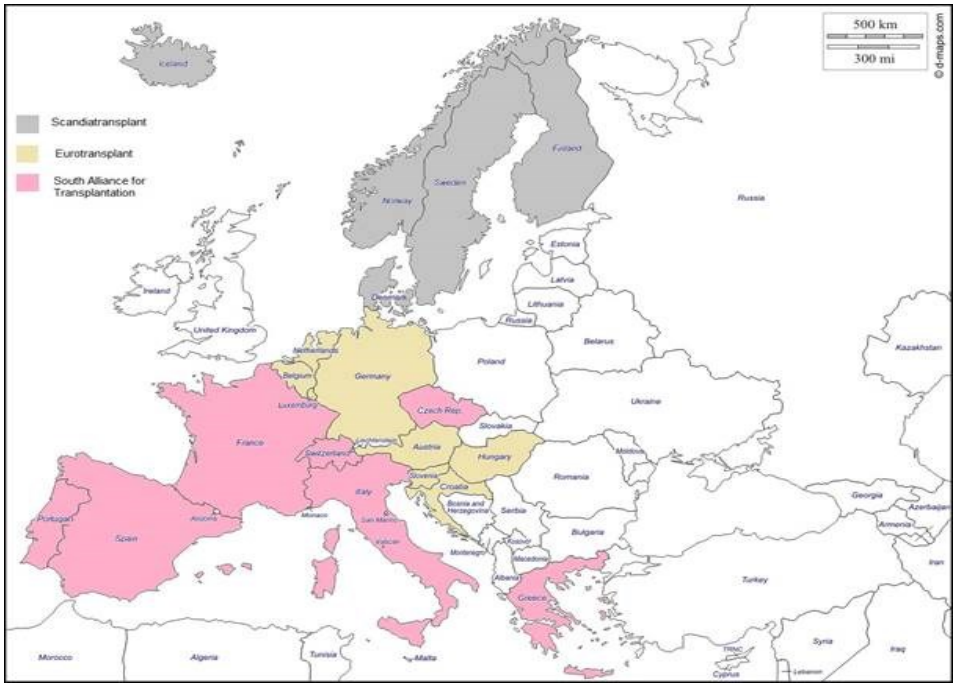

Figure 4: European Organ Exchange Organisations

However, many Member States have also set up direct collaborations and concluded ***bilateral agreements*** on the exchange of donor organs. Such cross-border agreements allow some countries to become very experienced in specific transplant procedures (for instance, lung transplant for Austria and Belgium, pancreas transplant for the UK, and Sweden), while other (neighbour) countries can benefit and access this expertise.

In addition, a number of countries (Czech Republic, Slovakia, Lithuania, Bulgaria, Switzerland, Italy, Spain, France, UK and Romania) have started to use a ***common organ exchange platform*** that was developed in the EU-funded FOEDUS joint action.[5] This organ exchange platform allows for allocation bodies (that match and decide donor organs with patients on the waiting list) to offer surplus organs, which are difficult to match to recipients in the own country. Often this concerns children. Inversely, these allocation bodies get access to offers from surplus organs donated in other countries. In the first 21 months, 380 organs have been offered on this platform leading to 53 transplanted organs, which otherwise would not have been used. More than one out of three of these transplants helped children under 10 years old. The platform is maintained at an annual cost around 10,000 Euro and more countries/allocation bodies are considering to participate.

Organ exchange is therefore increasingly important for many countries to optimize use of the limited number of donor organs and increase overall transplant rates.

In spite of this overall progress, 56 thousand people were still ***waiting for a transplant*** in the EU Member States by end 2015. The demand for organs in the EU continues to strongly exceed the supply. This is observed in all countries, albeit to varying degrees for specific organs.

[5] http://www.foedus-ja.eu/

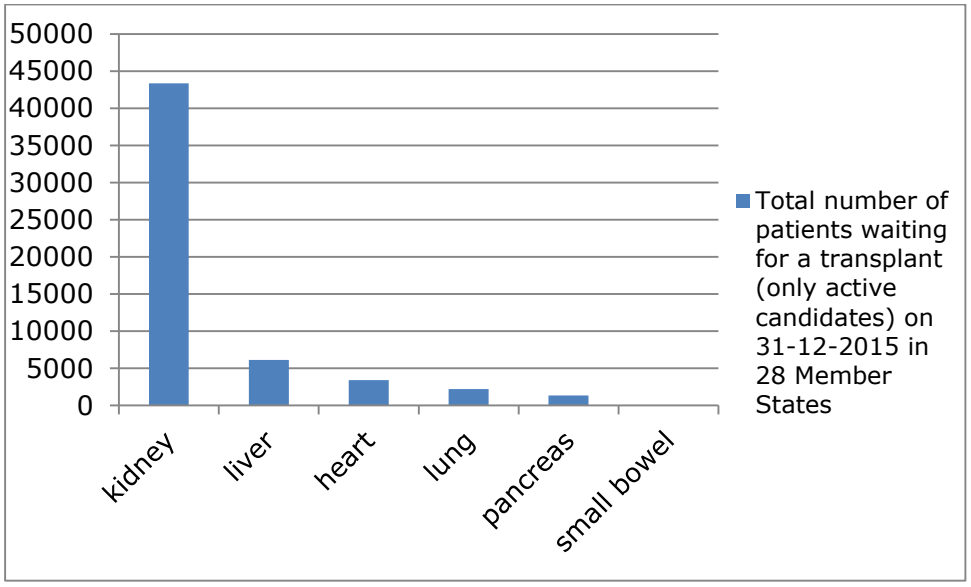

Figure 5: Total number of patients waiting for transplant in the EU (Source: Transplant Newsletter 2016, ONT/Council of Europe)

Some caution is however required when interpreting the number of patients on waiting lists. Waiting lists can rapidly change and the numbers on waiting lists cannot be compared across the EU for several reasons. For instance, a country usually does not have a waiting list for an organ if it does not have a transplant centre/program for this organ, which might lead to the wrong conclusion that no patients are waiting for such organ transplants in this country. Also the criteria for admission to the waiting list or removal from the waiting list differ between and within countries.

Overall, persistent organ shortages make ***countries look for new options*** to increase organ availability, in particular by:

- Promoting deceased organ donation inside and outside the intensive care units.
- Developing deceased donation also after circulatory death (besides donation after brain death).
- Optimizing living donation programmes, in particular for kidneys and livers.
- Increasing the donor pool through the use of organs from extended criteria donors (e.g. aged donors, non-standard risk donors, risk-positive donors for risk-positive recipients).
- Increasing the quality of the organs, for example by using machine preservation techniques.
- Exchanging surplus organs between countries, in particular for difficult to allocate organs.

The Action Plan has allowed exchanging know-how and developing common practices, to help Member States when implementing these options to increase availability.

Implementation of the Action Plan at the national level

A total of 36 countries (28 EU Member States and 8 other countries) participated in the FACTOR study, and reported back on national progress on each of the 10 Priority Actions.[6] While the inputs of all countries were assessed, the analyses focused in particular on the EU Member States.

[6] Nivel sent questionnaires to the competent authorities acting as representatives for the countries in the field of organ donation and transplantation. Data submitted was aggregated and evaluated. A stakeholder conference was held on 21.11.2016 to discuss the findings of the study.

The Action Plan has a voluntary nature and each Member State had a different starting position. In order to adapt the Action Plans to different national situations, taking account of local needs and resources, Priority Actions in the Action Plan were often translated into a set of corresponding National Priority Actions.

In short, the first challenge of the Action Plan, increasing organ availability seems to be taken up in most countries, as demonstrated by the continuous increase in both, deceased and living, donation rates in most countries. The second challenge, addressing efficiency and accessibility of transplantation systems, was mainly addressed through initiatives on organ exchange between countries. The third challenge, improving quality and safety of medical practices across the EU, has been addressed to a lesser extent within the Action Plan, but is of course the main focus of the EU legislation adopted in 2010.

The study confirmed that the Action Plan has been implemented by a majority of the countries, albeit to a varying degree (see Figure 6). Most importantly, the Action Plan helped countries to set their agenda in the field of organ donation and transplantation based on the priorities of the Action Plan.

Countries reported that most aspects of the Action Plan are being taken up at a national level, especially those Priority Actions which are most clearly defined. The following Priority Actions were perceived to have the clearest objectives and were implemented by the majority of countries:

- The appointment of transplant donor coordinators in hospitals to facilitate the identification of possible deceased donors and their transition to actual donation. This was by many considered a key success factor in increasing the number of deceased donors (PA1).
- The development of quality improvement programmes to optimise different organisational steps in the chain from deceased donation to transplantation (PA2).
- The set-up and/or development of living donation programmes to increase the donor pool (PA3).
- The building of public awareness, including communication training for professionals and working with the media to increase willingness to donate (PA4).
- The facilitation of organ exchange between countries to increase optimal use of available organs (PA8).

Some of the Priority Actions were considered by the countries as more complex to interpret and implement. Consequently, some Priority Actions were taken up to a lesser degree: identification of organs across Europe (PA5), involvement in twinnings (PA6), EU-wide agreements (PA7), the evaluation of post-transplant results on a national basis to improve transplant practice (PA9) and regular auditing/accreditation of procurement organisations and transplantation centres on a regular basis to assess, improve and align procedures (PA10).

The overview of the implementation of each of the PAs in the EU-28 Member States is summarised in Figure 6.

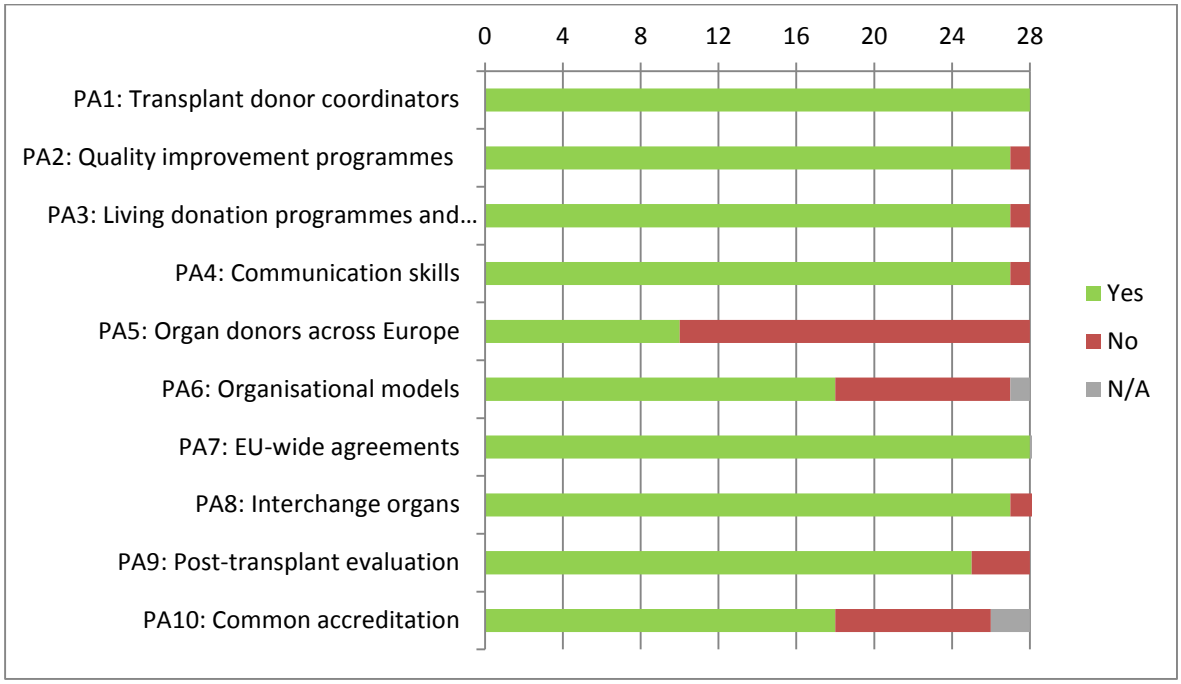

Figure 6: Implementation of the Action Plan per Priority Action in EU Member States

Overall, those Priority Actions and underlying sub-actions (see Annex 6) of the Action Plan that had clear objectives had been implemented to a larger extent than Priority Actions with the more complex nature. The later therefore might require further clarification, more EU-level support and/or more guidance for effective implementation.

EU support to implement Priority Actions

EU-funded projects have significantly contributed to the goals of the Action Plan. These EU-funded projects contributed in several ways to help Member States achieve the objectives of the Action Plan. In particular they allowed acquiring knowledge to implement Priority Actions; developing tools such as guidelines, trainings and manuals to facilitate this implementation; to exchange knowledge and best practices among countries; and to directly implement initiatives and achieve concrete changes.

EU-funded projects particularly contributed to the PA1 (donor coordinators), PA2 (quality programmes), PA3 (living donation), PA4 (communication), PA8 (organ exchange) and PA9 (post-transplant evaluation). In particular, the following EU projects can be highlighted:

- With regard to actions focused on improving outcomes from deceased organ donation, both by focusing on transplant donor coordinators in hospitals (PA1) and by increasing quality of donation activities (PA2), EU-funded actions allowed to train donor coordinators (Train the trainers[7]), to improve collaboration with intensive care units (ACCORD[8]), to compare and improve deceased organ donation programmes (MODE[9]), to assess protocols and critical steps (COORENOR[10]) and to develop quality system indicators (ODEQUS[11]).
- The ACCORD Joint Action[12] facilitated the organisation of living donor programmes (PA3) by improving Member States' information systems to register and follow-up on health of living organ donors. Follow-up is an essential element to organise living organ donation in a trustworthy way. Living donor follow-up was already prepared in the ELIPSY project and the approach is currently rolled-out under the EDITH[13] pilot project. Other EU-funded work in the field of living donation focused on ethical and legal aspects (EULID Project[14]), and explored existing organisational models (COORENOR[15] and EULOD[16]). Dissemination of these activities was ensured at EU-supported conferences like LIDOBS[17] and ELPAT[18].
- With regard to communication (PA4), the FOEDUS[19] joint action looked into communication strategies towards the general public, professionals and media. Both positive (campaigns) and negative (crises) communications were covered. The EU also funded the development of guidelines to organise a public European Organ Donation Day. The organisation of this event in 2010 in Slovenia allowed to document know-how that continues to serve the annual organisation of this awareness building event all over the EU. The recently launched pilot project EUDONORGAN[20] focuses on increasing social awareness and cooperation with patients' support groups and will further contribute to

7 European Transplant Coordinators (2012). Draft final report. European Transplant Coordinators: train the trainers course.
8 http://www.accord-ja.eu/
9 http://www.mode-ja.org/
10 https://coorenor.ders.cz/display/CRN/Home
11 http://www.odequs.eu/
12 http://www.accord-ja.eu/
13 http://edith-project.eu/
14 http://www.eulivingdonor.eu/eulid/what-is-eulid.html
15 https://coorenor.ders.cz/display/CRN/Home
16 http://www.esot.org/EULOD/home
17 http://wp2.eulivingdonor.eu/lidobs-project/
18 http://www.esot.org/ELPAT/home
19 http://www.foedus-ja.eu/
20 http://eudonorgan.eu/

implementing PA4. Finally it is worthwhile mentioning that, from 2010 to 2014, the Commission has run annual workshops introducing journalists into specificities of the organ transplant sector.

- On organ exchange (PA8), the FOEDUS joint action did not only develop organisational model agreements for organ exchange amongst countries, but has also set-up an IT platform for the exchange of surplus (unused) organs between countries. In the first 21 months, 53 transplants have already been carried out, often for children. Before that, also the COORENOR[21] project had already looked into organ exchange practices.
- An important contribution to allow for evaluation of transplant outcomes (PA9) came from the EFRETOS[22] project, which focused on the development of a register of registers for the follow-up of organ recipients. The EFRETOS project provided a data set and tools for the evaluation of post-transplant outcomes and set down the basis to build a European register of registries. Continuation of this project will be provided by the EDITH project focusing on the development and implementation of a recipient follow-up registry. Some additional follow-up aspects, mainly focused on vigilance, were addressed within the MODE Joint Action.

These Joint Actions bring many of the National Competent Authorities (NCA's) of the EU-28 Member States together on a regular basis. Almost all NCA's have been (and are) participating in one or more of these actions. Many Member States expressed explicitly that the EU-funded activities have supported them to implement the different Priority Actions in their country.

In addition, the European Commission organises regular meetings of National Competent Authorities for Organs[23], allowing NCA's to review and compare progress on a regular basis. These meetings are also good occasions to exchange know-how. This has led a.o. to the development of manuals for authorities on how to set-up living donation programs and how to improve deceased donation activities. Many national authorities have also used the occasions of these meetings to present and discuss their national activities to and with their peers. These regular meeting can therefore be considered to be a corner-stone supporting organ transplant activities in the EU.

The regular meetings of National Competent Authorities for Organs and the Commission services also followed progress in transplant activities, through a so-called annual indicator exercise including key data on donation and transplant activities in the EU-28. This was developed in close collaboration with the Spanish Transplant Agency (ONT) and the Council of Europe (CoE), who publishes annual transplant data in a Newsletter[24].

These EU activities should not be considered stand-alone but need to be seen within an **international context**, in alignment with the work of other international bodies or associations making important contributions to develop organ transplant activities in the EU and abroad. In particular worthwhile mentioning is the work by the Council of Europe's Directorate for the Quality of Medicines and Healthcare (CoE/EDQM, guidance on safety, quality and ethics), by the World Health Organisation (WHO, guiding principles), by professional associations like ESOT (European Society for Organ

21 https://coorenor.ders.cz/display/CRN/Home

22 http://www.notifylibrary.org/content/european-framework-evaluation-organ-transplants-efretos

23 https://ec.europa.eu/health/blood_tissues_organs/organs_en

24 https://www.edqm.eu/sites/default/files/newsletter_transplant_2015_2.pdf

Transplantation)[25] and EDTCO (The European Donation and Transplantation Coordination Organization)[26].

The Commission services and EU-28 National Competent Authorities have regular and good interactions with these key stakeholders.

Finally, other EU-funded programmes, managed outside the remit of European Commission DG SANTE, have also contributed to this sector. Noteworthy are initiatives supported by DG RTD (EULOD, DOPKI, ALLIANCE-O on organisational aspects and COPE on organ preservation) and by DG HOME (HOTT project on trafficking[27]).

Success factors and challenges

The Action Plan has helped countries in different ways, but most importantly by **setting a shared** agenda and by **facilitating EU-wide cooperation**.

The driving factor of the Action Plan is a strong **cooperation** between Member States, as mentioned in the sub-title of the Action Plan. The differences in practices and activity levels are a rich source to tap from when improving transplant programmes in the entire EU. Joint Actions and twinning projects were considered as a good way of achieving successful cooperation.

The fact that the common agenda in the Action Plan is aligned with and enforced by other **international activities,** in the Council of Europe (CoE) and in the World Health Organisation (WHO), is also considered an essential element of success. The fact that objectives of several EU-funded projects are aligned to these international initiatives increases the chances of sustainability.

This study found that the Action Plan and EU cooperation have been very helpful in developing national donation and transplant systems. The Action Plan was most effective for those Priority Actions that have been clearly defined. This highlights the need to clearly **define the roles of different parties** involved in implementing a Priority Action, the national or EU-level authorities, but also the professionals in transplant and donation programmes.

The role of the **Commission as central facilitator** also needs to be emphasized. The most important Commission activity is the organisation of regular meetings with the National Competent Authorities, responsible for organ donation and transplant activities in each of the EU-28 Member States. These meetings allow building a strong community open to exchange and develop know-how. The financial support through different EU-funded Actions is also considered a key facilitating factor in the field.

Some challenges for a successful implementation of the Action Plan have also been identified.

Countries with less developed donation and transplantation systems are often dealing with different institutional and organisational constraints which hamper implementation of some of the Priority Actions. Subsequently, it is difficult to accommodate the interests of countries with less developed donation and transplant systems, at the same time as the interests of the countries with more developed systems.

[25] http://www.esot.org/
[26] http://www.esot.org/EDTCO/home
[27] http://hottproject.com/

Another challenge is the **sustainability** of some EU-funded projects, in particular where they involve an IT component such as a common database. And many areas of activity increasingly require such IT-platforms (follow-up registries for recipients and for living donors, organ exchange platforms, knowledge exchange). Ensuring continuation of the projects and maintenance of the systems requires particular consideration.

Furthermore, the results of the projects could be better presented at the **political level** as the support of governments is essential to ensure sustainability of the projects. The political level might find it also interesting to learn more about the positive cost/benefit balance that organ transplant activities bring (savings compared to alternative organ-replacement therapies like dialyses). **Professional societies** such as ESOT[28] (European Society for Organ Transplantation) and EASL[29] (European Association for the Study of the Liver) could also be involved more to bolster sustainability.

Recommendations for the future

Many countries have emphasized that future EU cooperation in the area of organ donation and transplantation is essential and should benefit from the lessons learned during the implementation of the Action Plan in 2009-2015. The key lessons learned and ideas for the future approach are the following:

- Define **clear objectives**, using a bottom-up approach by involving all actors that participate in decision-making, such as (medical) professionals, administrations, political decision makers and the general public. This will allow having result-oriented and feasible actions that are broadly supported.
- Build upon the power of **mutual learning and knowledge** exchange.
- Seek opportunities to share with and learn from **experience in adjacent areas of expertise**, like tissues and cells, to increase the participatory and absorptive capacity of each country.
- Support countries with less developed donation systems to have a more explicit role. Individual **countries that face similar contexts can be brought together in groups** that are supported jointly by the EU. The Competent Authority meetings could also be organised in function of such different groups of Member States, and other relevant stakeholders could be invited to contribute to these meetings.
- Focus more on **implementation and sustainability**, including the maintenance of IT platform in an EU-funded project, to ensure a long-term impact.

Following areas were brought forward as most promising for future work at EU-level[30]:

- **Donation after Circulatory Death (DCD)**: DCD offers the potential of an important new source of organs and this practice should be further explored, so that it can be organised in more EU Member States. However, this requires for some countries changes in organisation and legal/ethical frameworks. Furthermore, possible joint work in this area should fully respect that national provisions on the donation or medical use of organs fall within the national competence and hence not in the remit of the European Union.
- **Living donation**: Supporting the further uptake of living donor follow-up and of living donor registries in a common and comparable way is crucial to ensure

[28] http://www.esot.org/

[29] http://www.easl.eu/discover/what-is-easl/easl-and-the-eu/organ-donation-and-transplantation

[30] In a stakeholder meeting, held in the framework of this study with country representatives and professionals on 21.11.2016.

public trust in this sensitive (ethical) but important transplant practice, which is now performed in almost every country.

- Furthermore, approaches and tools to increase the donor pool with **expanded criteria donors** is a promising development in order to further increase the number of donors. For instance, the use of expanded donors could be supported by quality improvement measurements like machine preservation.
- Collection of **Clinical Outcome Data** in recipients. Given the limited availability of organs, it is of key importance to know that the available organs are of optimal quality. This requires recipient follow-up and better common registers. Important lessons can be learned on critical factors like survival after transplantation, patient selection for transplantation, donor/recipient matching. In this respect, the collection and provision of data by countries is essential.
- The further development of common guidelines and standardization of evaluating, auditing **and benchmarking hospital performance**, and bio-vigilance will help to address specific aspects of quality and safety.
- **End-of-life care**: Understanding and overcoming the obstacles that critical care professionals face to incorporate donation in end-of-life care plans are considered important. Such efforts of course need to fully respect the primary objective of delivering critical care, which is to restore health of patients.
- **Communication**: Examine and develop different aspects of communication to assess and improve their effectiveness (such as public awareness campaigns, social media, education in schools and communication with the family of patients).
- **Education of professionals**: Consider a sustainable way that all professionals in the entire donation and transplantation chain could benefit from continuous training on differing aspects of organ donation and transplantation.
- **Efficiency**: Further research is needed to understand the differences between countries in the efficiency of the organisation of organ donation: for example the Study found significant differences between countries in the number of donations per donation centre.
- **Finances**: Demonstrating more widely, the cost-efficiency of transplantation programs is likely to obtain greater support at all levels, in particular with politicians and financing decision makers.
- **Research**: Opportunities were identified related to the evaluation and improvement of post-transplant outcomes, donor optimisation, immunogenicity, organ rehabilitation and organ preservation/perfusion, and new products such as combined cell therapies.

Conclusion

Organ donation and transplant practices have developed well in the EU in the course of the Action Plan. Overall, the total number of **organ donors** at the EU level has considerably increased, i.e. from 12.3 thousand to 14.9 thousand in 2008-2015 (21%). At the same time, there was an increase by 4.641 **transplants**, from 28.066 to over 32.707 in the same period (17%).

In first place this is an achievement of the professionals and the National Competent Authorities coordinating and overseeing transplant activities within each of the EU-28 Member States.

Most of these Member States[31] do however indicate the value of having a common set of priorities in form of the ***EU Action Plan***, in particular by having a shared agenda and by allowing the exchange of know-how. In particular, the Member States expressed the view that the Action Plan has helped them to improve their national policies and activities on organ donation.

[31] Representatives of National Competent authorities for Organs.

They also expressed that the **EU-funded activities** have supported them to implement the different Priority Actions in their country. Many countries have been actively engaged in the development, sharing and implementation of know-how within a variety of EU-funded projects.

Member States also seem to appreciate the development of a **peer network of National Competent Authorities** for Organs and a possibility to regularly participate in the meetings organised by the European Commission services.

This has allowed strengthening deceased donor programmes, a.o. through the role of donor coordinators, as well as living donor programmes. Also good progress was made in exploring the potential of public awareness building and of organ exchange.

There are however some learnings to be made from this experience of common work, like the need for clearly defined actions, the need to involve actors at professional, administrative and political level, and the need to work more in tailor-made sub-groups of countries facing common issues.

Member States have expressed their interest in continuing this work, and a first list of ideas was brought forward for future focus like exploring more types of donation, building awareness and looking into the financial aspects of organising transplant programmes.

Based on this positive evaluation, many Member States consider there is a need for a new, improved Action Plan, benefitting from lessons learned from the Action Plan in 2009-2015.

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 around the world. The use of human organs for transplantation has steadily increased.

Organ donation and transplantation numbers have been increasing in the EU in the last decade.
In 2015, the European Union population amounted to about 510 million inhabitants.[32] During this year, the total number of organ donors at the EU level amounted 15 thousand and there were over 32 thousand transplantations performed (Council of Europe, 2016). In particular, 4458 living donors[33] donated organs (mainly kidneys) along with 10,495 deceased donors (several types of organs from both donation after brain death and donation after circulatory death).
There are large differences in the deceased and living organ donor rates within Europe, and the numbers fluctuate over the years. For instance, average deceased donation rates in 2014-2015 donation rates varied from 4 PMP (Greece) to 38 PMP (Spain). Concerning living donation, average living donation rates in 2014-2015 varied from 0 PMP (Slovenia) to 31.3 PMP (the Netherlands).
There are various possible factors that explain those differences. Even among EU Member States with well-developed healthcare systems, there are considerable differences in organ donation and transplantation activity and it seems that some organisational models of organ donation and transplantation are performing better than others. Several aspects are dealt with differently in Member States depending on cultural, legal, administrative and organisational issues.

In spite of this, at the end of 2015, 56 thousand patients were still waiting for a transplant in the EU, and in the same year almost 4 thousand patients died while waiting for a new organ.[34]

In this context, the demand for organs in the EU Member States far exceeds the supply, which highlights the organ shortage. The challenge to accommodate the transplantation needs of patients is observed in every Member State, albeit to varying degrees.
The organ shortage has many intertwined causes, such as an increase in number of medical indications for transplants, failure to detect donors in intensive care unit, family refusals, etc. This scarcity is further influenced by other factors such as rising demand in the context of an ageing population and health trends such as obesity and alcohol consumption[35].

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[32] http://ec.europa.eu/eurostat/statistics-explained/index.php/Population_and_population_change_statistics

[33] Data extracted from 2016 Transplant Newsletter, International figures on donation and transplantation for 2015. https://www.edqm.eu/sites/default/files/newsletter_transplant_volume_21_september_2016.pdf

[34] The total number could be considerably higher since it is not known how many patients died once removed from or not admitted to the list because they became to ill to undertake transplantation or who were not registered on a waiting list but in need for an organ.

[35] http://www.who.int/mediacentre/multimedia/podcasts/2010/organ_transplants_20100806/en/

Added to the unequal distribution of wealth in the world, organ shortage has also lead to the worrying emergence of organ trafficking and transplant tourism, practices that violate fundamental human rights and pose serious risks to individual and public health[36,37].

Organ transplantation is however highly cost effective. Mendeloff *et al*. estimated the cost effectiveness of deceased kidney, heart, and liver donation and found a modest increase in healthcare costs of $16,000 for each quality-adjusted life year saved by the average donor (Mendeloff, Ko, Roberts, Byrne, & Dew, 2004). For end-stage renal failure, it is now the most cost-effective treatment and even allows for significant savings compared to alternative (dialyses) therapies. For end-stage failure of organs such as the liver, lungs and heart it is the only available treatment.

The need to tackle the problem of organ shortage has attracted widespread attention, not only at the national level but also at the international level (Squifflet, 2011). Governments and international organisations have therefore been seeking ways to increase the availability of organs in order to improve access to transplantation.
The EU recognised that the availability of organs for transplants was a subject that warranted joint endeavours between Member States and the Commission as far back as the early 1990s taking a number of initiatives[38].

The EU Action Plan

In 2007, the Commission issued a communication on organ donation and transplantation[39] outlining a set of actions the Commission was planning to take in response to the main policy changes in relation to organ donation and transplantation. The Impact Assessment[40] that followed made a number of suggestions for actions at the Community and Member State levels designed to help increase the supply of organ donors across the EU and ensure the quality and safety of the procedures.

The EU Action Plan on Organ Donation and Transplantation 2009-2015: Strengthened Cooperation between Member States (hereinafter referred to as the "Action Plan") was brought forward by the European Commission in 2008.[41] This Action Plan was established to help the Member States address three challenges: (1) increase donation rates, (2) enhance the efficiency and accessibility of transplant systems and (3) improve the quality and safety of organ donation and transplantation in the EU while

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36 http://www.europarl.europa.eu/RegData/etudes/STUD/2015/549055/EXPO_STU(2015)549055_EN.pdf

37 https://ec.europa.eu/anti-trafficking/sites/antitrafficking/files/hott_project_deliverable_1_1.pdf

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

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

40 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.

41 Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States" http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:sp0007.

fostering solidarity in the recognition of a common goal of progress and responsibilities[42].

In this Action Plan, ten Priority Actions were identified divided across five objectives. The Priority Actions were also grouped within three main challenges. An overview is presented in the Figure 1.1.

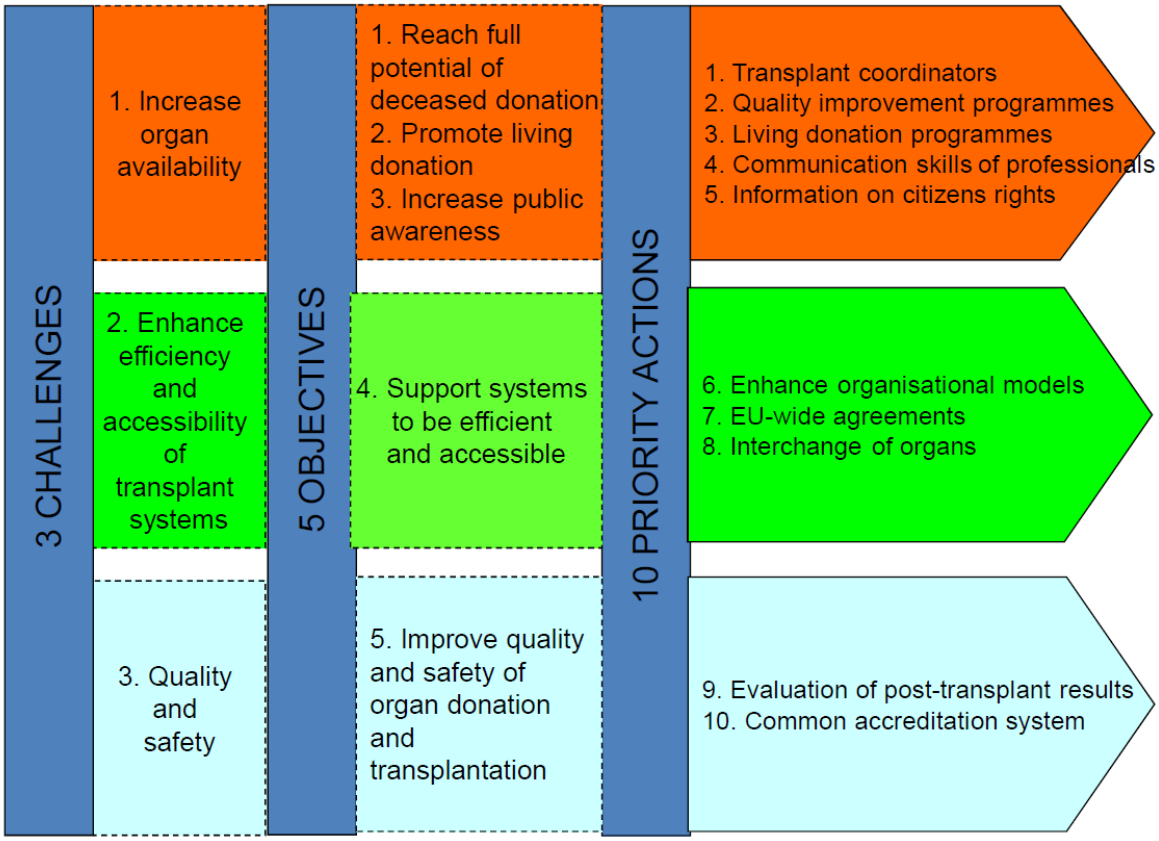

Figure 1.1 Overview of the Action Plan

1. Increase organ availability.

OBJECTIVE 1: Reach the full potential of deceased donations
To reach the full potential of deceased donations, Priority Actions 1 and 2 recommend promoting the role of transplant donor coordinators[43] and quality improvement programmes in every hospital where there is a potential for organ donation.

OBJECTIVE 2: Promote living donation programmes following best practices
At the same time, living donation should be a complementary source of organs and the EU Member States should promote the exchange of best practices on this subject and encourage registers of living donors (Priority Action 3).

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

[43] This is an overarching term for "a key donation person whose main responsibility is to develop a proactive donor detection programme", but in different countries, the profession's title may differ.

OBJECTIVE 3: Increase public awareness of organ donation
The efforts should be accompanied by initiatives to increase public awareness of organ donation. This implies improving the knowledge and communication skills of health professionals and patient support groups (Priority Action 4), as well as facilitating organ donor identification and cross-border donation in the EU (Priority Action 5).

2. Enhance the efficiency and accessibility of transplant systems.

OBJECTIVE 4: Support and guide transplant systems to make them more efficient and accessible
The organisational models of organ donation and transplantation in the EU Member States should be enhanced (Priority Action 6) and EU-wide agreements on aspects of transplantation medicine should be promoted (Priority Action 7). Moreover, the interchange of organs between Member States should be facilitated (Priority Action 8).

3. Improve the quality and safety of organ donation and transplantation.

OBJECTIVE 5: Improve the quality and safety of organ donation and transplantation
Priority Action 9 is directed at evaluating post-transplant results.
The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplant and in evaluating quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, post-transplantation data needs to be collected. Sharing such information between Member States should facilitate the further improvement of donation and transplantation across the Union.[44]
Priority Action 10 is about a common accreditation system for organ donation/procurement and transplantation programmes, with the aim of improving quality and safety.[45,46]

Directly linked to each of these Priority Actions, a total of 28 specific actions were defined to help implementing concretely the goals proposed.

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). While Directive 2010/53/EU[47] is a legally binding instrument focusing on quality and safety aspects in accordance with Article 168 of the Treaty on the Functioning of the European Union (TFEU), the Action Plan has a non-binding legal nature.

Hence, the EU Member States decided which of these Priority Actions to follow, which measures were to be taken according to their needs, resources, and a potential to accommodate into a set of National Priority Actions.

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[44] Cf. Article 24 of Directive 2010/53/EU.

[45] This aspect is also referred to in Directive 2010/53/EU, which stipulates that national competent authorities should "issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted." Cf. Article 17 e) of Directive 2010/53/EU.

[46] In the same way as for procurement organisations, Directive 2010/53/EU foresees an authorisation scheme for transplantation centres so that transplant activities and compliance with the conditions of procurement can be supervised.Cf. Articles 9 and 17 of Directive 2010/53/EU.

[47] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32010L0053

Since the adoption of the Action Plan in 2008, many activities have taken place at the national and EU levels in organ donation and transplantation. The implementation of the Action Plan has been supported by exchanges of experience at the EU level during the Competent Authorities meetings (a network of national representatives established by Article 19 of Directive 2010/53/EU that enabled inter alia a discussion on specific issues related to the Action Plan), as well as by EU-funded projects such as Joint Actions and twinning projects.[48]

To map the uptake of the Action Plan, the European Commission funded a mid-term review conducted by an external contractor NIVEL – Netherlands Institute for Health Services Research in 2012-2013.
The results were presented in so-called ACTOR study, i.e. 'Study on the setup of organ donation and transplantation in the EU Member States, uptake and impact of the Action Plan on Organ Donation and Transplantation (2009-2015)'[49].
The ACTOR study revealed that countries have undertaken activities in all Priority Action areas and that progress has been made. The ACTOR study also showed that there was room for improvement and that there were many opportunities for countries to share experiences and to learn from each other[50]. More specifically, the ACTOR study emphasised the following:

- Priority Actions relating to transplant donor coordinators, living donation programmes and cross-border exchange (PAs 1, 3 and 8) were increasingly being taken up by almost all countries. Several EU-funded projects supported these Actions: many countries were involved and endeavours go further than providing insight and sharing knowledge and aim to help implementation. It was considered that these Priority Actions have great potential for an EU-wide implementation.
- Priority Actions relating to quality improvement programmes, organisational models and post-transplant follow-up (PAs 2, 6 and 9) had been taken up by most countries. For these Priority Actions there is great potential for mutual learning through an exchange of experiences. The uptake of these Priority Actions seemed to have increased when compared to 2009.
- However, fewer countries had initiated activities in relation to communication skills, dissemination of information about citizens' rights concerning organ donation and transplantations, EU-wide agreements and accreditation systems (PAs 4, 5, 7 and 10). It was suggested that further discussions at the EU level on each of these Priority Actions were important to come to a shared understanding.

In 2014, the Commission adopted Staff Working Document on the mid-term review of the 'Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States'.[51] The Document concluded that good progress had been made by the Member States during the first half of the Action Plan period. The most important achievements related to the increase in the number and training of transplant donor coordinators (PA 1), the introduction or development of living donation programmes in some Member States (PA 3) and improvements in the organisational models (PA 6). In concrete terms, more coordinators were appointed and trained (PA 1), thus improving deceased donation rates; living donation programmes were created or developed, also with the aim of better protection for

48 E.g. http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20150929_ag_en.pdf
49 http://ec.europa.eu/health/blood_tissues_organs/docs/organs_actor_study_2013_en.pdf
50 http://ec.europa.eu/health/blood_tissues_organs/docs/organs_actor_study_2013_en.pdf
51 SWD(2014) 147 final http://ec.europa.eu/ health/blood_tissues_organs/docs/midtermreview_actionplan_organ_en.pdf

living donors (PA 3); and organisational models (PA 6) that proved to be efficient in some Member States were introduced in other EU or non-EU countries, with support for both groups from EU-funded projects or activities.
Thus the Commission suggested focusing at the EU level on living donation and the cross-border exchange of organs for the remaining two years of the Action Plan.

The conclusions reached by the Commission reflected the **Council conclusions on organ donation and transplantation** adopted in 2012[52]. The Council of the European Union concluded that endeavours have been made to meet the three challenges set by the Action Plan. In particular, the Council welcomed the establishment of bilateral and multilateral agreements between countries, the development of manuals for living donation practices and the sharing of good practice. However, the Council also concluded there was still room for improvement. The Council invited Member States to collect and share knowledge and expertise on several topics such as the expanded criteria for donors and national procedures for the authorisation of procurement organisation and transplantation centres. Furthermore, awareness and the importance of encouraging people to become donors were emphasised by the Council.

To bring the implementation of the Action Plan forward, the Commission co-financed several Joint Actions in organ donation and transplantation such as ACCORD (2012-2015) and FOEDUS (2013-2016). As proposed by the European Parliament in 2014, the European Union is currently funding two pilot projects, i.e. EUDONORGAN and EDITH Both projects started in 2016 and will continue for three years (for more info see in Chapter 4.

Final review of the Action Plan

To provide an overview of the state of implementation of the Action Plan, NIVEL was contracted by the European Commission in 2015. The final review of the Action Plan is presented in this Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member States (FACTOR study)[53].

The final review of the Action Plan aims to provide the European Commission and therefore also the EU Member States with an overview of the efforts during the period of the Action Plan and its state of implementation in every EU Member State and in other 8 countries[54] and at the EU level.

It provides a review of the endeavours made during the entire timeframe of the Action Plan. Based on this review, the report also proposes ideas for further action after the period covered by the Action Plan.

This study should enable EU Member States and other participating countries as well as the European Commission to streamline their activities after 2015 in organ donation and transplantation in areas where gaps or shortcomings in the implementation of the Action Plan have been identified, and in the areas where most value can be achieved. In particular, this should assist EU Member States and institutions as well as other stakeholders in their endeavours to fully implement EU-wide quality and safety standards for human organs intended for transplantation, to increase the number of

[52] 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
[53] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:sp0007
[54] Iceland, Norway, Macedonia (fYRoM), Switzerland, Turkey, Liechtenstein, Montenegro and Serbia.

organs available for transplantation and to further improve the efficiency and accessibility of transplant systems.

The following objectives were formulated for the FACTOR study. They were divided into four work packages (WP) and formulated as follows:

WP1: *Overview of donation and transplantation activities at the national level*. To provide a brief but accurate assessment of organ donation and transplantation activities in each of the Member States, including the set-up and organisation at the central and local levels *(cf. Chapter 2 and Country sheets (Annex 1)*;
WP2: *Action Plan activities at the national level*. To provide a mapping overview and assessment of the state of implementation and activities carried out, on-going and/or planned in each of the Member States *(cf. Chapter 3 and Country sheets (Annex 1)*;
WP3: Action Plan at the EU level. To provide an assessment of the engagement of Member States and Commission in common EU initiatives and the outcome of these initiatives in relation to the ten Priority Actions; *(Chapter 4; cf.)*
WP4: *Lessons learnt and future*. To provide an assessment of the strengths, weaknesses, opportunities and threats for the implementation of the Action Plan. Importantly, this includes recommendations for the period after the original timeframe of the Action Plan (2009-2015), at both the EU and national levels. *(Chapters 5 and 6).*

1.2 Methods

The study is based on a combination of desk research and the consultation of experts carried out by a multidisciplinary project team.

For Work Packages 1, 2 and 3, the research team built upon the findings of the ACTOR study corroborating them with the information retrieved from available sources (scientific literature, previous projects, policy papers and secondary analysis of existing data[55]. Only at the end of this phase the competent authorities[56] and other stakeholders were asked for additional information and validation.
For WP 4 a separate strategy was followed.

WP 1: Overview of transplantation activities at national level
WP 1 provides an assessment of organ donation and transplantation activities in each of the participating countries, including the setup and organisation at the central and local levels. Data is presented in a separate datasheet for each country, included in Annex 1 of this report. These provide insight into the organisation of organ donation and transplantation in each of the 36 countries.

The following information is provided:

- The organisation of organ donation and transplantation at the national level;
- A scale estimation of the number hospitals involved and donations/transplants carried out;
- A qualitative analysis of the donation and transplant system in place;
- Insight into key actors, funding, current policies, ongoing changes and other important issues.

The assessment was based mainly on input from the following sources:

[55] Council of Europe Transplant Newsletters, OECD and WHO data, the Commission's 'facts and figures', the presentations available on Commission's CIRCA BC platform, websites of EU-funded projects etc.

[56] Each country is represented by a competent authority. These authorities meet regularly to discuss issues concerning organ donation and transplantation, including the Action Plan.

- The website of the European Commission DG SANTE website;[57]
- The website of Chafea, the Executive Agency of the Commission, in particular the project databases for projects funded under the EU Health Programmes;[58]
- The platform CIRCA BC used by the European Commission to share documents with Member States competent authorities, for example for Competent Authority meetings;[59]
- Websites of European organisations dealing with organ donation and transplantation issues, such as EDTCO[60] (The European Donation & Transplant Coordination Organisation), ESOT[61] (European Society for Organ Transplantation), SAT[62] (Southern European Transplant Alliance), EUROCET[63] (European Register of Competent Authorities for Tissues), Eurotransplant[64] and Scandiatransplant[65], as well as international organisations such as the Council of Europe[66] and WHO (World Health Organisation)[67].

WP 2: Action Plan activities at the national level
WP 2 provides a country-specific mapping, analysis and assessment of the state of implementation of the 10 Priority Actions defined in the Action Plan as well as activities carried out, on-going and/or planned in each of the Member States relating to each of the ten Priority Actions.

Desk research
The desk research provided an overview of what is already known about the state of implementation of the Action Plan in each of the EU Member States, as well as at the European level. The desk research provided suggestions for additional indicators and information on the state of implementation of the ten Priority Actions.

Consultation of country and European services
Considering that not all information on the state of implementation of the Action Plan is publicly available or directly accessible to the contractor, competent authorities were contacted for additional information and validation. The research team focused not only on completed activities but also included on-going and planned activities. Among other things, the competent authorities were asked about the strengths of their national systems and their views on what the next steps should be at the country level and at the EU level.

Structured questionnaire
For this part, a structured survey was sent via email to the competent authorities. As part of the ACTOR study in 2012, a survey was held to gather information on the state of implementation of the ten Priority Actions. To be able to provide an in-depth analysis and demonstrate any progress in recent years, the questionnaire built upon the ACTOR survey adding additional indicators where needed.

A key indicator most closely related to the main issue in a Priority Action was selected by the research team (Figure 3.1) to aggregate the input.

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57 http://ec.europa.eu/health/blood_tissues_organs/policy_en
58 http://ec.europa.eu/chafea/projects/database.html
59 https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp
60 http://www.esot.org/EDTCO/home
61 http://www.esot.org
62 http://trapianti.net/en/sat-south-transplant-alliance/
63 http://www.eurocet.org/
64 https://www.eurotransplant.org/cms/
65 http://www.scandiatransplant.org/
66 http://www.coe.int/t/dghl/standardsetting/cdpc/pc_to_en.asp
67 http://www.who.int/transplantation/organ/en/

Any non-responding competent authorities were contacted by telephone to encourage them to respond and to offer assistance if needed. 34 out of 36 countries responded to the survey. In the event of non-response in the FACTOR study, NIVEL checked whether the country responded to the questionnaire in 2012. If it did, NIVEL considered the answers in 2012 as the most valid information (i.e. for 2 non-EU Member States).

Validation
Finally, the competent authorities were presented with a draft version of their country sheet providing information on the state of implementation of the 10 Priority Actions in the intended publication format (see Annex 1). They were encouraged to check and, if necessary, supplement the information compiled on their country for validation. In the end, 28 competent authorities responded and validated their country sheets.

WP 3: Action Plan at the EU level
This WP provides an assessment of the engagement of Member States and the Commission in common EU initiatives and projects and the outcome of these initiatives in relation to the 10 Priority Actions of the Action Plan.

Desk research
The desk research provided an overview of what is already known from the recent scientific literature, non-scientific literature and websites about common EU initiatives and projects.
It provided an overview of activities and projects that were initiated under the Action Plan, after the mid-term review, and an evaluation of these projects, including comparison of earlier projects under the Action Plan.

The study shows the results of these initiatives in each of the 10 Priority Actions in the last few years:

- working groups led by the Commission, projects such as ETPOD, EULID, EFRETOS, ELIPSY, EDD, COORENOR, ODEQUS, ELPAT, MODE until 2011;
- ACCORD and FOEDUS Joint Actions, the Commission and Chafea Journalist workshops, the LIDOBS Conference[68] and EU-funded projects in research as well as assistance in this field for neighbouring countries since 2011[69];
- pilot projects proposed by the European Parliament on chronic kidney diseases and training and social awareness, i.e. EUDONORG and EDITH (projects started in 2016) were also taken into account[70].

This study also includes an overview and assessment of initiatives undertaken by international organisations and associations such as:

- WHO (South East European Health Network, global projects, and others);
- The Council of Europe (e.g. Guides to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and cells, the Black Sea Network, Resolutions, Recommendations and Conventions);
- Eurotransplant, Scandiatransplant and SAT (Southern Alliance for Transplants);
- Associations and professional societies like ESOT (European Society for Organ Transplantation) and its different sections (for example ELPAT and EDTCO), ELTR (European Liver Transplant Register), EKHA (European Kidney Health Alliance), ERA-EDTA (European Renal Association / European Dialysis and Transplant Association) and others.

[68] http://ec.europa.eu/chafea/projects/database.html
[69] E.g. Annex 2 of the Commission Staff Working Document on the mid-term review of the Action Plan.
[70] http://eur-lex.europa.eu/budget/data/General/2015/en/SEC03.pdf (pages 866 to 869)

This overview is given in Annex 3.

The information that had been collected was assessed on its relevance for the different priority actions of the Action Plan.

WP 4: Lessons learned and the future
WP 4 provides an assessment of strengths, weaknesses, opportunities and threats for the implementation of the Action Plan and ideas for possible endeavours for the period following the Action Plan (2009-2015), both at the EU level and the national level.

Summarising the results of WPs 1, 2 and 3 and a first consultation
This work package provides a summary of the three previous work packages and identifies strengths, weaknesses/gaps and overlaps for each of the 10 priority areas. This summary was presented and discussed at an expert meeting in November 2016. Clear proposals for actions that could be taken in the period after the Action Plan were studied, discussed and presented.

Interviews
Furthermore, using input from this summary, interviews were held with representatives of 27[71] Competent Authorities and with stakeholders such as Eurotransplant, Scandiatransplant, SAT, professional associations and patient representatives to elicit their views on the strengths and weaknesses of the Action Plan. They were also asked for their views on the follow-up to the Action Plan. The questions concerned outstanding items, new ways of addressing the Priority Actions, new areas of interest and possible further steps. They were also asked about new aspects in organ donation and transplantation that might not have been relevant when the Action Plan was adopted in 2008 and that are currently developing. The related fields of blood, tissues and cells were also considered to assess whether good practices can be shared.

Stakeholder conference
A first draft analysis was performed of all the information that had been collected. The draft was evaluated during a stakeholder conference attended by 17 experts (from four relevant organisations in organ donation and transplantation and 12 competent authorities) in the organ donation and transplantation field.

The following evaluative questions were covered during the meeting:
- What worked and what did not work, and why?
- What were the key challenges and how were they overcome?
- What were the key successes and why were they important?
- What were the key failures and how could such failures be avoided in the future?
- Is there a need for a new Action Plan? If so, which actions should be included (or not) and why?

The research team elaborated on the degree of consensus on all of these evaluative questions during interactive sessions with all the experts, recognising that different Member States may have very different views on these questions.

Based on the feedback of the Competent Authorities and the results of the stakeholder meeting, a draft version was drawn up of the results of this WP.

[71] The other competent authorities were not reached after three call attempts.

The preliminary draft was built around three central issues:

- The successes and weak spots of the Action Plan, at both the national and EU levels;
- Possible ideas for action for the period after the Action Plan, at both the national and EU levels;
- New aspects in organ donation and transplantation that should be considered.

Peer review of the final draft report
The final report was peer reviewed by five experts. These experts were:

(1) Eurotransplant: Undine Samuel
(2) NTS: Bernadette Haase-Kromwijk
(3) ONT: Beatriz Dominguez-Gil
(4) ACCORD: Triona Norman (UK/NHSBT)
(5) FOEDUS: Alessandro Nanni Costa (IT/CNT-ISS)

2 OVERVIEW OF ORGAN DONATION AND TRANSPLANTATION ACTIVITIES AT THE NATIONAL AND EU LEVELS

This chapter summarises the key figures of organ donation and transplantation activities provided by the countries included in the study.

The following aspects of organ donation and transplantation in European countries were analysed in the study:
1. Deceased and living donation rates at the EU level.
2. Deceased donation rates at the national level.
3. Living donation rates at the national level.
4. The importance of expanded criteria donors, in particular having donors older than 60 years.
5. Transplants, organ-specific transplants, specifically pancreas and small bowel transplants, and the transplant rates per transplant centre.
6. Waiting lists.
7. Organ exchange organisations.
8. Consent systems.

The complete country sheets can be found in Annex 1[72].

2.1 Deceased and living donation rates at the EU level

In general, organ donation rates increased during the period of the Action Plan.

At the EU level, the total number of organ donors increased from 12,369 in 2008 to 14,953 in 2015. This accounts to an increase of +21% over the period of the Action Plan.

[72] The aggregated results cover the EU Member States. If available, the results were also provide for other European countries that participated in this study The results are based on Translant Newsletters, and tinformation provided by countries in the country sheets.

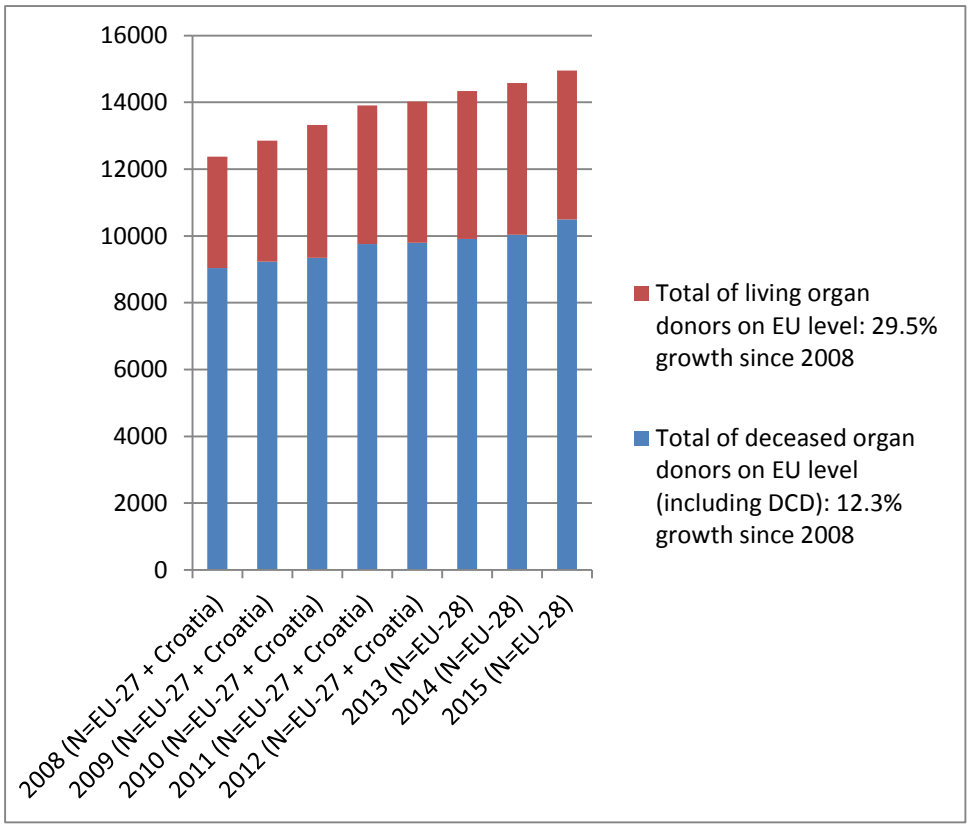

Figure 2.1: Total number of deceased and living organ donors in the EU in 2008-2015 (Source: Transplant Newsletter, ONT/Council of Europe, country sheets, Annex 1[73])

Living donation is performed mainly for kidney transplants and for some liver transplants (to a limited extent also for lung transplants).

In all Member States except one living donation was performed[74]. The increase in the number of living organ donors (on average 4.2% more per year) was larger than the increase in the number of deceased organ donors (on average 1.8% more per year).[75]

Deceased donation is a possible source for kidney, liver, heart, lung, pancreas and small bowel transplants. Kidney transplant is the main transplant procedure performed in countries.
Most deceased donations come from donors after brain death (DBD). These are deceased organ donors in whom death has been determined by neurological criteria. This is the standard method, and thus used by all countries where organ donation is performed.

A donor after circulatory death (DCD) is a deceased organ donor in whom brain death cannot be determined or is not expected to be brain dead. Then death will be determined by circulatory and respiratory criteria. It is a relatively new development in the field and can be seen as a possible new source of donors. This field of donation is explored only in few countries. Other countries wishing to implement or expand DCD programmes would need to develop their expertise or address legislative or ethical issues. Although the number of countries undertaking or considering the

[73] Croatia became a Member State in 2013.
[74] In Luxembourg, no living donations were performed.
[75] In Germany, deceased donation rates showed a significant decrease during 2008-2015, which has a large impact on EU numbers.

implementation of a DCD programme is not significant[76], the number of DCD donors has increased over the years, from 569 in the 10 of 27 EU Member States in 2008 to 1113 donors after circulatory death in 10 of 28 Member States in 2015.

2.2 Deceased donation rates at the national level

The deceased donation rate gives the number of deceased donors per million of the population (PMP) where a deceased donor is defined as an actual donor (at least one organ has been recovered for the purpose of transplantation).[77]
Significant differences are seen in deceased donation rates between countries. Figure 2.2 shows the actual deceased donation rates in the EU Member States and other countries in 2015.
The highest rates are found in Spain (in total 1851/40.2 PMP), Croatia (in total 169/40.2 PMP) and Iceland (in total 12/40.0 PMP).

[76] There might be changes in which Maastricht classification they use though. The modified Maastricht classification is widely used to categorize DCD. Categories I, II, and V describe organ retrieval that follows unexpected and irreversible cardiac arrest (uncontrolled DCD), while categories III and IV refer to retrieval that follows death resulting from the planned withdrawal of life-sustaining cardiorespiratory support (controlled DCD). (Manara, Murphy & Callaghan, 2012).

[77] Cf the definition of the 'Transplant Newsletter' of the Council of Europe and ONT. Definitions used may differ in different countries. Within Eurotransplant, for instance, an organ donor is a donor, where at least one organ could be procured and transplanted. In Spain, also a tissue donor is considered an "organ donor" and is counted as such.

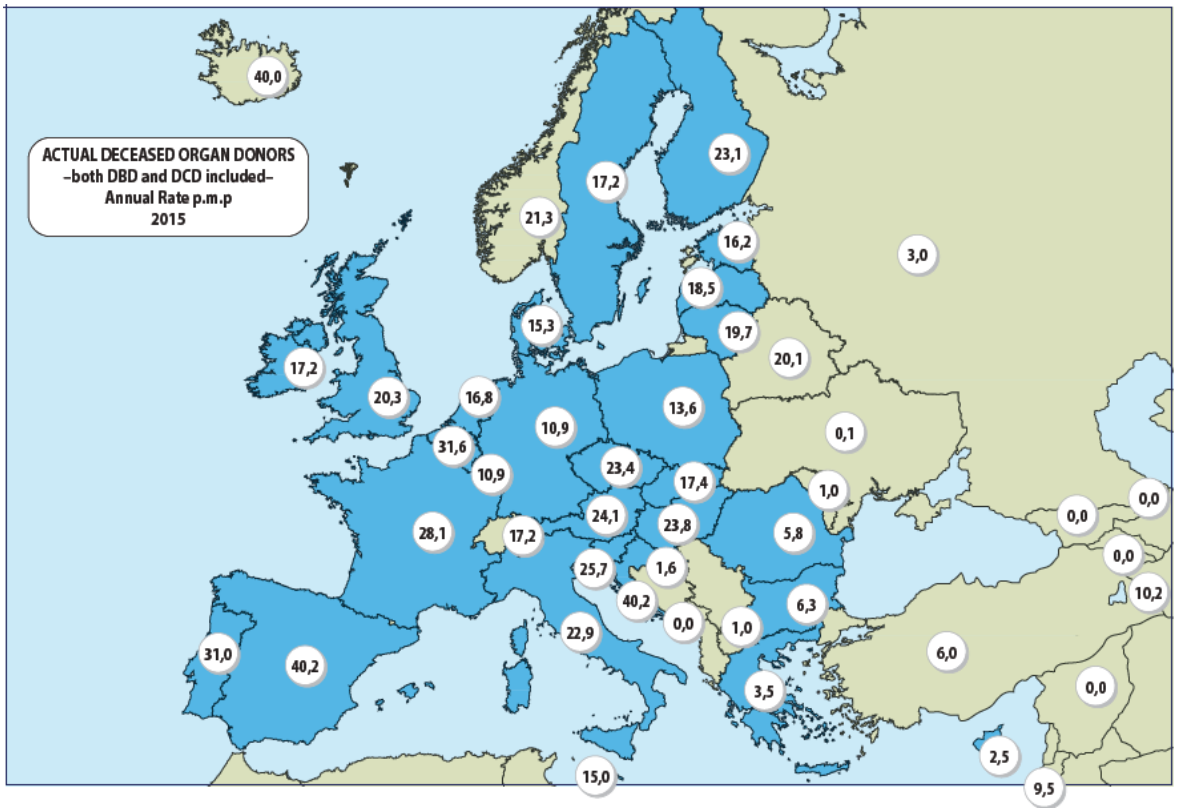

Figure 2.2: Deceased donation rates per million population in the EU Member States and other countries in 2015 (source: Transplant Newsletter 2016, ONT/Council of Europe)

Positively, deceased donation rates have been increasing in almost all countries since the adoption of the Action Plan.
Figure 2.3 shows the percentage change between the average deceased donation rates for the years 2008/2009 and 2014/15 at the national level.
Average deceased donation rates in 2008/2009 varied from 1.3 PMP in Bulgaria to 34.3 PMP in Spain. In 2014/2015, deceased donation rates varied from 4 PMP in Greece to 38 PMP in Spain.
Interestingly, deceased donation numbers considerably increased in some countries, e.g. Bulgaria (346%), Croatia (107%) and Hungary (54%).

However, some countries have shown a decrease. This may be attributable to a set of different factors. It may for instance have been influenced by a sudden decrease in public trust due to negative media attention financial and institutional constraints.

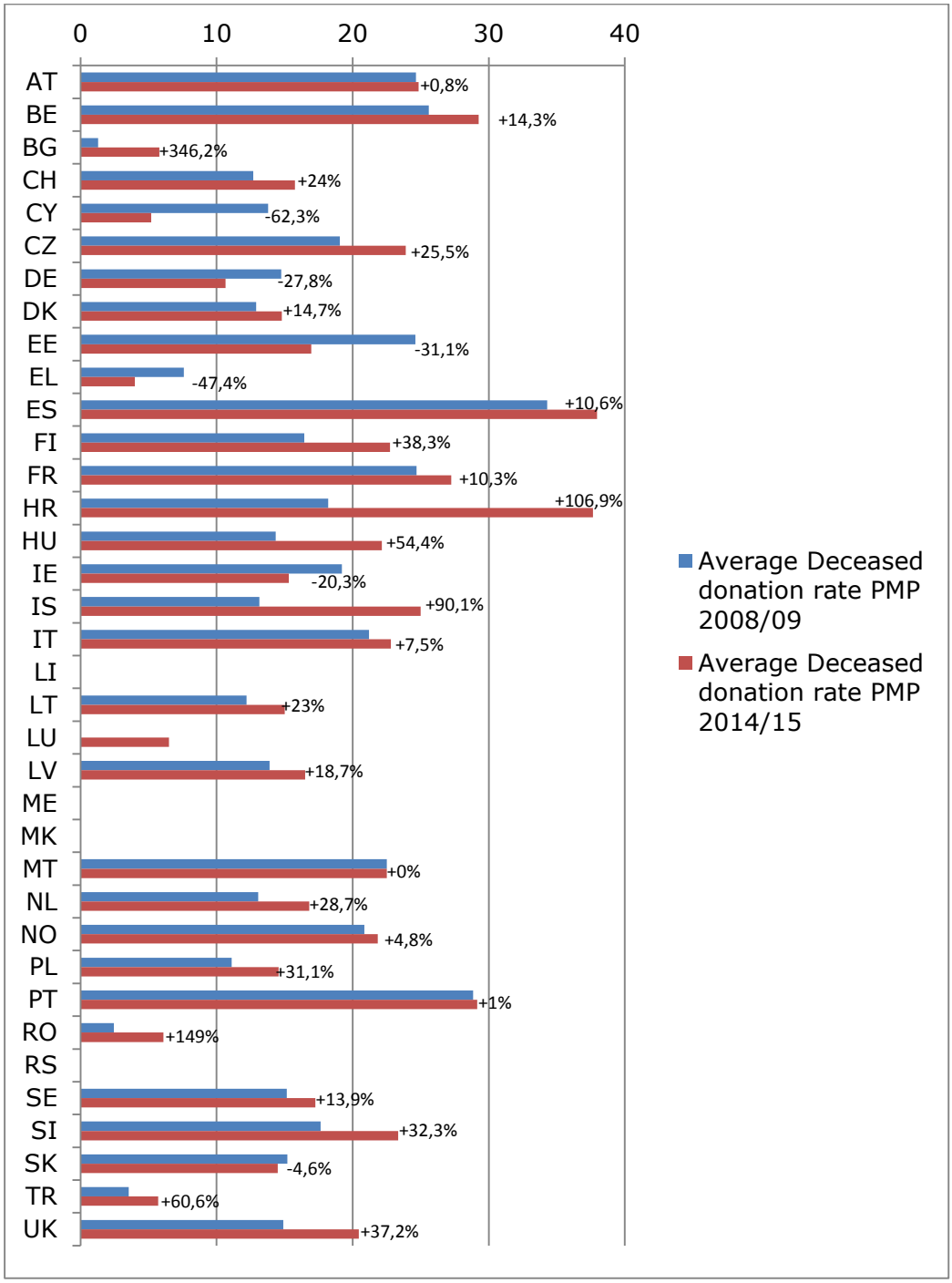

Figure 2.3: Deceased donation rates and increase in 2008/2009 compared to 2014/2015 for EU Member States and other countries[78,79] (Source: Transplant Newsletter 2016, ONT/Council of Europe, country sheets, Annex 1)

[78] See table in Annex 1 for country codes.

[79] The average increase was calculated over the rates for 2008-2009 and 2014-2015 in the 36 countries included in this study, in order to reduce the influence of fluctuations. For Montenegro, Luxembourg, Macedonia, Serbia and Liechtenstein, no/not all numbers were available to calculate average donation rates and percentage change.

2.3 Living donation rates at the national level

Living donation rates are increasing in most of the EU Member States.
In several countries living donor transplants contribute significantly to the total number of donations. In particular, the average living donation rates in 2014/2015 exceeded the deceased donation rates in Denmark, Montenegro, Turkey and the Netherlands.

Figure 2.4 gives an overview on living kidney and liver donation rates and the percentage change between the average rates in 2008/2009 and 2014/15. It shows that there are considerable differences between the countries.
It is observed that average living donation rates PMP are relatively high in Cyprus, Island, the Netherlands and Turkey. The percentage increase compared 2014/2015 with 2008/2009 is most prominent in Czech Republic (107%), Estonia (100%), Spain (92%), Finland (96%), France (130%), Ireland (146%), Italy (96%) and Latvia (200%).

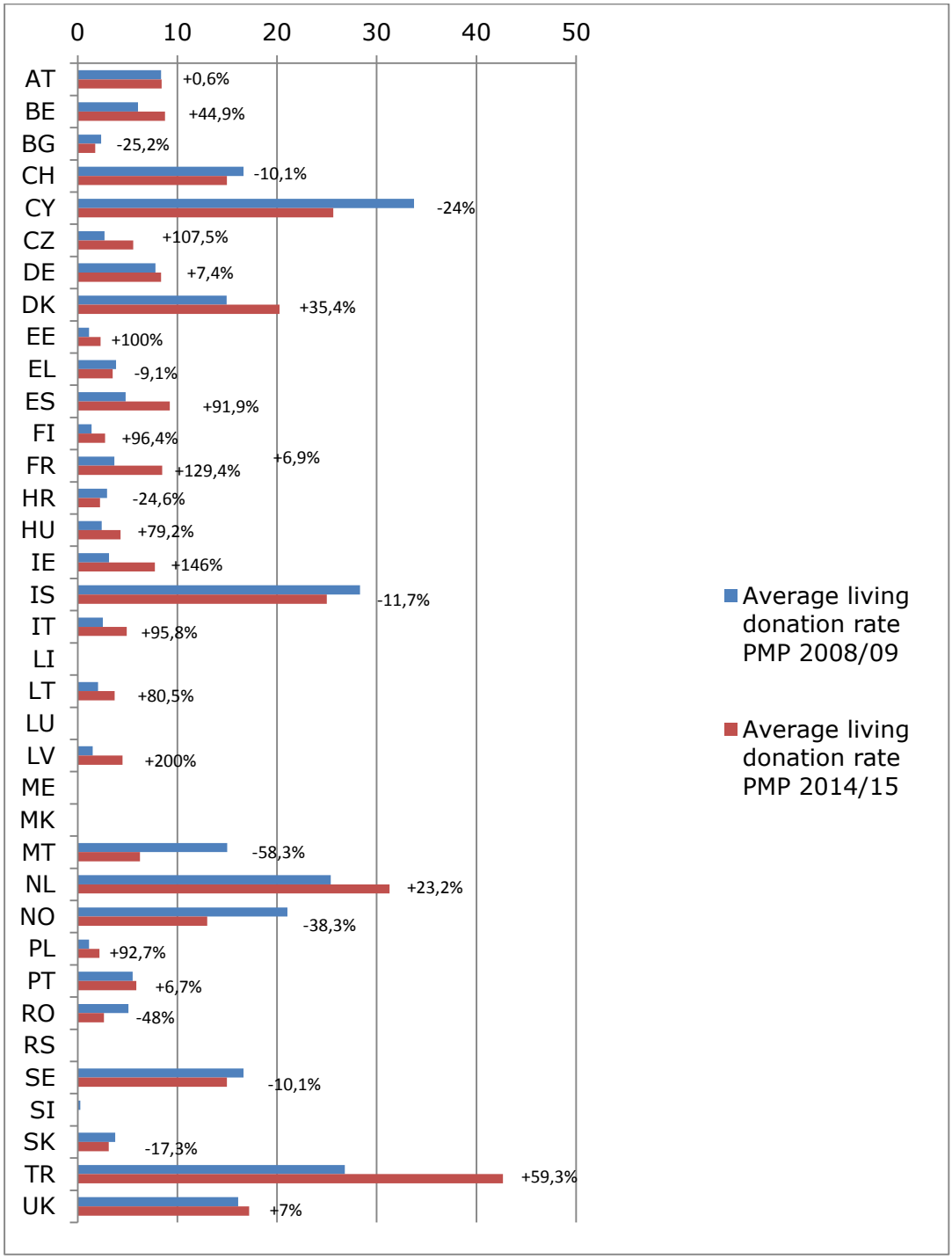

Figure 2.4: Living donation rates and increase in 2008/2009 compared to 2014/2015 for EU Member States and other countries[80] (Source: Transplant Newsletter 2016, ONT/Council of Europe, country sheets, Annex 1)

The figure below shows changes in the rates of both deceased and living donation in countries between 2008/2009 and 2014/2015 PMP.

[80] The average increase is calculated over the rates of 2008-2009 and 2014-2015 in the 36 countries included in this study, in order to reduce the influence of fluctuations. For Montenegro, Luxembourg, Macedonia, Serbia and Liechtenstein, no/not all numbers were available to calculate average donation rates and percentage change.

Both rates have increased in 16 out of 36 countries included in the study. In 3 countries out of 36, both rates have decreased. Additional analyses show that some countries that originally had a deceased donation rate below 15 PMP managed to increase their donation rate by more than 15% (12 countries). The same applies for countries that started with a living donation rate below 10 PMP (12 countries) (see Annex 4 for the results).

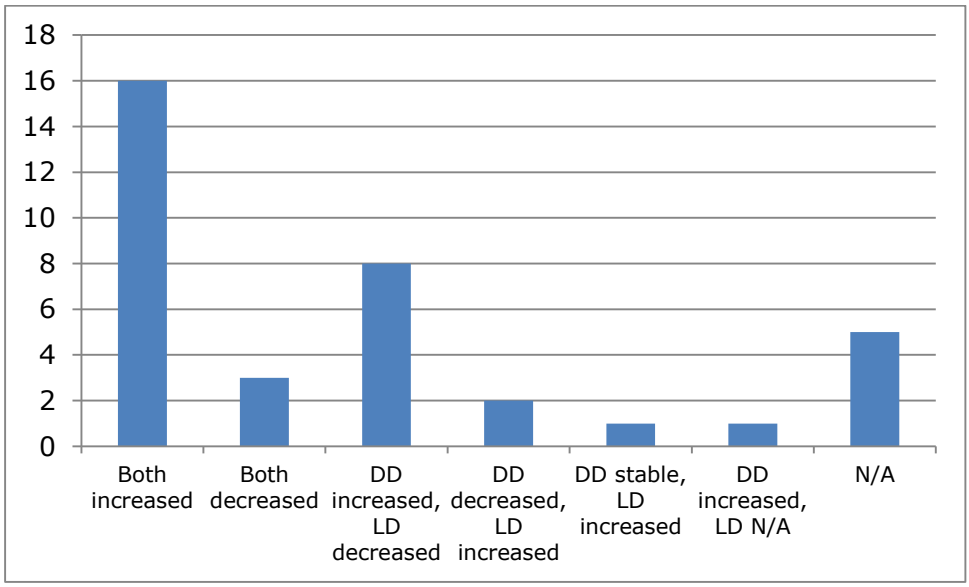

Figure 2.5: Changes in donations PMP for both deceased (DD) and living donation (LD) between 2008/2009 and 2014/2015 in 36 included in this study (source: country sheets, Annex 1)

2.4 The importance of expanded criteria donors

Because of organ shortages, donors aged over 60 are a growing part of the total donor pool. Some transplant professionals might be reluctant about the use of older donor organs because of a perceived greater chance of rejection by the recipient and because advanced donor age is a pervasive risk factor influencing organ quality (Port, *et al*., 2002).
However, although outcomes are generally poorer, the recent achievement of acceptable outcomes has allowed the progressive expansion of the donor pool to include a larger portion of older donors (Giessing *et al*., 2009). Moreover, kidney transplants from older donors still produce a benefit in recipient survival compared with dialysis. Results are encouraging especially for older recipients who represent a growing proportion of transplant patients (Segall *et al*., 2016). For instance, Eurotransplant started a successful senior programme in 1999, to achieve a more efficient use of kidneys from donors aged over 65 years of age and to reduce the waiting time for elderly patients (Frei *et al*., 2008).

The figure below shows the proportion of the deceased donation rate per million population (PMP) from donors aged over 60 in 2014 vs. deceased donors under 60. It highlights a significant variation between the countries. For instance, in Spain, Italy and Norway the number of deceased donors older than 60 exceeds the number of deceased donors under 60. The variation also reflects the uncertainties that there are about older donation (Aubert *et al*., 2015; Rao & Ojo, 2009).

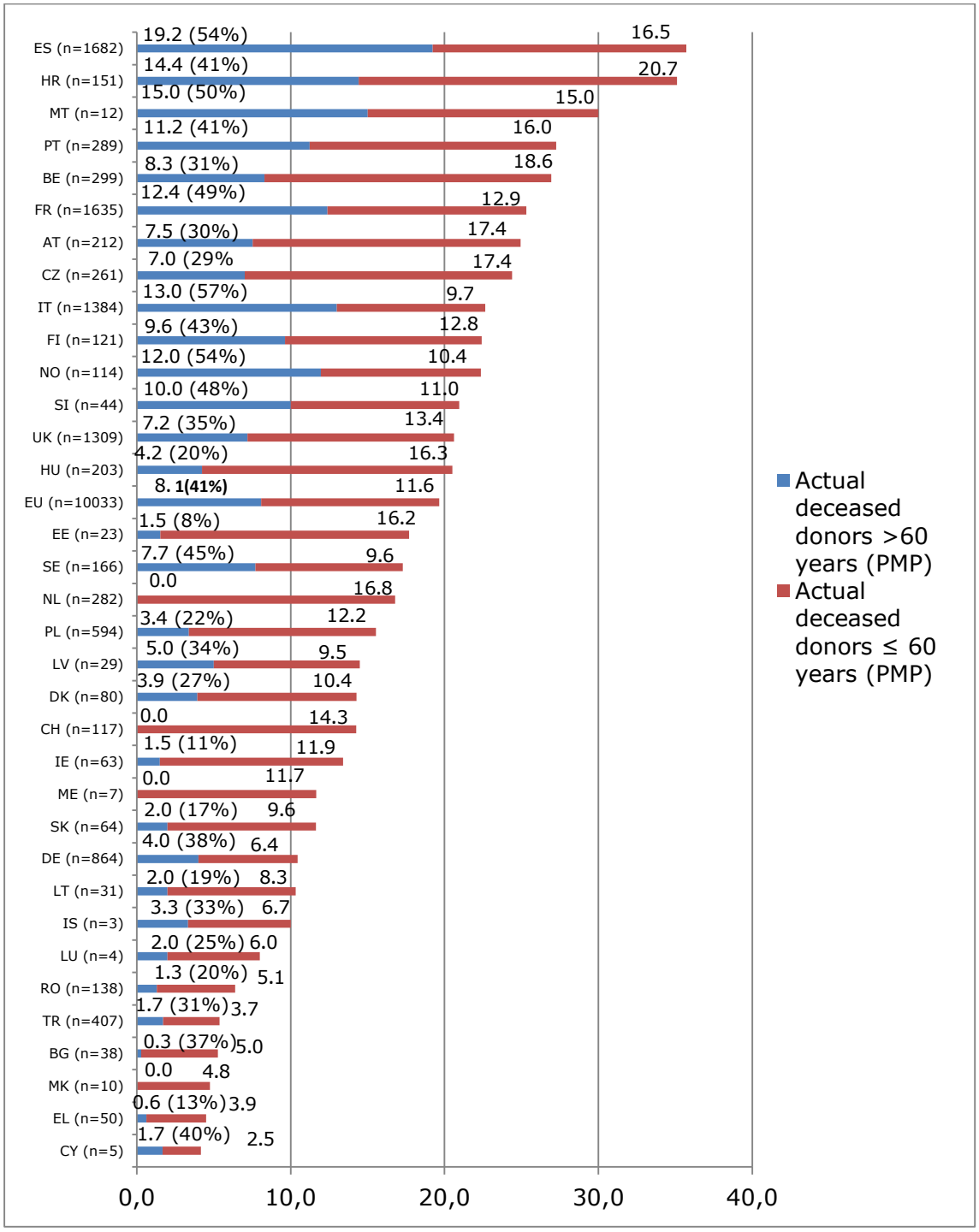

Figure 2.6: Number of deceased donors (PMP) divided into donors aged below and above 60 in 2014 for the Member States and other countries (source: Country sheets, Annex 1)

It is recognised that older donors bring a longer medical history and have potentially a higher risk of disease and co-morbidities. However in view of the significant shortage of donated organs in the EU, it also underlines the importance of the expansion of acceptance criteria for donors. For example a history of malignancy might become acceptable for donors under certain conditions (e.g. disease free for many years, and for specific recipients who have few other therapeutic options).
Lastly, it underlines the need to get more insight in the transplant results of these older donors and expanded criteria donors on the long term.

Another example is expanding the donor pool by the use of organs non-standard risk donors such as anti HCV (hepatitis C virus) positive donors. However, this is a very sensitive subject and any statements about this have to be made with caution.

2.5 Transplants at the EU level and organ-specific transplants

An upward trend has been observed in the number of transplants at the EU level over the period of the Action Plan. Overall, there was an increase from 28,066 transplants in 2008 to over 32,707 in 2015. This account to a 17% increase over the period.[81]

Overall, an increase in transplants of different organs is observed in the EU, despite fluctuating in some countries, (see Figure 2.7).

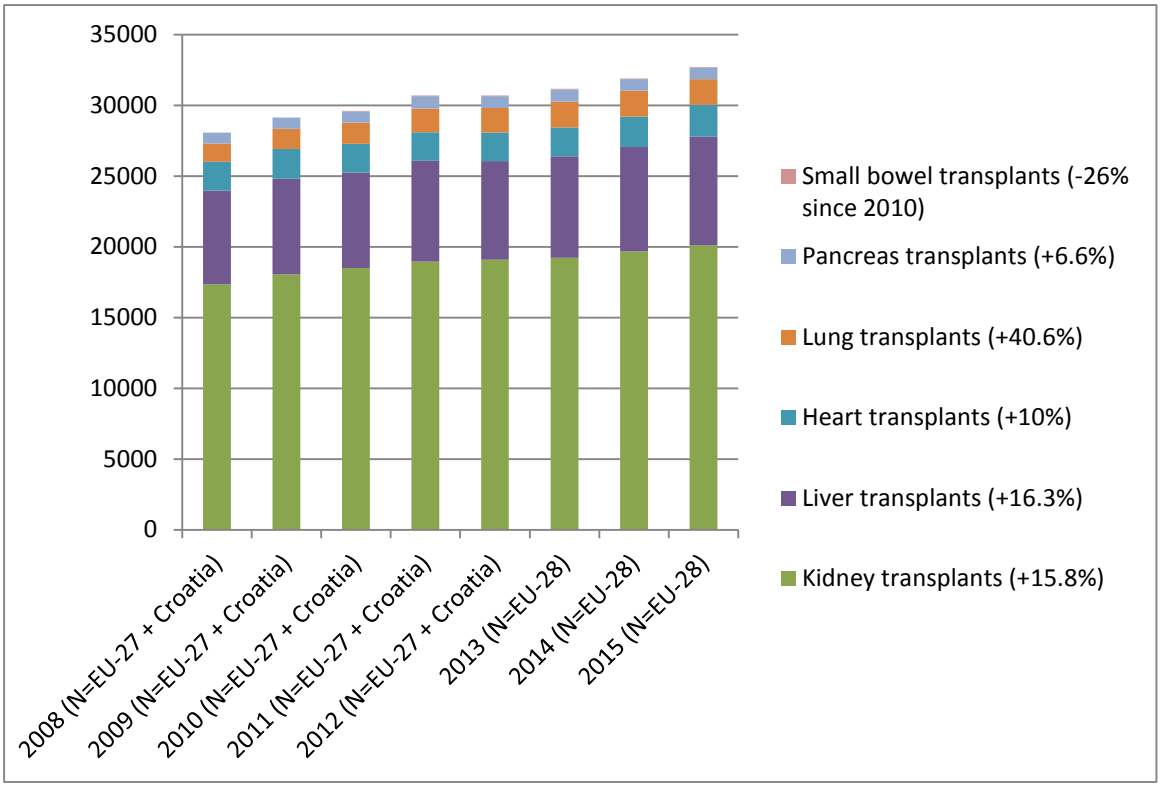

Figure 2.7: Total number of transplants from living and deceased donors per organ in 2008-2015 in EU Member States (Source: Transplant Newsletter 2016, ONT/Council of Europe)

The figure below shows the number of transplant patients per million population (PMP) in the EU Member States and other countries. The highest rates are seen in Spain (100.7 PMP), Croatia (93.1 PMP) and Austria (88.8 PMP).

[81] Although one country (Croatia) became a member of the EU in 2013, excluding it still gives an increase of 11%.

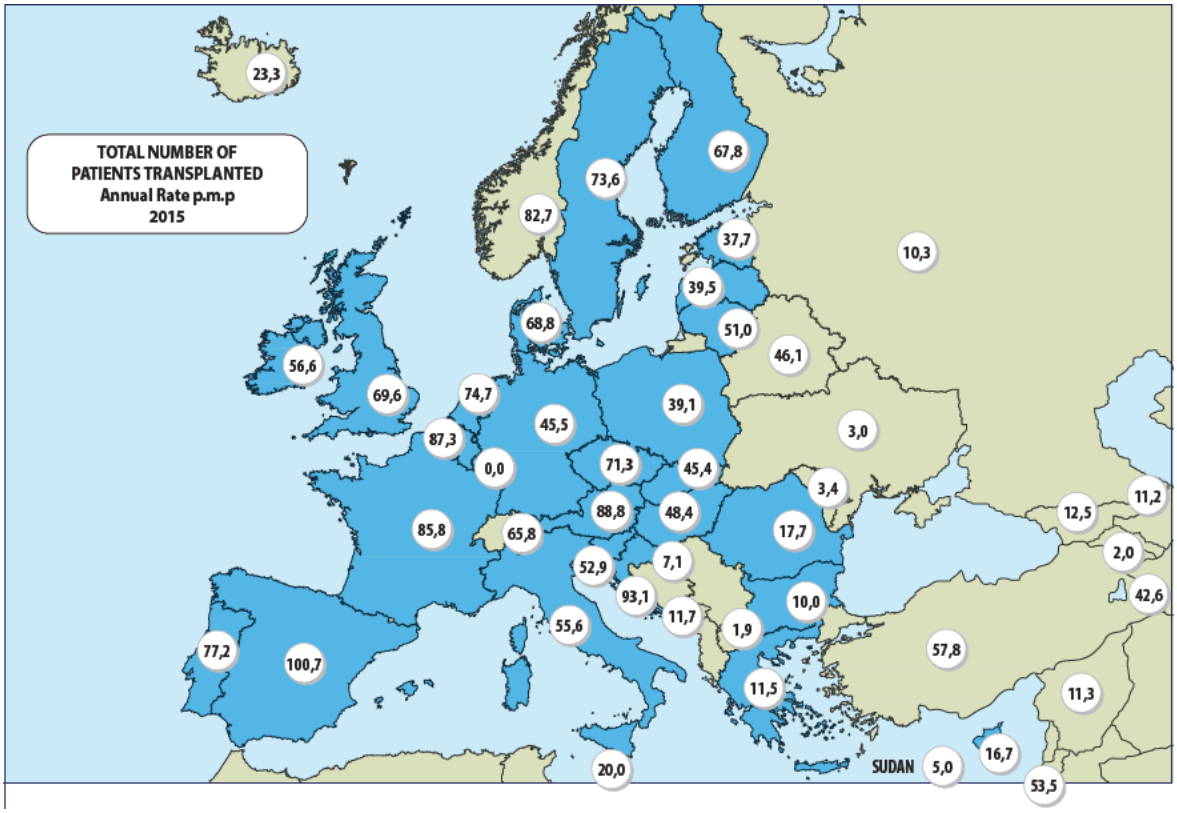

Figure 2.8: Number of transplant patients PMP, all organs combined in 2015 (source: Transplant Newsletter 2016, ONT/Council of Europe)

Overall, numbers of kidney and lung transplants increased over the years in most countries. In several countries the number of liver transplants increased slightly. The number of heart transplants is more or less stable.
Some countries have relatively high numbers of specific transplant procedures such as pancreas transplant for Norway, United Kingdom, and Sweden, or lunch transplants in Austria and Belgium.[82]

Based on the size of the country and the types of transplant undertaken, it can be seen that mainly countries with a large population, and therefore a large healthcare sector, have the capacity and resources to enable transplantation of relatively 'less common' organs such as pancreas (or pancreatic islets) and small bowel transplants.
Of the smaller countries with fewer than five million inhabitants, Slovenia and Croatia have a relatively high pancreas transplant rate (2.4 PMP and 1.9 PMP, respectively).
Pancreas transplantation is not as rare as small bowel transplantation, though boht are considered to be developing areas. In 2015, the following 23 countries performed pancreas transplants: Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden, UK, Croatia, Norway, Switzerland and Turkey.[83]

[82] In some instances, the increase in numbers is linked inter alia to bilateral cross-border agreements concluded between the countries.
[83] 12 of these countries had more than 20 pancreas transplants in 2015.

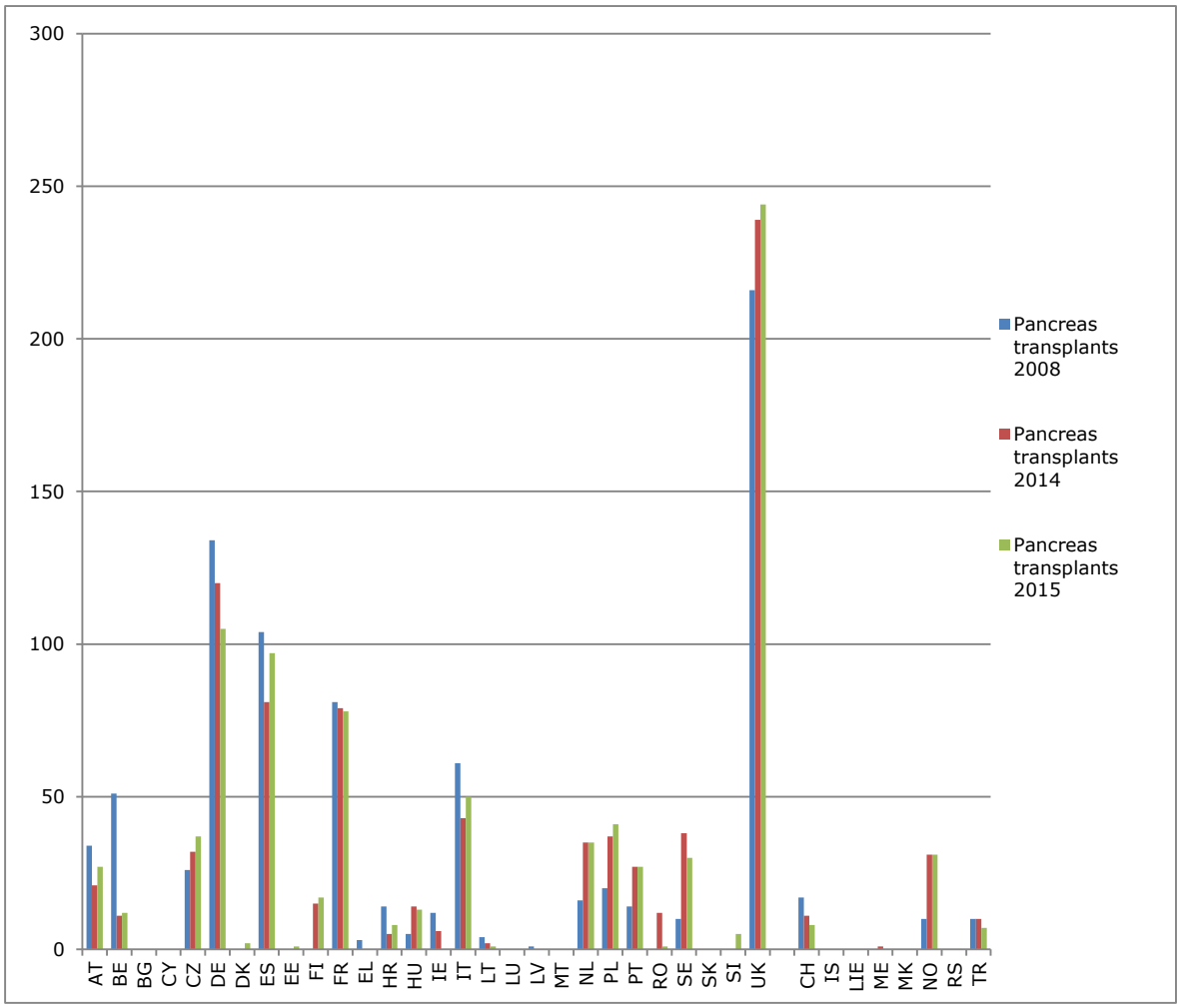

Figure 2.9: Total numbers of pancreas transplants in 2008, 2014 and 2015 in the Member States and other countries (source: Transplant Newsletter 2016, ONT/Council of Europe, Country sheets, Annex 1)

The number of countries that perform small bowel transplant procedures increased slightly from six in 2008 to ten in 2015 (Figure 2.10) (the Czech Republic, Germany, Spain, Finland, France, Italy, The Netherlands, Sweden, the United Kingdom and Turkey). Some of these countries undertake relatively high number of small bowel transplant procedures compared to others.

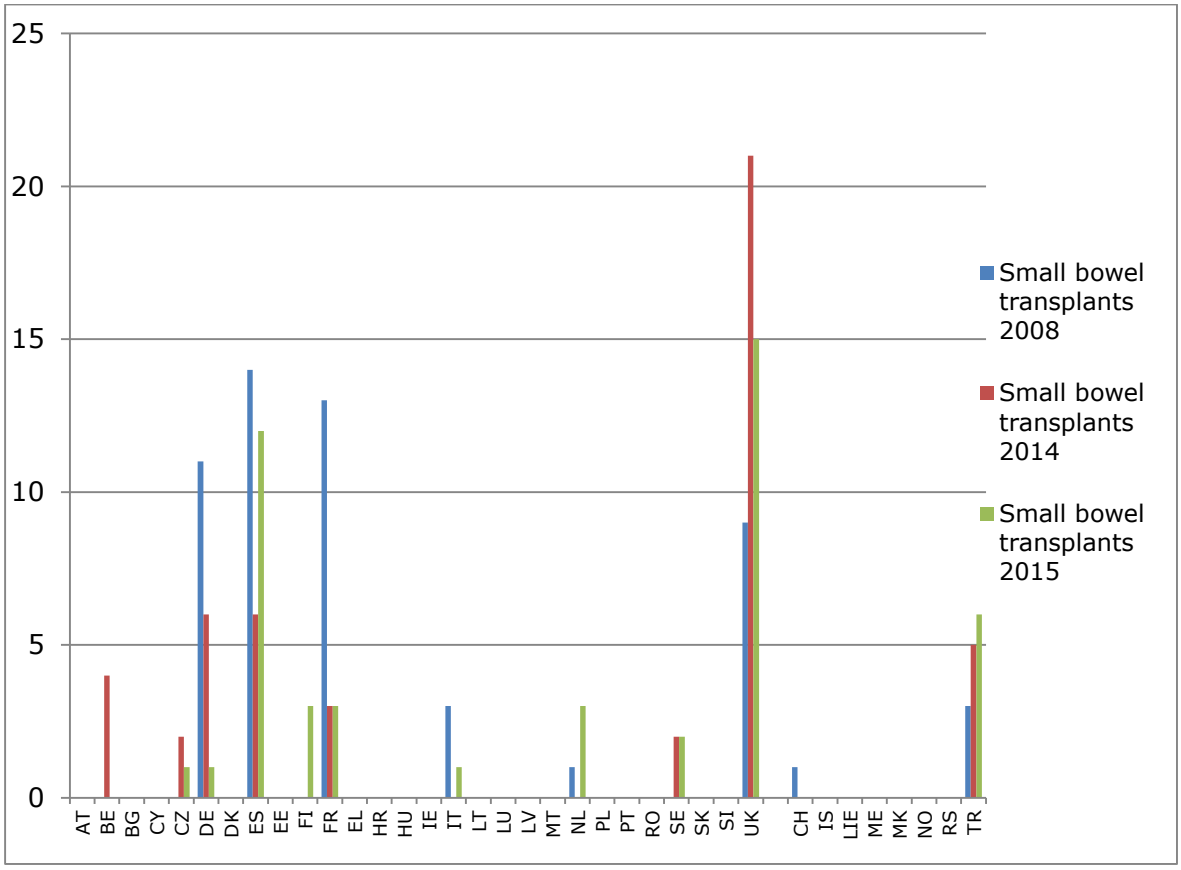

Figure 2.10: Total numbers of small bowel transplants in 2008, 2014 and 2015 in Member States and other countries (Source: Transplant Newsletter 2016, ONT/Council of Europe, Country sheets, Annex 1)

Given the complexities related to organ-specific transplants, it is obvious that only few centres/programmes in the EU can gain sufficient experience and economies of scale to successfully organise such transplants. Thus, collaboration between the countries in organising such transplants might be valuable.

Figure 2.11 gives the total number of transplant centres/programmes per organ in 36 countries included in this study.

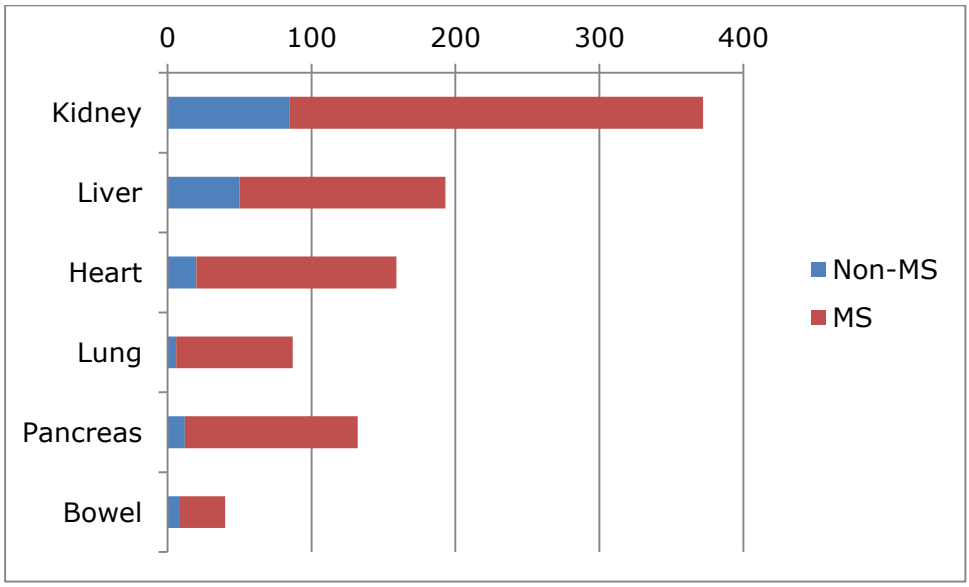

Figure 2.11: Total number of transplant centres/programmes per organ in 2015 in 36 countries (EU Member States and other countries) (source: Transplant Newsletter 2016, ONT/Council of Europe)

Overall, there are a total of 372 kidney transplant centres, 193 liver transplant centres, 159 heart transplant centres, 87 lung transplant centres, 132 pancreas transplant centres, and 40 small bowel transplant centres.
It is notable that the number of pancreas transplant centres exceeds the number of lung transplant centres/programme in Member States (120 vs. 81 in 2015) while the number of lung transplants exceeds the number of pancreas transplants in Member States (1818 vs. 821 in 2015).

Figure 2.12 shows the number of transplants carried out per transplant centre in each country. Large differences are observed. For instance, the figure shows that Finland and Norway had high numbers of kidney transplants per transplant centre in 2015, i.e. 230 and 191, respectively, compared to other countries. Furthermore, in the UK, the number of liver transplants per transplant centre was high in 2015, i.e. 141.3. The Czech Republic is ranking high in the number of hearts (37.5) and pancreases (37) transplanted per transplant centre.

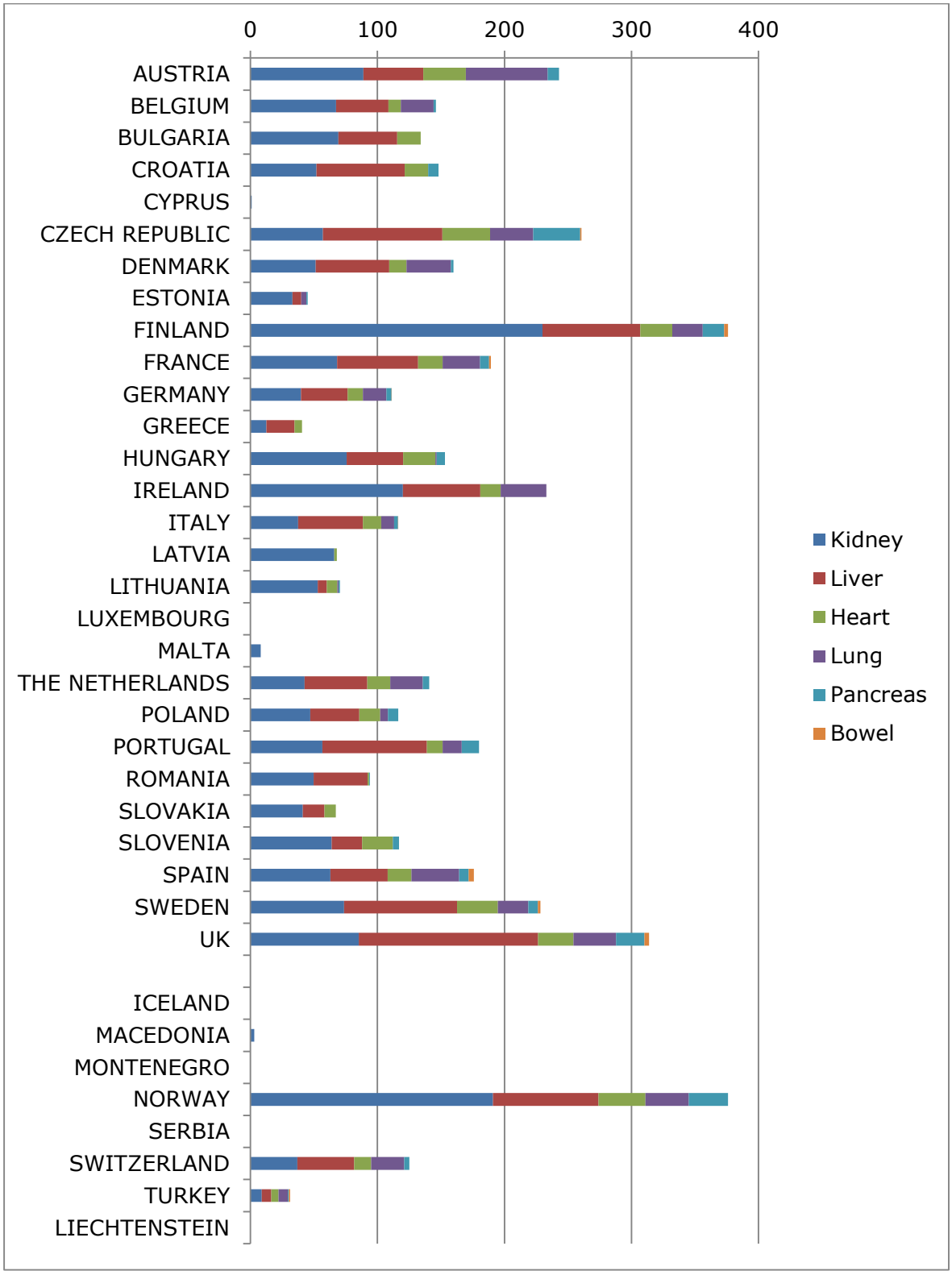

Figure 2.12: Number of organ transplants per transplant centre in 2015 in EU Member States and other countries (source: country sheets, Annex 1)

2.6 Extended donor criteria – use of older donors

Figure 2.13 shows the numbers of Member States and other countries that indicated they use donors over 60, donors after circulatory death, in 2008/2009 and 2014/2015. Overall, the number of countries that include donors over 60, relatively 'less common' organ transplants and DCD is increasing. Although this is a promising development to increase the number of donors, it is a sign of the growing organ shortage. Attention should also be paid to the quality of the organs and quality and safety of procedures.

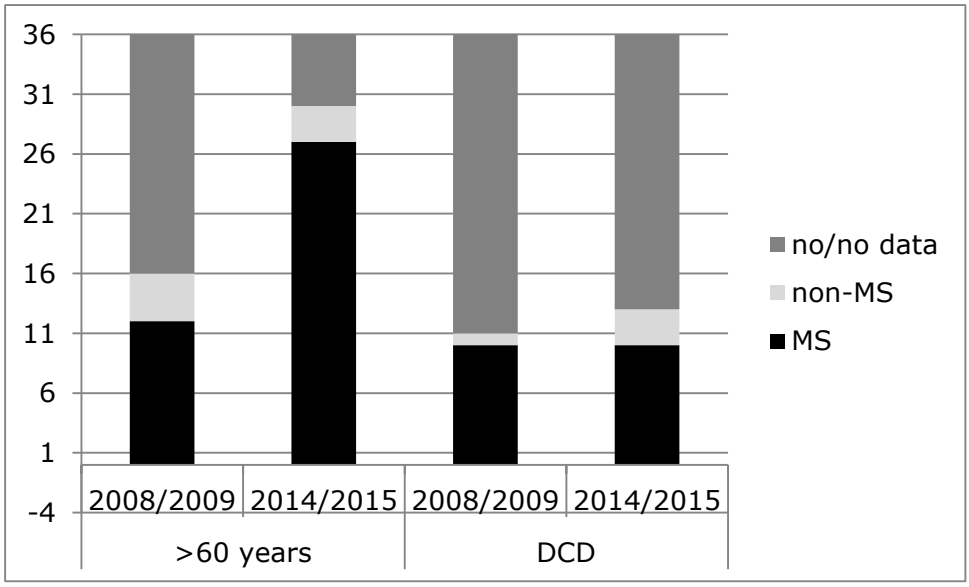

Figure 2.13: Numbers of countries that indicated they include donors aged >60, and donors after circulatory death, in 2008/2009 and 2014/2015, in Member States and other countries (36 in total) (source: country sheets, Annex 1)

2.7 Waiting lists

The demand for organs in the EU far exceeds the supply. This is observed in all countries, albeit to varying degree for specific organs.
There are transplant waiting lists in all countries with transplant programmes. On 31 December 2015, a total of 56 thousand patients were on waiting lists in the EU.

The total number of patients waiting for an organ transplant on 31 December 2015 for each organ is shown in Figure 2.14.

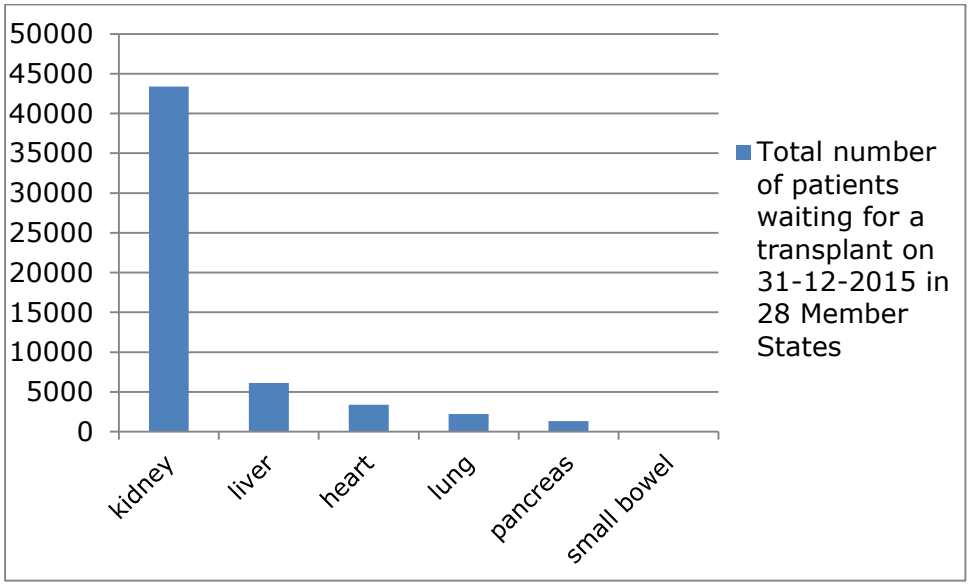

Figure 2.14: Total number of patients waiting for a transplant (only active candidates) on 31 December 2015 in EU Member States (Source: Transplant Newsletter 2016, ONT/Council of Europe)

Waiting lists can rapidly change and the numbers on waiting lists are difficult to compare across the EU for several reasons. Some countries do not have a waiting list, the criteria for admission to the waiting list or removal from the waiting list may differ between and within countries etc.
From the moment a country starts a national transplant programme and the number of transplants performed in the programme increases, the waiting list will grow (because of expectations among treating physicians that their patients can potentially get a transplant). In contrast, a drop in donation numbers can result in a drop in the number of patients on waiting lists. Not because fewer patients need a transplant, but because local physicians estimate the chances of receiving an organ for transplantation to be very low and therefore will not put them on the list, or the patients decide it themselves. It is worth noting that, the criteria for admission to the waiting list or removal from the waiting list differ between and within countries. In addition, there are no standards against which to decide whether a waiting list is long or short. For certain types of diseases, there is no alternative treatment to a transplant. Therefore, the numbers of patients on waiting lists should be interpreted with caution, and definitely not compared between countries.

2.8 European organ exchange networks

Organ exchange between countries serves three main purposes: firstly, it reduces the loss of donor organs for which there is no suitable recipient on the donor country's waiting list; secondly, it improves the possibility of specific patient groups receiving a matching donor organ; thirdly, it allows optimised donor-recipient matching, due to an expansion of the donor and recipient pools.

The Action Plan also reveals that cross-border exchange of organs plays an important role to optimise use of organs. There are three European organ exchange organisations (EOEOs), i.e. *Eurotransplant, Scandiatransplant and SAT* and a number of Member States participate in it[84].

- **Eurotransplant** (Austria, Belgium, Germany, Croatia, Hungary, Luxembourg, the Netherlands, Slovenia). Eurotransplant International Foundation is a non-

[84] Eurotransplant (AT, BE, DE, HR, HU, LU, NL, SI).
Scandiatransplant (DK, FI, IS, NO, SE).
the South Alliance for Transplantation (SAT) (ES, FR, IT, PT, CH, CZ).

profit service organisation responsible for the allocation of donor organs in eight European countries, covering 81 transplant centers and 135.8 million inhabitants. 6988 patients were transplanted in 2016. The allocation system is based upon medical and ethical criteria. Through conducting and facilitating scientific research, Eurotransplant aims at a constant improvement of transplant outcomes. Eurotransplant manages the complex process of achieving the best possible match between available donor organs and patients on one transplant waiting list.

- **Scandiatransplant** (Denmark, Finland, Iceland, Norway, Sweden). Scandiatransplant is comparable to Eurotransplant as an exchange organisation. It includes cooperation between all 12 Nordic transplant centres in addition to eight immunology laboratories. It covers a population of about 26.5 million inhabitants. About 2000 patients are transplanted yearly within the Scandiatransplant association. All Nordic patients waiting for an organ transplantation are listed on one common list for each organ. Scandiatransplant ensures that all necessary data are available for the transplant professionals to allocate the organs according to rules adapted by the association and monitors compliance with these rules.
- **The South Alliance for Transplantation** (SAT) (Spain, France, Italy, Portugal, Switzerland, Czech Republic). SAT was created in 2012 with the main goal of establishing formal cooperation between national donation and transplant agencies from countries in Southern and Western Europe. SAT does not perform the same tasks as Eurotransplant and Scandiatransplant. Every SAT partner has its own donation and transplantation systems, organ allocation rules, waiting lists etc., but most SAT partners (with the exception of Portugal) are users of the FOEDUS Platform for the exchange of surplus organs.

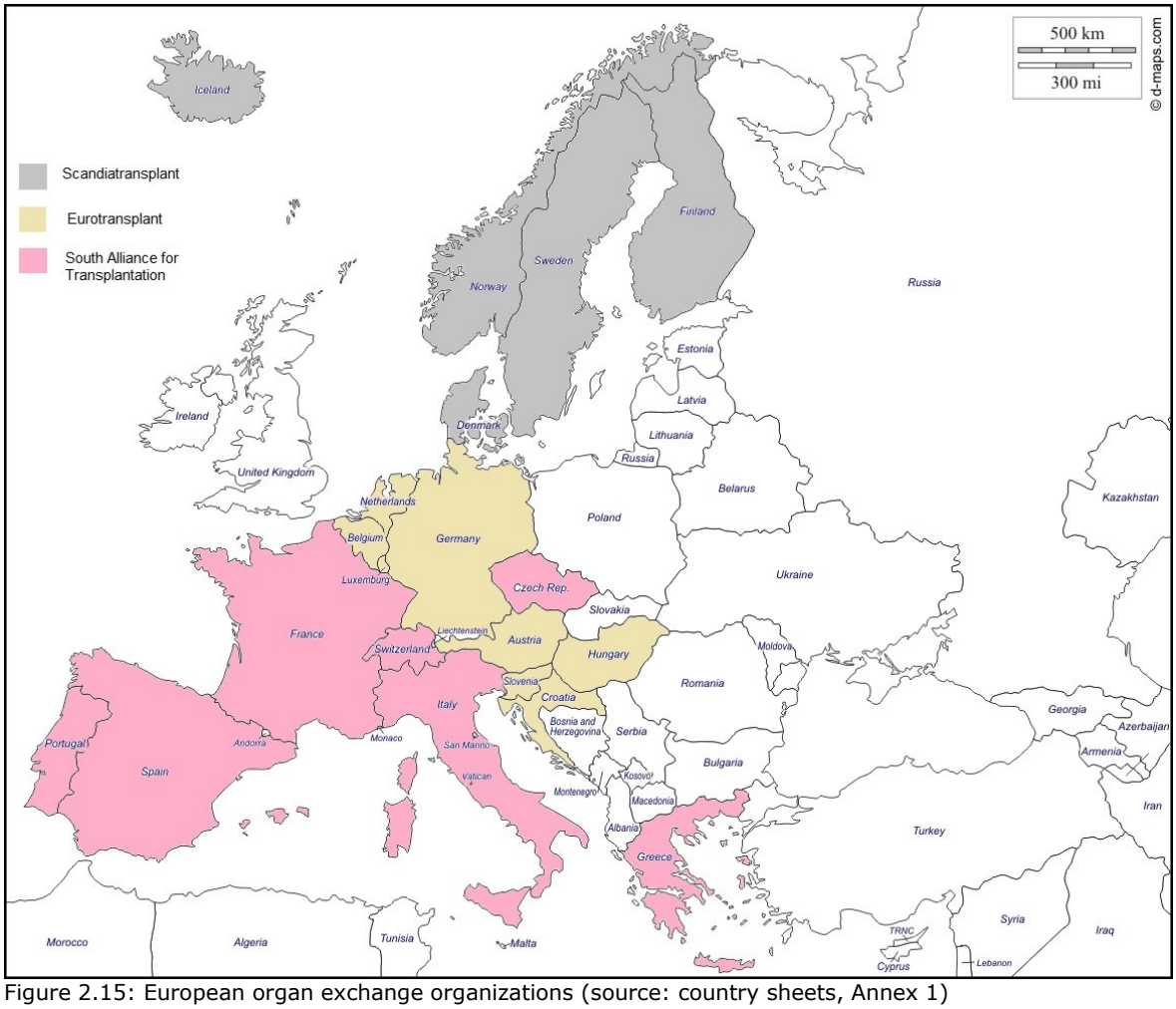

Figure 2.15: European organ exchange organizations (source: country sheets, Annex 1)

In addition, many Member States have set up collaborations and concluded bilateral agreements on the exchange of donor organs. Cross-border agreements allow that some countries become more "specialised" in specific transplant procedures (for instance, lung transplant for Austria and Belgium, pancreas transplant for the UK, and Sweden). Other countries can then benefit of this expertise by adding their donated organs and patients in need.

Importantly, a number of countries (Czech Republic, Slovakia, Lithuania, Bulgaria, Switzerland, Italy, Spain, France, UK and Romania) use an organ exchange platform developed in the FOEDUS joint action which has been supported by the EU[85]. This organ exchange network allows for allocation bodies to offer surplus organs which are difficult to match to recipients in the residential country, and therefore would otherwise not be used. For instance, there have been 380 organs offered through this platform and 53 transplanted.

The multi-lateral and bi-lateral agreements have been important for a number of countries to increase donor organ usage, improving donor organ evaluation and donor management programmes.

An example is the use of the lung transplant programmes in Austria, by its neighbouring countries and by other Eurotransplant member countries. This allows some of these countries to have their patients treated with a lung transplant in Austria, without the need to invest and develop such specialised programme/centre within their own country. In parallel, lungs from donors in these countries will also be send to and used in the Austrian programmes/centres.

2.9 Consent systems

Countries have different types of national (sometimes even regional) systems in place for consent to donate organs after death.
There are two main consent systems in Europe: an "opt-in" system under which people are required to explicitly give their consent for organ donation, and an "opt-out" system, which endorses the principle of presumed consent unless a specific request for non-removal of organs for donation is made before death.

A mixed system means that different regions have their systems differently organised, or that components of both opt-in and opt-out systems are implemented. However, regardless of the consent system, it is standard practice to approach thefamily members of the deceased prior to any decision to procure an organ.
Out of 36 countries included in the study, 20 countries have an opt-out system and 13 countries have an opt-in system in place (see Figure 2.16). Sweden and the UK have a mixed system.. In Liechtenstein, no transplants are performed.

[85] http://www.foedus-ja.eu/

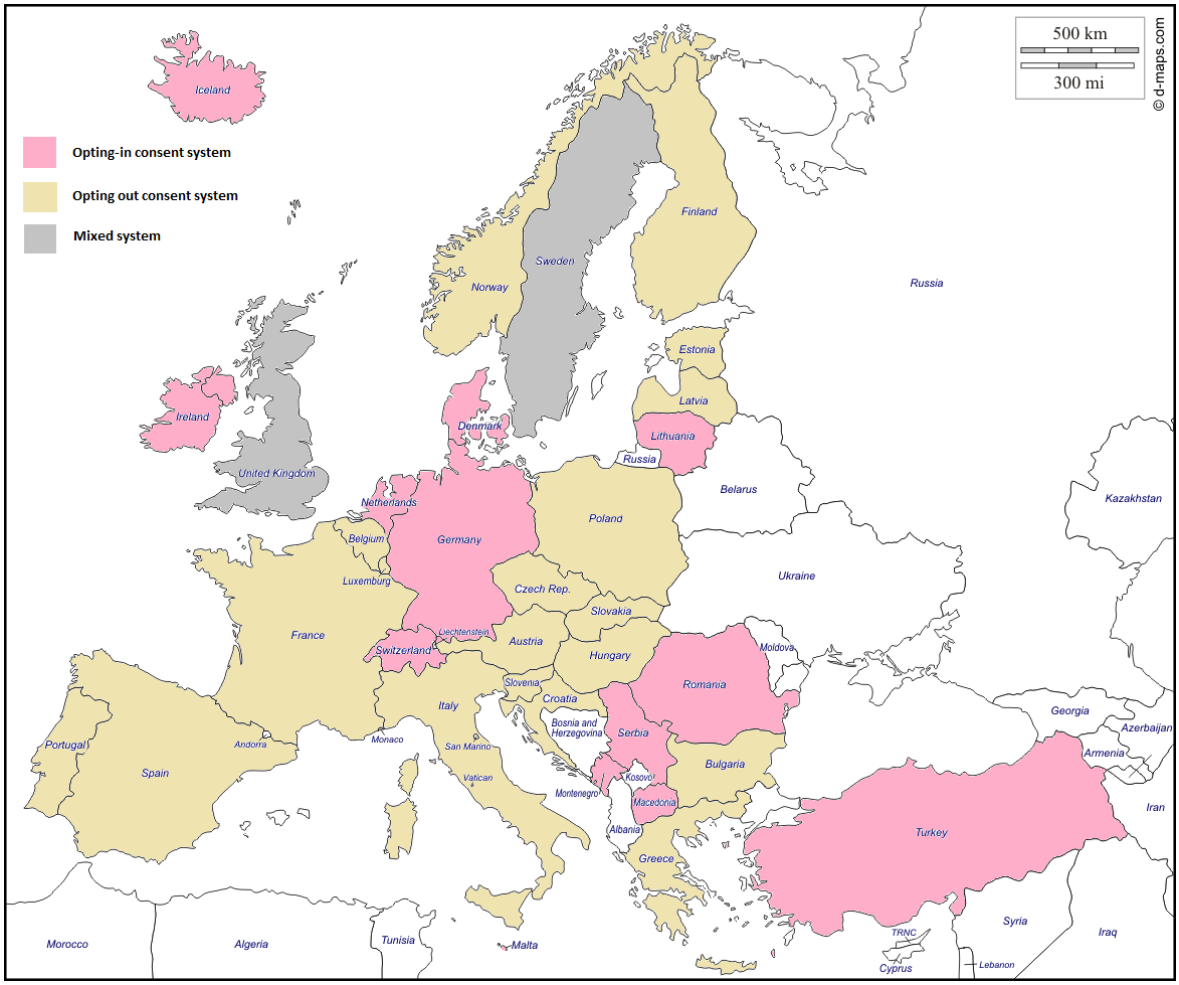

Figure 2.16: Consent systems to donate organs after death (source: country sheets, Annex 1)

2.10 Conclusions

In general, donation and transplant rates have been increasing in the EU over the period of the Action Plan.

The total number of organ donors increased from 12,369 in 2008 to 14,953 in 2015. This accounts to an increase of 21% over the period of the Action Plan. In most countries, deceased donation rates have increased (an average 1.8% increase per year) less than living donation rates (an average 4.2% increase per year). Differences between Member States indicate however that both, deceased donation and living donation, still have a lot of potential for optimization.

This has allowed for an encouraging trend in transplant numbers, with approx. 4600 extra transplants in 2015, a 17% increase compared to 2008. While the increase in absolute numbers is highest for kidney transplants (2746 transplants between 2008 and 2015) followed by liver and heart transplants, the percentual increase was highest for lung transplants (41%). It can therefore be concluded that countries are addressing the first challenge of the Action Plan, "Increasing organ availability".

While we can see kidney transplants programmes/centres present in every country, only 23 countries have programmes for pancreas transplants and 10 for small bowel transplants. Within the EU, there are 372 kidney transplant centres/programmes, with national average numbers of kidney transplants varying from below 10 to over 200 per year per programme/centre.

An interesting trend is the increased use of older donors. While only half of the countries used donors above 60 years in 2008-2009, almost all do so in 2014-2015. In Spain, Italy, Norway and Malta more than 50% of donors are above 60. Older donors come with a longer medical history, and hence more tailored, so-called extended donor criteria are applied.

Concerning waiting lists, a total number of 56 thousand patients are reported to be on a waiting list end 2015 in the EU. Waiting lists can rapidly change and the numbers on waiting lists are difficult to compare across the EU for several reasons. Some countries do not have a waiting list, the criteria for admission to the waiting list or removal from the waiting list may differ between and within countries etc.
Therefore, the numbers of patients on waiting lists should be interpreted with caution, and cannot be compared between countries.

Organ exchange plays an important role in optimizing the use of available donor organs. A key role is played by three European Organ Exchange Organisations are active in the EU (Eurotransplant, Scandiatransplant, Southern Alliance on Transplantation), but it is also important to mention the many bilateral agreements as well as an EU-funded IT-platform that allows exchange of surplus (unused, hard to match) organs.

Finally, different consent systems exist at the national level. Out of 36 countries included in the study, 20 countries have an opt-out system and 13 countries have an opt-in system in place, 2 - a mixed system. In practice however, it is reported that donor (family) consent is requested prior to donation, regardless of the national consent system.

3 IMPLEMENTATION OF THE ACTION PLAN

This chapter provides an overview of the of efforts made during the period of the Action Plan 2009-2015 to implement the Priority Actions and its state of implementation in every EU Member State and other eight countries[86] as well as at the EU level.

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.

Action Plan on Organ Donation and Transplantation (2009-2015)
• 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.

Table 3.1: Challenges and Priority Actions of the EU Action Plan

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). Given the voluntary nature of this Action Plan, each Member State had a different starting position and was free to decide whether and how to follow these guidelines. In order to adapt the Priority Actions to their own situation, needs and resources were translated into a set of National Priority Actions.

To provide an overview of the uptake of the Action Plan, a survey was submitted to the representatives of the countries[87] included in the study.

[86] Iceland, Norway, Macedonia (fYRoM), Switzerland, Turkey, Liechtenstein, Montenegro and Serbia.

[87] National Competent Authorities.

Figure 3.1 shows how many countries have implemented the Priority Actions laid down in the Action Plan. To compare, the same key indicators for EU Member States are shown in Figure 3.2. The results are described in more detail for each Priority Action below.

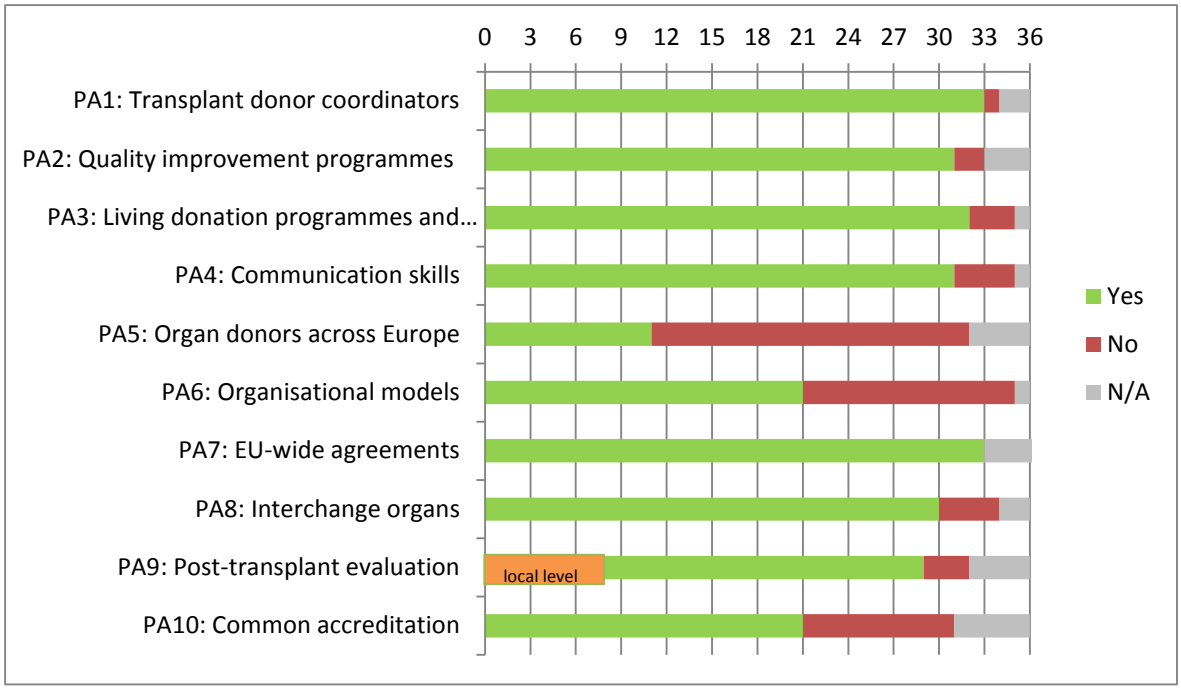

Figure 3.1: Implementation of the Action Plan per Priority Action in 36 countries[88]

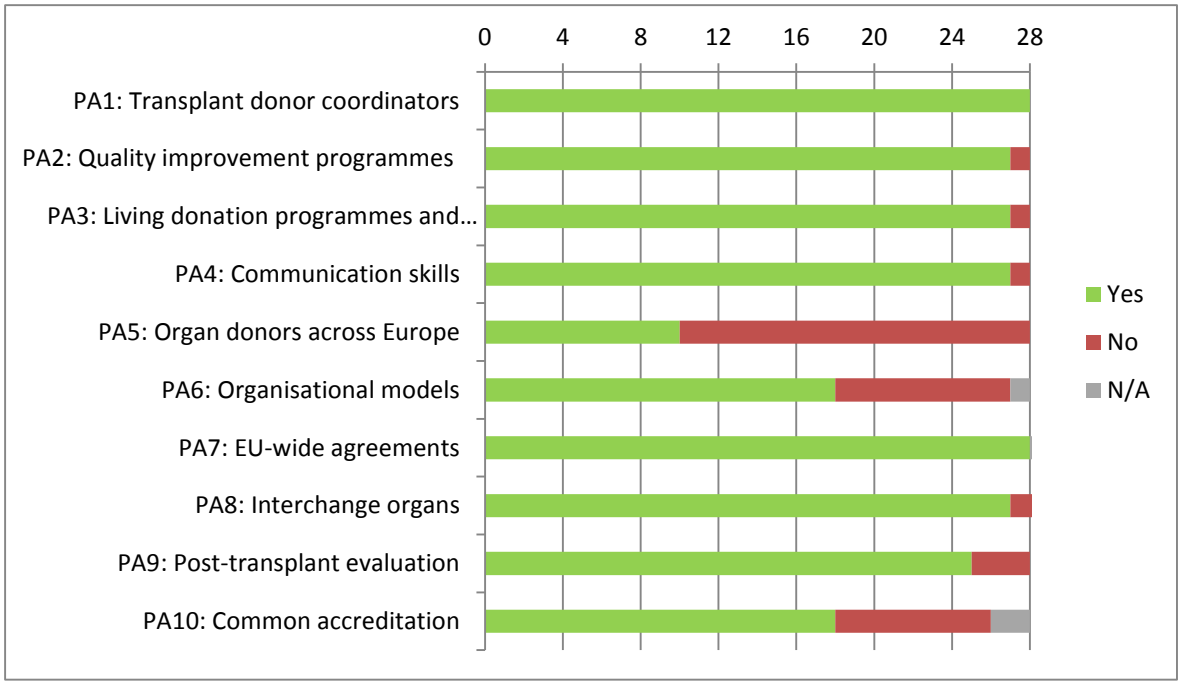

Figure 3.2: Implementation of the Action Plan per Priority Action in EU Member States

[88] The orange coloured bar represents 8 countries that indicated they evaluate post-transplant results but not systematically at the national level (all non-MS).

Priority Action 1: Promote the role of transplant donor coordinators[89] in every hospital where there is potential for organ donation. Design indicators to monitor this action.

"The combination of an efficient system for organ donor identification, detection and procurement has been identified as one of the keys to increasing deceased donation. In particular, the presence of a staff member dedicated to donation at the hospital level (i.e. a transplant donor coordinator), whose main responsibility is to develop a proactive donor identification/detection programme, is the most important step towards optimising organ donation and improving the donor detection rate. Member States should therefore aim to incorporate in their Sets of National Priority Actions the objective of gradually appointing Transplant Donor Coordinators (Priority Action 1) in all hospitals where there is potential for organ donation."[90]

In all EU Member States and majority of other participating countries, transplant donor coordinators have been appointed (see Annex 2 for details). However, transplant donor coordinators are not necessarily appointed at the hospital level in the countries, which is defined as the ideal position for transplant donor coordinators in the Action Plan. In particular, Transplant donor coordinators have been appointed in all 28 Member States and also in another 5 countries (see Annex 2 for details) which is one country more than in 2012. In 22 Member States and the 6 other countries, they are appointed at local/hospital level. Furthermore, various countries reported that they are also appointed at the regional (15) or national (23) levels.[91]

The results also show a need for continued efforts in education and training of the appointed transplant donor coordinators.

- Despite the fact that transplant donor coordinators have been appointed in almost all countries, implementation of training programme is not standard in every country. Transplant donor coordinators receive both initial and regular training in 2016 in only 16 Member States (and no other countries). This is an improvement compared to 2012 (in 2012, there were 11 countries).
- 9 Member States and 1 other country indicated that the training schemes are tested for effectiveness (cf. 7 countries in 2012). Furthermore, 8 Member States and 3 other countries indicated that they use national or international accreditation schemes for the qualifications of transplant donor coordinators (cf. 7 countries in 2012).
- Lastly, 15 Member States indicated that the Action Plan has influenced national policy on transplant donor coordinators, and in 15 Member States and 1 other country the EU-supported activities contributed to the promotion of the role of transplant donor coordinators.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 1[92]

"Transplant donor coordination is provided 24x7x365 under national law. Cooperation between donor hospitals and transplant centres is based on bilateral contract that are updated every year. Donor hospitals receive feedback about each

[89] This is an overarching term for "a key donation person whose main responsibility is to develop a proactive donor detection programme", but in different countries, the profession's title may differ. In the Action Plan, the hospital level is defined as the most ideal position for transplant donor coordinators.

[90] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

[91] In the survey, more than one answer was possible.

[92] Input from the National Competent Authorities submitted to NIVEL survey.

donor process after the organ transplants. Coordinators' activities (salaries, training etc.) are mostly financed from the state budget." (EE)

"The German Transplant Act was amended in 2012 making the appointment of an in-house transplant coordinator in donor hospitals mandatory and clearly defining their responsibilities" (DE)

"At the end of 2015: transplant coordinators have been appointed in 231 hospitals where there is potential for organ donation, compared with 2010 when 123 hospital transplant coordinators worked in the field. Improvement in organisation and information flow in process of coordination." (PL)

"The implementation of in-house transplant coordinators has doubled the number of donors and transplant procedures in Romania" (RO)

Priority Action 2: Promote quality improvement programmes in every hospital where there is potential for organ donation.

"It is equally important to promote Quality Improvement Programmes for organ donation (Priority Action 2) in every hospital where there is potential for organ donation. These programmes are primarily a self-evaluation of the whole process of organ donation according to the characteristics of the hospital and the health system. These will make it possible to compare results and thus to pinpoint areas for improvement. Consequently, it will also be beneficial in promoting accessibility to and training for a specific methodology in relation to these quality improvement programmes. An example of a quality improvement programme was the Joint Action ACCORD, which focused on the process of donation after brain death (DBD). The programme aims to monitor the potential donor pool, evaluating performance in the DBD process and identifying areas of improvement. The programme is based on a continuous audit of clinical charts of patients who died in intensive care units (ICUs). It includes an internal audit performed by donor coordinators locally. There is a wide variety of Quality Improvement Programmes."[93]

Almost all countries indicate that Quality Improvement Programmes are promoted by the government. There is however a great variability in these programmes, and much can still be learned from comparing and further improving these programmes.

In 2016, 27 Member States and 4 other participating countries indicated that their governments had introduced or encouraged initiatives to improve the quality of at least one out of five different aspects of the organ donation and transplantation process in individual hospitals (cf. 27 countries in 2012), including the identification of potential donors, the donation process, the procurement process, the transplantation process or follow-up care.[94]

- 15 Member States and 1 other country indicated that the Action Plan has influenced national policy on Quality Improvement Programmes.
- 10 Member States indicated that the EU-supported activities made a contribution to the promotion of Quality Improvement Programmes.

[93] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

[94] In the survey, more than one answer was possible.

Examples of the influence of the Action Plan in specific countries with regard to Priority Action 2[95]

"The experience with WP5 in the ACCORD Joint Action has helped us to broaden the scope of our Quality Assurance Programme in Deceased Donation[96]. This programme has been in place since 1999, and has inspired national, regional and local strategies for continuous improvements. ONT has then extended the ACCORD experience to more than 100 hospitals in the country in the framework of the ACCORD-Spain project. The tools have been refined and adapted to the Spanish needs and have been tested by the network. Based on the international and subsequent national experience, ONT is now redefining the existing Spanish Quality Assurance Programme, to incorporate new modules for a more comprehensive assessment of the potential of organ donation and of performance in the deceased donation process." (ES)

Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.
"As it complements deceased donation, living donation is a real alternative for improving the availability of organs for transplantation. Member States should therefore deploy the Action Plan to promote the exchange of best practices on living donation programmes (Priority Action 3)."[97]

In all EU Member States, directed[98] living donation is practiced. However, undirected[99] living donation, promoted in 14 EU Member States might be considered in more countries. Due to the sensitivity of the issue, legal, ethical, cultural, and religious considerations are be taken into account.

Living donation is practiced in most countries (27 Member States and 5 other participating countries) and the number has increased since 2012 (cf. 29 countries in 2012). It usually concerns directed living donation, meaning that the donor and recipient have a (social) relationship (partner, family or friend).

- Undirected living donation is not common in the countries: in 2016, 14 Member States and 2 other countries have undirected living donation programmes. This number has increased since 2012 (cf. 13 in 2012).
- 16 Member States and 3 other countries indicated that registers are established to follow up, evaluate and guarantee the health and safety of living donors at the national level (cf. 16 countries in 2012).
- Organ trafficking is explicitly prohibited in all 28 Member States except for Ireland. 6 other countries have explicitly prohibited it too and this number has increased since 2012 (cf. 27 countries in 2012).
- The Council of Europe Convention on Action against Trafficking in Human Organs, adopted on 25 March 2015, has been ratified according to 2 Member

[95] Input from the National Competent Authorities submitted to NIVEL survey.
[96] de la Rosa G, Domínguez-Gil B, Matesanz R, Ramón S, Alonso-Álvarez J, Araiz J, et al. Continuously evaluating performance in deceased donation: the Spanish quality assurance program. Am J Transplant 2012; 12(9): 2507-2513.
[97] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).
[98] Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).
[99] Undirected living donation (or altruistic living donation) means making a living donation to strangers.

States and 3 other countries at the moment the questionnaire was submitted (spring 2016).[100]

- In 14 Member States the Action Plan has influenced national policy on living donation programmes.
- 16 Member States stated that EU-supported activities assisted the promotion of living donation programmes following best practices.

[100] Reference date: The questionnaire was sent in April 2016. The date of response by countries varies.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 3[101]

"It was inspiring, living donation was expanded to extended family donors and friends. And a programme for cross-over donation was developed (between 2 pairs)." (FR)

"There is a proposal before the Finnish parliament to change the law allowing e.g. friends as donors."(FI)

"Establishment of the national living donor registry." (HU)

"During the last few years, the rate of living donor kidney transplantation has increased significantly." (LV)

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

"It has been proven that there is an important positive correlation between having discussed the issue of donation within the family and the willingness to actually donate organs. As public awareness and public opinion play a very important role in increasing organ donation rates, continuing education should form an essential part of all Member States' communication strategies on the issue."[102]

Many countries put efforts into increasing public awareness, which is a very positive result. While these activities are to be tailored to local needs and sensitivities, exchange of campaign/ communication experiences between countries could be useful.

27 Member States and 4 other participating countries made efforts to increase public awareness, including: establishment of communication guidelines; improving knowledge and skills of health professionals; improving the knowledge and skills of patient support groups; and organising periodic meetings with journalists.

- Communication guidelines for informing the public about organ donation and transplantation are present in 17 Member States and 3 other participating countries (cf. 13 in 2012).
- 27 Member States and 5 other participating countries make efforts to improve the knowledge and skills of health professionals (cf. 22 countries in 2012).
- 18 Member States and 3 other participating countries make efforts to improve the knowledge and skills of patient support groups (cf. 21 countries in 2012).
- 14 Member States and 1 other participating country organise periodic meetings with journalists (cf. 10 countries in 2012).
- 11 Member States indicated that the Action Plan has influenced their national policy on public awareness of organ donation.
- In 16 Member States, EU-supported activities have assisted the promotion of public awareness of organ donation.

[101] Input from the National Competent Authorities submitted to NIVEL survey.

[102] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 4[103]

"First: the Action Plan presents very clearly how important public awareness is and that we should work on the issue. The previously mentioned fact was very motivating for designing new projects and preparing studies, surveys to get more results and new knowledge.
Secondly: based on on-going work, we realise that the communication and public awareness may be improved when it is combined with knowledge of social marketing. We have therefore invited professionals from social science to cooperate with us in research." (SI)

"In 2015-2016, the Ministry of Health launched a national campaign (TV commercials, events, opinion polls) called "Yes for life" which promotes deceased donor organ donation. In recent years, a living related kidney donation public campaign was and is being conducted." (PL)

Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.
"People's mobility also underlines the need to facilitate the identification of organ donors across Europe and cross-border donation in Europe (Priority Action 5)."[104]

This Priority Action has been taken up to a lesser extent by the countries.

10 Member States and 1 other participating country provided easily accessible information to the general public about their legal position as a possible donor in other countries across the EU.

- Residents with a foreign nationality who die in the country can be donors in 27 Member States and 3 other participating countries (cf. 22 countries in 2012). 25 Member States and 4 other participating countries indicated that non-residents who die in that country can be donors (cf. 22 countries in 2012).
- Illegal persons who die in the country can be donors in 11 Member States and 1 other country (cf. 12 countries in 2012).
- In 3 Member States the Action Plan influenced national policy on cross border donation; in 5 Member States and 1 other participating country EU-supported activities contributed to the identification of cross border donors.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 5[105]

"Criteria for international organ exchange and for transplants in foreign patients have been revised and clarified." (EE)

"We are full member of International foundation Eurotransplant and therefore we are obligate to exchange the organs in the frame of this organization. The exception is only when procured organ is not allocated in the area of ET and we think that is good to use it. The system of allocation is published on the web, in the interviews, in the manual of Slovenija transplant Organ donation etc."(SI)

[103] Input from the National Competent Authorities submitted to NIVEL survey.
[104] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).
[105] Input from the National Competent Authorities submitted to NIVEL survey.

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

"Initiatives focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics are promoted by the Action Plan. The Action Plan calls on Member States to enhance the efficiency of transplant systems (Priority Action 6). To this end, they will develop their own sets of National Priority Actions in 2009. The Action Plan further encourages Member States to promote the twinning of projects[106] and peer review programmes, which should be part of a voluntary, mutual learning process. An example of a twinning project[107] is one in the Czech Republic that has been twinned with a project in Italy. The project was about developing a system for accreditation and audit of donation and transplantation activities, based on the Italian model."[108]

Priority Action 6 has been taken up to a lesser extent by the countries. However, real implementation also means changing the national organisational model, which implies a significant and long-term change.

Importantly, European support tools such as twinning or structural funds[109] have been instrumental to implementing this Priority Action.

In 2016, 18 Member States and 3 other participating countries indicated that they have been involved in twinning projects or peer reviews (cf. 16 countries in 2012). 13 countries indicated they had a learning role and 10 countries had a teaching role in the twinning projects.

- 7 Member States and 1 other participating country made use of structural funds and/or other community instruments[110] for the purpose of developing transplantation systems (cf. 4 countries in 2012).
- In 10 Member States and 1 other participating country there are transplantation centres or hospitals participating in networks of centres of reference (cf. 7 countries in in 2012).
- In 9 Member States the Action Plan influenced the organisational model of the donation and transplantation system.
- In 14 Member States the EU-supported activities enhanced the organisational model of donation and transplantation.

[106] "Twinning is the coming together of two communities seeking, in this way, to take action with a European perspective and with the aim of facing their problems and developing between themselves closer and closer ties of friendship".

[107] Twinning took place during the ACCORD joint action.

[108] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

[109] Structural and Cohesions funds are funds intended to facilitate structural adjustment of specific sectors, regions, or combinations of both (not specifically – but can be – dedicated to health systems).

[110] Projects funded by other programmes from the European Union such as the EU Health Programmes, the Framework Research Programmes (FP6, FP7, Horizon 2020), or Pre-Accession Aids for Candidate Countries (TAEIX credits, support from EU Delegations).

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 6[111]

"After a long-lasting twinning programme for lung transplants, Hungary started the national lung transplant programme in close collaboration with Vienna." (HU)

"Development of a transplant coordinators' network. More efficient cooperation between transplant donor coordinators and intensive care units. Living kidney donation awareness programme conducted for nephrologists, dialysis station staff and patients, as well as for the general public. Further development of national registries (waiting lists, transplant coordination, living donor registry, transplant follow-up registry)." (PL)

"All hospitals with intensive care or similar facilities were defined as 'Potential Donor Hospitals' and therefore, according to the legislation, were obliged to give feedback regarding the capacity and availability to became a Donor Hospital; the role of the Hospital Donor Coordinator, who must be a medical doctor, was set up by law in all Donor Hospitals." (PT)

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

"The Action Plan strongly supports EU-wide agreements on various aspects of transplant medicine (Priority Action 7). A cooperation method is the ideal context for discussing issues of mutual concern and coming up with common and shared solutions and monitoring mechanisms."[112]

This Priority Action has been taken up by many countries.

However, it should be noted that the scope of all the agreements varies significantly. While agreements have been concluded by most countries on exchanging organs, more agreements could be concluded on training/certification of professionals, data collection or research.

28 Member States and 5 other participating countries indicated they have agreements with other countries on at least one aspect of the seven described below.

- 13 Member States indicated that they have agreements[113] with other countries (including European Organ Exchanges Organisations, European Professional Societies or Registers had been established) on at least four aspects:
  - exchanging organs (27 Member States, 2 other participating countries);
  - treating each other's patients (16 Member States, 1 other country);
  - helping the development of new transplantation programmes (11 Member States, 1 other participating country);
  - training/certifying healthcare professionals (surgeons, coordinators) (14 Member States, 2 other countries);

[111] Input from the National Competent Authorities submitted to NIVEL survey.

[112] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

[113] Also see Annex to of the Staff Working Document on the mid-term review of the "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States": http://ec.europa.eu/health/blood_tissues_organs/docs/midtermreview_actionplan_organ_en.pdf

  - collecting data with/for countries (ELTR (European Liver Transplant Register), ERA-EDTA (European Renal Association / European Dialysis and Transplant Association, etc.) (15 Member States, 1 other country);
  - research activities (9 Member States, no other countries);
  - other aspects of transplant medicine (4 Member States, no other countries).
- In 10 Member States the Action Plan influenced the development of EU-wide agreements.
- In 11 Member States EU-supported activities contributed to the development of EU-wide agreements.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 7[114]

"The impact of international agreements has been great for Estonia: donor organ usage has increased, thereby giving us wider experience in donor organ evaluation and donor management and it has been a good opportunity to improve coordination and logistics; our professionals have had possibilities to improve knowledge and practical skills in various centres; we have had direct support for starting laparoscopic donor nephrectomies; we have had support for launching national lung and pancreas transplant programmes; heart transplantations are available for Estonian patients in cooperation with Helsinki and heart-lung transplantations in cooperation with Vienna." (EE)

"In 2012, Italy, France and Spain started the South Alliance for Transplant cooperation agreement." (IT)

"The wide agreements will be helpful for special groups of patients, e.g. hypersensitised patients and urgent patients. There are problems treating such patients in a country with a relatively small donor pool." (SK)

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

"If there is no exchange of organs between Member States, then recipients who need an uncommon match will have very low prospects of finding an organ, while at the same time donors will not be considered because there are no compatible recipients on the waiting lists. This is of particular relevance in "difficult-to-treat" patients (paediatric, urgent or hypersensitised patients who require very specific matching) and for small Member States in general. There are, however, significant differences between the number of organs exchanged across borders between Member States that have set up bodies and rules for the international exchange of organs, such as Eurotransplant, Scandiatransplant and SAT, and the other Member States. Without such comprehensive exchange agreements, Member States exchange far fewer organs, but the rate could potentially increase if there are bilateral agreements in place."[115]

Many countries have set up collaborations with other countries, allowing for the exchange of organs.

[114] Input from the National Competent Authorities submitted to NIVEL survey.

[115] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

The majority of the countries (27 Member States and 3 other countries) are part of fixed multilateral (22) and/or bilateral (16) collaborations with other countries. This number has increased since 2012 (cf. 23 countries in 2012: 12 multilateral and 11 bilateral agreements). The agreements concern the following organs:

  - Liver: 22 Member States and 2 other countries (cf. 24 countries in 2012);
  - Kidney: 20 Member States and 2 other countries (cf. 18 countries in 2012);
  - Heart: 22 Member States and 1 other country (cf. 17 countries in 2012);
  - Lung: 24 Member States and 2 other countries (cf. 21 countries in 2012);
  - Other (pancreas, small bowel): 13 Member States and 2 other countries (cf. 14 countries in 2012);
  - Other: 1 Member State and no other countries (cf. 1 country in 2012).

- In 8 Member States the Action Plan influenced national policy on the interchange of organs between countries.
- In 11 Member States EU activities helped the interchange of organs between countries.
- 23 Member States and 2 other countries used an organ exchange platform developed in the FOEDUS joint action allowing for allocation bodies to offer surplus organs that are difficult to match to recipients resident in another country that therefore would otherwise not be used.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 8[116]

"This interexchange is important for our country because currently in our country no transplants are performed of lungs, heart-lungs, the pancreas and small bowel. This means there is an opportunity for patients with severe diseases who are in need of organ transplant to be treated on time." (BG)

"The action plan created better conditions for organ exchange between member countries and this will be helpful for our patients. It depends on agreements between SK and other countries." (SK)

Priority Action 9: Evaluation of post-transplant results.

"The Action Plan sets out to complement this legal framework by compiling information in the form of registers facilitating the evaluation of post-transplant results (Priority Action 9), which will in turn help to develop good medical practices in organ donation and transplantation. Evaluating post-transplant results through common definitions of terms and methodology, as suggested in the Action Plan, could help to promote EU-wide registers, if necessary, in compliance with the existing European legal framework on the protection of personal data consisting in particular of the Data Protection Directive 95/46/EC, or create a methodology for comparing the results of existing post-transplant follow-up registers of organ recipients."[117]

Many countries have taken up this Priority Action, but efforts have to be made in particular to improve the evaluation of post-transplant results.

[116] Input from the National Competent Authorities submitted to NIVEL survey.

[117] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

25 Member States and 4 other countries indicated that they evaluate post-transplant results of organ recipients at a national/regional (8 at regional) level and results are systematically collected in a national database/register. This number has increased (cf. 22 in 2012).

- 14 Member States and 2 other countries indicated that the evaluation of post-transplant results backed by a monitoring system. 11 countries participated in the EU-funded project EFRETOS, which set up a basis for creating a Europe-wide register.
- A number of countries indicated donor organs are accepted from:
  - donors with diabetes mellitus (27 Member States and 4 other countries, cf. 22 in 2012);
  - donors with hypertension (27 Member States and 5 other countries, cf. 25 in 2012);
  - donors with renal insufficiency (20 Member States and 4 other countries, cf. 21 in 2012);
  - donors with infectious diseases such as hepatitis (18 Member States and 3 other countries, cf. 16 in 2012);
  - Donors aged over 60 (28 Member States and 5 other countries, cf. 29 in 2012);
  - donors with HIV (4 Member States and 1 other country, cf. 5 in 2012).
- In 4 Member States, the Action Plan influenced national policy on the evaluation of post-transplant results.
- In 4 Member States, EU-supported activities made a contribution to the evaluation of post-transplant results.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 9[118]

"Further development of transplant registries, living donors registry data is ready for the implementation of the European registry of registries."(PL)

"The experience in EFRETOS (and previously in DOPKI) has helped us to further develop our non-standard risk donor project, based on the prospective assessment of the outcomes of patients transplanted with organs from donors diagnosed of potentially transmissible diseases or conditions likely to impact upon the quality of the transplanted organ – donors with a past or present history of malignancy, infectious diseases, poisoning, rare diseases, and other conditions." (ES)

"We have revised our national criteria for donor organ quality and safety. We have begun to use more of expanded criteria donors." (EE)

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

"The Action Plan also seeks to develop a methodology that could support the EU legal framework in order for Member States to accredit programmes on organ donation, procurement and transplantation. This could help, in the long run, to build a common

[118] Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 9.

accreditation system for organ donation/procurement and transplantation programmes (Priority Action 10) at the EU level and provide backing for centres of excellence."[119]

The implementation of this Priority Action was relatively moderate.

18 Member States and 3 other countries checked or audited procurement organisations and transplantation centres on a regular basis.

- 12 Member States and 3 other countries promote accreditation systems.
- In 7 Member States, the Action Plan influenced national policy on the promotion of accreditation systems.
- In 10 Member States, EU-supported activities helped promote accreditation systems.

Examples of the impact of the Action Plan (according to specific countries) with regard to Priority Action 10[120]

"The EU Action Plan led to the EU Directive which required a Quality and Safety Framework. This has been implemented in Ireland and requires that all staff involved in the process is appropriately trained." (IE)

"In general the need for accreditation has been promoted by EU Action Plan."(NL)

"We have started cooperation with KST, Czech Republic in international auditing of transplant centres according to the methodology of ACCORD project." (SK)

Box 1: An example of activities undertaken in Finland in the context of the Action Plan

Key activities:

1) Finland changed from informed consent to presumed consent in 2010 (a provision on presumed consent was included in the Tissues Act 2010);
2) Success in maintaining positive attitude towards donation in the general population – positive media;
3) Implementation of EU Directive (2010/53/EU) together with Action Plan prompted the Ministry of Social Affairs and Health to appoint an expert group to develop a proposal for a National Action Plan on organ donation and transplantation;
4) Priority Action 1 on donor coordinators in the hospitals: National action plan includes requirement that a donor coordination team should be established in every donor hospital (Action 1). Hospitals may decide on the composition of team (at least a donor coordinator and a physician responsible for organ donation);

   Donor coordination teams audit organ donation activities and analyse the data of the deceased donation in the hospital at regular intervals to improve the identification of potential donors. The key target is to assess the possibility of organ donation in the case of each critical patient with neurological illness;
5) Priority Action 2 on quality improvement programmes: The Ministry of Social

[119] Communication from the Commission: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM(2008) 819/3).

[120] Input from the National Competent Authorities submitted to NIVEL survey.

Affairs and Health and the transplantation centre (only one centre in Finland) have, since 2013, organised national training events for all procurement hospitals, inviting all coordination teams. The target of the event is to expand their knowledge of organ donation, to share experiences and to give information on how to audit organ donation activities in the hospitals and survey the attitudes of the personnel;

6) The Ministry of Social Affairs and Health has appointed a national steering group for organ donation composed of physicians responsible for organ donation and donor coordinators at the university hospitals as well as representatives from the transplantation centre;
7) The Finnish Medicines Agency (Fimea) was nominated as the CA for carrying out the inspections of the transplantation centre and procurement hospitals as well as assessing the implementation of the national action plan.

Conclusions

Overall, the majority of Priority Actions have been taken up by the EU Member States to a large extent. In particular, it is worthwhile mentioning Priority Action 1 (transplant donor coordinators), Priority Action 2 (quality improvement programmes), Priority Action 3 (directed living donation programmes), Priority Action 4 (public awareness building) and Priority Action 8 (organ exchange), which have been taken up by most Member States. There were few Priority Actions for which uptake was relatively limited, in particular Priority Action 5, 6 and 10.

Importantly, many countries report that the EU Action Plan did have an impact on their national policies, especially when setting the national agenda and implementing activities under the first three Priority Actions (on transplant donor coordinators, activities to improve quality and directed living donation). Some countries mention that the activities covered by Priority Actions had already been launched before the Action Plan was adopted.

Many countries reported being supported by EU(-funded) activities, especially helping them with the set-up of transplant donor coordinators (PA1), directed living donation (PA3), public awareness (PA4) and twinning (PA6). These results suggest that Priority Actions relating to concrete actions in the field are most likely to be influenced by the Action Plan and EU-funded Actions.

Table 3.2 gives an overview of the national uptake of the Priority Actions (figures are given for all countries that participated in the FACTOR-study and the EU Member States only), and the influence of the Action Plan and the EU-funded activities.

Priority action[121]	Number of countries stating they implemented the specific Priority Action[122] (number of countries/only EU Member States)	Number of countries stating that the Action Plan influenced national policy (number countries/ only EU Member States)	Number of countries stating that EU-funded activities supported their country on this Priority Action (number of countries/only EU Member States)
1: Transplant donor coordinators	33/28	15/15	16/15
2: Quality Improvement Programmes	31/27	16/15	10/10
3: Living donation	32/27	14/14	16/16
4: Public awareness	31/27	11/11	16/16
5: Identification of cross border donors	11/10	3/3	6/5
6: Organisational models	21/18	9/9	14/14
7: EU-wide agreements	33/28	10/10	11/11
8: Cross-border exchange	30/27	8/8	11/11
9: Evaluating post-transplant results	29/25	4/4	4/4
10: Accreditation of procurement organisations and transplantation centres	21/18	7/7	10/10

Table 3.2: Influence of the Action plan on national policies and support by EU funded activities

Priority Action 5 (cross-border donor identification) and Priority Action 10 (common accreditation systems) dealing with quality assurance aspects are more complex, and have been taken up to a lesser extent by the countries. If those Priority Actions are to be developed further, some clarifications will be needed in the future to assist countries in advancing the implementation.

Overall, those Priority Actions and underlying sub-actions of the Action Plan that had clear objectives had been implemented to a larger extent than Priority Actions with a more complex, less clearly defined nature. The later therefore might require further clarification, EU-level support and guidance for effective implementation.

[121] Based on one key variable of the questionnaire filled out by competent authorities.

4 EU-FUNDED ACTIVITIES RELATED TO THE ACTION PLAN

This chapter provides a detailed overview of EU-funded projects and their contributions to the goals of the Action Plan. For each Priority Action, the activities directly managed by the Commission are described. Subsequently, activities of other organisations that relate specifically to the Priority Actions are described. Projects and activities of organisations that relate indirectly to the Action Plan are described in Annex 3. The conclusions describe where gains can still be made and where the gaps are. This chapter will focus on the second half of the Action Plan period, as earlier results can be found in the ACTOR study report. Firstly, we give an overview of the types of EU-funded initiatives in chronological order and the EU-funded initiatives (Table 4.1), followed by an overview of their contribution to the Priority Actions (Table 4.2). Finally, Table A1 (in Annex 3) provides an overview of the involvement of countries in EU-funded projects.

The Commission implements the EU Health Programme mainly through financing five types of activities: projects (after calls for proposals), conferences, Joint Actions, tenders and operating grants (as well as a direct grant to the Council of Europe for activities in "substances of human origin": blood, tissues and cells, organ transplantation). All activities that are related to the Action Plan and therefore related to this study are shown in Table 4.1.

Project acronym	Project	Joint Action	Conference	Tender
Alliance-O (European Group for Coordination of Research Programmes on Organ Donation and Transplantation) (2004-2007)	x*			
DOPKI (Improving the Knowledge and Practice of Organ Donation) (2006-2009)	x*			
ETPOD (European Training Programme on Organ Donation)				x
EULID (Euro Living Donor) (2007-2010)	x			
EDD (European Donation Day) (yearly)	x			
ELPAT platform (Ethical, Legal and Psychosocial Aspects of organ Transplantation) (conferences funded in 2010 and 2013)			x	
EFRETOS (European Framework for the Evaluation of Organ Transplants) (2009-2011)	x			
ELIPSY (Euro Living Donor Psychosocial Follow Up) (2009-2012/3)	x			
COORENOR (COORdinating a European initiative among National organisations for ORgan transplantation) (2009-2012)	x			
EULOD (Living Organ Donation in Europe) (2010-2012)	x*			
ODEQUS (Organ Donation European Quality System) (2010-2013)	x			
European Training Course in Transplant Donor Coordination ("Train				x

Project acronym	Project	Joint Action	Conference	Tender
the trainers")				
MODE (Mutual Organ Donation and transplantation Exchanges: Improving and developing cadaveric organ donation and transplantation programmes) (2011-2012)		x		
ACCORD (Achieving Comprehensive Coordination in ORgan Donation throughout the European Union) (2012-2015)		x		
ACTOR (Study on the setup of organ donation and transplantation in the EU Member States, uptake and impact of the Action Plan on Organ Donation and Transplantation (2009-2015)				x
The ONE study (2010-2015)	x*			
BIO-DrIM (2012-2017)	x*			
EUROSTAM (2012-2017)	x*			
COPE (2013-2017)	x*			
STELLAR (2012-2017)	x*			
FOEDUS (Facilitating Exchange of Organs Donated in EU MS) (2013-2016)		x		
Also (regularly renewed): Direct Grant to the Council of Europe for activities in blood transfusion, tissues & cells, and organ transplantation				
HOTT project: Trafficking in Human Beings for the Purpose of Organ Removal (2012-2016)				x*
Seminar on Illegal & Fraudulent activities involving Organs, TC, Paris, April 2013			x	
LIDOBS Conference, November 2014			x	
A study on the uptake and impact of the Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member States. Final Review. (FACTOR) (2016-2017)				x
The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes. (2016)				x
EUDONORGAN (Platform for increasing organ donation in the European Union and neighbouring countries) (2016)	x			
For direct links to various project websites, see http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20121009_contact_points.pdf For project databases of public and other health programmes, see http://ec.europa.eu/eahc/projects/database.html For research programmes, see http://cordis.europa.eu/search * Funded by DG RTD				

Table 4.1: Types of EU-funded and cofunded initiatives related to organ donation transplantation in chronological order

To be able to report on the impact of these activities, we assessed each activity using the following types of possible impact that the projects can have:

1. *Knowledge acquisition*: activities that give insights into the current state of affairs
2. *Development of tools*: activities with the aim of developing instruments, guidelines, toolkits, recommendations etc.
3. *Exchange of knowledge*: activities with the aim of (actively) exchanging knowledge and best practices (courses, training schemes, congresses etc.)
4. *Change*: activities that intervene in or change actual practice

This classification into four different types of activities indicates the nature of the contribution to a Priority Action. It is important to note 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 or made available for the purpose of the present study by **Chafea** (Consumers, Health and Food Executive Agency)[123],[124]. 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 – if available – project evaluations are used.

Priority Actions										
	1	2	3	4	5	6	7	8	9	10
1. Knowledge acquisition	x	x	x	x	x	x	x	x	x	x
2. Development of tools	x	x	x	x		x	-	x	x	x
3. Exchange of knowledge	x	x	x	x	x	x	-	x	x	x
4. Change	x*			x*		x		x	x*	
No. of projects dedicated	4	5	7	6	5	7	5	3	6	4
No. of countries involved	27	27	24	19	24	28	10	24	14	20
No. of countries stating that EU-supported actions helped their national policy	16	10	16	16	6	14	11	11	4	10

Table 4.2 Activities of projects supported by Chafea involving organ donation, classified into different types
* represents progress since the ACTOR study (2012/2013)
- Means not applicaple, no sign means the specific activity was not achieved

Projects that could be linked to the aims as stated in the Priority Actions are mostly aimed at acquiring knowledge, tool development, and the exchange of knowledge and best practices by providing training programmes and organising congresses. Since the ACTOR study in 2012, we found an increase in activities directed at actual change. Such activities were new for three Priority Actions (1, 4 and 9).

[123] EAHC changed its name to the "Consumers, Health and Food Executive Agency (Chafea)" on 01/01/2014
Same mandate as before (not a "new" agency); Chafea is the legal successor of EAHC.

[124] Also see the brochure: http://ec.europa.eu/chafea/documents/health/leaflet/transplantation-transfusion.pdf

Table 4.2 also shows the number of projects dedicated to each Priority Action, the number of countries involved, and the number of countries that reported that the Action Plan had influenced their national policy on each Priority Action. The correlation between the experienced support and the number of participating countries is somewhat higher (0.37) than the correlation between the number of projects and the support experienced (0.19), suggesting that the number of projects (to a lesser extent) and the number of countries involved in activities (to a larger extent) are related to receiving more support. For Priority Actions 1, 3 and 6 for instance, the number of countries involved in EU-funded projects was higher, as was the number of countries reporting that the Action Plan had influenced their national policy. Additionally, for the Priority Actions where actual change has been achieved, more countries seem to be involved. A table presenting the involvement in projects for each single country has been included in Annex 3.

Details are discussed below for each Priority Action for the achievements since 2012. Achievements that were made before 2012 can be found in the ACTOR-report. At the end of each Priority Action, a box is presented that includes all the projects that were involved in the Priority Action, all countries that played a part in those projects, the reported contribution of the EU-funded activities according to the various countries, and some examples of the reported contribution.

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.

EU-funded projects
Three EU-funded projects are directly related to Priority Action 1: **'Train The Trainers', ODEQUS and ACCORD**. Until 2012, the project activities related to Priority Action 1 mainly consisted of knowledge acquisition, the development of tools, and the exchange of knowledge.

The **'Train the trainers'** 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 therefore "consolidated" as (or become) trainers in charge of the professional training for other coordinators in the Member States (Dominguez-Gil et al., 2012; European Transplant Coordinators, 2012).

The main objective of the **ODEQUS** was 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) (ODEQUS, 2009).

After 2012, **the ACCORD Joint Action**[125] (funded under the Health Programme) was the main contributor to this Priority Action. ACCORD started in 2012 and ran until 2015. Objectives of the ACCORD Joint Action were to facilitate the cooperation between intensive care professionals and donor transplant donor coordinators to improve deceased donation. 15 Member States participated in WP5 of ACCORD, with a minimum of two hospitals per Member State; 66 hospitals participated in total (Norman, 2014). Participating hospitals participated in an assessment of end-of-life care practices relevant to organ donation in their countries (ACCORD, 2012). A **Rapid Improvement Toolkit Recommendation was also developed and implemented**. The Toolkit can be used as a basis for rapid improvement to promote collaboration between donor transplant donor coordinators and others. It provides key steps in understanding the barriers that seem to exist to improvement and their possible

[125] http://www.accord-ja.eu/

causes, stakeholder analysis, service improvement models, linking frontline changes to strategic objectives, implementation and durability, and the importance of teamwork (ACCORD, 2015a). Furthermore, workshops in several countries were organised to disseminate and provide assistance for working with the toolkit (ORGANIZACIÓN NACIONAL DE TRASPLANTES SPAIN, 2015). The results of the whole project were also passed on via presentations at several meetings in various countries including a meeting organised by EDTCO in September 2015[126]. The final dissemination conference of ACCORD was held in June 2015.
This project demonstrated that collection of good data – at a local level – can identify possible areas for improvement and that implementation of a standard change improvement methodology could be effective (again, at a local level). These activities within ACCORD, and specifically this work package, are classified as type 2 actions: the development of tools.

Activities directly managed by the Commission
The **working group on deceased donation**, the first working group that was set up, directly contributed to this Priority Action. This working group produced a manual on how to set up a system for transplant donor coordination, with several national examples (Le Borgne, 2012a).

Secondly, **a TAIEX workshop** was organised in 2013. It aimed to facilitate specialised educational training in all steps of the deceased donation process, specifically focusing on implementation of a deceased donation programme at the hospital level, with an emphasis on early detection and identification of potential donors and brain death diagnosis. The multi-country workshop aimed to bring together healthcare professionals (i.e. ICU doctors, neurologists, hospital transplant donor coordinators) from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Israel, the Former Yugoslav Republic of Macedonia, Moldova, Montenegro, Romania and Serbia for education in proactive organ donor detection systems in donor hospitals.[127]

Efforts of other organisations
With regard to this Priority Action, the **Council of Europe** renewed the guide to the safety and quality assurance for the transplantation of organs, tissues and cells. The guide provides exhaustive guidelines for physicians and transplant donor coordinators with a useful overview of the most recent progress in the field, to ensure a high level of quality and safety standards for donor detection and selection, procurement, preservation, allocation, distribution and transplantation of organs, tissues and cells. It helps harmonise these activities among European countries, facilitating uniform standards and practices. The guide will be continuously updated. It is addressed at the 47 CoE member states. Participating countries were Argentina, Belgium, France, Germany, Italy, Netherlands, Norway, Portugal, Spain, Turkey, and the United States (López-Fraga, 2013).

With regard to Priority Action 1, **EDTCO** (European Donation and Transplantion Coordination Organization) developed a **European Union of Medical Specialists (UEMS)** certification for transplant coordination. This contributes to sub-action 4 of Priority Action 1 of the Action Plan.
The **Board of Transplant Coordination (BTC)** has been created within the Division of Transplantation of the UEMS. The BTC operates in close collaboration with EDTCO and is a non-profit entity. The main objective of the BTC is to guarantee the best standard of care in organ and tissue donation and transplant coordination in Europe by establishing homologous standards of practice and ensuring that training in donation and transplant coordination is maintained at the highest level by accrediting and

[126] http://esot2015.esot.org/edtco-organ-donation-meeting
[127] https://webgate.ec.europa.eu/TMSWebRestrict/resources/js/app/tmsweb/library/detail/50267 retrieved on 31 March 2017.

examining transplant donor coordinators on their knowledge and practice. In total, 111 coordinators from 15 European countries were certified in 2015 (Sándor Mihály, 2015; Teixeira et al., 2014). These endeavours are classified as type 4 activities, because sub-action 4 (accreditation schemes for transplant donor coordinators) is now effectively implemented.

Projects contributing to Priority Action 1:

- Train the trainers
- ODEQUS
- ACCORD

Countries that participated in projects that supported Priority Action 1:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Slovenia, Slovakia, Spain, Sweden, Netherlands, Romania, Turkey, United Kingdom.

15 EU Member States and 1 other country indicated that EU-funded activities helped promote the role of transplant donor coordinators in their country (BG, DE, EE, ES, FR, EL, HU, IE, IT, LV, LI, PL, PT, SK, SI, TR)

Examples of contribution of EU-funded activities in countries:[128]
"In 2010 the 'Transplant coordinator's Manual' was published in Slovakian. The manual was elaborated by medical professionals and was financially supported by the Ministry of Health in the Slovak Republic (CA)." (SK)

"Estonia actively participated in the ETPOD[129] programme and it gave good input for training courses and seminars at the national and local level." (EE)

"ETPOD programme trainings in donor hospitals continued, 18 courses in 2015 alone with 1950 persons trained" (PL)

[128] Examples have been taken from open answer options in the survey sent to Competent Authorities.

[129] The ETPOD (European Training Program on Organ Donation) project was an early project that ended in 2009, and focused on promoting the role of the Transplant Donor Coordinator.

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

EU-funded projects
Four EU-funded projects can be directly related to Priority Action 2: **ACCORD, COORENOR, MODE and ODEQUS**.

Until 2012, the activities of the projects related to Priority Action 2 consisted of knowledge acquisition, development of tools, and exchange of knowledge. COORENOR contributed to Priority Action 2, since one of its objectives was to make an overview of existing quality assurance programmes in EU Member States. 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 were analysed (Costa, 2012). MODE's main objective was the exchange of best practices in the field of organ donation and transplantation by organising bilateral contacts between Member States (MODE, 2011).

Since 2012, the largest EU-funded contributor to Priority Action 2 is the ODEQUS project. The **ODEQUS project** (Organ Donation European Quality System) was funded under the Health Programme and lasted from 2010 to 2013. Hospitals and authorities from 11 European countries participated in ODEQUS as associated partners. Five countries participated as collaborating partners (M. Manyalich, Guasch, Gomez, Paez, & Teixeira, 2013). One main objective of the project was to identify the best organisational models and make recommendations for improving donation rates, by providing quality criteria and quality indicators to use at the hospital level. So far, the project has identified 130 Quality Criteria and developed 30 Quality Indicators (structure, process and outcomes). Those indicators have been tested in 12 European hospitals by means of internal and external evaluations. Achieving similar results in different evaluations demonstrates that the Quality Indicators created are effective in measuring the hospitals' quality performance in organ donation.[130]
Furthermore, a training manual for applying the indicators in hospitals and an audit guide for evaluating the organ donation process in hospitals were developed (ODEQUS, 2013a, 2013b). The results were disseminated through conferences (Marti Manyalich, Guasch, & Gómez, 2013). The results of ODEQUS also help Member States implement Directive 2010/53/EU with regard to Article 4, the framework for quality and safety, "Member States shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal" and articles 17 and 18, "ensure that procurement organisations and transplantation centres are checked or audited on a regular basis to ascertain compliance with the requirements of this Directive; grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres". The endeavours of the ODEQUS-project can be classified as type 1, 2 and 3 actions. The results are a first step towards a uniform Quality Improvement Programme (ODEQUS, 2009).[131]

Also the **ACCORD** Joint Action contributed to Priority Action 2 after 2012.
If different models of end-of-life care exist across Europe, there may be potential to adapt such models in ways that are compatible with optimum care of the patient whilst also maintaining the possibility of eventual donation – and to make clinical decisions that do not rule out possible donation. The aim of WP-5 of ACCORD was to describe the usual end-of-life care pathways applied to patients who die as a result of a devastating brain injury in Europe, and to explore their impact on the potential for donation, and on the realization of the deceased donation process. The data clearly

[130] http://www.odequs.eu/index.html, retrieved on 1-6-2016.
[131] http://www.odequs.eu/index.html, Retrieved on 21-08-2012.

demonstrate variations, in particular in the possible use of donation after cardiac death (DCD). Furthermore, recommendations for improvement and toolkit methodology were developed, with systemic improvements in end-of-life care pathways to promote organ donation. Hospital staff who are trying to improve performance in complex systems such as deceased organ donation may find it helpful to turn to tools that allow specific barriers for improvement to be identified and interventions to be designed and tested against them. The effective rapid improvement toolkit supports modifications in end-of-life management that maintain the possibility of donation, adapted to each identified end-of-life care model (ACCORD, 2015). These activities within ACCORD, and specifically this work package, are classified as type 2 actions: the development of tools.

Projects contributing to Priority Action 2:

- ACCORD
- COORENOR
- ODEQUS
- MODE

Countries that participated in projects that supported Priority Action 2:

Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Germany, Greece, Hungary, France, Hungary, Italy, Ireland, Latvia, Lithuania, Malta, Norway, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Turkey, United Kingdom.

10 EU Member States indicated that the EU-funded activities helped promote Quality Improvement Programmes in their country (HR, FR, DE, IE, IT, PL, PT, SI, ES, UK).

Examples of contribution of EU-funded activities in countries:[132]
"Participation in ODEQUS […] helped us to develop an auditing system for the donation process, which is on-going." (PT)

"The ACCORD project has provided ONT with new tools to evaluate the potential of donation outside of the ICU, identify areas for improvement in the DBD process inclusive of phases that relate to end-of-life care decisions made by the treating physician or team, estimate the potential of controlled DCD and evaluate performance in the controlled DCD process. In addition, ONT was provided with tools for the application of the PDSA methodology to deceased donation and with the training to transfer the knowledge to the network of donor hospitals. These tools were piloted in Spain (ant other 14 EU Member States) during the life-time of the project." (ES)

[132] Examples have been taken from open answer options in the survey sent to Competent Authorities.

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

EU-funded projects
A total of nine projects are related to this Priority Action: **EULID, ELIPSY, EULOD, COORENOR, ACCORD, and the LIDOBS and ELPAT conferences**. In addition, **two new pilot projects** related to this Priority Action started in 2016.

Until 2012, the project activities related to Priority Action 3 mainly consisted of knowledge acquisition, development of tools, and exchange of knowledge.

The EULID project, which finished in 2009, has analysed and compared ethical, cultural and legal aspects of living donation (EULID, 2007). 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. The ELIPSY project has designed living donor follow-up tools and methodologies as well as a recipient follow-up methodology (ELIPSY, 2011).

EULOD (2010-2012) especially focused on new EU Member States. A description of living donation practices was provided by EULOD, since the 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.[133]

One part of COORENOR also aimed to develop a common strategy on living donation procedures, based on an analysis of existing procedures in the participating countries (COORENOR, 2010).

From 2012, EU-funded activities that made a contribution to Priority Action 3 were **ACCORD**, the **LIDOBS** and **ELPAT** conferences, and two new pilot projects[134] that started in 2016 ("The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes (EDITH)" and "Platform for increasing organ donation in the European Union and neighbouring countries: EUDONORGAN 2015-2016").

The objective of WP4 of the **ACCORD** project is "to improve MS information systems on live organ donation through the provision of recommendations on the design and management of structured living donor registries and through establishing a model for supranational data sharing". Part of the ACCORD WP4 was to test the recommendations that were developed during the project by performing a pilot phase of the living donor register. Nine countries (Spain, United Kingdom, Croatia, Lithuania, Latvia, Netherlands, Poland, Portugal and Slovakia) participated in the pilot, including a total of 2909 donors in the pilot register (ACCORD, 2015c).
The most important conclusions were that the pilot register is a suitable way of collecting living donor follow-up information. Some technical problems were found. Recommendations were made for wider implementation. For instance, a common dataset and data definitions are essential for an international register, enabling national and international data analysis (ACCORD, 2015c). This pilot is the first step towards collecting data about living donation on an international basis, and can be classified as type 2 and 3 actions.

[133] http://www.eulod.org/?section=WorkingPackages&item=13, Retrieved on 21-08-2012.

[134] Although these new pilot projects started after the period of the EU Action Plan, we considered them still worth describing as they are linked to the Priority Actions of the Action Plan.

Another contribution to Priority Action 3 was the International Conference on Living Donation, the **LIDOBS** conference held on 6-7 November 2014 in Barcelona. During the conference, the results from EU-financed programmes on living donation were disseminated. Furthermore, a common follow-up model for living donors was elaborated and offered to all the centres applying living donation programmes. The final aim of LIDOBS was to achieve recommendations for high-quality programmes formulated under a consensus widely agreed that will benefit high-quality practices in living donation and transplantation (LIDOBS, 2014). The LIDOBS conference also resulted in a consortium agreement. Currently, 28 professionals from 20 institutions situated in 13 countries have signed the consortium agreement (LIDOBS, 2015).

Lastly, the **ELPAT** conference was organised in 2013 for the third time. This joint event between ELPAT, ESOT and The Transplantation Society (TTS), co-funded by the Commission, was visited by 360 delegates from 52 countries including psychologists, ethicists, ethnologists, physicians, philosophers, lawyers and policy makers. Topics included organ tourism and organ trafficking, living liver donors, psychological care, establishment of transplant programmes, anonymity and donation, children as donors, and religious and cultural aspects of organ donation.

The conferences benefit type 3 actions: the exchange of knowledge.

A new pilot project, started in 2016, has the title **"The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes (EDITH)."**

This pilot project will compare (from microeconomic and macroeconomic perspectives) the various treatment procedures for chronic kidney diseases (CKD) in EU Member States and associated countries, by investigating the factors that influence the treatment choice (by patient or doctor) and the impact of that choice on healthcare budgets. In addition, the project will examine obstacles to improving kidney donation and transplantation rates (deceased donation and living donation being considered). It will answer the question of why there is such an enormous variability in practice in the overall management of CKD and access to transplants in Europe, and how these practices could be aligned in order to ensure equal and better patient access to all treatment procedures and quality of care while reducing costs. The first overall project goal, to be implemented via one work package, is to provide an overview of the various treatment procedures and the factors that influence the selection of those modalities in Member States and associated countries, with a view to aligning end-stage kidney disease treatments and improving the availability of transplantation across Member States, while at the same time reducing healthcare costs and improving the quality of care, patient survival and quality of life. This WP should build upon the results of previous and on-going EU-funded projects (EULID, ELIPSY, WP4 within the Joint Action ACCORD, POSAT, COPE, DIREKT, Kidney Injury, Technology, OLDIAS and SCOPE) and also take account of professional associations (e.g. ESOT, kidney-oriented associations) and tools and networks already available such as in the ERA-EDTA registries (Le Borgne, 2016b; European Commission, 2015a). This second overall objective will be implemented via two work packages, one being dedicated to the follow-up of living kidney donors, the other focusing on the follow-up of transplant kidney patients. These two work packages will help ensure the quality and safety required by EU legislation in the field, and hence the protection of donors and patients, and they will also be beneficial for the transplant community as a whole, as lessons from such registers will allow better indications to be proposed for (future) patients on transplant waiting lists (European Commission, 2015a).

Endeavours directly managed by the Commission

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.

The Commission also coordinated a **working group on living donation**. The objectives of this group were first discussed with the competent authorities in 2011 and the first face-to-face meeting took place in February 2012. The objective of the working group on living donation was to provide a manual/toolbox on the experiences of Member States with living donation (Working Group on Living Donation, 2014). The manual contains information about legal aspects, ethical principles, donor evaluation, selection and protection, donor registration, psychological aspects, financial and economic aspects of living donation programmes and optimising living donations (European Commission, 2012b). The toolbox is available at the website of the Commission.[135] The following countries participated in the working group: Belgium, France, Germany, Hungary, Italy, the Netherlands, Norway, Poland, Slovenia, Spain, Sweden, the United Kingdom and Eurotransplant (Working Group on Living Donation, 2014).

Regarding both deceased and living donation, 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, measures will be taken to accompany them, as is already the case with the work package on living donation registers under 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 frameworks for living donation will continue to differ from one EU country to another, efforts should be maintained to get to know about the different systems and share best practices. The Commission is carrying out a transposition check, in which an implementation survey is submitted to Member States. This survey checks whether the provisions of Directive 2010/53/EU are transposed into the national laws of the countries. The survey focuses on five subjects: General, Competent Authorities, Procurement, Traceability & Reporting, and Donor Selection (McGeehan, 2016).

Endeavours of other organisations

Aspects related to organ trafficking were mainly dealt with at the level of the Council of Europe. In June 2011, a joint meeting between the Commission, the Council of Europe and Chafea was organised to avoid duplication of efforts. DG SANCO followed up at the Commission level with the continuous integration of the concept of "trafficking for the purpose of removal of organs" into the new EU strategy and legislation about trafficking in human beings (Directive 2011/36/EU, for which the deadline for transposition was 6 April 2013)[136], led by DG Home Affairs, as well as in projects funded by this DG, such as the HOTT project. DG SANCO provided information for the competent authorities, who could propose experts 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.

[135] http://ec.europa.eu/health//sites/health/files/blood_tissues_organs/docs/ eutoolbox_living_kidney_donation_en.pdf

[136] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:101:0001:0011:EN:PDF

The recently adopted **Council of Europe Resolution** on the same topic (read more under Priority Action 7) explicitly mentions ACCORD deliverables as reference documents[137] and thus confirms and expands the recognition of their value to non-EU Member States as well (European Commission, 2016). The Council of Europe is also reflecting on additional resolutions or texts on ethical aspects of living donation and in particular on safeguarding and protecting living donors.

Projects contributing to Priority Action 3:

- EULID
- ELIPSY
- EULOD
- COORENOR
- ACCORD
- LIDOBS CONFERENCES
- ELPAT CONFERENCES
- New EDITH pilot project: "The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes."

Countries that participated in projects that supported Priority Action 3:

Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the Netherlands, Turkey, United Kingdom.

16 EU Member States indicated that the EU-funded activities helped promote of living donation programmes following best practices in their country (BG, CZ, DE, EE, ES, FR, HR, HU, IT, LV, LT, MT, PL, PT, SK, NL).

Examples of contribution of EU-funded activities in countries[138]:
"The dataset and data dictionary for living donor registries agreed upon in the ACCORD project have inspired changes in our registry. Our national policy has been influenced by other best practices exchanged in living donation through projects such as EULID, ELIPSY, LIDOBS and the Working Group on living donation." (EE)

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

EU-funded projects
Three projects can be linked to this Priority Action: **EDD, FOEDUS and the new pilot project EUDONORGAN**. Until 2012, the activities of the projects related to Priority Action 4 consisted of knowledge acquisition, development of tools, and exchange of knowledge. "European Organ Donation Days", are hosted every year in a different country since 2008.

[137] Resolution CM/Res(2015)11 on establishing harmonised national living donor registers with a view to facilitating international data sharing and its Explanatory Memorandum - see more at https://www.edqm.eu/sites/default/files/resolution_on_establishing_harmonised_national_living_donor_registries_with_a_view_to_facilitating_international_data_sharing_2015_11.pdf
https://www.edqm.eu/en/organ-transplantation-recommendations-resolutions-74.html

[138] Examples have been taken from open answer options in the survey sent to Competent Authorities.

An important contributor to Priority Action 4 is the joint action **FOEDUS**. FOEDUS ran from 2013 until 2016 and focused mainly on cross-border exchanges in organ transplantation, but also had a work package, led by Slovenia and Germany, that focused on public awareness. 22 European countries and one international organisation participated (FOEDUS SOHO TEAM, 2011).
The second important aim, linked to the first, is the development of a tested methodology for informing the general public about organ donation in general and international exchanges in particular, teaching experts to avoid wrong communication attitudes. A manual on how to communicate efficiently about organ donation and cross-border exchange was developed as well as a methodology for measuring the effectiveness of the campaigns that will help optimise initiatives to increase public awareness. Expected outcomes include the adoption of a common communication strategy to raise awareness of organ donation and international cross-border exchanges. But most of all, this is an opportunity to agree common general rules that would set up a transparent framework, helping prevent illicit practices in a very sensitive field. In addition, FOEDUS is expected to improve communication with specialised media (FOEDUS, 2016a)[139]. The results of the joint action have been widely spread, including via Wikipedia and YouTube (Mihály, 2015). These results are type 1, 2 and 3 activities.

The new pilot project **EUDONORGAN** is also an important contributor to Priority Action 4. The course that will be provided focuses in particular on increasing social awareness. The course will include components on communication, quality improvement methodologies, donor identification, "approaching the family" (in the case of deceased donation) or approaching possible donors such as living donors, cooperation with patients' support groups and other elements for increasing social awareness – also within healthcare establishments – and for improving the use of donated organs.
The pilot project will focus on training and social awareness to encourage public reflection on organ and tissue donation. It will include training for health professionals (for example transplant donor coordinators, psychologists involved in the donation process), activists, networks and professionals (for example patient support groups, journalists, communications departments of healthcare establishments or national/regional authorities). They will be trained in how to best identify donors (PA 1), how to best organise donation activities (taking account of national specifics) and how to pass on the main positive aspects of donation within the hospitals and the rest of society (PA 6). The training course will encompass results from EU-funded projects that included training and improvement methodologies, e.g. the European Training Course in Transplant Donor Coordination, ETPOD, ODEQUS, and the ACCORD Joint Action.

The second phase will involve the organisation of several communication events (e.g. awareness or information days, journalists' workshops) (Le Borgne, 2016a; European Commission, 2015b).

Lastly, **European Organ Donation Day** is held each year. The main purpose of the project EDD was preparation of a theoretical basis for the organisation of an EDD (a model and guidelines). A final result of the project was a Toolkit for Event Organisers guidebook, which is in use for preparation of EDD celebration still today.
Slovenija-Transplant was the initiator and the main partner of the project: Developing Guidelines for the Organisation of a European Donation Day (EDD 2011a).

Endeavours directly managed by the Commission
The EC organised **journalists' workshops** centrally to make journalists aware of their key role in this issue, of the complexity of the issue and of the added value of

[139] http://www.foedus-ja.eu/about-foedus

working at the EU level, and generally indirectly to increase public awareness at least by creating a positive culture around organ donation. The organisation of journalists' workshops is in line with the objective of the Action Plan to increase public awareness of organ donation and Priority Action 4 and its sub-actions.
Journalists' workshops were organised by DG SANCO in the context of the campaign 'Europe for patients', a communication campaign for informing the general public about EU healthcare policies and actions. Health experts, media and EU personnel exchange best practices about effective and ineffective strategies to improve public awareness (DG Health and Consumer (SANCO) - Organ Donation and Transplantation, 2010). The workshops were held in 2012 and 2013.
Specific objectives of the workshops are increasing journalists' awareness of the various aspects and complexity of organ donation and transplantation; the importance of the media's role; the need to improve the level of information to the public about these topics; the possible consequences of adverse publicity; the added value of working at the EU level on these topics; and generating media coverage and multiplying the key messages.

The journalists' workshops have positive effects. Journalists are largely satisfied with the whole workshop and most of them publish articles afterwards. The Commission/speakers' messages are being well taken up in the articles published. Over time, coverage is increasing in terms of total numbers and countries covered. However, improvements can still be made. As a result of the journalists' workshops in 2012, 16 articles have been published and three TV spots or reports were broadcast (Le Borgne, 2013).

The TAIEX workshop described under Priority Action 1 also contributes to Priority Action 4, because it focuses on training healthcare professionals.

Projects contributing to Priority Action 4:
- EDD
- FOEDUS
- EUDONORGAN

Countries that participated in projects that supported Priority Action 4:

Belgium, Bulgaria, Croatia, Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Malta, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, United Kingdom.

16 EU Member States indicated that the EU-funded activities helped promote public awareness in their country (BE, BG, HR, CY, EE, EL, DE, HU, IE, IT, LT, PL, PT, SI, ES, UK).

Examples of contribution of EU-funded activities in countries[140]:
"One of the WP leaders resulting in the development of a communication handbook in the FOEDUS project was the German organ procurement organisation (DSO). The Bundeszentrale für gesundheitliche Aufklärung closely collaborated with the DSO." (DE)

"It all begins and end with the publics. So it is of utmost importance to communicate with the public in order to create a positive attitude toward organ donation. EU projects such as the European Donor day, FOEDUS and journalists' workshops are helpful materials that provide guidelines how to communicate with

[140] Examples have been taken from open answer options in the survey sent to Competent Authorities.

the public." (HR)

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

EU-funded projects
While this Priority Action was less developed, there were five projects that contributed directly or indirectly to information on citizens' rights concerning organ donation: **EULID, EULOD, ELPAT, COORENOR and FOEDUS**.

Until 2012, the project activities related to Priority Action 5 consisted mainly of knowledge acquisition and the exchange of this knowledge. 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 & 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. Furthermore, the ELPAT congresses also covered legal aspects of organ donation and transplantations (ELPAT, 2011).

A continuation and development on the basis of the mapping of legal aspects in COORENOR is the Joint Action FOEDUS.

FOEDUS that started in 2013 is assigned to Priority Action 5.
Within the FOEDUS workpackages on communication, specific attention was given on messages around international exchanges[141]. This contributes to dissemination of information and knowledge on citizen's rights with regard to (cross border) organ donation.
Part of the FOEDUS-activities overlap with the activities that contribute to Priority Action 8. The activities that include those of the Commission will therefore be described under Priority Action 8.

Projects contributing to Priority Action 5:
- EULID
- EULOD
- ELPAT
- COORENOR
- FOEDUS

Countries that participated in projects that supported Priority Action 5:

Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Germany, France, Hungary, Iceland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the Netherlands, United Kingdom.

5 EU Member States and one third country indicated that the EU-funded activities contributed to the identification of cross-border donors in their country (BG, EE, FR,

[141] http://www.foedus-ja.eu/about-foedus/project-organization

EL, PL, CH).

Examples of contribution of EU-funded activities in countries:[142]
"Poland took part in COORENOR organ exchange and now in FOEDUS organ exchange through web-based applications. In 2015, 6 pairs of lungs donated in Poland were transplanted in Austria, Germany and France."(PL)

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

EU-funded projects
Tackling a core issue within the Action Plan ("organisational models"), Priority Action 6 is broadly formulated, with four sub-actions, which is why various projects can be related to this action: in particular **COORENOR, ODEQUS, MODE and ACCORD** (as well as **Alliance-O, 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[143] in organ donation & transplantation).

Until 2012, the project activities related to Priority Action 6 consisted of knowledge acquisition, development of tools, exchange of knowledge and implementation. The focus of one work package of COORENOR lied on the analysis of existing transplant programmes. This part of the project builded on the outcomes of the Alliance-O project (Costa, 2012a). The main objective of the ODEQUS project was 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 were 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), to make them available for the whole transplant community afterwards. This project started in 2010 and finsihed in 2013.

The MODE project also contributed to Priority Action 6, since its main objective was the exchange of best practices in the field of organ donation and transplantation through twinning projects. The main topics on which the project focused were 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, 2011).

More older projects are Alliance-O, ETPOD, and DOPKI. 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 (ALLIANCE-O, 2007). 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, 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

[142] Examples have been taken from open answer options in the survey sent to Competent Authorities.
[143] "Twinning is the coming together of two communities seeking, in this way, to take action with a European perspective and with the aim of facing their problems and developing between themselves closer and closer ties of friendship".

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 (ETPOD, 2009).
The DOPKI[144] 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 (DOPKI, 2007).

Since 2012, the contributors to this Priority Action were ACCORD plus a new pilot project started in 2016. As part of ACCORD, **twinning activities** were defined as a direct support from Member State to another by means of practical collaboration. Such twinning concepts were developed as a complement to actions usually provided by EU projects or joint actions that are rather more theoretical than practical, and that do not target a specific Member State for transferring operational expertise (on-site implementation). Twinning activities in ACCORD were anticipated to promote expertise, knowledge or practical tools developed by one Member State in another Member State. Depending on the Member State, different aspects of the Organ Donation and Transplant system can be reinforced through cooperation, as long as these are in line with the Member State's national Action Plan and/or the Directive.
CNT (Centro Nazionale Trapianti, the Italian Competent Authority) has developed a challenging multiple twinning project. This provided concrete promotion of several harmonised practices and processes among the supported Member States. The Guide on Essentials for developing Authorisation and Audit systems of Transplant Centres can also be easily adapted to every National Health system within the EU. It therefore has the potential to be widely distributed and adopted by other Member States, and so could be the e-learning training programme for auditors. Experience gained by the multiple partnerships is useful for detecting specific aspects that would allow the common system to run within a diverse environment of legislation, specificities and needs.

Overall, twinning activities of **ACCORD** showed directly measurable results and led to valuable transfers of knowledge and expertise between Italy, the Netherlands, Hungary, Malta, Cyprus, Lithuania, the Czech Republic, France and Spain. Twinning activities also helped strengthen the network at the Competent Authority level and to facilitating collaborations (ACCORD, 2015d).
In Hungary, an optional training scheme is now available within the continuous education programme for medical doctors (FONT-SALA, 2014). France already started to train surgeons about abdominal organ retrieval on this platform. Some other countries showed interest as well. This means that tools developed by one Member State can meet the needs of others.

On top of reporting results of twinning, twinners also generated a Guidelines for Twinning activities with a specific focus on organ donation and transplantation, building upon the experience gained through twinning activities by pairs and by larger groups. This guide is aiming to facilitate new twinning initiatives once the ACCORD joint action is completed (ACCORD, 2015b).

[144] 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

Thanks to the twinners' commitment and volunteered participation as the testers, this multi-country project was a success. As the National Transplant Bureau twinner from Lithuania stated, audits are now positively considered by professionals on-site as opportunities for changes and improvements (ACCORD, 2015d). Twinning therefore seems to be a fruitful approach. The results of ACCORD are classified as type 4 actions, because changes are achieved in several countries.

Endeavours directly managed by the Commission

The **TAIEX workshop** described under Priority Action 1 also makes a contribution to Priority Action 6, because it focuses on the organisational models within hospitals.

With regard to sub-action 6.4, the Commission is planning to support Member States in the development of European Reference Networks (ERNs) to link existing highly specialised healthcare providers across the European Union (EU). ERNs aim to tackle complex or rare diseases and conditions that require highly specialized treatment and a concentration of knowledge and resoureces. for rare desaases. TransplantChild is an ERN for Paediatric Transplantation both Solid Organ Transplantation (SOT) and Hematopoietic Stem Cell Transplantation (HSCT) which are low-prevalence and complex conditions that requires highly specialized expertise and resources.[145]

Projects contributing to Priority Action 6:

- COORENOR
- ODEQUS
- MODE
- ACCORD

Countries that participated in projects that supported Priority Action 6:
Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, Switzerland, Netherlands, Turkey, United Kingdom.

14 EU Member States indicated that the EU-funded activities helped enhance the organisational model of the donation and transplantation system in their country (BG, CZ, DK, EE, FR, EL, HU, IE, IT, LT, MT, PL, PT, UK).

Examples of contribution of EU-funded activities in countries[146]:
"DOPKI (Improvement of Knowledge and Practices in Organ Donation) based procedures (monitoring at hospitals with a potential for DBD donation) are being introduced in donor hospitals. At the national level, transplant coordinators activities are being reported through the web net tool (koordynator.net) and analysed." (PL)

"The Danish Centre for Organ Donation has attended the ACCORD Workshop – a service improvement workshop – and is using the ACCORD Improvement toolkit to implement best practices for organ donation in Denmark." (DK)

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

[145] http://www.transplantchild.com

[146] Examples have been taken from open answer options in the survey sent to Competent Authorities.

EU-funded projects

For the overall duration of the Action Plan, EU-funded activities of organisations such as the **European Society for Organ Transplantation** (ESOT) with her sub sections as ELPAT and EDTCO, **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) and initiatives like the **EULOD** project. Until 2012, the activities undertaken consisted mainly of cooperation and knowledge exchange between countries on various topics. . It should certainly be mentioned that those activities which focused 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 were also involved (ELPAT, ESOT conferences such as on DCD, FOEDUS). In February 2013, the last ESOT's conference on DCD took place in Paris and was co-funded by the Competent authorities in charge of organ donation & transplantation from France, the Netherlands, the United Kingdom and Spain. Furthermore, one of the objectives of the older project EULOD was linked to Priority Action 7, namely to gain insight in organ trafficking in Europe. Finally, it should be noted that the Joint Action **FOEDUS** contributed to finding a scientific consensus on the organ and donor characterisation which could lead, in the future, to "EU-wide agreements".

Projects on Organ Trafficking

The **HOTT project** has been contributing to this Priority Action since 2012, specifically to sub-action 7.3 on organ trafficking, by creating insights into the practices of trafficking in persons for the purpose of organ removal. This was the first EU-funded project against this 'new' and neglected form of human trafficking. This project aimed to increase knowledge and information, raise awareness about the crime and to improve its non-legislative response. The project finished at the end of 2015. The reports were circulated among police forces and other key stakeholders worldwide[147] (Ambagtsheer & Weimar, 2015).

These activities are classified as type 1 and 3 activities, as knowledge is generated and disseminated. This could help promote EU-wide agreements on this important topic.

Projects on Research

Several EU-funded projects in research or public health tackle "aspects of transplantation medicine" that could lead in the future to "EU-wide agreements". It was and is for example the case with

- Alliance-O

as well as with research projects funded under the 7th Framework programme[148] which started at the 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 hypersensitised patients on the 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).

[147] http://hottproject.com/

[148] All the projects are presented in the Cordis database for EU Research projects: http://cordis.europa.eu/projects/

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 reaching scientific consensus on many aspects of the transplantation medicine within Europe.

Endeavours of other organisations

The **Council of Europe** recently adopted **a Convention against Trafficking in Human** Organs (López-Fraga, Domínguez-Gil, Capron et al., 2014; López-Fraga, Domínguez-Gil, Fehily et al., 2014). This convention is a seminal international legal instrument that for the first time reaches illicit transplant practices that currently escape prosecution. By complementing each other, this convention on trafficking of human organs and the instruments on human trafficking for organ removal provide a comprehensive legal framework for preventing and combating transplant activities that violate basic human rights (Nanni Costa, 2014a).

Furthermore, an anti-trafficking day is organised annually by DG Home.

In 2012, a high-level conference in Brussels was organised under the Cyprus presidency, focusing on the implementation of the EU strategy.

In 2013, a conference was organised in Vilnius with the main theme 'Internet linked to trafficking in human beings'.

Lastly, two international organisations wrote reports about organ trafficking:

- The organisation for Security and Cooperation in Europe (OSCE) wrote a report called 'Trafficking in Human Beings for the purpose of the removal of organs in the OSCE region, Analysis and Findings, 2013.
- The UN wrote a report by the Special Rapporteur from 1 August 2012 to 31 July 2013, including a thematic analysis of trafficking in human beings (THB) for the removal of organs (Bogers, 2013).

Projects/organisations contributing to Priority Action 7:

- ESOT
- EULOD
- ELPAT
- HOTT-project

Countries that participated in projects that supported Priority Action 7:
Belgium, Bulgaria, Estonia, France, Germany, Macedonia, the Netherlands, Poland, Romania, Sweden.

11 EU Member States indicated that the EU-funded activities contributed to the development of EU-wide agreements in their country (BG, EE, FR, EL, IT, LT, PL, PT, SK, ES, UK).

Examples of the contribution of EU-funded activities in countries[149]:
"Bulgaria, through the BEAT, has been one of the first EU countries to be participants and users of the COORENOR portal since 2014. We will in addition be signing an agreement for maintenance of the FOEDUS IT platform for cross-border organ exchange."(BG)

"The promoted agreements between countries (e.g. through FOEDUS) for organ exchange, facilitating research activities and exchange of best practices (e.g. LIDOBS) and progressively building international consensus on key topics (e.g. through the meetings of Competent Authorities)." (ES)

[149] Examples have been taken from open answer options in the survey sent to Competent Authorities.

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

EU-funded projects

Over the total duration of the Action Plan, two projects were related to Priority Action 8: **COORENOR** and **FOEDUS**.

As mentioned before, COORENOR provided 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. 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 system includes email notifications and an SMS gate for national coordinators (Costa, 2012a) The IT-portal was tested during COORENOR and further developed and expanded within FOEDUS.

The joint action called **FOEDUS** ran from 2013 and is wholly to Priority Actions 5 and 8. The focus of this action is on facilitating collaboration on organ donation between national authorities in the EU as prescribed by Art. 3.1.4.2 of the Community Action Health Programme of 2012. This focus had a twofold approach: 1) supplying the Member States with concrete theoretical support for organising optimum allocation and 2) use/transplantation of donated organs through multilateral and bilateral arrangements between the various transplant systems and analysing all the existing barriers. This specific field of cooperation is also foreseen in Directive 2010/53/EU and in the Action Plan 2009-2015 set by the EU Commission. FOEDUS aimed to show policy makers and the general public how the competent authorities and EOEOs are trying to handle the problem of unallocated organs. Eurotransplant developed a questionnaire to identify barriers to international organ exchange and circulated this among 31 countries (28 EU + 3 non-EU), including the countries being members of Eurotransplant, Scandiatransplant and SAT. A report on current practices regarding cross-border organ exchange was written taking account of two major items:

- current practice and obstacles regarding the handling of non-allocable organs across Europe;
- the existing international agreements regarding cross-border organ exchange across Europe (Nanni Costa, 2014b).

The basis for reaching this result is the development of an EU-wide common approach to the issue of organ exchange, along with better knowledge of current barriers and obstacles (financial, logistic, legal) that are presently hindering this practice. This would also give the EU Commission the correct input for addressing these issues at their level, if relevant.[150] Within FOEDUS a template agreement for cross border organ exchange as well as several recommendations to facilitate this has been developed under the guidance work package leader Eurotransplant.

Furthermore, increasing the availability of organs is expected to encourage some Member States to invest resources to develop their own transplant programmes for achieving self-sufficiency and meet their own patient requirements.

Another aim of FOEDUS is identifying financial pathways for coverage of cross-border organ exchanges in different EU countries and patient mobility for organ transplantation. During COORENOR, it has become clear that not all EOEOs are aware of the financial mechanisms regulating cross-border transplantation in their countries versus the EU. A clear identification of existing pathways will allow transplant organisations to tackle this issue at the institutional level and provide solutions.

[150] http://www.foedus-ja.eu/about-foedus

During the Joint Action, common donor forms (organ-specific) to be used for international cross-border exchanges have been developed. These forms are needed because of the following existing barriers:

- organ offers sent round in the national language;
- medical information is not always sufficient;
- disparities in units (µM; µg/ml etc.);
- difficulties in getting additional information by phone (language, availability etc.);
- very little feedback on organ utilisation;
- poor feedback on potential technical problems;
- logistical problems (Nanni Costa, 2014b).

A list of common agreed definitions and selected items that are necessary for donor evaluation will facilitate the collection and transmission of all the essential information necessary for organ acceptance in other Member States, hence speeding up exchanges by avoiding the loss of time consequent to the request of complementary tests.

Until 2012, the project activities related to Priority Action 8 consisted of knowledge acquisition, development of tools, and exchange of knowledge. In addition to this, several activities may have influenced daily practice to a certain degree already.

As mentioned above, FOEDUS builds upon the results of the COORENOR project. FOEDUS started in 2013 and has developed and implemented an IT portal for the exchange of organs between countries. The use of an IT portal is expected to bring about an increase in exchange organs over the short term, as this helps speed up communication and provides agreed tools to overcome existing barriers affecting organs that are already available. In the long run, the action will help increase the number of organs retrieved per donor. In March 2016, 83 users were registered with the IT portal from Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Malta, Moldova, the Netherlands, (Eurotransplant) Norway, (Scandiatransplant) Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland and the United Kingdom (Nanni Costa, 2016). Of those countries, nine are offering organs and seven are requesting organs. Since the start of the portal, 24 transplants were carried out as a result of exchanges via the portal (FOEDUS, 2016b). Creating the tools for cross-border organ exchange will bring the EU one step closer to having a common policy at least for special cases such as paediatric, urgent and hypersensitised patients (FOEDUS, 2016a).
The activities of FOEDUS are classified as type 4 activities: change.

Endeavours directly managed by the Commission
According to Directive 2010/53/EU (articles 9, 12 and 17), the Commission can ask Member States to provide information about the transportation of organs and for instance how they make sure that healthcare staff coming from abroad are suitably qualified to perform their tasks (Le Borgne, 2015).

Projects contributing to Priority Action 8:

- COORENOR
- FOEDUS

Countries that participated in projects that supported Priority Action 8:
Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Romania, United Kingdom

9 EU Member States indicated that the EU-funded activities helped the interchange

of organs between countries (BG, CZ, FR, EL, IT, LT, PL, SI, UK)

Examples of contribution of EU-funded activities in countries[151]:
"The experience with FOEDUS has facilitated the exchange of organs between member countries of SAT and other countries." (ES)

"We're using the FOEDUS application for organ exchange." (PL)

Priority Action 9: Evaluation of post-transplant results

EU-funded projects
Three projects focus directly on the evaluation of post-transplant results: **EFRETOS, MODE** and a new pilot project with the titled "The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes (**EDITH**)." Until 2012, the activities of the projects related to Priority Action 9 mainly consisted of knowledge acquisition, development of tools, and exchange of knowledge.

The main project to address post-transplant results was **EFRETOS**, and it made a major contribution on this topic. 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 organizational and legal prerequisites for realizing a pan-European registry. The ultimate goal of EFRETOS was 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 (EFRETOS, 2008). These activities are considered type 2 actions, because tools are developed which are preparatory for the development of an actual registry. Such efforts may need to be continued, also in the future, preferably with more participating countries.

In addition, the **MODE** Joint Action also addressed post-transplant results. Onsite visits were organized for the purpose of exchanging best practices. The stronger countries organized host visits, and weaker countries got the change to have up to five exchange visits on different topics. One of the topics the course reported on was adverse events and reactions (MODE, 2011b). The reporting of adverse events and reaction was a new topic, but there is growing interest for this activity and its focus on important aspects of the implementing Directive such as bio vigilance and surveillance on substances of human origin in Europe. Therefore, specific training on this issue was developed (di Ciaccio, 2013). The training can be considered as a type 3 activity, because knowledge is actively exchanged.

The new pilot project on kidney diseases that started in 2016 is making a major contribution to this Priority Action. One objective of the project is to assist Member States' endeavours in putting in place operational tools (registers) to follow up living donors and transplant patients, based on the experience gained and recommendations formulated by previous EU-funded projects. This objective will be implemented via two work packages, one for follow-up of living donors, the other focusing on the follow-up of transplant patients. These two work packages will help ensure the quality and safety aspects required by EU legislation in the field, and hence the protection of donors and patients, but they will also benefit the transplant community as a whole, as lessons from such registers will enable proposals for better allocation for (future)

[151] Examples have been taken from open answer options in the survey sent to Competent Authorities.

patients on transplant waiting lists (European Commission, 2015a). It is expected that some of the Member States participating in the project will be able to use it as a stepping stone towards successful implementation of EU policies and legislation in chronic diseases and organ transplantation, in particular Directive 2010/53/EU of the European Parliament and the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. Work Package 2 will support the establishment by EU Member States of registries to follow up living kidney and liver donors, in line with Article 15 of Directive 2010/53/EU.
Work Package 3 will support the establishment of follow-up registers for transplant recipients: at least at the national level (supporting national endeavours) and possibly at the European level if Member States confirm the need to having a common tool (e.g. in a European meeting of National Competent Authorities in 2015). (European Commission, 2015a). If the objectives of this project are achieved, the activities could be classified as type 4 activities.

Endeavours directly managed by the Commission
Several registers developed and kept by transplant professionals and associations – such as ERA-EDTA[152] for kidneys or ELTR[153] for livers – also play a key role in these topics. Several competent authorities collaborate with them and the Commission encourages such cooperation by inviting them to meetings with all the authorities in Brussels. This contributes to Priority Action 9.

[152] Register of the European Renal Association - European Dialysis and Transplant Association: http://www.era-edta.org/
[153] European Liver Transplant Register: http://www.eltr.org/

Projects contributing to Priority Action 9:
- EFRETOS
- MODE
- New pilot project: "The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes (EDITH)."

Countries that participated in projects that supported Priority Action 9:
Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Lithuania, Portugal, Slovakia, Slovenia, Spain, the Netherlands, United Kingdom.

4 EU Member States indicated that the EU-funded activities contributed to the evaluation of post-transplant results in their country (DE,EL, ES, UK).

Examples of contribution of EU-funded activities in countries[154]:
"The experience in EFRETOS (and previously in DOPKI) has helped us to further develop our non-standard risk donor project, based on the prospective assessment of the outcomes of patients transplanted with organs from donors diagnosed with potentially transmissible diseases or conditions likely to impact upon the quality of the transplanted organ – donors with a past or present history of malignancy, infectious diseases, poisoning, rare diseases, and other conditions" (ES)

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

EU-funded projects
The wording of this Priority Action is very open, and it is the only Priority Action where no sub-action was defined. Four projects, which were described earlier, can be related more or less directly to Priority Action 10: **COORENOR, ODEQUS, ACCORD and MODE**.

Until 2012, the activities for the projects related to Priority Action 10 mainly consisted of knowledge acquisition, development of tools, and exchange of knowledge.

COORENOR can be related to this Priority Action because the projects provided 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 was 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 were 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). In the ACCORD and MODE Joint Actions, twinning activities between countries were organised. In each project, one of the twinning activities was focused on the development of an accreditation system (ACCORD, 2012; MODE, 2011c).

Since 2012 there have been no new activities relating to EU-funded projects.

[154] Examples have been taken from open answer options in the survey sent to Competent Authorities.

Endeavours directly managed by the Commission

Directive 2010/53/EU, adopted in July 2010 after the Action Plan (December 2008), 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 Commission or any other Member State can be asked 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) via an implementation survey. Questions regarding authorisation for procurement organisations and transplantation centres, controls and audits, and the qualification and training of healthcare personnel have been asked.

Endeavours made by other organisations together with joint action ACCORD

The Division of Transplantation of the UEMS provides training courses in various areas: Transplant Surgery, Transplant Coordination, Transplant Immunology and Transplant Medicine. The e-learning platform for 'Multi-organ donor procurement surgery' first developed by Leiden University Medical Center and the University Medical Center Groningen with support of the NTS (Dutch Transplantation Association, and further developed and distributed by the ACCORD joint action has been formally accredited by the European Accreditation Council for Continuing Medical Education (EACCME) of the UEMS. It is now also available for countries other than the Netherlands and Hungary (de Graauw *et al*., 2014).

Projects contributing to Priority Action 10:
- COORENOR
- ODEQUS
- MODE
- ACCORD

Countries that participated in projects that supported Priority Action 10:
Austria, Croatia, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Netherlands, United Kingdom.

10 EU Member States indicated that the EU-funded activities helped promote accreditation systems in their country (BG, HR, CZ, EL, IE, LV, LT, PL, SK, UK).

Examples of contribution of EU-funded activities in countries[155]:
"We have started cooperation with KST from the Czech Republic in international auditing of transplant centres according to the methodology of the ACCORD project." (SK)

Concluding remarks

The Action Plan is well embedded and backed by a diverse network of stakeholders at the national and the EU levels that provide ethical frameworks and legal principles, projects, actions, expertise and experts.

The EU funding instruments for funding have been used widely, with initiatives ranging from acquiring the necessary knowledge base to initiatives that focus specifically on

[155] Examples have been taken from open answer options in the survey sent to Competent Authorities.

knowledge sharing. For several Priority Actions, change was achieved in countries through the EU-funded projects. For Priority Actions 6 (organisational models) and 8 (organ exchange) change had already been achieved by 2012/2013. For Priority Actions 1 (transplant donor coordinators), 4 (awareness) and 9 (post-transplant results), change was mainly achieved during the second half of the Action Plan Period.

On Priority Actions 6 (organisational models) and 8 (exchange of organs), much progress had already been achieved by the EU-funded projects by 2012 (as the ACTOR study concluded). While progress was made on Priority Action 6 by a small number of individual countries, many organisational changes were achieved through the EU-funded projects, mainly through twinning activities and international exchange agreements. For instance, several training schemes for medical personnel and tools were widely disseminated and implemented in various twinning countries. Twinning in particular seems to be a fruitful approach.

Since 2012, progress has been made in particular on three Priority Actions: 1 (transplant donor coordinators), 4 (awareness) and 9 (evaluation of post-transplant results).

For Priority Action 1 (transplant donor coordinators), a large step was made by developing a certification from the European Union of Medical Specialists (UEMS) for transplant coordination by EDTCO. This helps implement and professionalise the work of transplant donor coordinators, which has already been proven to increase the amount of donors in hospitals.

With regard to Priority Action 4, the FOEDUS Joint Action developed a methodology for informing the general public, and a new pilot project focused on increasing public awareness, EUDONORGAN, has started in 2016. These are promising developments.

For Priority Action 9 (evaluation of post-transplant results), the activities of the new pilot project named "The Effect of Differing Kidney Disease Treatment procedures and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes" (EDITH pilot project) are on-going but, if they are implemented well, the work is expected to help come the participating Member States towards successful implementation of follow-up registries. This would help them implement in particular to implement art 15 of Directive 2010/53/EU.

Particularly for Priority Action 7 (EU-wide agreements), many activities are continuing to be organised by a variety of international stakeholders. There are many on-going initiatives, particularly for organ trafficking. The convention on organ trafficking recently adopted by the Council of Europe is very relevant for this Priority Action. This convention on trafficking of human organs and the instruments on human trafficking for organ removal provide a comprehensive legal framework to prevent and fight against transplant activities that violate basic human rights.

For Priority Actions 2 (Quality Improvement Programmes), 3 (living donation) and 10 (accreditation schemes), much has been done but more endeavours are needed to effectively implement the objectives set at the EU level by the Action Plan. For instance, for Priority Action 2 (Quality Improvement Programmes), the first steps have been taken by the activities of ODEQUS towards a uniform Quality Improvement Programme. However, real implementation still requires follow-up. For Priority Action 3 (living donation), a pilot phase of the living donor register was set up by the ACCORD project. However, some obstacles still have to be dealt with for wider implementation of such a register at the EU level. At this moment, this receives further follow up within the new EDITH project, in which one of the work packages focus on further implementation of such an (inter)national registry.

For Priority Action 10 (accreditation schemes), the formulation leaves much room for different interpretations. Priority Actions that are less clearly formulated may also be implemented less easily by countries.

Participation in projects related to the Action Plan on Organ Donation and Transplantation has been increasing. Projects that started recently have a larger number of participating countries than projects that started earlier. When a larger number of countries are involved in such projects, more positive results are reported.

For the new projects that have started, it would be good that countries with less well-developed organ donation and transplantation systems and relatively 'new' EU Member States and candidate countries are more involved. Countries 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 yet they still face a wide gap between the demand for donor organs and the supply). In other countries a system for organ donation is still being set up. The practical problems these countries face are different and in many cases unique. To maintain the durability of the results of projects, it is beneficial to have a good balance between countries that have already participated in numerous projects and countries that are relatively new to it.

5 CONCLUSIONS AND KEY SUCCESS FACTORS

This chapter summarises the findings with respect to the implementation of the Action Plan, and consequently identifies and discusses key success factors.

These findings relate to the EU Member States but also include EEA countries (Iceland, Liechtenstein, Norway and Switzerland) and candidate/associated countries (the former Yugoslav Republic of Macedonia, Montenegro Serbia, and Turkey). National competent authorities from 27 countries provided input for this chapter during interviews. Input from other stakeholders was also used to elicit views on the strengths and weaknesses of the Action Plan. Topics were discussed in detail with representatives from national competent authorities and stakeholders at a dedicated workshop on 21 November 2016. The ideas brought forward during that meeting have been incorporated in this chapter.

5.1 Conclusions on the implementation of the Action Plan

Challenge 1: Increasing organ availability

In general, donation and transplant rates have been increasing in the EU over the period of the Action Plan (2009-2015), with a 21% increase of donors and a 17% increase of transplants. The increase in living donations was larger than the increase in deceased donations.

We also see an increase in use of older donors, donors after cardiac death and of extended donor criteria, which all allow for an increased availability in organs.

More and more countries are putting effort into these different practices. Knowledge can be exchanged and more can be learned from EU Member States and others that are doing well in these areas, such as Spain, Italy and Norway for extended criteria donors; Denmark and the Netherlands for living donation; Spain, Denmark, France, Italy and the UK for pancreas transplants and Spain and the UK for small bowel transplants (to name just some areas). By putting such practices more explicitly on the political agenda, the EU can help promote organ transplantation.

The underlying Priority Actions (PA 1-4) of this challenge were taken up well by the participating countries. Three of these Priority Actions (PA1, 2 and 3), and the supporting EU-funded projects, were mentioned most frequently as offering support to national policies. These 3 PAs are also those that were best defined in the Action Plan and can be followed-up most easily. For instance, in almost all countries, transplant donor coordinators have been appointed (PA 1); countries have implemented quality improvement programmes (PA 2), have directed living donation programmes (PA 3) and are working on public awareness (PA 4).

A number of countries indicated that the EU-funded activities have had significant influence on their national policy.

Challenge 2: Enhancing the efficiency and accessibility of transplantation systems

Initiatives focused on identifying the most efficient systems, sharing experience and promoting organ exchange. In particular Priority Actions 6 (organisational models) and 8 (organ exchange) have been taken up well.

Several EU-funded projects, in which many European countries participated, have played a key role factor in addressing this challenge succesfully. A number of countries indicated that the ACCORD and FOEDUS projects had been particularly helpful.

Twinning activities were mentioned as having a great impact for Priority Action 6 (organisational models). Also the countries that acted as the ´teacher´ in the twinning activities indicated to have learned from the ´student´ countries.

For instance, the UK led the ACCORD work on collaborating with intensive care units. The feedback from other countries was very helpful to them and allowed the UK to take on board various tools, strategies and manuals developed by other countries. Another example are the tools developed in the ACCORD Joint Action which have inspired changes in the (already very advanced) Spanish system for monitoring performance in deceased donation and have facilitated the application of changes to the organisation of deceased donation.

An interesting observation regarding the organisational models is the large difference between countries in number of organs transplanted per transplant centre. This can raise questions whether there is such a thing as an optimum transplant rate per centre or whether a minimum level of activity should be set. Of course, there are numerous good reasons for the variation that are not linked to efficiency (geography, size of country, number of donors and patients on the waiting list, type and severity of disease, …) as well as political factors which are to be taken into account and explored further.

An important observation is that many countries have concluded agreements to exchange surplus organs (Priority Action 8), which allows for an optimal use of all available organs. A key role here is played by European Organ Exchange Organisations like Eurotransplant, Scandiatransplant and the Southern Alliance for Transplantation (SAT). Also the development and use of an organ-exchange IT platform within the FOEDUS Joint Action, facilitating exchange of surplus organs between countries, is considered important. In addition, countries that have no specific transplant centres for certain organs have opportunities to make agreements on cross-border programmes and offer these transplants to their citizens.

Challenge 3: Improving quality and safety

Elements that deal with quality assurance aspects and preconditions for organ donation have been taken up to a lesser extent within the Action Plan. This also means that Priority Actions 9 (post-transplant results) and 10 (accreditation of transplant and procurement centres) have been addressed to a lesser extent through the Action Plan.

Nevertheless the challenge of improving quality and safety has been addressed by Member States, who had to transpose and implement Directive 2010/53/EU. Several of the provisions in this Directive directly strengthen safety and quality, like Article 4 which requires a framework for quality and safety covering all the stages from donation to transplantation.

The main EU-funded initiative was the EFRETOS Joint Action that has developed a model for a common registry on post-transplant results.

Overall implementation of the Action Plan

Overall, countries report that most aspects of the Action Plan are being taken up at a national level, especially the Priority Actions with clear objectives.

Several of the elements of the Action Plan were less clearly defined and perceived as complex regarding their exact implications. Priority Actions that were formulated less clearly and were therefore taken up less often by the countries were on the identification of organs across Europe (PA5), involvement in twinnings (PA6), EU-wide agreements (PA7), the evaluation of post-transplant results on a national basis to improve transplant practice (PA9) and regular auditing/accreditation of procurement

organisations and transplantation centres on a regular basis to assess, improve and align procedures (PA10).

Nevertheless, the Priority Actions that are addressed to a lesser extent by individual countries were often addressed by the EU-funded projects and Joint Actions in the second half of the period of the Action Plan. This seems to have helped to achieve the goals set.

Participation in projects related to the Action Plan on Organ Donation and Transplantation has been increasing over time. Projects that started recently have a larger number of participating countries than projects that started at an earlier date. It seems that the number of countries involved rather than the number of projects is what is related to positive results.

However, to maintain the durability of the results of projects, it may be beneficial to have a good balance between countries that have already participated in earlier projects and countries that are relatively 'new'. This means that the results of older projects can also be disseminated, used and maintained by the 'new'parties. Furthermore, the results of projects could be made more visible to governments. The support of government is essential to continue with the results of projects. Professional societies such as ESOT and EASL could be more involved and help increase success. The durability of the projects should be guaranteed by those involved parties.

5.2 Key success factors of the Action Plan

Firstly, the Action Plan helped countries set ***a shared agenda*** in organ donation. The Action Plan helped address problematic issues within a common perspective:

- In the countries with less well-developed systems, political backing for reorganisation and launching new policies in the field was observed. For instance, in Romania the Action Plan was very helpful in convincing the authorities about the essential role of the in-house transplant donor coordinators in order to develop an efficient transplant system. This led to an increase of almost 150% in transplants between 2008 and 2015 in this country.
- In the countries with well-developed systems, further improvements were achieved with the support of the Action Plan, and the EU-funded actions that supported the Action Plan. For instance in Spain, the experience and knowledge gained during the coordination and participation in the ACCORD Joint Action has been critical to further broaden the scope of the previously existing Spanish Quality Assurance in Deceased Donation. The tools developed during this Joint Action have inspired further changes in the national system to monitor performance in deceased donation.
- The fact that the common agenda in the EU Action Plan is backed by activities in other international organisations, such as the Council of Europe and WHO, was important for the Member States. For instance, several EU-funded projects relate to initiatives such as the Global Observatory on Donation and Transplantation by the WHO.

Secondly, the Action Plan ***facilitated EU-wide collaboration***. Such cross-border interactions were very important and allowed to create a platform to share experiences between different countries.

- For instance, best practices on living donation programmes were exchanged, and the medical staff in different countries built closer relationships and learned from each other about how to audit their activities.
- Cooperation during international projects brought useful new ideas and practices to be implemented in the participating Member States. For instance, Poland acquired experience with living kidney donation programmes and learned from other countries how to create a register.

- Twinning activities also played an important role and were perceived as very efficient. In particular, the countries that acted as 'teachers' in twinning activities indicated that they also learned from the 'learning' countries.
- Furthermore, during the course of the Action Plan new organ exchange agreements were concluded between countries. For instance, Bulgaria and Lithuania – not members of Eurotransplant – started organ exchange programmes and signed agreements with Eurotransplant.

Thirdly, the Action Plan was most effective for the actions that were ***clearly defined and imply tangible changes*** in organ donation.

- This observation provides a challenge for the future. On the one hand, this observation shows that the impact is best recognised when it is tangible. On the other hand, organ donation also needs to work on less tangible issues, such as continuous education and evaluation, or the development of quality systems and registers to follow up survival rates. Apparently, there would be a need for other instruments for effectively addressing these less tangible issues. Possibly, some tools supporting education in general, like the ERASMUS+ programme, could be explored here. A clear definition of the roles of the various parties involved in implementing a Priority Action could be considered, such as professionals or actors at the administrative level.

- However it also needs to be noted that, during the last years of the Action Plan, the EU-funded Joint Actions delivered tangible outputs for the participating countries, like the Joint Actions ACCORD (setting up living donor registers) and FOEDUS (offering an IT portal for the exchange of organs between countries).

6 RECOMMENDATIONS AND THE FUTURE

Many EU Member States[156] expressed the view that the Action Plan helped to improve their policies on organ donation. Based on this positive evaluation, many countries consider there is a need for a new, improved Action Plan, benefitting from lessons learned from the Action Plan in 2009-2015.

Key considerations for a new Action Plan are:

1. Invest more in defining clear objectives of the new Action Plan by using a bottom-up approach. Ensure that the representatives of different levels are involved: professional, administrative, political and the public. There should be fewer objectives but aiming for a stronger impact.
2. Build further upon the power of mutual learning and knowledge exchange. Individual countries that face similar issues can be given support jointly. The Competent Authority meetings could also be organised on this basis, and other relevant stakeholders could be invited more regularly to contribute.
3. Seek opportunities to share with and learn from adjacent areas of expertise, like tissues and cells, to increase the participatory and absorptive capacity of each country.
4. Support countries with less developed donation systems to bring their topics forward, and have a more explicit role in the agenda.
5. Reflect more on implementation and sustainability, including the maintenance of IT components in projects, for more of a long-term impact, by commitment of involved parties (government, professional organisations, etc.).

6.1 Recommendations

Many countries agree that future European cooperation is very important to further increase organ transplantation, and that EU activities should be continued. Overall, the Action Plan has proved its worth and there is a need for a new, improved Action Plan. Some recommendations for the future of organ donation and transplantation and EU cooperation in this field are outlined below.

6.1.1 Define objectives jointly at the professional, political, administrative and public levels

Any future Action Plan needs to involve four levels: (1) professional/technical, (2) administrative, (3) political and (4) general public.

As it is important to ensure that the Priority Actions are comprehensive and have clear objectives. The Priority Actions should be defined by Member States and professionals jointly. Such a bottom-up approach will create opportunities for bringing up additional ideas and allow for successful implementation.

The benefits of these actions should be presented and endorsed at the political level. It would also be good to reflect upon how the Commission could help facilitate such discussions at the political level. In areas such as communication, the input of patients' associations can also be highly valuable. Lastly, the public should be informed, encouraged and convinced of the value of these joint, EU policies that are implemented in the various countries.

Objectives of future activities should be clearly defined and have a timeline. This can

[156] Representatives of National Competent authorities for Organs.

only be done when all the levels are involved. It will allow for commitment and ensure eventual uptake and implementation of the outcomes.

6.1.2 Mutual learning and exchange of know-how between countries

Cooperation between countries proved to be a rich source of inspiration and progress. Twinning projects could be taken up again; this worked very well according to both the learning and the teaching countries. Twinning projects could also be transformed into official cooperation between governments of countries. Twinning projects could also become bigger, hence becoming new networks. For instance eight South-Eastern countries near the Black Sea, many with a similar context, are now 'twinning' amongst themselves. In addition, cooperation allows small countries to get help from national experts from other countries.
The role of having regular Competent Authority meetings organised by the Commission can also be a source of deepening trust amongst Member States as it allows for exchange of expertise and experiences.

It is important to involve the political, administrative and technical levels into such cross-border collaborations.

6.1.3 Building expertise about and with related areas of expertise

It might be useful to strengthen exchange of knowledge and practices with the related sector of tissues and cells. There is good experience in the tissue and cells sector that can be leveraged, for example to help quality management tools in testing protocols or identifying and addressing communicable diseases of common interest. Conversely, the tissue and cells sector can learn a lot about donor protection from the organs field. Vigilance is another activity that is well developed in the tissue and cells sector, from which the organs sector can learn a lot.

Such cross-sectoral learning has already been seen in the latest Joint Actions, covering tissues/cells and blood. This allows for efficiency, as these fields are often taken care of by the same experts within a country and many of the issues concerned are aligned.
Creating common initiatives in organ and tissues and cells sectors might increase expertise. It was noted that the blood sector is, in comparison, more distant from the organs sector.

6.1.4 Focus on countries with less well-developed systems

European countries differ, not only in size and the availability of resources but also in culture and religion: they are too different to expect complete harmonisation. Therefore, results of projects cannot always be projected equally on every country.
New activities could be more focused on countries with less well-developed systems of organ donation. It is important to pay attention to the different stages countries are at with regard to organ donation and transplantation, and how to address this in a way that is valuable.
One frequently mentioned theme is the need for more standardisation in Europe. However, this should not be a goal in itself. Another point to take into account is that in some smaller countries, with few patients eligible for donation or transplantation, and with a small community of doctors and patients, activities like registering and monitoring are sometimes seen as a relatively large amount of bureaucracy for few patients.
Tailor-made approaches should therefore be considered. Countries that experience similar problems could share their issues in joint groups, to find out how to deal with these common problems. The Commission could provide support to such groups of countries, e.g. by organising dedicated expert (sub-) meetings and transition programmes.

Another priority for any future Action Plan could be to provide a platform for the further development of donor programmes in all European countries, and especially to support the countries with less well-developed donation systems.

6.1.5 Optimise planning, dissemination and sustainability of outcomes

Another recommendation for the future is that more efforts could be made to improve effective dissemination of results and focus more on sharing results of different EU-funded Actions in Europe. It seems, for instance, that the results of older projects such as DOPKI are no longer well-known among newer attendees of the Competent Authority meetings.

The coherence and coordination between different actions and projects should also be verified to avoid duplication or gaps.

Furthermore, more attention could be paid to the sustainability of the results of projects. Professional societies such as ESOT and EASL and governments can play a role here. This is another reason for including them in the projects and ensures their support. Professionals can bring data, help define outcomes and assist dissemination and implementation. Furthermore, to maintain the sustainability of the results of projects, it may be beneficial to have a good balance between countries that have already participated in numerous projects and countries that are relatively 'new'.

Sustainability of IT-outputs from (EU-funded) Actions and projects has to be reflected up from the beginning. Many Actions and projects develop websites, information platforms, databases that remain useful after the end-date of the Action or project, and therefore require some further maintenance. Consolidation of all these organ-related IT-outputs within a common platform could be explored as a possible cost-effective solution.

Impact of research and innovative projects, depends greatly on the degree to which productive interactions are created between the various stakeholders. Results from this analysis show that the more countries are involved in a project, the more impact they perceive and support they get. Participation and interaction are therefore just as essential elements in EU-supported actions as innovation and research are.

Lastly, the results of projects could be made more visible to governments, preferably using interactive strategies. This may contribute to their commitment and support implementation of the results of projects.

6.1.6 Specific elements of the Action Plan that merit continuation

A lot of work has been done in cross-border exchange. There are still many opportunities here to strengthen exchanging surplus organs between countries. This will require additional efforts at the EU level as well as the country level. The work done by the Joint Action FOEDUS should be continued and expanded in the future. It could focus on the cross-border exchange of organs that are not procured in all countries, such as the pancreas and thoracic organs.

In undirected living donation, there are opportunities for countries to increase the number of donor organs. Hence also the importance of past and ongoing work on living donor registries. However, this is of course dependent on legal, ethical, cultural and religious considerations.

6.1.7 Further areas to explore with countries

Countries' national priorities often focus on quality and safety issues, such as developing accreditation and audit systems, inspection, training for inspections, and

the collection of more data on quality performance.
All these improvements will increase the possibilities for exchanging organs between neighbouring countries. The exchange of surplus organs and agreements between countries about urgent requests could still be improved

Furthermore, the development and application of new technologies is a priority for many countries. This covers for instance Donation after Circulatory Death (DCD) and the identification of possible donors outside intensive care units, particularly at accident and emergency departments, as well as in general hospital wards. Much of this can be developed in one/a few countries and then shared at EU level.

Many countries mentioned to agree that quality indicators should be developed at the EU level. Several countries have pointed out that they consider the development of common quality standards to be an important step for the future. Agreement on quality standards will facilitate exchange and mutual learning between the experts of the Member States. This may help when disseminating results of all the EU-funded projects. Furthermore, it seems that there is a demand for a common and agreed auditing methodology.

6.2 New aspects for future consideration

A new Action Plan might contain new elements.

The following overview may serve as a list of potential topics, to be discussed between parties and professionals – both administrative and political – in the preparation of a new Action Plan[157].

- **Donation after Circulatory Death (DCD)**: The potential for an EU expansion in DCD is a key area that should be further explored as it has the potential to significantly increase the availability of donor organs. It should therefore be a priority focus, although it is clear that not all countries are ready (yet) to move into DCD, as this may require changes in skills, organisation and legal/ethical frameworks. Furthermore, as national provisions on the donation or medical use of organs fall within the national competence, it is clear that the role of the European Union is limited to support.

- **Living donation**: the further uptake of living donor follow-up, and with that of living donor registries, as far as possible in a common/comparable way, is crucial to ensure public trust in this sensitive (ethical) transplant practice. Suggestions have also been made regarding the creation of a European network for paired kidney donation, however this requires thorough preparation including reflections on a.o. organisational, ethical and economic elements.

- **Communication**: various aspects of communication have been mentioned as areas with potential to further increase organ transplantation. These include as communication with and through the families of patients, education in schools, generating overall public awareness, and the use social media.

- **Education of professionals**: all professionals in the entire donation and transplantation chain could benefit from further education on various aspects of organ donation and transplantation. Doing this jointly, would impact on other aspects that were brought up: standardisation of training programmes, and collaboration between countries and sharing of best experiences.

[157] In the discussions with country representatives and professionals, new subjects were discussed that might be included in a new Action Plan.

- **The exchange of experiences on minorities and new groups**: Europe has many minority groups and also Europe has a relevant influx of people from other countries. Providing appropriate care for these groups, in the roles of both recipient and donor, requires extra effort. Countries and professionals could benefit from sharing their (first) experiences in this field.

- **Quality and Clinical Outcomes**: Given the limited availability of organs, it is of key importance to know that the available organs are optimal. This requires follow-up by improving registers with a focus on survival after transplantation, patient selection for transplantation, donor/recipient matching. In this respect, the (joint) collection and provision of data by professionals and national administrations is essential.

- The further development of common guidelines and standardization of evaluating, auditing and benchmarking **hospital performance** help to improve overall efficiency.

- The further development of **bio-vigilance** will help to address specific aspects of quality and safety. Furthermore, although increasing the donor pool with expanded criteria donors is a promising development in order to increase the number of donors, extra attention is required when using such organs, and the related (future) procedures.For instance, the use of extended donors could be increased once novel techniques like machine preservation are implemented more widely.

- **End–of-life care**: Understanding and overcoming the obstacles that critical care professionals face to incorporate donation in end-of-life care plans are considered critical. Suggestions were made to broaden the identification of donors outside the ICU. Further ideas relate to the integration of organ donation into the medical care provided at the end of life, to hospital notification systems/methods, to cultural changes among professionals and awareness of who is a potential donor (beyond the transplant community). Obviously, full respect is to be given to the primary objective of the critical care professionals, which remains the restoration of full health of the patient.

- **Efficiency**: this study suggests that there are differences between countries in the efficiency of the organisation of organ transplantation: we found large differences between countries in the number of transplants per transplant centre. These differences may partly be explained by geographical needs, but it seems that such an explanation is not complete. Exchanging knowledge on optimising the donation chain may help spend the limited funds on the solutions that provide the best results in terms of quality, safety and numbers. In this regard, forces could also be combined to encourage the joint development of transplant programmes for of 'less common' transplantations such as the small bowel.

- **Finances, differences between countries**: demonstrating the cost-efficiency of transplantation programmes, which are usually very positive (in particular kidney transplants allow for significant savings compared to alternative dialyses therapies), is seen as valuable. This can strengthen the national call for funding and investment in transplant systems. In this context, it is important to understand national funding mechanism, including health expenditure, health insurance schemes and hospital reimbursement. An EU cost-benefit study into kidney transplants is ongoing within the EDITH pilot project. Results should be presented to the political level and to the general public. This was one of the five topics especially mentioned in a workshop of representatives from countries and professionals.

- **Research**: Opportunities were identified relating to the evaluation and improvement of post-transplant outcomes, donor optimisation, immunogenicity (link to HSC transplants), organ rehabilitation and organ preservation/ perfusion, new products and combined cell therapies.

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Turkey: http://www.europeantransplantcoordinators.org/NKMData/pdf/turkey.pdf

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

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

European Commission Policy (Directorate General for Health & Consumers)

European Commission (2008). White Paper "Together for Health: a Strategic Approach

for the EU 2008-2013" COM (2007) 630 final.

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

http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm

http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm#fragment1

http://ec.europa.eu/health-eu/newsletter/80/newsletter_en.htm

http://ec.europa.eu/health-eu/europe_for_patients/organ_donation_transplantation/index_en.htm

http://ec.europa.eu/health-eu/newsletter/89/newsletter_en.htm

http://ec.europa.eu/health/programme/events/ev_20120503_presentations_en.htm

http://ec.europa.eu/health-eu/journalist_prize/

http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&language=en&pcode=tps00001&tableSelection-=1&footnotes=yes&labeling=labels&plugin=1,

http://ec.europa.eu/health/programme/docs/success_stories_hp_2008-2013_en.pdf

http://ec.europa.eu/health/blood_tissues_organs/docs/organs_council_ccl_2012_en.pdf

http://ec.europa.eu/health-eu/europe_for_patients/organ_donation_transplantation/index_en.htm

http://ec.europa.eu/chafea/projects/database.html

http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=50267,

http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20150929_ag_en.pdf

http://ec.europa.eu/health/blood_tissues_organs/docs/infographic_obtc_en.pdf

http://ec.europa.eu/health/blood_tissues_organs/docs/midtermreview_actionplan_organ_en.pdf

http://ec.europa.eu/health/blood_tissues_organs/docs/organs_actor_study_2013_en.pdf

http://ec.europa.eu/health/blood_tissues_organs/docs/organs_council_ccl_2012_en.pdf

http://ec.europa.eu/health/blood_tissues_organs/policy_en

Annual Work Plans for the EU Health Programme & related Commission decisions

http://ec.europa.eu/eahc/news/news188.html

http://eur-lex.europa.eu/JOHtml.do?uri=OJ%3AL%3A2007%3A301%3ASOM%3AEN%3AHTML

http://ec.europa.eu/health/index_en.htm

http://ec.europa.eu/health/programme/docs/wp2012_en.pdf

http://ec.europa.eu/health/programme/docs/wp2011_en.pdf

http://ec.europa.eu/health/programme/docs/wp2013_en.pdf

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF

http://ec.europa.eu/health/programme/key_documents/index_en.htm#anchor3_more

http://eur-lex.europa.eu/LexUriServ/
LexUriServ.do?uri=OJ:L:2009:340:0001:0046:EN:PDF

http://eur-lex.europa.eu/LexUriServ/
LexUriServ.do?uri=OJ:L:2009:053:0041:0073:EN:PDF

http://eur-lex.europa.eu/LexUriServ/
LexUriServ.do?uri=OJ:L:2008:056:0036:0062:EN:PDF

http://eur-lex.europa.eu/LexUriServ/
LexUriServ.do?uri=OJ:L:2008:056:0036:0062:EN:PDF

http://eur-lex.europa.eu/budget/data/General/2015/en/SEC03.pdf (pages 866 to 869)

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:sp0007

http://eur-lex.europa.eu/LexUriServ
LexUriServ.do?uri=OJ:L:2011:101:0001:0011: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[158]:

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

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

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

[158] The original number "2010/45/EU" was wrongly attributed and consequently corrected; "2010/53/EU" is the right number.

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_publisha ble_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

EUDONORGAN: http://eudonorgan.eu/

EDITH: http://edith-project.eu/

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

ETPOD: http://www.etpod-dissemination.eu

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

http://www.foedus-ja.eu/about-foedus

HEPAMAB:
http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ_RCN=13463381

Hott-Project: hottproject.com

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

http://www.coe.int/t/dghl/standardsetting/cdpc/pc_to_en.asp

http://www.edqm.eu/en/organ-transplantation-projects-1452.html

https://www.edqm.eu/en/news/transfusion-and-transplantation

https://www.edqm.eu/en/organ-transplantation-recommendations-resolutions-74.html

https://www.edqm.eu/sites/default/files/newsletter_transplant_volume_21_september_2016.pdf

https://www.edqm.eu/sites/default/files/resolution_on_establishing_harmonised_national_living_donor_registries_with_a_view_to_facilitating_international_data_sharing_2015_11.pdf

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/

http://www.eurotransplant.org/cms/index.php?page=about_brief

https://www.eurotransplant.org/cms/mediaobject.php?file=Factsheet+January+2016.pdf

ESOT:

http://www.esot.org/Content.aspx?item=12

http://www.esot.org/EDTCO/home

http://esot2015.esot.org/edtco-organ-donation-meeting

SAT:

http://trapianti.net/en/sat-south-transplant-alliance/

Scandiatransplant:

http://www.scandiatransplant.org/members/ntcg/minutes_NTCG_may_2016.pdf

WHO:

http://www.who.int/transplantation/tra_song/en/index.html

http://www.who.int/ethics/topics/human_transplant/en/

http://www.who.int/mediacentre/multimedia/podcasts/2010/organ_transplants_2010

0806/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/

http://www.eltr.org/

http://www.eurocet.org/

ANNEX 1: COUNTRY SHEETS

N.B.: A plus sign means a positive endeavour on the specific priority or sub-action, a bullet point means endeavours still have to be made. Numbers are based on the Transplant Newsletter as published by the OECD. However, numbers may not always match as some competent authorities have corrected their numbers.

Other data is based on questionnaires and interviews with the competent authorities representing the countries. The data is therefore the interpretation of the competent authorities of the specific countries.

Country codes used in the figures			
AT	Austria	IT	Italy
BE	Belgium	LI	Liechtenstein
BG	Bulgaria	LT	Lithuania
CH	Switzerland	LU	Luxembourg
CY	Cyprus	LV	Latvia
CZ	Czech Republic	MK	Macedonia
DE	Germany	MT	Malta
DK	Denmark	ME	Montenegro
ES	Spain	NL	Netherlands
EE	Estonia	NO	Norway
FI	Finland	PL	Poland
FR	France	PT	Portugal
UK	United Kingdom	RO	Romania
EL	Greece	SK	Slovakia
HR	Croatia	SI	Slovenia
HU	Hungary	TR	Turkey
IE	Ireland	SE	Sweden
IS	Iceland	RS	Serbia

1. Austria

Background information[159]

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

With a **deceased donation rate** per million of the population of above 20 in 2015, Austria's deceased donation rate PMP is amongst the highest of the countries in this study. However, it has been observed that there are extreme differences in the emergence of deceased donors between the regions / Federal States. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases. Austria has a relatively high number of lung transplants, with more than 100 lung transplants a year.
With a living kidney donation rate per million of the population of less than 10 in 2015, Austria's **living kidney donation** rate PMP is among the lowest of the countries included in this study. Living donor transplant procedures were carried out in 2015 involving kidneys and livers. Austria is part of Eurotransplant[160] and donor organs are allocated through Eurotransplant (IT system).

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

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

Financing of organ donation

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

[159] Sources for Austria, in addition to common sources: FACTOR 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), Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers No. 4. Leuven, Transplant Jahresberichte 2008 und 2010 (Annual reports 2008 and 2010 of the Austrian Coordination office).

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

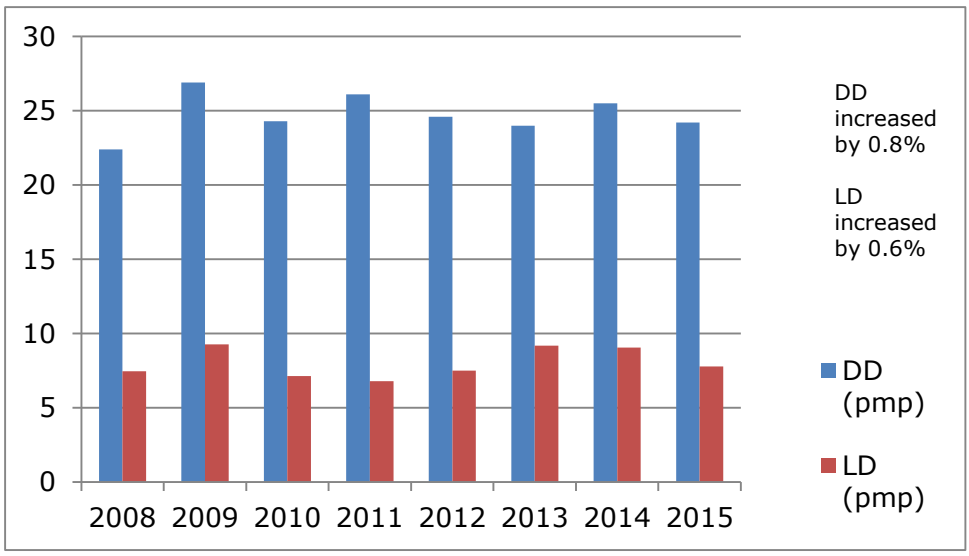
Key figures[161]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	8.3	8.3	8.4	8.4	8.4	8.5	8.5	8.6
Family refusal rate (refusals/times asked)	53/158	-	-	-		56/244	70/276	63/242
Actual deceased donation rate (total/per million population, pmp)	186/ 22.4	224/ 26.9	203/ 24.3	219/ 26.1	207/ 24.6	203/ 24.0	217/ 25.5	208/ 24.2
Multi-organ donation rates (% of total)	76.6	78.9	78.0	71.3	73.2	75.9	81.2	77.9
Number of utilised donors (total/pmp)	167/ 20.1	209/ 25.1	191/ 22.9	195/ 23.3	190/ 22.6	187/ 22.1	207/ 24.3	195/ 22.7
Number of donors after circulatory death - DCD	3	1	0	6	4	3	6	6
Number of donors older than 60	39	66	56	70	64	68	64	54
Number of transplant centres								
Kidney	5	5	5	5	5	5	4	4
Liver	3	3	3	3	3	3	3	3
Heart	3	3	3	3	3	3	3	3
Lung	2	2	2	2	2	2	2	2
Pancreas	3	3	3	3	3	3	3	3
Bowel	1	1	0	0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	303/ 36.5	363/ 43.6	349/ 41.8	360/ 43.0	360/ 42.8	347/ 41.1	375/ 44.1	356/ 41.5
Liver	112/ 13.5	146/ 17.5	138/ 16.5	126/ 15	125/ 14.9	130/ 15.4	136/ 16	141/ 16.6
Heart	62/7.5	73 /8.8	69/8.3	51/6.1	62/7.4	64/7.6	68/8	67/7.8
Lung	119/ 14.3	110/ 13.2	114/ 13.7	120/ 14.3	126/ 15.0	128/ 15.1	134/ 15.8	129/ 15.0
Pancreas	34/4.1	33/4.0	31/3.7	16/1.9	14/1.7	19/2.3	21/2.5	27/3.1
Bowel	1/0.1	1/0.1	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	58/7.0	69/8.3	58/6.9	55/6.6	63/7.5	74/8.8	71/8.3	62/7.2
Liver	4/0.5	7/0.8	2/0.2	2/0.2	0/0	2/0.2	6/0.7	5/0.6
Lung	0/0	1/0.1	0/0	0/0	0/0	2/0,2	0/0	0/0

- = not known to the research team

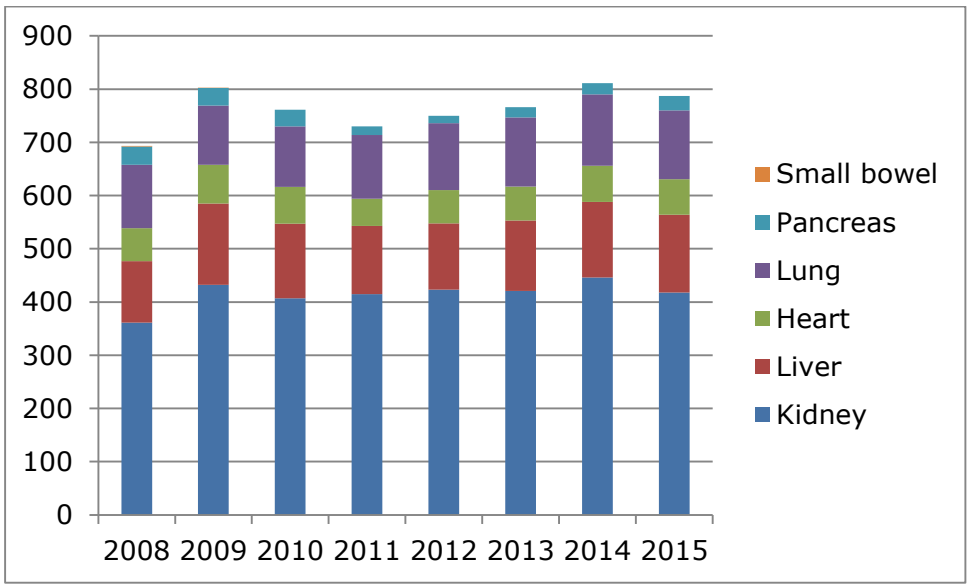
[161] Numbers are based on Statistics of Eurotransplant and the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Austria*



* Deceased Donation rates are based on the numbers published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rates for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 25 at the local/hospital level and 5 at the regional level.
	●	Transplant donor coordinators have not yet received training.
	●	Austria does not use an accreditation scheme.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	The EU-supported activities have not helped promote the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has encouraged initiatives for improving the quality of the donation process, the transplantation process, the procurement process and the follow-up care.
	●	The EU Action Plan has not influenced the national policy on Quality Improvement Programmes through national audits.
	●	EU-supported activities have not helped promote Quality Improvement Programmes.
Priority Action 3: Exchange best practices on living donation	+	Austria has directed[162] living donation programmes.
	●	There are no undirected living donation programmes.
	+	4 hospitals have a living donation programme.
	●	There is no independent body for evaluating living donors before the start of the procedure.
	●	There are no registers for evaluating and guaranteeing the health and safety of living donors yet.
	+	Organ trafficking is prohibited by law.
	●	National policy on living donation programmes is not influenced by the EU Action Plan through the living donor register.
	●	Not known whether EU-supported activities helped promote living donation programmes.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public.
	+	Austria has programmes for improving the knowledge and communication skills of personnel who deal with organ transplants.
	●	Periodic meetings with journalists have not yet been organised.
	●	No guidelines and deliverables developed by EU-supported activities are used for informing the public and improving the knowledge and skills of health professionals.
	●	The national policy on public awareness of organ

[162] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		donation is not influenced by the EU Action Plan; there were actions at the time of the European Donor Day.
	●	It is not known whether the EU-supported activity EDD helped to promote public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Austria does not provide easily accessible information to the general public about their legal position as a possible donor in other countries across the EU.
	+	90% of transplant patients are local residents, 10% are non-residents.
	●	EU-supported activities did not contribute to the identification of cross-border donors.
	●	EU-supported activities (such as in the COORENOR and FOEDUS projects) did not contribute to the identification of cross-border donors in Austria.
Priority Action 6: Enhance organisational models	●	Austria is not involved in twinning projects.
	●	The EU Action Plan did not influence the organisational model of the country's donation and transplantation system.
	●	It is not known if EU-supported activities (such as COORENOR, MODE and ACCORD) helped to enhance the organisational model of the donation and transplantation system in Austria.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Austria has agreements with other countries for exchanging organs, supporting the development of new transplantation programmes, and collecting data (ELTR, ERA-EDTA registries…).
	●	Austria has no agreements with other countries to prevent and address organ trafficking.
	●	It is not known whether EU-supported activities contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Austria is part of a fixed collaboration: a multilateral collaboration and bilateral collaboration with Southern Tyrol (Italy) and Hungary. All patient groups and all organ types are involved.
	+	In 2015, 304 organs came from abroad and 225 organs left the country.
	●	Austria does not yet evaluate procedures for offering non allocated organs to other countries.
	+	Austria has procedures in place for exchanging organs for urgent and difficult-to-treat patients.
	●	Austria does not participate in the use of an IT tool for facilitating cross-border exchange.
	●	EU activities did not contribute to the interchange of organs between countries.
	●	It is not known if EU activities such as EFRETOS, COORENOR, FOEDUS and ACCORD contribute to the interchange of organs between countries.
Priority Action 9: Evaluate post-transplant results	+	Post-transplant results of organ recipients are evaluated systematically.
	+	Donor organs are accepted from donors with diabetes mellitus, donors with hypertension, donors with renal insufficiency, donors with infectious diseases such as hepatitis, donors with HIV and donors aged over 60.
	●	EU-supported activities did not help in the

		evaluation of post-transplant results.
	●	It is not known if EU-supported activities (such as EFRETOS) contributed in Austria to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are checked or audited on a regular basis.
	●	Austria does not yet promote an accreditation system for procurement organisations and transplantation centres.
	●	EU-supported activities did not contribute to the promotion of accreditation systems.
	●	It is not known if EU-supported activities (such as ACCORD, ETPOD, the European Training Course in Transplant Donor Coordination, ODEQUS and EFRETOS) help promote accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects, Austria was initially the work package leader in EDD[163], but withdrew from this position and was replaced by Croatia. Austria was also initially the 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.

The country participated in 2011 in the working group on indicators[164]. In addition, it is a member of the Council of Europe "Committee (Partial Agreement) on Organ Transplantation" (CD-P-TO[165]).

Contribution of the Action Plan and future
No additional information available.

Conclusions
Both Austria's deceased and living donation rates increased slightly over the years, which is a positive sign. However, there are still opportunities for Austria in living donation and small bowel transplants. Activities have been started in Austria for each of the Priority Actions. A next step could be focusing more on issues regarding education, implementation and quality assurance in these fields.

[163] For more information about EU-funded projects, see chapter 3.
[164] For more information about the working groups, see chapter 3.
[165] For more information about CD-P-TO, see Annex 3.

2. Belgium

Background information[166]

With a deceased donation rate PMP of above 20 in 2015, Belgium's deceased donation rate per million population is amongst the highest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels. With a living kidney donation rate PMP between 5 and 10 in 2015, Belgium's living kidney donation rate is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out regarding kidney and liver. Belgium has a relatively high number of lung transplants with more than 100 lung transplantations a year. Belgium also has a relatively high number of liver transplants. Belgium is part of Eurotransplant[167] and donor organs are allocated through Eurotransplant.
Regarding EU-funded projects, Belgium was core work package leader in the EU funded project EULOD[168], collaborating partner in ACCORD, and is associated partner in FOEDUS.

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

Since 1986, an **opt-out system** is in place, in which Belgian citizens or residents in Belgium since 6 months are donors except when the person himself/herself has given objection. Belgian citizens or residents in Belgium since 6 months can go to the townhouse for registration in the national donor register (for 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.

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.

[166] Sources: FACTOR 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.

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

[168] For more information about EU-funded projects, see chapter 3.

Key figures[169]

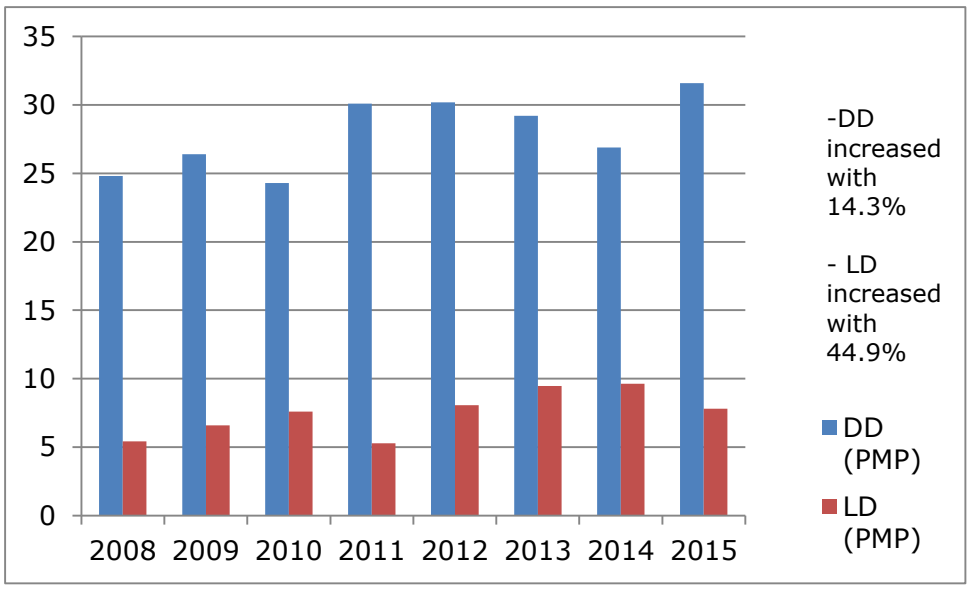
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	10.7	10.8	10.8	11	10.8	11.1	11.1	11.3
Family refusal rate (refusals/times asked)	-	-	-	-	-	76/641	49/396	87/676
Actual deceased donation rate (total/per million population, pmp)	265/ 24.8	285/ 26.4	263/ 24.3	331 / 30.1	326/ 30.2	324/ 29.2	299/ 26.9	357/ 31.6
Multi-organ donation rates (% of total)	73.6	78.6	74.9	77.3	77.3	-	76.9	79.7
Number of utilised donors (total/pmp)[170]	-		-	-				
Number of donors after circulatory death - DCD	48	61	45	64	71	78	83	105
Number of donors older than 60	38		50	-	-	-	92	94
Number of transplant centres								
Kidney	-	-	-	-	8	7	7	7
Liver	-	-	-	-	6	6	6	6
Heart	-	-	-	-	7	7	7	8
Lung	-	-	-	-	4	5	5	5
Pancreas	-	-	-	-	7	6	6	6
Bowel	-	-	-	-	-	6	6	6
Number of deceased donor transplant procedures (total/pmp)								
Kidney	448/ 41.9	428 /39.6	408/ 37.8	474/ 43.1	480/ 44.4	437/ 39.4	414/ 37.3	471/ 41.7
Liver	217/ 20.3	222/ 20.6	228/ 21.1	264/ 24	252/ 23.3	250/ 22.5	221/ 19.9	248/ 21.9
Heart	75/7.0	68 /6.3	67/6.2	76/6.9	70/7.1	75/6.8	82/7.4	78/6.9
Lung	149/ 13.9	90 / 8.3	197/ 18.2	111/ 10.1	129/ 11.9	101/ 9.1	103/ 9.3	129/ 11.4
Pancreas	51/4.8	25/2.3	40/3.7	14/1.3	13/1.2	8/1	11/1	12/1.1
Bowel	-	-	-	-	-	0	4/0.4	0
Number of living donor transplant procedures (total/pmp)								
Kidney	45/4.2	49/4.5	49/4.5	40/3.6	57/5.3	63/5.7	67/6	57/5
Liver	13/1.2	23/2.1	33/3.1	35/3.2	30/2.8	42/3.8	40/3.6	32/2.8

- = not known to the research team

[169] Numbers are based on Statistics of Eurotransplant and the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

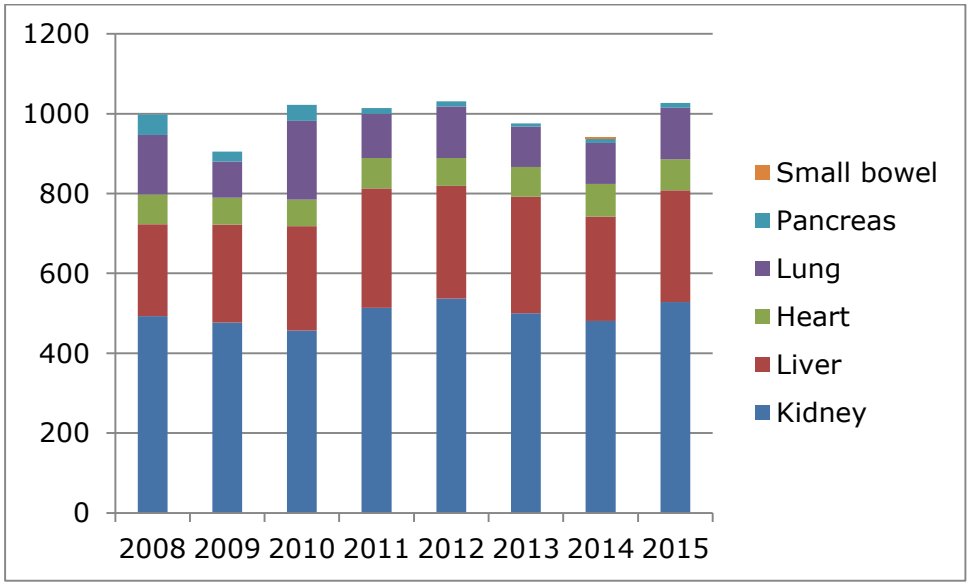
[170] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Belgium*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 90 at the local/hospital level and 8 at the regional level.
	+	Transplant donor coordinators have been appointed: 90 at the local/hospital level and 8 at the regional level.
	+	Summary of the training: • Base Training: – ICU staff worker Personnel – Experience of 3(5) years intensive care (at least 4/5 time equivalent) • Complementary Training:
	+	Knowledge of the Belgian Law, the legal aspects and ethical principles concerning Organ Donation and Transplantation.
	+	The knowledge of the mandatory informatics tool for data register.
	+	The knowledge of the system of invoices concerning the Belgian Illness and Disability Insurance.
	+	The knowledge of the methods of early detection of brain death or cardiac death.
	+	To act the haemodynamic surveillance of the potential donor.
	+	The communication with the intervening teams: laboratories, transplant coordinators ,teams from abroad.
	+	The centralization of all the data concerning retrieval of organs and tissues and have them actualized.
	●	The trainings have not been tested for effectiveness.
	●	Belgium does not use an accreditation scheme, but each donor coordinator receives a training every year of the ministry of health. Each Transplant centre must organize a symposium for the collaborating donor hospitals. Transplant coordinators have an international training, such as TPM or ESOT course.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators, because Belgium did that already.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes through National audits.
	●	EU supported activities have not contributed to the

		promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Belgium has directed[171] living donation programmes. Belgium does not require a certain relationship for LOD, but has established procedural safeguards. The living donor must have the capacity to give consent. Consent in writing. The Belgian law stipulates a subsidiarity for certain defined cases only: if the removal of an organ may have serious consequences for the donor or if it relates to a non-regenerative organ, LOD can only be conducted if the recipient's life is at risk and the deceased organ donation does not produce an equally satisfactory result. This is held to be justified by the risks LOD imposes on the donor and by the need for protection of living donors against external pressure, such as money offers to sell their organs. Mostly, de donor is emotional related. Since the last 2 years, we started also a cross-over program between the Belgian centres.
	+	There also are undirected living donation programmes with no restrictions regarding the donor-recipient relationship.
	+	7 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, and Belgium has ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan through the living donor register.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Belgium deploys programs to improve knowledge and communication skills of all health care (hospital) personnel and patient associations.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is not influenced by the EU Action Plan, there were actions at the time of the European Donor Day.

[171] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	The EU supported activity EDD contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Belgium does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Belgium: residents with a foreign nationality who die in Belgium, and non-residents who die in Belgium.
	+	Criteria required to be admitted to the waiting list: residency in Belgium, local nationality. Everyone who is 6 months domiciliated in Belgium can be a donor or can come on the waiting list.
	●	National policy on cross-border donation is not influenced by the EU Action Plan. We are working with EUROTRANSPLANT.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Belgium is not involved in twinning projects.
	●	It is not known whether transplantation centres or hospitals participate in any networks.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Belgium has agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, training/certifying health care professionals (surgeons, coordinators), collecting data, research activities, and other aspects of transplant medicine. Working together with Eurotransplant. Supporting programs with other countries like split liver transplantation, robot-transplantation, DCD. Welcome other specialists of countries who are starting with specific programs.
	+	Belgium has agreements with other countries to prevent and address organ trafficking: the main challenges are: Organ transplantation for children, helping starting with programs.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Belgium is part of a fixed collaboration: a multilateral collaboration, namely Eurotransplant.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel. Further information on cross-border transplantation can be found with Eurotransplant.
	+	Belgium has procedures for the exchange of organs of urgent and difficult-to-treat patients.

	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	Belgium participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, HIV, and from donors older than 60 years.
	+	National policy on the evaluation of post-transplant results is influenced by the EU Action Plan.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	+	Belgium promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation systems used are for donation (coordinators) and for procurement (surgeons).
	+	The EU Action Plan has influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

In 2010 and 2011 the country participated in the working group on indicators[172]. 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[173]).

Conclusion

Both Belgium's deceased and living donation rates increased since 2008, which is positive. There are still opportunities for Belgium to increase their living donation rate and chances are lying within the field of small bowel transplantation.

The Belgian CA stated the importance for Belgium of the European guideline that introduces transplant donor coordinators in every hospital. European protocols are important tools to help each hospital with reporting and registration of donor and transplant activities.

[172] For more information about the working groups, see chapter 3.
[173] For more information about CD-P-TO, see Annex 3.

Also, in Belgium it is important to continue with the current policy. The results are good, but they have to be maintained. Budgets are under pressure. The government must be convinced that the present funding is needed for continuing the registration, training of medical personnel, etc.

Finally, at the European level the 'allocation' programs like Eurotransplant are important, better cooperation is needed according to Belgium. People often do not think about organ donation when they are dealing with very ill children. More international exchange of knowledge and of information about potential donors and receivers is needed.

3. Bulgaria

Background information[174]

With a deceased donation rate PMP between 5 and 10 in 2015, Bulgaria's deceased donation rate PMP is amongst the lowest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, and hearts. With a living kidney donation rate PMP of less than 5 in 2015, Bulgaria's living kidney donation rate PMP is among the lowest of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver. Donor organs are allocated at national level.

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

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.

[174] Sources: FACTOR 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.

Key figures[175]

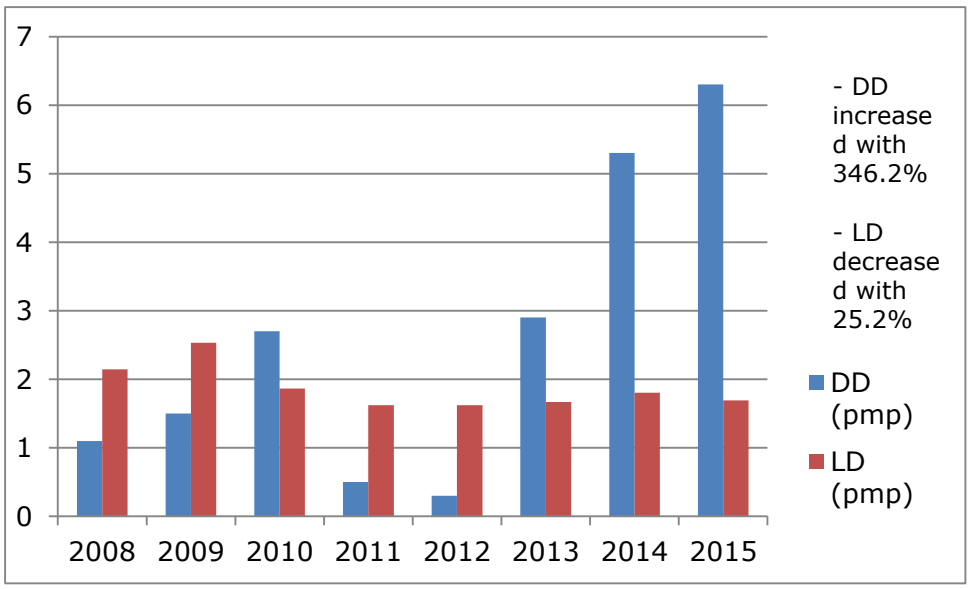
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	7.0	7.5	7.5	7.4	7.4	7.2	7.2	7.1
Family refusal rate (refusals/times asked)	8/10	-	4/24	3/10	0/9	5/21	6/38	17/36
Actual deceased donation rate (total/per million population, pmp)	8/1.1	11/1.5	20/2.7	4/0.5	2/0.3	21/2.9	38/5.3	45/6.3
Multi-organ donation rates (% of total)	70	100	80	50	-	100	57.9	-
Number of utilised donors (total/per million population)[176]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	-	0	-	0	0	-	-	-
Number of donors older than 60	0		0	-	-	-	2	
Number of transplant centres								
Kidney	-	4	4	4	4	4		3
Liver	-	2	2	2	4	3	3	3
Heart	-	2	2	2	2	2	2	2
Lung	-	0	1	0	-	-	-	0
Pancreas	-	0	0	0	0	-	-	0
Bowel	-	0	0	0	0	-	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	6/0.9	17/2.3	36/4.8	8 / 1.1	4/0.5	17/2.4	44/6.1	38/5.4
Liver	5/0.7	9/1.2	13/1.7	3/0.4	2/0.3	7/1.0	18/2.5	15/2.1
Heart	3/0.4	5/0.7	5/0.7	2/0.3	2/0.3	4/0.6	4/0.6	7/1
Lung	0	0	0	0	-	-	0	0/0
Pancreas	0	0	0	0	0	0	-	0/0
Bowel	0	0	0	0	0	-	0	0/0
Number of living donor transplant procedures (total/pmp)								
Kidney	11/1.6	15/2.0	12/1.6	9/1.2	9/1.2	11/1.5	12/1.7	13/1.8
Liver	4/0.6	4/0.5	2/0.3	3/0.4	2/0.3	-	1/0.1	1/0.1

- = not known to the research team

[175] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

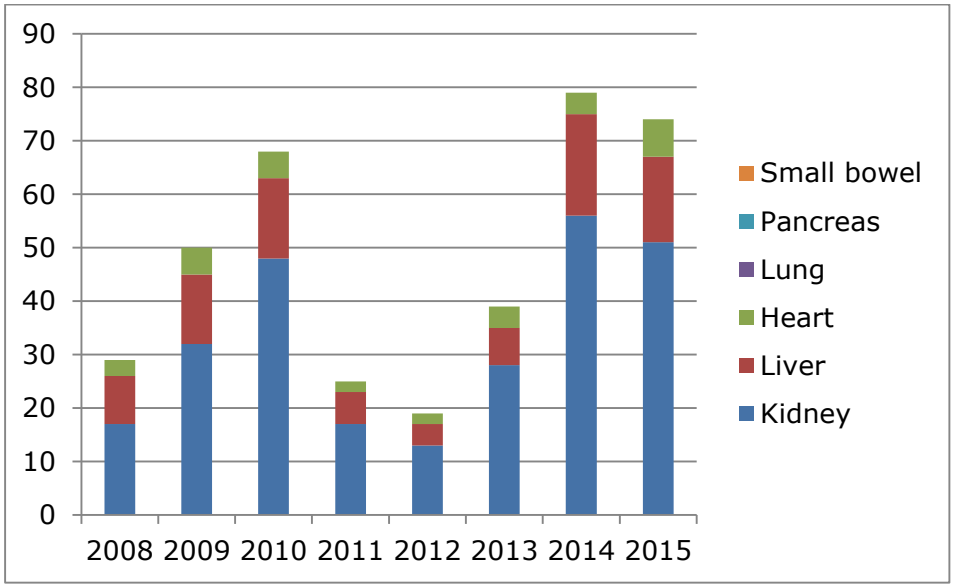
[176] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Bulgaria*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed at the local/hospital level.
	+	Transplant donor coordinators receive regular training.
	+	The training is on all topics related to the detection of the potential donor, diagnosis and maintenance of a potential donor with detected brain death; obtaining family consent; extended criteria donor.
	●	The trainings have not yet been tested for effectiveness.
	●	Bulgaria does not use an accreditation scheme.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: We consider that the transplant donor coordinators who have been well trained will be sure they work according to European donation criteria.
	+	The EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: by exchange of experience and deepening the knowledge.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, and the procurement process.
	+	The EU Action Plan will influence the national policy on Quality Improvement Programmes in the future by creating programmes for quality improvement.
	●	It is not known whether EU supported activities have contributed to the promotion of Quality Improvement Programmes. Bulgaria did not participate in ODEQUS.
Priority Action 3: Exchange of best practices on living donation	●	Bulgaria does not have directed[177] living donation programmes: Only Bulgaria, Estonia and Lithuania determine the range of possible donor-recipient relationships exactly without providing an open clause. The laws of Bulgaria, the Czech Republic, Finland, Lithuania, Moldova, Slovakia, Slovenia and Switzerland contain a provision stating that performing LOD is only legitimate when other methods of therapy are less effective or do not provide comparable efficiency. In Austria, Germany and the Netherlands, donor and recipient are included in a post-care process. In contrast, Bulgaria, the Czech Republic, Portugal and Spain only concentrate on one of the patients.
	●	There are no undirected living donation programmes.

[177] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	5 hospitals have living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Bulgaria has not ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan through upgrading our registers on living donors.
	+	EU supported activities will be useful for Bulgaria. They participated only in ACCORD and COORENOR.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public yet.
	+	Bulgaria deploys programs to improve knowledge and communication skills of health professionals and of patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: The public awareness policy of organ donation and transplantation of our institution is based on very strong collaboration with mass media (TV, radios, newspapers, social networks). The participation in different kind of programmes, related to community health and social status give us the opportunity to improve the knowledge and public information on the subjects like donation and transplantation. The organization of seminars and open lessons with health specialists, students at schools and universities, and patients' associations help the Bulgarian Executive Agency for Transplantation to reach more and different representatives of the society (students, academic fields in general, citizens, interested people in donation and transplantation).
	+	EU supported activities contribute to the promotion of public awareness: The Journalist Workshops increase the knowledge of the participants about organ donation and transplantation and thus they can increase the public awareness on these subjects. EU supported activities, such as FOEDUS, create valuable guidelines and train the health professionals how to communicate about donation and transplantation.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	Bulgaria provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. The society is informed and there is an Ordinance concerning the possibility of cross-border transplantation that

		is regulated by a Commission to the Ministry of Health. Currently the opportunity for cross-border exchange can be used by patients who need transplantations, which are not performed in Bulgaria.
	+	The following people can legally be donors in Bulgaria: residents with a foreign nationality who die in Bulgaria.
	+	Criteria required to be admitted to the waiting list: residency in Bulgaria, local nationality, signed up with local social security or health care insurance.
	+	100% of transplanted patients are local residents.
	+	National policy on cross-border donation is influenced by the EU Action Plan: We have not yet direct influence as a result of the EU Action Plan. We have started activity with EUROTRANSPLANT according to our Twinning Agreement with EUROTRANSPLANT.
	+	EU supported activities contribute to the identification of cross-border donors: We expect increasing the cases of cross border organ exchange in near future.
Priority Action 6: Enhancing organisational models	+	Bulgaria is involved in twinning projects, its role is learning, various topics are addressed.
	+	Bulgaria has been working together with France, Spain, Italy, Slovenia, and Croatia.
	+	These projects led to the following changes: Increasing deceased donation due to improvement of organization on a hospital and a national level; establishment of registries on organ donation and transplantation; increasing public awareness.
	+	It is known that Bulgaria uses structural funds and/or other community instruments for the purpose of the development of transplantation systems: Projects funded by the EU Health Programmes of the European Union- Horizon 2020.
	+	Transplantation centres or hospitals do not participate in any networks. Bulgaria does not have centres of reference.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: Bulgarian National policy is according to the EU Action Plan and we hope we will achieve a higher rate of donation and transplantation as we have increased the public awareness on the problem in the society and in the patient support groups on organ transplantation.
	+	EU supported activities contribute to enhancing the organisational model of the donation and transplantation system: In the framework of ACCORD JA we have had support for drawing up updated SOP-s, which are useful for implementing more efficient and effective policies of deceased donation.
Priority Action 7: Promote EU-wide agreements on aspects of	+	Bulgaria has agreements with other countries for exchanging organs: They have a Twinning Agreement, Model A, with Eurotransplant since

transplantation medicine		2013.
	●	Bulgaria does not yet have agreements with other countries to prevent and address organ trafficking: the main challenges are: considering to be good when the health establishments, by each suspicious action for organ trafficking, to inform the police and BEAT about that case. Years ago there have been cases when people have travelled abroad with the only purpose to sell an organ – mainly kidney.
	+	Future research programs should ideally focus on the following: To organize and conduct a national research on the relationship between the most frequent organ/organs in trafficking of people for organs and the rate of morbidity/end-stage diseases resulting in the same organ/organs. As well in these programs to be included general practitioners, health establishments, BEAT, patients' organizations and the legislative authorities.
	+	The development of EU-wide agreements is influenced by the EU Action Plan, but Bulgaria has only one Agreement with Eurotransplant, which is mentioned above. Bulgaria, through the BEAT, has been one of the first EU countries - participants and users of the CORRENOR portal since 2014. We will sign in addition an Agreement for maintenance of the FOEDUS IT platform for cross border organ exchange.
	+	EU supported activities contribute to this development: As a result of these EU supported activities we have signed an Agreement with Eurotransplant and participate in the use of the COORENOR/FOEDUS portal.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Bulgaria is part of a fixed collaboration: bilateral collaborations, with (neighbouring?) countries and Eurotransplant.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel, and combined transplantations.
	+	In 2015 5 organs left the country.
	+	In 2015, Bulgaria has offered 7 'non-allocated' organs (liver, heart, lung) to other countries.
	●	The procedure for non-allocated organs is not evaluated.
	●	Bulgaria has no procedure for the exchange of organs of urgent and difficult-to-treat patients, but 5 organs for difficult –to-treat patients were exchanged across borders.
	+	Bulgaria participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs is influenced by the EU Action Plan. This interexchange is important for Bulgaria because currently no transplantations are performed of lungs, heart-lungs, pancreas and small bowel. In

		this way there is an opportunity for patients with severe diseases, who are in need of organ transplant to be treated on time.
	+	EU activities contributed to the interchange of organs between countries: Bulgaria has participated in COORENOR JA and FOEDUS JA and we consider that they contribute very much to the interexchange of organs via the exchange platform and generally by regulating the policies of the countries on interexchange and the opportunity for sharing good practices on this topic.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3, 6 and 12 months after transplantation, starting 2 times a week after leaving the hospital and afterwards on regular protocol as stated above.
	●	The evaluation of post-transplant results is not supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, infectious diseases such as hepatitis, and from donors older than 60 years.
	+	National policy on the evaluation of post-transplant results will be influenced by the EU Action Plan: The active post-transplant follow-up will contribute to analyses of the results of organ transplantations and the shortcomings, determined during the follow-up, which will assist to their suspension and elimination.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	●	Bulgaria does not promote an accreditation system for procurement organisations and transplantation centres.
	+	The EU Action Plan will influence national policy on the promotion of accreditation systems: The need of implementing an accreditation system is obvious and it will help us to build a common accreditation system on EU level that will provide support to all healing establishments for organ donation and transplantation.
	+	EU supported activities contribute to the promotion of accreditation systems: they will contribute for establishing an accreditation system on donor procurement and transplantation programs in our country using the EU members' experience and experts.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Bulgaria was leader of a core[178] work package in the projects EULOD[179] and was an associated partner in ETPOD and is an associated partner in ACCORD and FOEDUS. Bulgaria is co—beneficiary in the HOTT-project[180].

In 2010, 2011 and 2012, the country participated in the data collection under the working group on indicators[181]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[182]).

Conclusions

Overall, Bulgaria's deceased donor rates increased since 2008, but they decreased between 2009-2010 and between 2011-2012 they decreased to critical level. From 2013 the DD transplants increased 8-10 times. For Bulgaria, there are chances to increase their deceased and living donation rates. Furthermore, chances lie within the area of expanded criteria donors, DCD, aged donors, and multi organ donation. For the latter subject, exchange programmes with other countries could increase the efficient use of donors across Europe.

CA in Bulgaria reported that the Action Plan helped Bulgaria to reorganize its organ donation system. All priority actions are important. It is very important to have transplant donor coordinators in every hospital. What is also very important to Bulgaria is the international contacts and collaboration, to learn from other countries about the best practice on living donation programs, to have a closer relationship with the medical staff in other countries and learn from other countries about their audit-system. Bulgaria is not a Member of Eurotransplant, but started an organ exchange program.

Until a few years ago Bulgaria had a very low number of organ donations (0.3 per million). The priorities in Bulgaria for the next 5 years are to rebuild its organ donation and transplant infrastructure, to establish a transplant donor coordinator in every hospital, to train IC doctors and to increase public awareness.

The next step for the EU as a whole would be according to Bulgaria, first, to continue with the annual meetings of the Competent Authorities. These meetings are very important to see and discuss practical examples from different countries. Next, Bulgaria would like to see an increase in the number of scientific meetings with doctors from the field. Third, to further improve cross-border organ exchange international cooperation is very important, not only for the program, but for the health of patients.

[178] 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.

[179] For more information about EU-funded projects, see chapter 3.

[180] Hottproject.com

[181] For more information about the working groups, see chapter 3.

[182] For more information about CD-P-TO, see Annex 3.

4. Croatia

Background information[183]
With a deceased donation rate PMP of 40 organ donors PMP in 2015, Croatia's deceased donation rate is amongst the highest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts and pancreases. Croatia has a relatively high number of liver transplants. With a living kidney donation rate PMP of less than 5 in 2015, Croatia's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out regarding liver and kidney. Croatia is part of Eurotransplant[184] and donor organs are allocated through Eurotransplant.

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

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

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

[183] Sources: FACTOR 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.

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

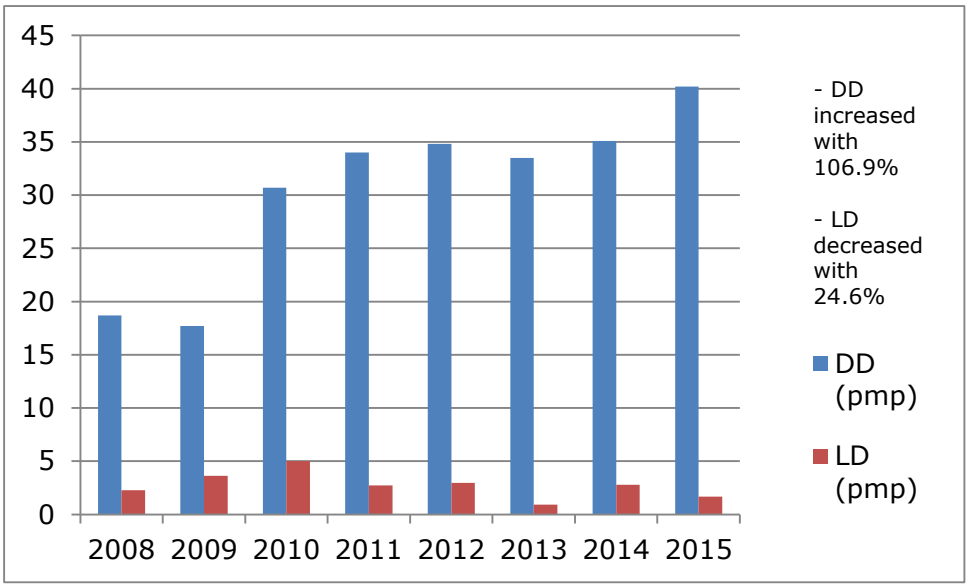
Key figures[185]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	4.4	4.4	4.4	4.4	4.4	4.3	4.3	4.2
Family refusal rate (refusals/times asked)	-	-	32/167	42/192	-	39/191	39/190	33/202
Actual deceased donation rate (total/per million population, pmp)	83/ 18.7	78/ 17.7	135/ 30.7	150/ 34	153/ 34.8	144/ 33.5	151/ 35.1	169/ 40.2
Multi-organ donation rates (% of total)	83.1	82.1	85.8	87.8	92.8	82.6	14.6	68
Number of utilised donors (total/pmp)	79/17.6		127/28.6	144/33.5	-	-	--	
Number of donors after circulatory death - DCD	0	-	0	-	0	0	0	0
Number of donors older than 60	-		-	-	-	-	62	
Number of transplant centres								
Kidney	-	-	4	4	4	4	4	4
Liver	-	-	3	3	4	2	2	2
Heart	-	-	2	2	2	2	2	2
Lung	-	-	0	0	-	0	0	0
Pancreas	-	-	1	1	1	-	3	1
Bowel	-	-	1	-	-	1	-	1
Number of deceased donor transplant procedures (total/pmp)								
Kidney	149/ 33.9	156/ 35.5	224/ 50.9	228/ 51.8	222/ 50.5	205/ 47.7	186/ 43.2	208/ 49.5
Liver	64/ 14.5	60/ 13.6	103/ 23.4	121/ 27.5	124/ 28.2	114/ 26.5	124/ 28.8	139/ 33.1
Heart	20/4.5	20 /4.5	36/8.2	38/8.6	44/10	33/7.7	34/7.9	37/8.8
Lung	-	-	-	-	0	0	0	0/0
Pancreas	14/3.2	13 /2.9	6/1.4	12/2.7	8/1.8	7/1.2	5/1.2	8/1.9
Bowel	-	-	-	-	-	0	0	0/0
Number of living donor transplant procedures (total/pmp)								
Kidney	9/2.0	14/3.2	20/4.5	9/2.0	9/2	3/0.7	11/2.6	5/1.2
Liver	1/0.2	2/0.5	2/0.5	3/0.7	4/0.9	1/0.2	1/-	2/0.5

- = not known to the research team

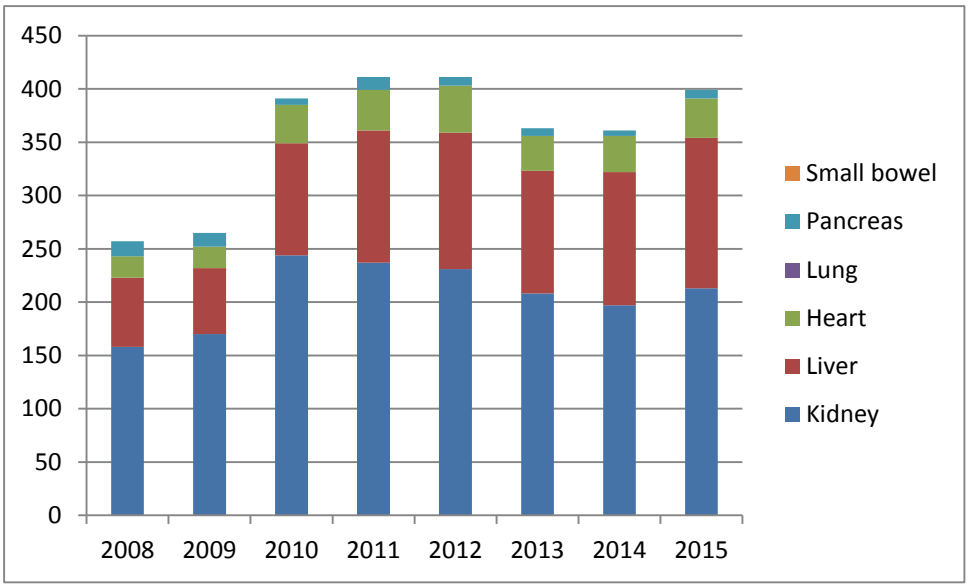
[185] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Croatia*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 28 at the local/hospital level and 1 + 6 junior at the national level.
	+	Transplant donor coordinators receive initial training.
	+	Summary of the training: Training programs on optimal donor management for coordinators have been launched on national level. Transplant Procurement Management TPM training, Barcelona - international level- every year 3 Croatian participants attend the TPM course.
	+	The trainings have been tested for effectiveness.
	+	Croatia uses an accreditation scheme to qualify transplant donor coordinators: EDTCO transplant coordinators certification.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: Promoting the role of transplant coordinators in every hospital where there is potential for organ donation. Continuous education of transplant coordinators in order to reach the full potential of deceased donations in their hospitals.
	●	No information whether the EU supported activities have contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process and the transplantation process.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: Croatia started Donor quality assurance program and its implementation resulted in some improvements.
	●	No information about the contribution of EU supported activities to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Croatia has directed[186] living donation programmes. Croatia requires the consent to be approved by an Ethical Committee of the transplant center and also explicitly require the recipient to consent as well.
	+	There also are undirected living donation programmes: Croatia allows living donation (including altruistic donations under specific conditions defined by legislation); Hospital ethical committees are evaluating bodies of living donors; Register of Living Donors already in place under

[186] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		Eurotransplant membership (database) however without donor follow up (future plans include donor follow up program).
	+	3 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Croatia has not yet ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan: Exchange of best practices on living donation programmes among EU Member States; Development of registers of living donors and transplanted patients.
	●	No information whether EU supported activities contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Croatia deploys programs to improve knowledge and communication skills of for healthcare professionals involved in transplant program and patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: In public it all begins and everything ends. So, it is of outmost importance to communicate with the public in order to create the positive attitude toward organ donation. The EU projects such as European Donor day, FOEDUS and also Journalist workshops are helpful materials that provide guidelines how to communicate with public.
	●	No information whether The EU supported activities contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	Croatia provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU: by media, web portal, emails.
	+	The following people can legally be donors in Croatia: residents with a foreign nationality who die in Croatia, and non-residents who die in Croatia.
	+	Criteria required to be admitted to the waiting list: residency in Croatia, local nationality and signed up with local social security or health care insurance.
	+	99% of transplanted patients are local residents.
	●	No information whether national policy on cross-border donation is influenced by the EU Action Plan. Croatia is member of Eurotransplant International

		Foundation and ET is responsible for organ exchange and allocation.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Croatia is involved in twinning projects, in a learning and a teaching role: ACCORD, FOEDUS, ODEQUS, IPA 2009 twinning project. Croatia indicates that it has been involved in a twinning project with Austria, in the framework of the University of Vienna Lung Transplant Program.
	+	Croatia has been cooperating with SEEHN countries: Romania (February 2014) - FYR of Macedonia (February 2014) - Montenegro (June 2014) - Albania (June 2014) - Serbia (November 2014) - Federation of Bosnia and Herzegovina (November 2014) and Austria. This has led to Progress of transplant activities in SEEHN countries.
	●	Croatia has plans to use structural funds: TAIEX, HORIZON 2020.
	+	Transplantation centres or hospitals participate in networks, but these are not specified.
	●	No information whether the organisational model of the donation and transplantation system is influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Croatia has agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, training/certifying health care professionals (surgeons, coordinators) and collecting data. Croatia is member of Eurotransplant since 2007.
	●	Croatia does not have agreements with other countries to prevent and address organ trafficking: the main challenges are: - to prevent and combat the trafficking in human organs by providing for the criminalisation of certain acts; - to protect the rights of victims - to facilitate co-operation at national and international levels on action against the trafficking in human organs.
	●	No information on the influence of the development of EU-wide agreements by the EU Action Plan.
	●	No information whether EU supported activities contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Croatia is part of a fixed collaboration: a multilateral collaboration, namely Eurotransplant.
	+	Patient groups involved are: Patients with urgent needs for transplantation and Paediatric patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	In 2015 119 organs came from abroad, 161 organs left the country.
	+	Croatia has offered non-allocated organs to other countries, organs involved are liver, kidney, heart, lung, pancreas, small bowel.

	●	Procedures for offering non-allocated organs are not evaluated.
	+	Croatia has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	●	Croatia does not participate in the use of an IT-tool for the facilitation of cross-border exchange.
	●	No information on the influence of the national policy on the interchange of organs by the EU Action Plan.
	●	No information whether EU activities contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	●	Post-transplant results of organ recipients are not yet evaluated on a national level.
	+	Results are measured 3, 6 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors older than 60 years.
	●	No information on the influence of the national policy on the evaluation of post-transplant results by the EU Action Plan.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	+	Croatia promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation systems used are for donation (coordinators), for procurement (surgeons) and for transplantation.
	●	No information on the influence of the EU Action Plan on national policy on the promotion of accreditation systems.
	+	EU supported activities contributed to the promotion of accreditation systems through a training course in transplant donor coordination.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Croatia was core work package leader in the project EDD[187] (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[188]. In addition, it is a member of the Council of Europe Committee (Partial

[187] For more information about EU-funded projects, see chapter 3.
[188] For more information about the working groups, see chapter 3.

Agreement) on Organ Transplantation (CD-P-TO[189]).

Conclusions
Croatia's deceased donor rates increased since 2008, but the living donor rates decreased slightly since 2008. Croatia is doing very well in the area of deceased donation, but they may have opportunities to increase the living donation rates. Other chances lie within small bowel transplantation and the use of expanded criteria donors.

Croatia already had a high level of activities before the Action Plan was introduced. However, according to the CA in Croatia the Action Plan helped with closely monitoring all activities. Croatia appreciates the Action Plan and appreciates the efforts made by the EU and think this should continue in the future.

A priority in Croatia for the next years is a long term follow up system for patients and grafts, and a register of patients and grafts. Furthermore, a platform for exchange and collaboration. The EU could help by facilitating consensus on this, to come to a standardized way on how to follow up on patients and grafts, and have a register which makes it possible to benchmark. Another priority for Croatia is register on living donation, which is also an obligation of the EU Directive.

As a next step for the EU as a whole, the Croatian CA mentioned that registries are already there, but a 'register of registries' is needed, or a common platform for standardization in Europe. Therefore, Croatia thinks that European cooperation is still needed.

[189] For more information about CD-P-TO, see Annex 3.

5. Cyprus

Background information[190]

The population of Cyprus relevant to Transplantation is rounded up to 800,000 (in fact around 770,000 in the last Census of 2011 – the population was effectively unchanged between 2008 to 2016). The Competent Authority in Cyprus has already written to the authors of the CoE Newsletter to take this into account when drafting their statistics (instead of using the UN published population figures which also include the population in the occupied areas of Cyprus which are not under the effective control of the Republic of Cyprus).

A new Transplant Law was implemented in 2012 incorporating the Directive for Quality and Safety of organs intended for transplantation. Transplant Donor Coordinators were appointed for Living and Deceased Donation

With a deceased donation rate PMP under 5 in 2015, Cyprus' deceased donation rate PMP is amongst the lowest of the countries included in this study. Deceased donor transplant procedures were only carried out involving kidneys and Pancreas

With a living kidney donation rate PMP of above 20 in 2015, Cyprus' living kidney donation rate PMP is among the higher of the countries included in this study. Transplant procedures from living donors were carried out for kidneys only.

Transplant Law allows deceased organ donation when a person had not expressed objection and the next of kin had given consent.

[190] Sources: FACTOR survey filled in by national Competent Authority, 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.

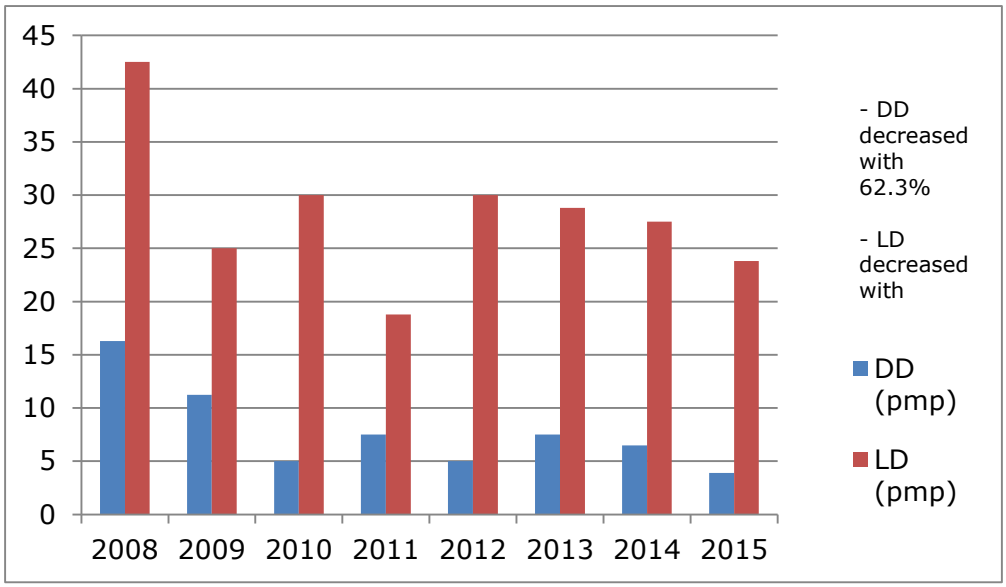
Key figures[191]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
Family refusal rate (refusals/times asked)	-	0/8	3/7	3/9	1/6	3/9	3/8	5/11
Actual deceased donation rate (total/per million population, pmp)	13/ 16.3	8 / 11.25	4/ 5	6/ 7.5	4/ 5	6/ 7.5	5/ 6.5	3/ 3.9
Multi-organ donation rates (% of total)	100	50	100	100	100	100	100	33
Number of utilised donors (total/pmp)	1	1	1	2	0	0	2	2
Number of donors after circulatory death - DCD	-	-	0	-	0	0	0	0
Number of donors older than 60	-		-	-	-	-	2	
Number of transplant centres								
Kidney	1	1	1	1	1	1	1	1
Liver	-	-	-	-	0	0	-	0
Heart	-	-	-	-	0	0	-	0
Lung	-	-	-	-	0	0	-	0
Pancreas	-	-	-	-	1	1	1	1
Bowel	-	-	-	-	-	0	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	24/30	15/18.8	8/10	12/15	5/6.3	9/11.3	9/11.3	1/1.3
Liver	-	-	-	0	-	-	0	0
Heart	-	-	-	-	-	0	0	0
Lung	-	-	-	-	-	-	0	0
Pancreas	-	-	-	-	1/1.3	-/0	0	0
Bowel	-	-	-	-	-	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	34/ 42.5	20/25	24/30	15/ 18.8	24/30	23/ 28.8	22/ 27.5	19/ 23.8
Liver	-		-	-	-	-	0	0

- = not known to the research team

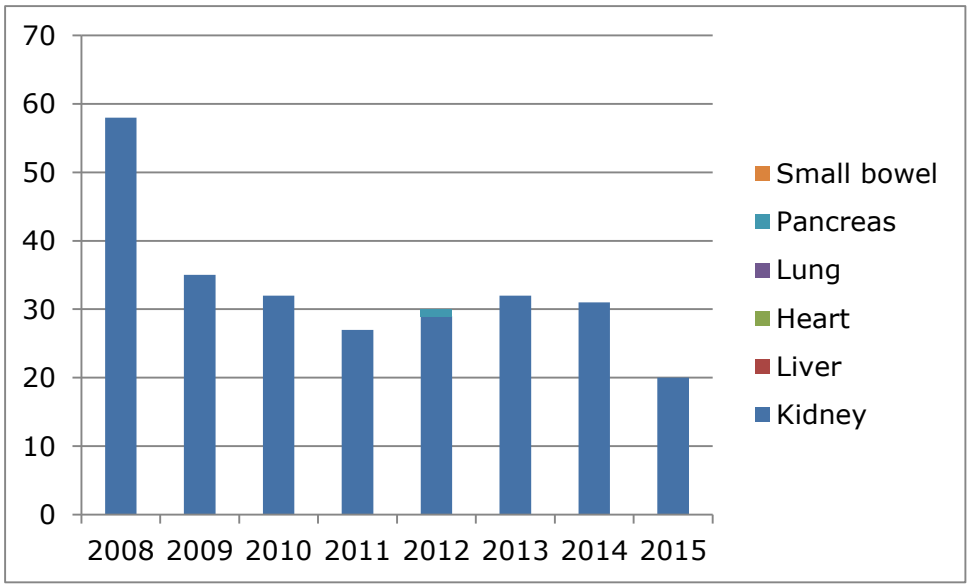
[191] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Cyprus*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter, and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 3 at the national level (2 TDC of Living Organ Transplantation and 1 TDC-.deceased organ donation) and over the period of the coming years 3 TDC at the Local Hospital level for deceased organ donation.
	+	Transplant donor coordinators receive specific training: Among other this training included Advanced International Training in Transplant Coordination, Family approach, Donor detection, Brain Death, Organ allocation, Tissue and Cells Donation, Training for Trainers, ETPOT training, Master on organ donation, which were organised by TPM,-DTI and University of Barcelona .The trainings have not been tested for effectiveness.
	●	Cyprus does not use national nor the UEMS Certification for Transplant Coordinators as accreditation scheme to qualify transplant donor coordinators.
	●	The EU Action Plan has influenced national policy on transplant donor coordinators. The number of transplant donor coordinators for deceased donation was increased from one to four at local.
	●	EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: Along with the Directive 2010/53/EU, incorporating it to the national legislation.
	●	EU supported activities did not contribute to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Cyprus has directed[192] living donation programmes. The current legislation (Article 13 (5) provides for the directed living donation for by blood relatives up to third degree, or in case the Transplant Council confirms "close personal relationship" that justifies altruistic donation from the donor to the recipient.
	+	There also are undirected living donation programmes.
	+	1 hospital has a living donation program.

[192] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Cyprus has not yet ratified the Council of Europe Convention.
	●	No specific information on whether the national policy on living donation programs is influenced by the EU Action Plan, but EU Action Plan areas along with the Directive 2010/53/EU, have been incorporated into the national legislation.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public (Website of Transplant Council www.moh.gov.cy and written information material)
	+	Cyprus deploys programs to improve knowledge and communication skills of for all health care (hospital) personnel and patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: Principles of EU Action Plan indirectly influenced it along with the Directive 2010/53/EU, incorporating them into the national legislation.
	+	EU supported activities contributed to the promotion of public awareness: indirectly along with other related activities.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	Cyprus provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU: MOH websites.
	+	The following people can legally be donors in Cyprus: residents with a foreign nationality who die in Cyprus, non-residents who die in Cyprus and illegal persons who die in Cyprus.
	+	Criteria required to be admitted to the waiting list: residency in Cyprus, medical criteria.
	+	100% of transplanted patients are local residents.
	●	No information whether national policy on cross-border donation is influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Cyprus is involved in twinning projects, in a learning role: Cyprus 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. Austria indicated that

		they have been involved in twinning project with Cyprus on lung transplantation. These projects did not yet lead to change.
	●	Cyprus has not used structural funds and/or other community instruments (EU funding) for this purpose.
	●	Transplantation centres or hospitals do not participate in networks. There is a single hospital in the Country where Donation and Transplantation activity takes place.
	●	No information whether the organisational model of the donation and transplantation system is influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Cyprus has agreements with other countries for exchanging organs and treating each other's patients and MOU with Austria for lung transplant.
	●	Cyprus does not have agreements with other countries to prevent and address organ trafficking: the main challenges are: No problems of organ trafficking are encountered in Cyprus. The small size of the Country, the use of a single hospital for all Transplant and Donor activities makes supervision of activities very easy.
	●	No information on the influence of the development of EU-wide agreements by the EU Action Plan, but EU Action Plan issues along with Directive 2010/53/EU, were incorporated into the national legislation.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	●	Cyprus is not yet part of a fixed collaboration. However the Ministry of Health is currently in discussion with Israel for facilitating a Paired Exchange Scheme.
	●	In 2015 no organs came from abroad.
	+	Cyprus has offered 4 non-allocated kidneys to other country because no recipient matched through the national allocation system.
	+	Cyprus had offered 72 organs to other European and neighbouring countries. Most of cases of deceased organ donation had multiorgan retrieval. Organs like hearts, lungs, livers and kidneys left the country and offered to European Transplant Centres through their National Transplant Organisations. During the period of 2008 – 2015 a total of 8 hearts, 15 lungs, 45 livers were offered.
	●	Procedures for offering non-allocated organs are not evaluated.
	+	Cyprus has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	●	Cyprus does not participate in the use of an IT-tool for the facilitation of cross-border exchange.
	+	Cyprus participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.

	+	Currently in negotiations with Israel for an IT based Paired Exchange Scheme with Israel.
	●	The EU Action Plan has not influenced national policy on the interchange of organs.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected prospectively in a database/register at national level.
	+	Results are measured immediately after transplantation.
	●	The evaluation of post-transplant results is not supported by a vigilance system. Since Feb 2011 we conducted 162 kidney and 1 simultaneous kidney-pancreas transplant – only 4 kidneys have failed since then (1 from infection, 2 from rejection and 1 from recurrence of the original cause of Renal Failure). Therefore the small size of the program and the close monitoring of the patients resulted in excellent results.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency (but only in case of ACUTE renal insufficiency in a young donor), and from donors older than 60 years.
	●	The EU Action Plan has not influenced the national policy on the evaluation of post-transplant results.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are controlled or audited on a regular basis by the Transplant Council. Also, we publish all our results and complications at the annual Hospital report freely available on the website.
	●	An accreditation system for procurement organisations and transplantation centres. is NOT applicable for a Country with a single centre for both.
	●	EU Action Plan on national policy has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Cyprus was initially core work package leader in the EU funded project ELIPSY[193], but withdrew from this position.[194] 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.

[193] For more information about EU funded projects, see chapter 3.
[194] Personal communication with policy officer European Commission.

In 2011 and 2012, the country participated in the annual data collection of the working group on indicators[195]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[196]).
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[197] 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.

Conclusions
Both the deceased and living donation rates of Cyprus had a fluctuation and decreased since 2008. However, it has to be taken into account that the system underwent organisational change in Jan 2011. All Donation and Transplantation activity was undertaken at a Private Institution (but non profit organization) prior to Jan 2011 and in Jan 2011 the system of Organ Donation & Transplantation was transferred to a single Public Sector Hospital with very strict monitoring of criteria for donation and Transplantation, according to International Standards. In the first year, 2011, the new system was being optimised. In the Years 2012-2014 there was a steady number of Live Donor procedures (22-24 per year) but a decreasing number of Deceased Donor procedures. In 2015 there was yet again another organisational restructuring of the system with a resultant drop in numbers (19 Live Donor procedures and only 1 Deceased Donor Kidney transplant). In 2016 the system is undergoing another reorganisation. It would seem important to closely monitor these developments.

Opportunities for Cyprus are to increase deceased donation, make use of the good multi-organ donation rates and enhance their agreements with other countries on exchanging organs. This would contribute to the efficient use of organs across Europe. Furthermore, chances lie within the field of living donation.
For the future, Cyprus would like to have EU joint activities in the areas of communication strategy, common accreditation system and training.
According to Cyprus, the most valuable contribution of the Action Plan is upgrading organ donation and transplantation in a structured way, aligned between EU MS.

The priorities in the field of organ donation in Cyprus for the next five years are to enhance further altruistic donation programs, enhance public information campaigns, to introduce a local & International paired exchange program and to introduce a Pan European accreditation system for organ donation, procurement and transplantation.

The next steps from the EU as a whole, according to Cyprus, should be joint activities in the area (communication strategy, common accreditation system, training).

[195] For more information about the working groups, see chapter 3.
[196] For more information about CD-P-TO, see Annex 3.
[197] 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

6. Czech Republic

Background information[198]

With a deceased donation rate PMP of above 20 in 2015, the Czech Republic belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.
With a living kidney donation rate PMP of 5 in 2015, Czech Republic's living kidney donation rate PMP is among the lower of the countries included in this study. Donor organs are allocated at national level.

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

Since May 30th 2002 an **opt-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 Register 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.

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.

[198] Source: FACTOR 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.

Key figures[199]

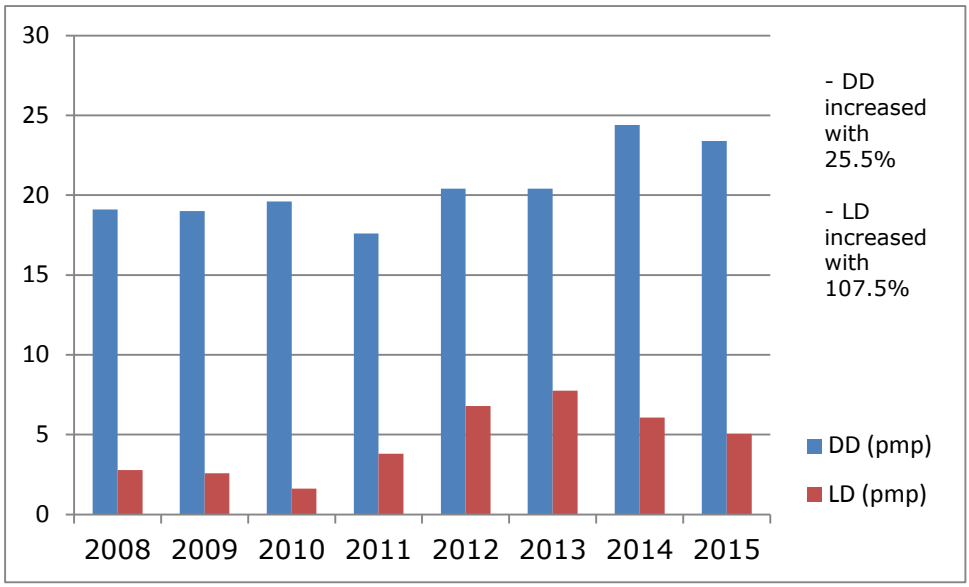
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	10.4	10.5	10.5	10.5	10.6	10.7	10.7	10.5
Family refusal rate (refusals/times asked)	10/263	-	13/278	13/285	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	198/ 19.1	200/19.0	206/ 19.6	185/ 17.6	216/ 20.4	218/ 20.4	261/ 24.4	246/ 23.4
Multi-organ donation rates (% of total)	54.1	58.5	58.3	56.8	56.9	57.8	62.5	63
Number of utilised donors (total/per million population)[200]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	1	0	2	1	2	1	4	8
Number of donors older than 60		47	56	50	75	67-	75	83
Number of transplant centres								
Kidney	7	7	7	7	7	7	7	7
Liver	2	2	2	2	2	2	2	2
Heart	2	2	2	2	2	2	2	2
Lung	1	1	1	1	1	1	1	1
Pancreas	1	1	1	1	1	1	1	1
Bowel	1	1	1	1	1	1	1	1
Number of deceased donor transplant procedures (total/pmp)								
Kidney	305/ 29.3	346/33.1	347/ 33.0	320/ 30.5	361/ 34.1	377/ 35.2	444/ 41.5	400/ 38.1
Liver	97/ 9.3	102/9.7	102/ 9.7	88/ 8.4	114/ 10.8	119/ 11.1	167/ 15.6	188/ 17.9
Heart	59/ 5.7	80/ 7.6	70/ 6.7	68/ 6.5	73/ 6.9	68/ 6.4	87/ 8.1	75/ 7.1
Lung	20/ 1.9	22/ 2.1	17/ 1.6	18/ 1.7	20/ 1.9	17/ 1.6	32/ 3	34/ 3.2
Pancreas	26/ 2.5	28/ 2.7	20/ 1.9	32/ 3.0	26/ 2.5	35/ 3.7	32/ 3.7	37/ 3.5
Bowel	0	0	0	0	0	0	2/0.2	1/0.1
Number of living donor transplant procedures (total/pmp)								
Kidney	29/ 2.8	27/ .6	17/ 1.6	40/ 3.8	71/ 6.7	83/ 7.8	63/ 5.9	53/ 5
Liver	0	0	0	0	1/0.1	0	2/0.2	0

- = not known to the research team

[199] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

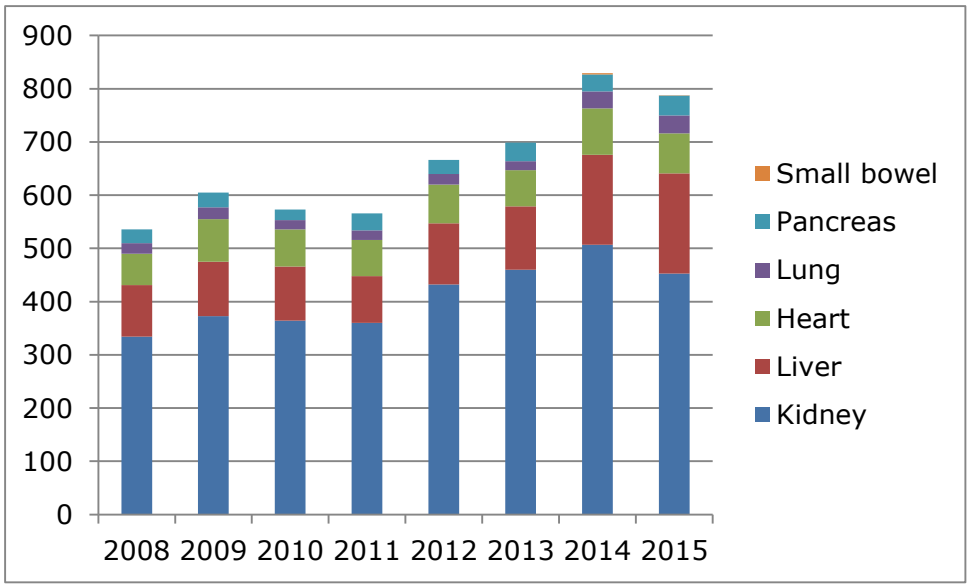
[200] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Czech Republic*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 68 at the local/hospital level, 10 at the regional level and 6 at the national level.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: Educate transplantation coordinators systematically and bring them face to face with foreign counterparts by the means of specialised educational training courses, international certification, labour exchange with foreign coordination centres etc. This will bring higher qualification and language skills, both being advantageous international organ exchange. New legislation was adopted in 2013, coordinators trained accordingly.
	●	The trainings have not yet been tested for effectiveness.
	●	Czech Republic does not yet use an international accreditation scheme to qualify transplant donor coordinators: only a national.
	●	No information on the influence of the EU Action Plan on national policy on transplant donor coordinators.
	●	Not known whether the EU supported activities contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: - Increase in number of donors - Amendment of transplant legislation - More publicity to transplant program.
	●	Not known whether EU supported activities contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Czech Republic has directed[201] living donation programmes. public relation, increase in living donation figures.
	●	There are no undirected living donation programmes.
	+	7 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.

[201] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	A register is established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, and Czech Republic has ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan: Increase of numbers.
	+	EU supported activities Coorenor, Foedus contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Czech Republic deploys programs to improve knowledge and communication skills of for healthcare professionals involved in transplant program and patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: TV series.
	●	No information whether The EU supported activities contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Czech Republic does not yet provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Czech Republic: residents with a foreign nationality who die in Czech Republic, and non-residents who die in Czech Republic.
	+	Criteria required to be admitted to the waiting list: local nationality.
	+	98% of transplanted patients are local residents, 1% are foreign residents, 1% are non-residents.
	●	No information whether national policy on cross-border donation is influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Czech Republic is involved in twinning projects, in a learning and a teaching role. This has led to introduction of auditing system, international organ exchange.
	+	Czech Republic has plans to use structural funds: for in house donor coordinators, for auditing system of transplant centers.
	+	Transplantation centres or hospitals do not yet participate in networks.
	●	No information whether the organisational model of the donation and transplantation system is influenced by the EU Action Plan.

	+	EU supported activities contributed to enhancing the organisational model of the donation and transplantation system: International organ exchange, auditing.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Czech Republic has agreements with other countries for exchanging organs and about auditing of transplant centres.
	+	Czech Republic has agreements with other countries to prevent and address organ trafficking.
	+	Future research programs should focus on international cooperation.
	●	No information on the influence of the development of EU-wide agreements by the EU Action Plan.
	●	Not known whether EU supported activities contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Czech Republic is part of a fixed collaboration: a multilateral collaboration, namely South Alliance for Transplants (SAT) and bilateral collaborations, with next countries.
	+	Patient groups involved are: Patients with urgent needs for transplantation, Paediatric patients and Patients with rare HLA-patterns.
	+	Organs involved are liver, kidney, heart and lung.
	+	In 2015 13 organs came from abroad, 2 organs left the country.
	+	Czech Republic has offered non-allocated organs to other countries, organs involved are liver, kidney and heart.
	+	Procedures for offering non-allocated organs are evaluated.
	+	Czech Republic has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver and heart.
	+	Czech Republic participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	No information on the influence of the national policy on the interchange of organs by the EU Action Plan.
	+	EU activities contributed to the interchange of organs between countries, namely Slovakia and Italy.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a regional or local level.
	+	Results are measured 3 and 12 months after transplantation.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, infectious diseases such as hepatitis, and from donors older than 60 years.
	●	No information on the influence of the national policy on the evaluation of post-transplant results by the EU Action Plan.
	●	Not known whether EU supported activities contributed to the evaluation of post-transplant

		results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	Czech Republic promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation systems used are for donation (coordinators), for procurement (surgeons), for transplantation and for other staff involved in donation and transplantation.
	+	The EU Action Plan on national policy has influenced national policy on the promotion of accreditation systems, through International audit.
	+	EU supported activity Accord contributed to the promotion of accreditation systems through a training course in transplant donor coordination.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects the Czech Republic was core work package leader in COORENOR[202], 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[203]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[204]).

Conclusions
Both Czech Republic's deceased donor rates and living donor rates increased since 2008. This is very positive. Increasing the multi organ donation rates might still be a chance for Czech Republic.

The Czech CA reported that the Action Plan helped Czech Republic to summarize problematic issues and to solve them in the frameworks of a wider perspective. Czech Republic used the Action Plan to form its own National Action Plan divided in three areas: (i) National Donor Program, (ii) Legislation related to procurement and transplantation of organs, and (iii) International cooperation. In total, the Czech's National Action Plan had 13 points, out of which 12 has been achieved.

At present, Czech Republic has got two main issues to work on within the next five years. The first one is international exchange of surplus organs, whilst the latter is increase of DCD donation.

European cooperation is essential for further improvement of transplant medicine. From the point of view of the Czech Republic support of continuation of FOEDUS platform for international organ exchange and support to bi-lateral smaller "programs" would be appreciated.

[202] For more information about EU-funded projects, see chapter 3.
[203] For more information about the working groups, see chapter 3.
[204] For more information about CD-P-TO, see Annex 3.

7. Denmark

Background information[205]

With a deceased donation rate PMP between 10 and 20 in 2015, Denmark belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases.

With a living kidney donation rate PMP of above 10 in 2015, Denmark's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidneys. Denmark is part of Scandiatransplant[206] and donor organs are allocated through Scandiatransplant.

In Denmark, an opt-in system is in place. The system requires express consent from the donor but allows the donation with the consent of the next of kin when no express consent from the deceased donor has been given during their life time.

[205] Source: FACTOR survey filled in by national Competent Authority, Nys, H. (2007). Removal of Organs in the EU, European Ethical-Legal Papers N°4. Leuven. Scandiatransplant (2011). Transplantation and waiting lists figures 2011.

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

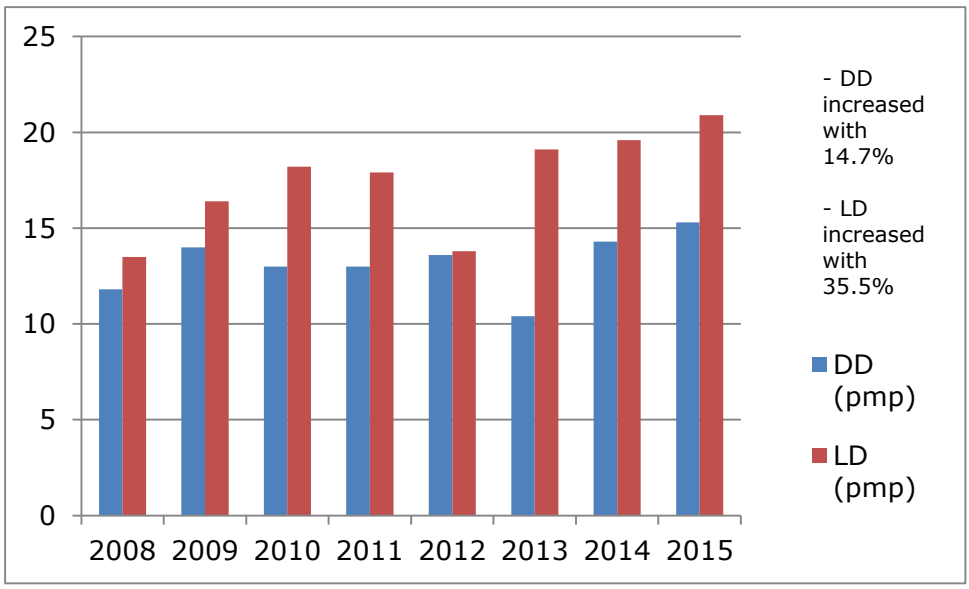
Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	5.5	5.5	5.6	5.6	5.4	5.4	5.4	5.7
Family refusal rate (refusals/times asked)	-	-	-	-				-
Actual deceased donation rate (total/per million population, pmp)	65/ 11.8	77/ 14.0	73/ 13	73/ 13	76/ 13.6	58/ 10.4	80/ 14.3	87/ 15.3
Multi-organ donation rates (% of total)	65	60	70	68.5	76.3	69	80	79.3
Number of utilised donors (total/per million population)[207]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	-	0	0	0	0	-	0	0
Number of donors older than 60	-		-	-	-	-	22	
Number of transplant centres								
Kidney	4	4	3	3	3	3	3	3
Liver	1	1	1	1	1	1	1	1
Heart	2	2	2	2	2	2	2	2
Lung	1	1	1	1	1	1	1	1
Pancreas	0	0	0	0	0	0	1	1
Bowel	0	0	-	-	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	122/ 22.2	141/ 26.6	130/ 23.2	135/ 24.1	137/ 24.5	108/ 19.3	139/ 24.8	154/ 27
Liver	44/ 8	40 / 7.3	47/ 8.4	51/ 9.1	48/ 8.6	42/ 7.5	47/ 8.4	58/ 10.2
Heart	20/3.6	27/4.9	22/3.9	29/5.2	26/4.6	17/3	32/5.7	27/4.7
Lung	18/3.2	29 /5.3	31/5.5	30/5.4	30/5.4	31/5.5	29/5.2	35/6.1
Pancreas	-	0	-	-	0	0	-	2/0.4
Bowel	-	-	-	-	0	-	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	74/ 13.5	90/ 16.4	102/ 18.2	100/ 17.9	77/ 13.8	107/ 19.1	110/ 19.6	119/ 20.9
Liver	0	0	0	0	0	0	0	0

- = not known to the research team

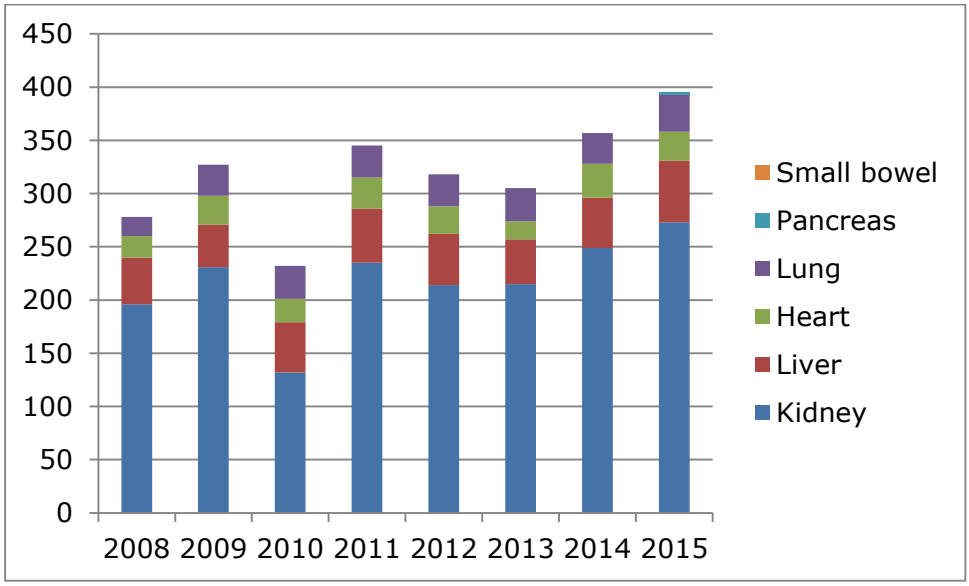
[207] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Denmark*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed at the national level. The Danish Center for Organ Donation has established an education programme, training donor coordinators.
	+	The education program concerning the donor coordinators - entails the following five topics: Identification of potential donors: • Management of the Quality Improvement Program at the ICU • Education and Information towards the doctors and nurses at the ICUs • Securing the quality of the critical pathway of organ donation • Follow up on quality of the process of organ donation.
	●	The trainings have not been tested for effectiveness.
	●	Denmark does not use an accreditation scheme.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: The EU Action Plan has inspired us in Denmark to make a formalised education programme for donor coordinators.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes in the future by creating programmes for quality improvement. The EU Action Plan has inspired Denmark to make a national Quality Improvement Programme according to the critical pathway of organ donation and define quality standards accordingly.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	+	Denmark has directed living donation programmes. Direct access to donation centers. No need for referral via GP or other hospitals. Information to donors via special programmes together with recipients and via internet or telephone.
	●	There are no undirected[208] living donation programmes. Denmark does not require a specific

[208] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed

		donor-recipient relationship. We examine the law and the medical practice itself in Denmark. The law does not require a specific donor-recipient relationship. However, there is a common medical practice that used to only accept LOD within the family. Later, it started accepting LODs for friends. We can conclude that the legal situation and the medical practice differ, since LOD for an not known recipient is legal, but not actually performed.
	+	3 hospitals have living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, Denmark has ratified the Council of Europe Convention.
	●	National policy on living donation programs is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the promotion of living donation programmes following best practices.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public, but there are some information leaflets informing the public about organ donation and transplantation, about family care and about consent to organ donation.
	+	Denmark deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation, health professionals and of patient support groups.
	●	Periodic meetings with journalists have not been organised.
	●	Guidelines and deliverables developed by EU supported activities are not used to inform the public.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	Denmark provides no easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Denmark: residents with a foreign nationality who die in Denmark, on-residents who die in Denmark and illegal persons who die in Denmark.
	+	Criteria required to be admitted to the waiting list: residency in Denmark, signed up with local social security or health care insurance.
	+	National policy on cross-border donation is not influenced by the EU Action Plan.

living donation means that the donor and recipient have a social relationship (partner, family or friend).

	●	EU supported activities have not contributed to the identification of cross-border donors.
Priority Action 6: Enhancing the organisational models of organ donation and transplantation	●	Denmark is not involved in twinning projects.
	+	Transplantation centres or hospitals participate in networks with specialty Kidney, Thorax, Liver and Pancreas.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: The Danish Center for Organ Donation has attended the ACCORD Workshop – a service improvement workshop and is using the ACCORD Improvement toolkit to implement best practice of organ donation in Denmark.
	+	EU supported activities contribute to enhancing the organisational model of the donation and transplantation system: ACCORD.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Denmark has agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, training/certifying healthcare professionals (surgeons, coordinators), collecting data and research activities.
	●	Denmark does not have agreements with other countries to prevent and address organ trafficking: the main challenges are: Organ Tourism, although only very few cases.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Denmark is part of a multi-lateral collaboration, namely Scandiatransplant.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	In 2015 36 organs came from abroad, 38 organs left the country.
	+	Denmark has offered 48 'non-allocated' organs (liver, kidney, heart, lung, pancreas, small bowel) to other countries.
	●	The procedure for non-allocated organs is not evaluated.
	+	Denmark has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Denmark participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
	●	EU activities have not contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 12 months and 5 years after transplantation.
	+	Donor organs are accepted from patients with diabetes mellitus, infectious diseases such as hepatitis, and from donors older than 60 years.

	+	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	●	Denmark does not promote an accreditation system for procurement organisations and transplantation centres.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities have not contributed to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)
In 2011 the country participated in the annual data collection prepared by the working group on indicators[209]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[210]).

Contribution of the Action Plan and future
The Action Plan has been important for the effort in Denmark in the area for organ donation.
The Danish Centre for Organ donation has continuously compared their priority effort to the Action Plan and think they meet the plan.

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The Danish Centre for Organ donation has continuously compared their priority effort to the Action Plan and think they meet the plan.

Conclusions
Denmark's living donation rate increased since 2008, and the deceased donation rate is slightly increased since 2008. This is very positive. Chances for Denmark may lie within the field of DCD and extended donor criteria. Furthermore, Denmark could consider the possibility to appoint transplant donor coordinators at hospital level and to focus on the impact on donation rates and quality of these coordinators.

[209] For more information about the working groups, see chapter 3.
[210] For more information about CD-P-TO, see Annex 3.

8. Estonia

Background information[211]
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 PMP between 10 and 20 in 2015, Estonia belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, lungs and pancreases.
With a living kidney donation rate PMP of 5 in 2015, Estonia's living kidney donation rate PMP is among the lower of the countries included in this study. Donor organs are allocated at national level.

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

Since 2002, an opt-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.

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

[211] Sources: FACTOR 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.

Key figures[212]

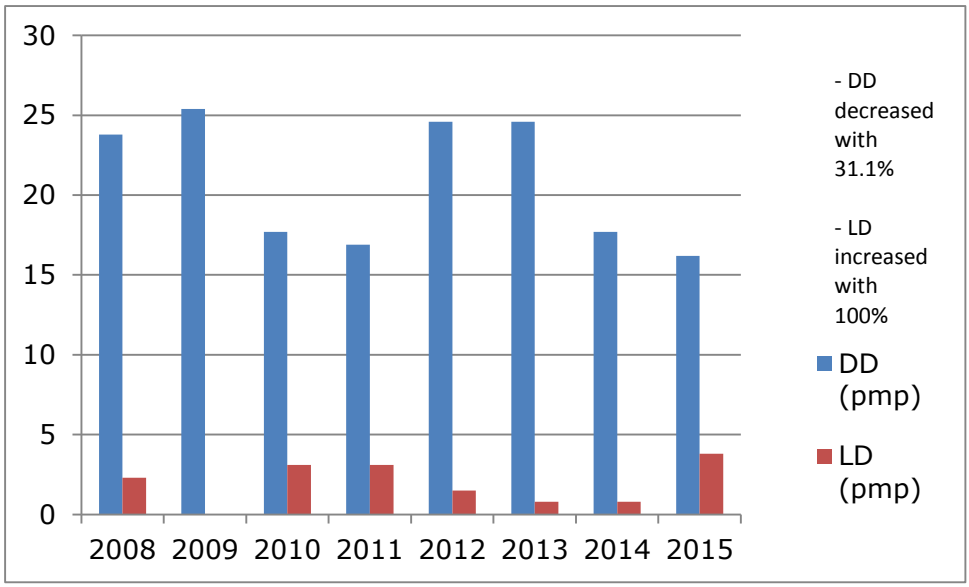
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
Family refusal rate (refusals/times asked)	16/50	30/63	7/30	10/40	12/49	11/53	6/32	12/36
Actual deceased donation rate (total/per million population, pmp)	31/ 23.8	3 / 25.4	23/ 17.7	22/ 16.9	32/ 24.6	32/ 24.6	23/ 17.7	21/ 16.2
Multi-organ donation rates (% of total)	2	24	6	59.1	56.3	56.3	73.9	85.7
Number of utilised donors (total/per million population)[213]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	0	-	0	0	0	0	0	0
Number of donors older than 60	0		0	-	-	-	2	
Number of transplant centres								
Kidney	1	1	1	1	1	1	1	1
Liver	1	1	1	1	1	1	1	1
Heart	-	-	-	-	0	0	-	0
Lung	-	-	1	1	1	1	1	1
Pancreas	-	-	-	-	0	0	1	1
Bowel	-	-	-	-	0	0	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	54/ 41.5	49/ 37.7	35/ 26.9	40/ 30.8	57/ 43.8	47/ 36.5	31/ 23.8	33/ 25.4
Liver	2/1.5	4 /3.1	3/2.3	8/6.2	9/6.9	9/6.9	10/7.7	7/5.4
Heart	0	-	-	-	0	0	0	0
Lung	0	-	1/0.8	3/2.3	2/1.5	3/2.3	6/4.6	4/3.1
Pancreas	-	-	-	-	0	0	0	1/0.8
Bowel	-	-	-	-	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	3/2.3	-	4/3.1	4/3.1	2/1.5	1/0.8	1/0.8	5/3.8
Liver	-	-	-	-	0	0	0	0

- = not known to the research team

[212] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

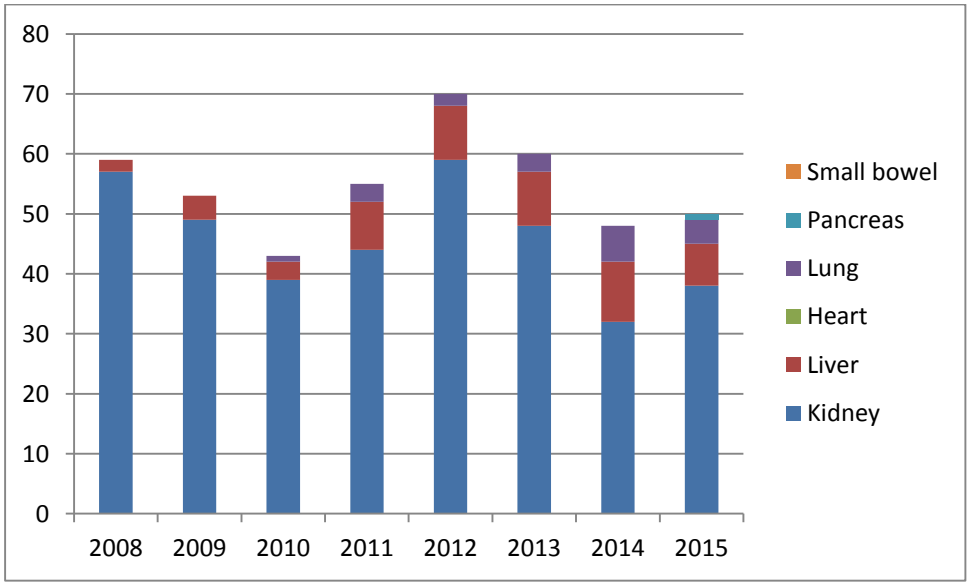
[213] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Estonia*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account. No numbers on living donation rates were available for year 2009.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 3 at the local/hospital level and 5 at the national level.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: – initial training in the workplace (legislation, quality and safety guidelines, ethics, donor management, organization of organ retrieval, preservation and allocation, international organ exchange) + practical trainings in other transplant centres (mainly in Scandiatransplant area) + regular participation in local/national seminars and international events (organized by EDTCO, ESOT, STS, TPM etc.).
	●	The trainings have not been tested for effectiveness.
	●	Estonia does not use an accreditation scheme to qualify transplant donor coordinators.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators Transplant donor coordination is provided 24 / 7 / 365 under the national law. Cooperation between donor hospitals and transplant centre is based on bilateral contracts, which are updated every year. Donor hospitals receive feedback about each donor process after the organ transplantations. Coordinators' activities (salaries, training etc.) are mostly financed from the state budget.
	+	EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: Estonia actively participated in the ETPOD program and it gave a good input for training courses and seminars at the national and local level.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process and the transplantation process.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: All stages of organ procurement, handling and transplants are covered by licensing. Activity licenses for organ procurement and handling are issued and supervised by the Agency of Medicines. Activity licenses for organ transplantation are issued and supervised by the Health Board.
	●	No information about the contribution of EU supported activities to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices	+	Estonia has directed[214] living donation programmes. In Estonia organ may be removed

[214] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation

on living donation		from a living donor only if the purpose of removal is its transplantation into a person with whom the donor has a genetic or emotional connection.
	●	There are no undirected living donation programmes.
	+	1 hospital has a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Estonia has not yet ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan: The option for potential living donors is expanded (previously there was only genetically related donation allowed, now also the emotional relationship). Living organ donors must receive psychological counselling before the donation. The expenses of health services provided to a living donor not covered by health insurance which are connected with the procurement and handling of organs and treatment due to a state of health having occurred after removal of an organ are compensated from the state budget.
	+	EU supported activities contributed to the promotion of living donation programs: We are more aware of the COORENOR and ACCORD projects and the results of these are given a useful input for later follow-up of living organ donors and encouraged to develop a national register.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public. Estonia deploys programs to improve knowledge and communication skills of for healthcare professionals involved in transplant program but not for patient support groups.
	●	Periodic meetings have not been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public and to improve knowledge and skills of health professionals and of patient support groups.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: Under the new national law it is regulated for now that transplantation council (formed in 2016) and national transplantation agency (creation is in process) will be responsible for improving the public awareness of organ donation.

(or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	EU supported activities contributed to the promotion of public awareness: The results of the FOEDUS influenced us to investigate how in Estonia particular media events impact on people's intention to donate organs for transplantation after death (results were presented at STS congress in 2016).
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Estonia does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Estonia: residents with a foreign nationality who die in Estonia, and non-residents who die in Estonia.
	+	Criteria required to be admitted to the waiting list: Citizens of another EU Member State, a country of the European Economic Area or a third country or persons without citizenship may also be registered on the waiting list on the condition that the waiting list manager shall be submitted a guarantee concerning the financing of the organ transplantation and a written confirmation by the person, bearing his or her handwritten signature, on the fact that he or she has not been registered on the organ transplant waiting list of another state.
	+	98% of transplanted patients are local residents, 2% are foreign residents.
	+	The EU Action Plan influenced national policy on cross-border donation: Criteria for international organ exchange and also for transplanting foreign patients have been revised and clarified.
	+	EU supported activities contributed to the identification of cross-border donors: We are aware with results of COORENOR and FOEDUS projects and it has contributed to the development of amendments to the law and provided input to the relevant documentation.
Priority Action 6: Enhancing organisational models	●	Estonia is not involved in twinning projects.
	+	Estonia has used structural funds: Estonia has participated in ETPOD, COORENOR, MODE, ACCORD and FOEDUS projects.
	+	Transplantation centres or hospitals participate in networks: Estonia has joined UEMS-EBS Division of Transplant Surgery. We also have a close cooperation with Scandiatransplant centres and also with Vienna University Hospital, so our surgeons and coordinators have had opportunity to improve their knowledge and practical skills in various transplant centres (Oslo, Gothenburg, Stockholm, Helsinki, Vienna). Our histocompatibility lab is accredited by EFI.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: We have a new national law (passed in 2015) and it is clearly defined that the

		transplantation infrastructure is composed of transplantation council, national transplantation agency, transplantation centre, the procurers and handlers of cells, tissues and organs, Estonian Health Insurance Fund, State Agency of Medicines, Health Board and
	+	Ministry of Social Affairs; and also the rights and obligations of all parties.
	+	EU supported activities contributed to enhancing the organisational model of the donation and transplantation system: we are aware with results of all 3 mentioned projects and we have used their for revision of our national regulation.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Estonia has agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, training/certifying health care professionals (surgeons, coordinators) and collecting data. - Agreements on organ exchange with Baltic States, Eurotransplant and Scandiatransplant. - Twinning agreement with Helsinki University Hospital in the field of heart transplants - initially transplants will be held in Finland with Estonian donor organ and Estonian recipient; our professionals (surgeons, cardiologists, anaesthesiologists, nurses etc.) can participate and learn until we will be ready to start a national heart transplant program. - Twinning agreement with Vienna University Hospital in the field of combined heart-lung transplants – initially this collaboration was for enhancing our national lung transplant program (method was similar as described previously), for now lung transplantation program is in work and twinning continues for heart-lungs. - Data collection for ELTR and ERA-EDTA registries.
	●	Estonia does not have agreements with other countries to prevent and address organ trafficking: the main challenges are: We don't have any special agreement, but it is an essential part of any international collaboration.
	+	Future research programs should ideally focus on - Finding effective treatment options for transplanting highly immunized patients. - Wider use of biomarkers to prevent complications and improve outcomes. - Use of advanced therapy medicinal products in the treatment of end stage organ failures.
	+	The EU Action Plan influenced the development of EU-wide agreements: The impact of international agreements has been great for Estonia: donor organ usage has increased, thereby we have got wider experience in donor organ evaluation and donor management and it has been a good opportunity to improve coordination and logistics; our professionals have had possibilities to improve knowledge and practical skills in various centres; we have got direct support for starting laparoscopic

		donor nephrectomies; we have got support for launching national lung and pancreas transplant programs; heart transplants are available for Estonian patients in cooperation with Helsinki and heart-lung transplants in cooperation with Vienna.
	+	EU supported activities contributed to this development: Impact has not been very direct, but uniformed requirements for donor organ quality and safety; and for international organ exchange have greatly increased the confidence between different EU member states and thereby supported cross-border collaboration in every level.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Estonia is part of a fixed collaboration: a multilateral collaboration, namely Eurotransplant and multi-lateral collaboration, namely Scandiatransplant.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas.
	+	In 2015 3 organs came from abroad,21 organs left the country.
	+	Estonia has offered 19 non-allocated organs to other countries, organs involved are liver, kidney, heart, lung, pancreas.
	+	Procedures for offering non-allocated organs are evaluated.
	+	Estonia has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, kidney, lung, pancreas. In 2015 1 organ has been exchanged.
	+	Estonia participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange, not actively, only as observers.
	+	The EU Action Plan has influenced national policy on the interchange of organs by.
	+	EU activities have contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at national level.
	+	Results of graft and/or patient survival are measured.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors older than 60 years.
	+	The EU Action Plan has influenced national policy on the evaluation of post-transplant results: We have revised our national criteria for donor organ quality and safety. We have begun to use more of expanded criteria donors
	●	Not known whether EU supported activities contributed to the evaluation of post-transplant results.

Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	Estonia promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation systems used are: activity licenses for organisation (separately for procurement, handling and transplantation); qualification requirements for competent persons and persons responsible for procurement.
	+	The EU Action Plan has influenced national policy on the promotion of accreditation systems.
	+	EU supported activities contributed to the promotion of accreditation systems: Mainly ACCORD and ETPOD, as an input for auditing deceased donor potential and develop training courses for different target groups.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects,[215] Estonia was an associated partner in ETPOD, EULOD and MODE. It is an 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[216]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[217]).

Conclusions
Estonia's deceased donor rate decreased since 2008, however its living donation rate increased since 2008. Opportunities for Estonia may be to change the decrease in the deceased donation rates. Also Estonia might benefit from DCD, extended donor criteria and living donation.

According to Estonia's CA, the Action Plan makes very clear what the importance is of the topics, also to policy makers. It is a very particular topic with patients having special needs. The Action Plan also contributes to increasing public awareness about this topic.

Estonia's first Priority is to join Scandiatransplant. The country is now applying for an associated membership. Estonia has such a small population, so it is very difficult to find suitable donors from such a small donor pool. Estonia has some collaboration with Eurotransplant. But the geograhic location of Scandiatransplant may be more suitable for Estonia.

Priorities for the future are EU-wide registers for living donation, urgent requests and follow up of patients. European collaboration is absolutely needed in the future. A new Action Plan is absolutely needed, according to Estonia. It may contain similar topics. However, the differences that exist between countries should be considered more explicitly. For instance, the Joint Action FOEDUS is good for centrally localized countries, but not so helpful for Estonia due to the long distances. The country is so small, all doctors and surgeons know each other and every patient, and also all patients on the waiting lists. So for Estonia, sometimes it is relatively much paperwork for so few patients.

[215] For more information about EU-funded projects, see chapter 3.
[216] For more information about the working groups, see chapter 3.
[217] For more information about CD-P-TO, see Annex 3.

9. Finland

Background information[218]

With a deceased donation rate PMP of above 20 in 2015, Finland belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and bowels. All deceased donors are DBD and DCD program has never been implemented. With a living kidney donation rate PMP of less than 5 in 2015, Finland's living kidney donation rate PMP is among the lower of the countries included in this study. Finland is part of Scandiatransplant and donor organs are allocated through Scandiatransplant and at national level. Finland has only one transplant centre.

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

Financing of organ donation

In case of deceased and living donation, financing occurs through residence based public funding. All transplantation takes place in public Helsinki University Hospital.

[218] Sources: FACTOR 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.

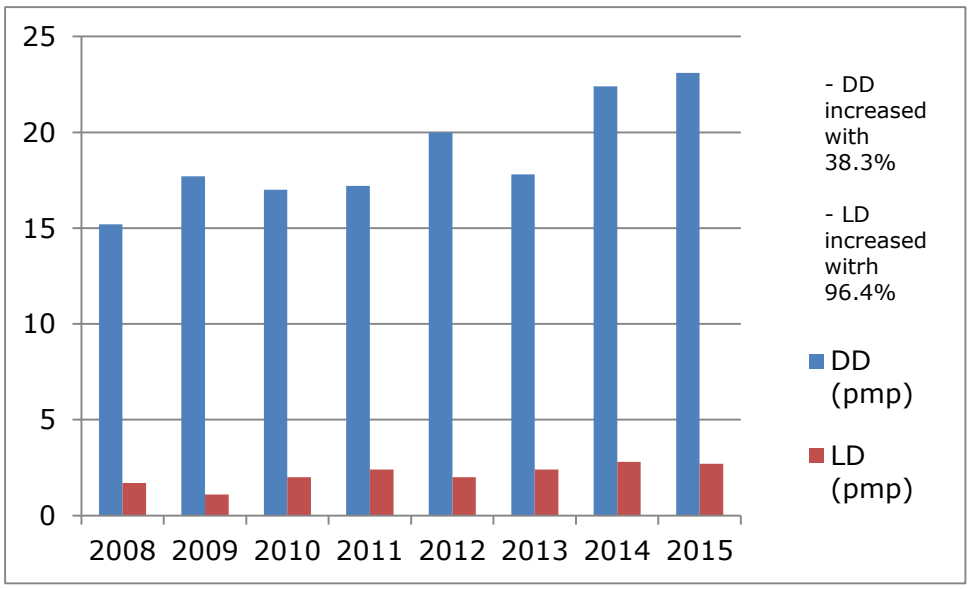
Key figures[219]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	5.3	5.3	5.4	5.4	5.4	5.4	5.4	5.5
Family refusal rate (refusals/times asked)	-	-	-	-	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	81/ 15.2	94/ 17.7	92/ 17.0	93/ 17.2	108/ 20	96/ 17.8	120/ 22.4	127/ 23.1
Multi-organ donation rates (% of total)	79	66	63.0	67	66.4	63.2	56.7	67.5
Number of utilised donors (total/per million population)	81/ 15.2	94/ 17.7	92/ 17.0	93/ 17.2	107/ 20	95/ 17.8	120/ 22.4	126/ 23.1
Number of donors after circulatory death - DCD[220]	-	-	-	-	-	-	-	-
Number of donors older than 60	-		-	-	-	-	52	
Number of transplant centres								
Kidney	1	1	1	1	1	1	1	1
Liver	1	1	1	1	1	1	1	1
Heart	1	1	1	1	1	1	1	1
Lung	0	1	1	1	1	1	1	1
Pancreas	-	0	1	1	1	1	1	1
Bowel	0	0	1	1	1	1	1	1
Number of deceased donor transplant procedures (total/pmp)								
Kidney	141/ 26.6	174/ 32.8	164/ 30.4	164/ 30.4	188/ 34.8	176/ 32.6	225/ 41.7	230/ 41.6
Liver	47/ 8.9	48/ 9.1	50/ 9.3	56/ 10.4	52/ 9.6	49/ 9.1	59/ 10.9	77/ 14
Heart	21/4.0	13 /2.5	22/4.1	18/3.3	23/4.3	21/3.9	26/4.8	25/4.9
Lung	12/2.3	14 /2.6	15/2.8	23/4.3	27/5	15/2.8	17/3.1	24/4.4
Pancreas	-	0	2/0.4	1/0.2	8/1.5	10/2.8	15/2.8	17/3.1
Bowel	-	1	1/0.2	-	2/0.4	1	0	3/0.5
Number of living donor transplant procedures (total/pmp)								
Kidney	9/1.7	6 /1.1	11/2.0	13/2.4	11/2	13/2.4	15/2.8	15/2.7
Liver	0	0	0	0	0	0	0	0

[219] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

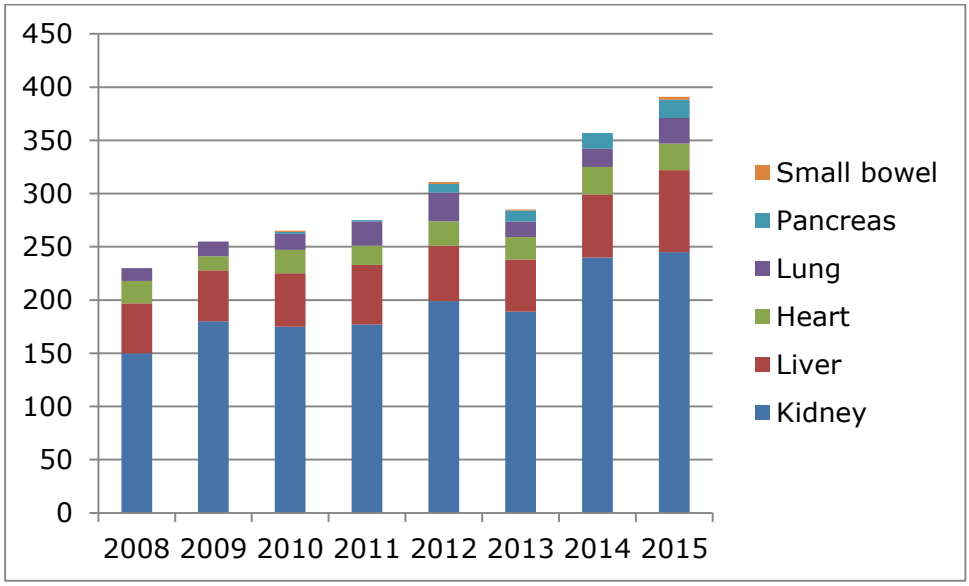
[220] Only percentages were given for 2008 and 2010.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Finland*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators appointed in all hospitals.
	+	Five Transplant donor coordinators at regional level. Transplant donor coordinators receive regular training.
	+	Training is arranged as part of the personnel training programmes of hospitals and professional networks.
	+	Ministry for Welfare and health started the process to nominate a national transplant donor coordinator. The national coordinator will have the responsibility to organize training on national level in the future.
	●	The training for transplant donor coordinators has not been tested for effectiveness.
	●	Finland does not use national or international accreditation schemes to qualify transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	Government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	+	Finland has directed[221] living donation programmes.
	●	Finland does not have undirected living donation programmes.
	+	There is an independent body that evaluates the living donor, before the start of the procedure.
	+	At national level, there are registers established to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public about organ donation and transplantation.
	+	Programmes are deployed to improve knowledge and communication skills of health professionals dealing with organ transplantation.
	●	No programmes are deployed to improve knowledge and communication skills of patient support groups on organ transplantation. However, patient support groups actively co-operate with governmental organisations.
	●	No periodic meetings with journalists were organized since the EU Action Plan was implemented.
Priority Action 5:	●	Finland does not provide easily accessible

[221] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

Facilitate the identification of organ donors across Europe		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	+	Finland has been involved in cooperation activities with Estonia.
	+	Transplant centre in Finland acts in Scandiatransplant network.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Finland has agreements with other organ exchange organisations in place regarding:
	+	Exchanging organs, collecting data with/for the country.
	●	Finland does not have agreements with other countries to prevent and address possible cases of organ trafficking.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	For the interchange of organs between national authorities, Finland is part of Scandiatransplant.
	+	All patients are involved in this interchange.
	+	Organs that are involved: liver, kidney, heart, lung, pancreas, small bowel.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, 3, 6 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Finland accepts donor organs from donors with diabetes mellitus, hypertension, renal insufficiency and donors aged over 60.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	●	Finland does not promote an accreditation system for procurement organisations and transplantation centres.

Participation in EU-funded projects during the Action Plan period (2009-2015)

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

Finland regularly contributed to annual Indicators' exercise prepared in the working group on indicators[222]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[223]).

Conclusions
Both Finland's deceased donation rate and living donation rate increased since 2008. This is positive. Chances may lie within DCD, expanded criteria donors and living donation.

Since the EU Action Plan, Finland published a national action plan (2015), nominated a national expert group on organ donation and transplantation and hospitals have set up working groups and audit systems.

[222] For more information about the working groups, see chapter 3.
[223] For more information about CD-P-TO, see Annex 3.

Finland's CA indicated some next steps at national level concerning the Action Plan:

1) keeping the donation working groups and audit systems active;
2) nominate a national donor coordinator;
3) work on training programs and
4) change the legislation in order to make kidney donation possible for non-family donors.

For the European cooperation, Finland indicated that it would be desirable to continue cooperation in the form of

1) working groups;
2) strengthen the cooperation between the field of tissues and cells;
3) have more attention for guidelines for the quality of laboratories;
4) prevention of criminal and illegal activities;
5) develop the reporting system for serious adverse reactions and
6) have more cooperation between competent authorities in general.

10. France

Background information[224]
With a deceased donation rate PMP of above 25 in 2015, France's deceased donation rate is amongst the highest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, heart-lungs, pancreases and small bowels.
With a living kidney donation rate PMP of less than 10 in 2015, France's living kidney donation rate PMP is among the lowest of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver.
Donated organs are allocated at the local and national levels and allocation is based on a scoring system. Together with Italy and Spain, France formed a new cooperation agreement, the South Transplant Alliance (SAT) (SAT, 2013).

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

Since 1976 ("Caillavet law"), an **opt-out system** (presumed consent) is in place. In practice, if the will of the deceased is not registered in the non-donor registry, the opinion of the **next-of-kin** is nevertheless respected if they can show evidences that the deceased person was opposed to donation or if they have very strong objections against organ donation. Refusal to be an organ donor can be expressed in the non-donor **register** from the age of 13 years or in a signed written document.

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

[224] Sources: FACTOR 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.

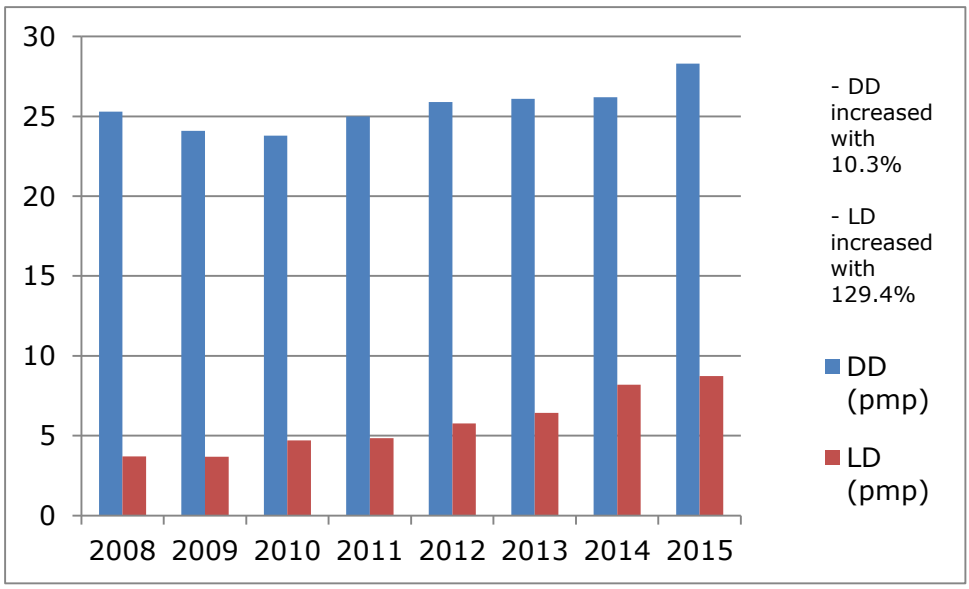
Key figures[225]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	63.6	63.9	64.7	65.1	63.5	64.3	64.6	64.4
Family refusal rate (refusals/times asked)	976/-	526/-	559/	616/-	727/-	700/-	716/-	738/-
Actual deceased donation rate (total/per million population, pmp)	1610/ 25.3	1543/ 24.1	1538/ 23.8	1630/ 25	1642 /25.9	1680/ 26.1	1695/ 26.2	1824/ 28.3
Multi-organ donation rates (% of total)	67.9%	70.8%	73.5%	73.1%	73.3%	74.3%	76.5%	73.8%
Number of utilised donors (total/per million population)	1490/ 23.4		1433/ 22.1	-	-	-	-	-
Number of donors after circulatory death - DCD	47	62	62	58	53	53	40	55
Number of donors older than 60	399		407	-	-	-	801	
Number of transplant centres								
Kidney	44	44	44	44	43	43	-	43
Liver	24	24	23	23	22	21	-	21
Heart	26	25	26	26	25	25	-	25
Lung	13	14	13	13	13	12	-	12
Pancreas	11	15	12	16	11	10	-	11
Bowel	5	6	6	6	5	4	-	2
Number of deceased donor transplant procedures (total/pmp)								
Kidney	2663/ 41.9	2603/ 40.7	2609/ 40.3	2674/ 41.1	2687/ 42.3	2673/ 41.6	2718/ 42.1	2939/ 45.6
Liver	990/ 15.6	1023/ 16.0	1067/ 16.5	1131/ 17.4	1144/ 18.0	1221/ 19.0	1263/ 19.6	1331/ 20.7
Heart	379/ 6.0	380/ 5.9	375/ 5.8	410/ 6.3	417/ 6.6	421/ 6.5	436/ 6.7	479/ 7.4
Lung	215/ 3.4	252/ 3.9	263/ 4.1	324/ 5.0	342/ 5.4	310/ 4.8	340/ 5.3	353/ 5.5
Pancreas	81/ 1.3	89 /1.4	96/ 1.5	73/ 1.1	72/ 1.1	85/ 1.2	79/ 1.2	78/ 1.2
Bowel	13/0.2	7 /0.1	9/0.1	10/0.2	7/0.1	3/0	3/0	3/0
Number of living donor transplant procedures (total/pmp)								
Kidney	222/ 3.5	223/ 3.5	283/ 4.4	302/ 4.6	357/ 5.6	401/ 6.2	514/ 8	547/ 8.5
Liver	10 /0.2	12 /0.2	17 /0.3	14 /0.2	9 /0.1	13 /0.2	12 /0.2	15 /0.2

- = not known to the research team

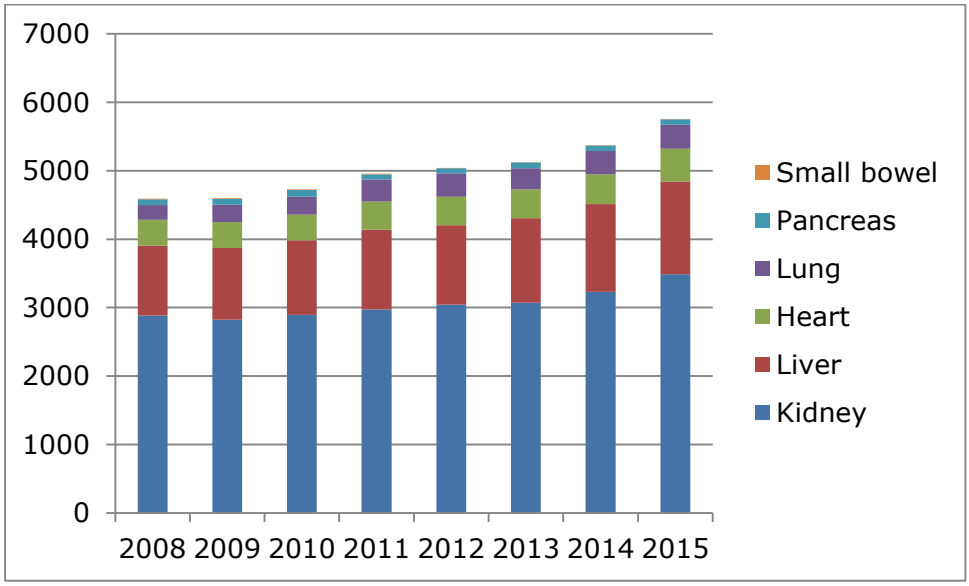
[225] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in France*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased, domino and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level, 186 MD and 694 nurses (some full time, but most of them part time or on duty).
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: We consider that the training course of a donor-coordinator should include a minimal number of procurement to be realised, a regional (Seminar of Initiation on the Procurement and transplantation), and a national training with 2 sessions per year and 50 participants per session, completed by 8 specific courses on the procurement activity.
	+	The trainings have been tested for effectiveness, but mid and long term evaluations are not easy.
	+	Hospital coordination teams are accredited by the National Authority for Health and activities as part of the national Hospital accreditation program and are authorised by the Regional Health Agencies (the Agence de la biomedicine is consulted). A Quality Assurance program (Cristal Action) has been developed Additionally, a self-evaluation manual was drafted by ABM, allowing donation coordination team to perform continuous quality control of their activity. Audits are conducted, they analyse the overall organisation of the coordination team based on defined items included in a formalised chart.
	+	The EU supported activities have contributed to the promotion of the role of the transplant donor coordinators, because they are open to other systems and practices.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan allowed comparison with other Member States quality control systems.
	+	EU supported activities have contributed to the promotion of Quality Improvement Programmes: ACCORD update of living donors follow-up register.
Priority Action 3: Exchange of best practices on living donation	+	France has a directed[226] living donation programme which was a priority in the 2012 - 2016 Action Plan. Main objectives of the national transplantation action plan 2012-2016 were: Promote coelioscopic technique for kidney retrieval (more than 90 %);

[226] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		Support motivated and active centres; Strengthen transplant coordination staff; Follow-up Register of living donors : improve items definition and exhaustivity of the data collected; A National study of Quality of Life was carried out that showed that « 98% of the living donors feel like they would do it again (if it were possible) »; Communication plan to professionals and patients (public in a 2nd time); Improve financial neutrality for the donor.
	●	There are no undirected living donation programmes.
	+	There is an independent body to evaluate the living donor's understanding of the donation process and the donor's consent before the start of the procedure of living donation.
	+	A register is established at the national level for the follow up of living donors.
	+	Organ trafficking is prohibited by law, but the 2015 Council of Europe Convention against organ trafficking has not yet been signed by France.
	+	National policy on living donation programs is influenced by the EU Action Plan: It was inspiring, living donation was enlarged to extended family donors and best friends. And programme for cross over donation was developed (between 2 pairs).
	+	EU supported activities did contribute to the promotion of living donation programs: COORENOR & ACCORD for Living donors practices, Living Donors tool kit/best.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. France deploys programs to improve knowledge and communication skills of all health care (hospital) personnel and patient associations.
	+	Periodic meetings have been organised with journalists and patient associations.
	●	Guidelines and deliverables developed by EU supported activities are used by the professionals.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	France does not provide information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in France: national residents, residents with a foreign nationality who die in France.
	+	Criteria required to be admitted to the waiting list: registration is done by the transplant team and must be confirmed by the director of the transplant centre (administrative control).
	+	5746 transplanted patients in 2015: 77.6 % were local residents, 20.4 % foreign residents, and 2 % non-residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.

	+	EU supported activities contributed to the identification of cross-border donors: COORENOR and FOEDUS facilitated and enhanced cross-border organ exchanges and FOEDUS even harmonized Donor evaluation and the quality of Organs being exchanged.
Priority Action 6: Enhancing organisational models	+	France is involved in twinning projects. Twinning activities led by the Agency of biomedicine in France consist of providing direct support to Member States from one to another by the mean of practical collaborations on the lines of the EU "Action plan on Organ Donation and Transplantation" (2009-2015) and the "Organ" Directive 2010/53/EU. • Thanks to this concrete transfer of expertise, the overall aim is to support candidates in developing their organ donation and transplantation system. Supported Member States seeking developments identified areas of interest and collaboration was organized with a supporting Member State showing extensive experience in the targeted area. Finally, three different twinnings were programmed 1) Twinning to develop a training programme for organ procurements in Hungary, 2) Twinning to develop the Bulgarian Transplant system, 3) Twinning to develop an Authorization and Audit system for Transplant Centres in Lithuania Cyprus, Malta and Czech republic. • Twinning with Moldova: to develop their transplant system and agency notably dealing with those activities. • Bilateral Cooperation with Swisstranplant: organ donation and transplantation. • France is part of the South Alliance for Transplant.
	+	These projects led to the following changes: Know-how exchanges, increased cross-border organ exchanges, paired cross-border living donation with Switzerland.
	●	France has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.
	+	Transplantation centres or hospitals participate in networks. Additionally each tool and guide developed by the Agence de la biomedecine is a national collaborative effort with professionals; depending on the targeted step, different professionals are called in working groups. Either for recommendations, tools, guidelines developed by the Council of Europe.
	●	The organisational model of the donation and transplantation system has not been influenced by the EU Action Plan.

	+	EU supported activities contributed to enhancing the organisational model of the donation and transplantation system: COORENOR thanks to the mapping of other MS systems in place. ACCORD thanks to the twinning activities and the training/ certification of surgeons for abdominal organ retrieval.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	France has agreements with other countries for exchanging organs (Bilateral agreement with Swisstransplant, Member of the South Alliance for Transplant (SAT)), mainly organ exchange through the Foedus platform and liver exchange through a bilateral agreement with Swiss transplant).
	●	France has no agreements with other countries to prevent and address organ trafficking: the main challenges are: Worldwide: Lack of tight regulation and traceability even in Europe; Lack of transplant programmes and regulating/ controlling agencies in some countries. However France has been conducting regular surveys since 2006, among transplant and dialysis centres, to identify patients who went abroad (outside the EU) to be transplanted.
	+	Future research programmes should ideally focus on Quality and safety: bio-vigilance register and DO's procedures; Training for surgeons; Training for coordinators; Donor management: guideline and training; Training on the use of perfusion machines; Setting bilateral agreement for paediatrics transplant.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	+	EU supported activities: COORENOR, ACCORD, and FOEDUS contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	France is part of a fixed collaboration: a multi-lateral collaboration, namely the South Alliance for Transplants (SAT), and of bilateral collaborations, with neighbouring countries.
	+	Patient groups involved are: all patients, patients with urgent needs for transplantation, highly immunised and Paediatric patients for instance.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	In 2015 10 organs came from abroad, 30 organs left the country.
	+	France has offered non-allocated organs to other countries, the organs involved were liver, kidney, heart and lung.
	+	Procedures for offering non allocated organs to other countries are evaluated.
	+	France participates in the use of the FOEDUS IT-platform for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
	+	EU activities COORENOR and FOEDUS contributed to the interchange of organs between countries.

Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are evaluated 1, 3, 6 and 12 months after transplantation and then on a regular basis to evaluate the graft or the patient long term survivals.
	+	Organs are accepted from donors with comorbidities (extended criteria donors): diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors older than 60 years.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute, to the evaluation of post-transplant results: France had already an evaluation programme in place.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are authorized by the regional health agencies.
	●	The EU Action Plan has not influenced national policy on the promotion of authorisation and accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, France was coordinator of the Alliance-O project[227] 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, France participated in the working group on indicators[228] 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[229]). 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.

Conclusions

Both France's deceased donation rate and living donation rate have increased since 2008. This is very positive. The challenge for France would be to maintain this development.

France's CA indicated that the important topics for European attention would be: biovigilance systems, quality improvement programmes, cross border exchange of donors.

[227] For more information about EU-funded projects, see chapter 3.
[228] For more information about the working groups, see chapter 3.
[229] For more information about CD-P-TO, see Annex 3.

11. Germany

Background information[230]
With a deceased donation rate PMP between 10 and 20 in 2015 Germany belongs to the majority of the countries included in this study, though these rates are decreasing. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.

With a living kidney donation rate PMP of around 8 in 2015, Germany's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver. Austria has a relatively high number of lung transplants, with more than 100 lung transplants a year.
Germany is part of Eurotransplant[231] and donor organs are allocated through Eurotransplant.

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

Since November 5th 1997 an **opt-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 not known, 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.

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

[230] Sources: FACTOR 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.

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

Key figures[232]

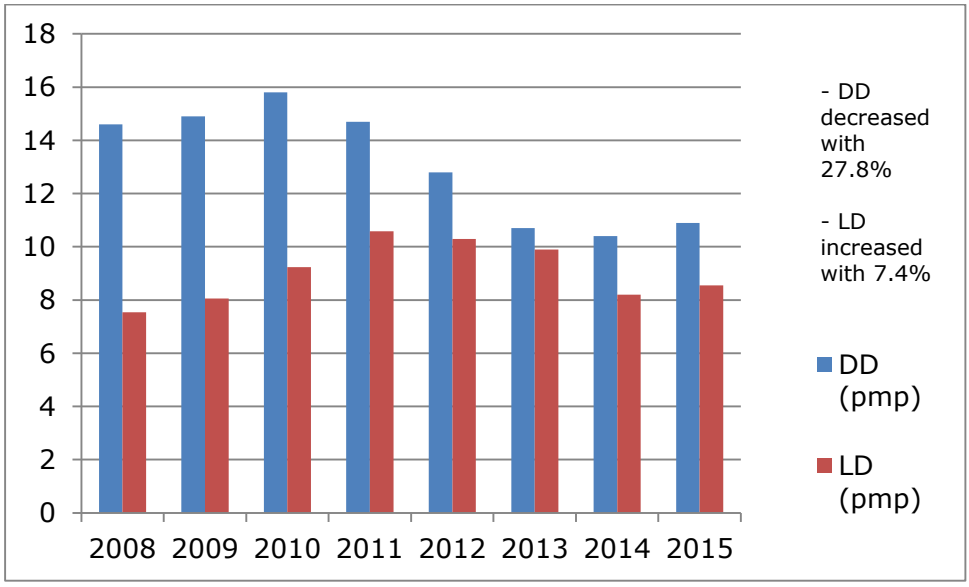
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	82.2	81.9	81.8	81.8	82	82	82.7	80.7
Family refusal rate (refusals/times asked)	-	-	-	-	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	1198/ 14.6	1217/ 14.9	1296/ 15.8	1200/14.7	1046/ 12.8	876/ 10.7	864/ 10.4	877/ 10.9
Multi-organ donation rates (% of total)	85.3	86.2	87.0	86.8	90.3	89.9	88.9	88.3
Number of utilised donors (total/per million population)	1183/ 14.4	1197/ 14.6	1270/ 15.5	1177/ 14.4	1023/ 12.5	866/ 10.6	851/ 10.3	863/ 10.9
Number of donors after circulatory death - DCD[233]	-	-	-	-	-	-	-	-
Number of donors older than 60	396	453	479	441	417	307	313	345
Number of transplant centres								
Kidney	40	40	40	40	39	39	39	39
Liver	24	24	24	24	24	24	24	23
Heart	27	26	26	25	25	24	24	24
Lung	17	17	16	17	16	16	16	16
Pancreas	27	27	27	27	26	26	26	26
Bowel	9	9	9	9	9	9	9	9
Number of deceased donor transplant procedures (total/pmp)								
Kidney	2188/ 26.6	2172/ 26.5	2272/ 27.8	2055/ 25.1	1820/ 22.2	1547/ 18.9	1508/ 18.2	1551/ 19.2
Liver	1060/ 13.0	1119/ 13.7	1187/ 14.6	1116/ 13.8	1017/ 12.4	884/ 10.8	879/ 10.7	846/ 10.5
Heart	382/ 4.6	363/4.4	393/ 4.8	366/ 4.5	345/ 4.2	313/ 3.8	304/ 3.7	286/ 3.5
Lung	270/ 3.3	272/ 3.3	298/ 3.6	337/ 4.1	357/ 4.4	371/ 4.5	352/ 4.3	297/ 3.7
Pancreas	137/ 1.6	115/ 1.4	163/2.0	171/ 2.1	161/ 2	128/ 1.6	120/ 1.5	105/ 1.3
Bowel	11/0.1	8 /0.1	10/0.1	9/0.1	6/0.1	5/0.1	6/0.1	1/0.0
Number of living donor transplant procedures (total/pmp)								
Kidney	565/ 6.9	600/ 7.3	665/ 8.1	795/ 9.7	766/ 9.3	725/ 8.8	619/ 7.5	645/8
Liver	55/0.7	60 /0.7	91/1.1	71/0.9	78/1	83/1	58/0.7	45/0.6

- = not known to the research team

[232] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

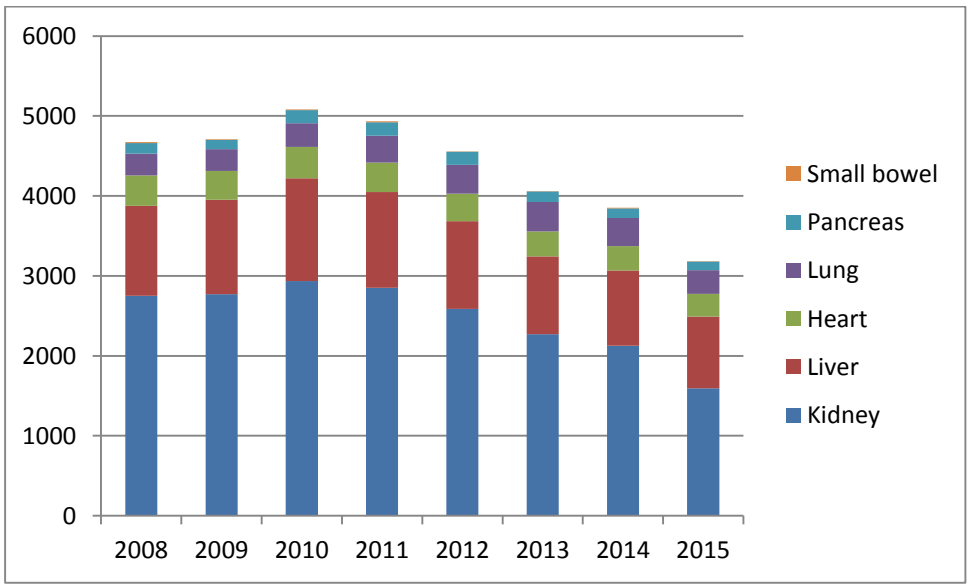
[233] Donation after Circulatory Death (DCD) is, by law, not allowed in Germany.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Germany*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level 1689, however the main role is taken by a limited number of coordinators at the national level (88).
	+	Transplant coordinators receive both initial and regular training. It is not fully clear how this varies between local and national coordinators.
	+	Summary of the training: Training on the job (organ protective intensive care medicine, management of brain death diagnosis), basic training course (organ transplantation, ethics, communication skills, law/agreements, EDP, finances, quality management), communication seminars, advanced training courses (Organ Donation, Indications, contraindications, risk evaluation / expanded donor criteria Brain Death Diagnosis Organ Protective Intensive Care Medicine Crisis Intervention Skills (family-care, consent) Organ Removal Techniques Organ Preservation Team-/ Organ Transports), periodical "refresher" seminars (Updated Items of Training-Courses Hospital Consultation (Role-play/Video) Family Care (Role-play/Video) Organ Protective Therapy (Simulator-Training).
	●	The trainings have not been tested for effectiveness. Interest was expressed, but not yet implemented, to improve training programmes at local level.
	+	Germany uses an accreditation scheme: Accreditation by the Aerztekammer (German Medical Association).
	+	The EU Action Plan has influenced national policy on transplant donor coordinators - The German Transplant Act was amended in 2012 making the appointment of an in-house transplant coordinator in donor hospitals mandatory and clearly defining their responsibilities (in line with PA1). - In transposition of Article 4 of Directive 2010/53/EU the German Transplantation Act foresees that the German organ procurement organization (DSO) adopts and implements operating procedures for specific parts of the donation process and that these are binding also for all donor hospitals (in line with PA 2). - The German Medial Association has developed a framework for the training of in-house transplant coordinators that includes training of communication skills of all in-house coordinators (in line with PA 4). The donor coordinators of the DSO have been and continue to be trained in communication skills already for many years (s.a.).

	+	EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: The manual developed by the working group of deceased donation is one of the reference documents used in the training of coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: - In transposition of Article 4 of Directive 2010/53/EU the German Transplantation Act foresees that the German organ procurement organization (DSO) adopts and implements operating procedures for specific parts of the donation process and that these are binding also for all donor hospitals (in line with PA 2). - The guidelines for the determination of irreversible cessation of brain function (brain death) as one of the central aspects of donor identification includes the obligation for every donor hospital to develop OPs for the organisation of the determination of brain death in the donor hospital.
	+	EU supported activities have contributed to the promotion of Quality Improvement Programmes: The manual developed by the working group of deceased donation is one of the reference documents used in the training of coordinators.
Priority Action 3: Exchange of best practices on living donation	+	Germany has directed[234] living donation programmes. In the Czech Republic, Finland, Germany, Hungary, Italy, Poland and Sweden, in addition to the listed relationships, additional donor-recipient relationships are possible due to an open clause. The regulations in Finland, Germany and Hungary usually require a-specific donor-recipient relationship, but a LOD might also be legal if there is a close personal relationship between donor and recipient. The details of the rules differ, though. Living donation is prohibited when a deceased organ is available. In Germany, for example, the distinction between regenerative and non-regenerative organs is relevant with regard to the donor-recipient relationship. The removal of a kidney, part of a liver or other non-regenerative organ, is only admissible for the purpose of transplanting to relatives of the first or second degree, spouses, registered life partners,

[234] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		fiancés or other persons with whom the donor obviously entertains an especially close personal relationship.
	●	There are no undirected living donation programmes Germany.
	+	At present (January 2016) 43 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not ratified by Germany.
	●	National policy on living donation programs is not influenced by the EU Action Plan.
	+	EU supported activities contributed to the promotion of living donation programs: Representatives of different transplant centers and the procurement organization (DSO) and the allocation organization (Eurotransplant, ET) actively participated in the different projects and meetings and reported key findings/proposals back to the German authorities and the German transplant community.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. According to the German Transplantation Act the "Bundeszentrale für die gesundheitliche Aufklärung" responsible for public information on organ donation and organ transplantation is obliged to inform the public without prejudice on the complete scope of the decision to donate organs, tissues and cells.
	+	Germany deploys programs to improve knowledge and communication skills for all health care (hospital) personnel and for patient support groups.
	●	Periodic meetings with journalists have not been organised.
	+	Guidelines and deliverables developed by EU supported activities are used for informing the public, improving knowledge and skills of health professionals, and improving knowledge and skills of patient support groups.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: One of the WP leaders resulting in the development of a communication handbook in the FOEDUS project was the German organ procurement organization (DSO). The "Bundeszentrale für gesundheitliche Aufklärung" closely collaborated with the DSO.
	+	EU supported activities contributed to the promotion of public awareness: many of the measures undertaken by the "Bundeszentrale für die gesundheitliche Aufklärung" coincide with the measures proposed in the FOEDUS project.

Priority Action 5: Facilitate the identification of organ donors across Europe	+	Germany provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. The "Bundeszentrale für die gesundheitliche Aufklärung" also informs the public about the regulation of organ donation in other countries via brochures and in the internet. (https://www.organspende-info.de/infothek/ gesetze/europa-regelungen). In this context the public is informed that the German organ donor card "Organspendeausweis" is valid in other countries. In order to facilitate this the "Bundeszentrale für die gesundheitliche Aufklärung" also provides for translations of the organ donor card in all 24 official languages of the European Union and in Russian and makes them available in the internet to be downloaded.
	+	The following people can legally be donors in Germany: residents with a foreign nationality who die in Germany, non-residents who die in Germany and illegal persons who die in Germany.
	+	The decision regarding the placement on the waiting list is based solely on medical grounds and on rules that reflect the current state of medical knowledge, especially the necessity of an organ transplant and its chances of success.
	+	0,5 % of transplanted patients are non-residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors, as member state within Eurotransplant Germany has always been very active.
Priority Action 6: Enhancing organisational models	●	Germany is not involved in twinning projects.
	●	Transplantation centres or hospitals do not participate participate in any networks of centers of reference.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: The German Transplant Act was amended in 2012 making the appointment of an in-house transplant coordinator in donor hospitals mandatory and clearly defining their responsibilities (in line with PA1).
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Germany has agreements with other countries for exchanging organs (Eurotransplant), collecting data (ELTR, ERA-EDTA registries…): Eurotransplant collects data for Germany and exchanges data with different registries according to consent from the centers, and for research activities: The member states within Eurotransplant support research on organ allocation and transplantation.

	+	Germany has agreements with other countries to prevent and address organ trafficking. The main challenges are: Organ shortage remains the main challenge with regard to organ trafficking.
	+	Suggestions for future research programmes: With regard to the cooperation within Eurotransplant it is research on allocation, allocation development, outcome of transplantation.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Germany is part of a multi-lateral collaboration, Eurotransplant.
	+	Patient groups involved in this collaboration are: all patients.
	+	Organs involved are liver, kidney, heart, lung and other, being pancreas, small bowel.
	●	No information about how many organs came from abroad, or left the country. Germany is a member state of Eurotransplant.
	●	Germany has not offered non-allocated organs to other countries, there were no 'non allocated' organs.
	●	Evaluation procedures for offering non allocated organs to other countries are not applicable.
	●	Procedures for the exchange of organs of urgent and difficult-to-treat patients are not applicable, Germany is a member state of Eurotransplant.
	●	Participation in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange is not applicable.
	●	Influence of the EU Action on the national policy on the interchange of organs is not applicable.
	●	Contribution of EU activities to the interchange of organs between countries is not applicable, Germany is a member state of Eurotransplant.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level: results are systematically collected in a database/register at national level.
	+	Results are measured 3 and 12 months after transplantation and currently yearly up to three years, extension of the follow-up period is planned.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors older than 60 years.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	+	EU supported activities contributed to the evaluation of post-transplant results: structure and principles for data set of the planned transplant register will take into account the EFRETOS data set.

Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis but Germany not yet promotes an accreditation system for transplantation centres, but it is planned by 2017 (year).
	+	The following accreditation systems are used: - for donation (coordinators): specialisation and training, regional (Landesaerztekammern) and national - for procurement (surgeons): specialisation and training, national (Bundesaertzekammer, Deutsche Transplantationsgesellschaft) - for transplantation: specialisation (Zusatzweiterbildung Transplanta-tionsmedizin), national Bundesaertzekammer, Deutsche Transplantationsgesellschaft) - for other staff involved in donation and transplantation: national (Deutsche Transplantationsgesellschaft.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Germany was core work package leader in the projects ELIPSY[235] (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 2012, the country participated in the working group on indicators[236] 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[237]).

Conclusions

Germany's deceased donor rate decreased since 2008, and the living donor rate increased since 2008.

Germany has a long tradition of organ donation and transplantation. According to the German CA Prioriy Action (PA) 1 has been important for them, because it has reinforced Germany's own actions and supported the amendment of transplant laws in Germany. Next to the coordinators of the German organ procurement organization who are responsible for the coordination of the organ donation and procurement process, in 2012 so-called transplant donor responsible persons were mandatorly introduced at all potential donor hospitals in Germany. They are mainly responsible for identifying potential donors and rising awareness for organ donation among hospital personell. In addition, PA 4 (improve knowledge) has been valuable, especially the cooperation with other countries, and PA 9 (evaluation of post-transplant results) has been valuable in Germany as support for the amendment of the transplant law and the establishment of a national register.

A few years ago there was a transplant scandal in Germany and that has led to a loss of public trust. As a consequence a series of measures were taken to intensify

[235] For more information about EU-funded projects, see chapter 3.
[236] For more information about the working groups, see chapter 3.
[237] For more information about CD-P-TO, see Annex 3.

supervision as well as increase transparency in organ transplantation and thereby attain public trust. German CA's state that to increase the donation rate, Germany needs not only to regain the public trust, but also to investigate why the donation rate is so low in Germany. It needs to be better able to identify possible donors locally within the hospitals, in the context of end-of-life care. In this context focus on the wishes of donors is of crucial importance. Now that the transplantation law has been amended and a national register is installed, the focus is on implementing this law. Key words are: quality, safety, organizational capacity and transparency.

EU cooperation should continue regarding the in-hospital organ transplant coordinator. They need to find their place in the hospitals and within the organ donation process.

EU cooperation is also important to improve transparancy, to exchange data between different countries and to learn from each other. More standardisation is needed but complete harmonisation should not be a goal because the countries are too different, not only in size but also in culture. Learning from each other through this platform is essential.

12. Greece

Background[238]
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 PMP under 5 in 2015, Greece's deceased donation rate PMP is amongst the lowest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers and hearts.
With a living kidney donation rate PMP of less than 5 in 2015, Greece's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.
Donor organs are allocated at national level.

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

Since 2013, an **opt-out system (presumed consent)** is in place. After death of a citizen who had not expressed any opposition to donation during his/her life, a family's written consent is required.

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

[238] Sources: FACTOR 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.

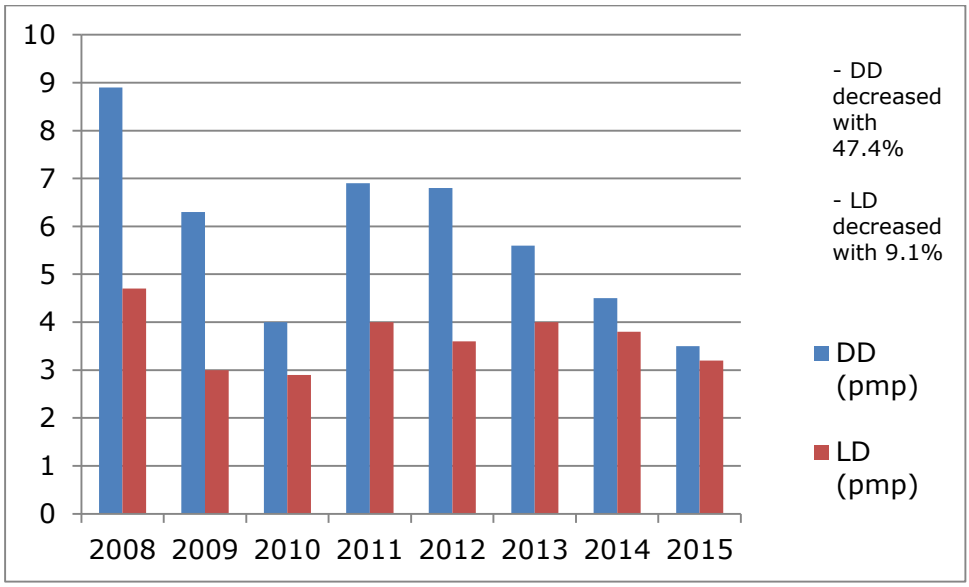
Key figures[239]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	11.0	11.2	11.2	11.4	11.4	11.1	11.1	11.0
Family refusal rate (refusals/times asked)	53/158	18/110	6/13	-	40/117	32/122	-	-
Actual deceased donation rate (total/per million population, pmp)	98/8.9	71 /6.3	45/4.0	79/6.9	77/6.8	62/5.6	50/4.5	39/3.5
Multi-organ donation rates (% of total)	79.6	71.8	87.0	64.6	85.7	83.8	92	79.5
Number of utilised donors (total/per million population)	98/8.9	71 /6.3	45/4.0	79/6.9	77/6.8	62/5.6	50/4.5	39/3.5
Number of donors after circulatory death - DCD[240]	0	0	0	0	0	0	0	0
Number of donors older than 60	17	-	8	-	20	21	7	10
Number of transplant centres								
Kidney	4	4	5	5	5	5	5	5
Liver	2	2	1	1	1	1	1	1
Heart	1	1	1	1	1	1	1	1
Lung	1	1	1	0	0	0	0	0
Pancreas	1	1	0	1	0	0	0	0
Bowel	0	0	0	0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	186/ 16.9	116/ 10.4	76/ 6.8	137/ 12.0	130/ 11.4	107/ 9.6	88/ 7.9	63/ 5.7
Liver	58/5.3	33 /2.9	25/2.2	40/3.5	47/4.1	31/2.8	27/2.4	22/2.0
Heart	16/1.5	8 /0.7	5/0.4	6/0.5	18/1.6	9/0.8	12/1.1	6/0.5
Lung	3/0.3	3 /0.3	2/0.2	0	0	0	0	0
Pancreas	2/0.2	3 /0.3	0	1/0.1	0	0	0	0
Bowel	0	0	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	52/4.7	34 /3.0	32/2.9	46/4.0	41/3.6	44/4.0	42/3.8	35/3.2
Liver	0	0	0	0	0	0	0	0

[239] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

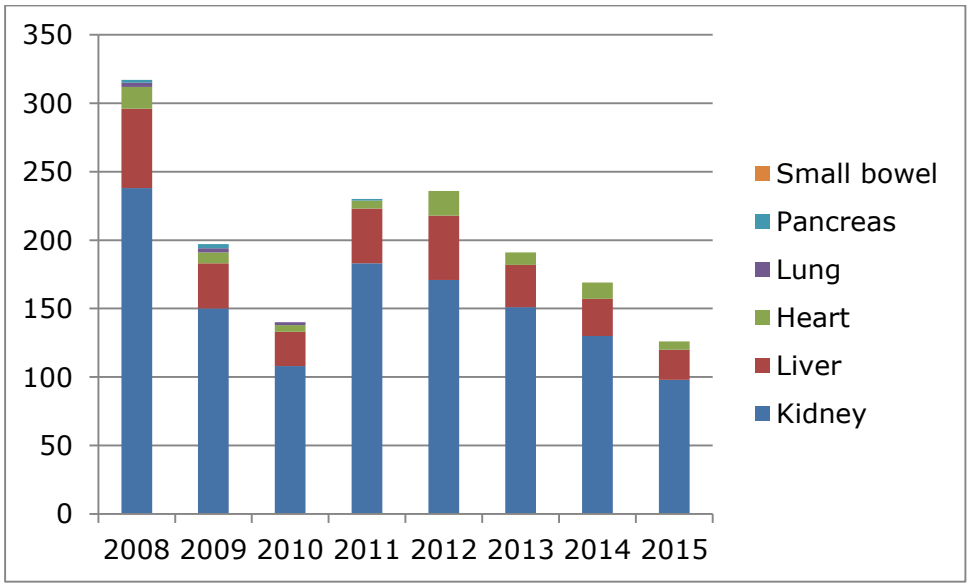
[240] Donation after Circulatory Death (DCD) is not allowed in Greece.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Greece*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 100 at the local/hospital level, 3 at the regional level and 5 at the national level.
	+	Transplant donor coordinators receive specific training: Seminars organised by EOM.
	+	Summary of the training: Training of the local coordinators and other health professionals from our hospitals in order to create teams for the early detection of donors, the improvement of family approach and the preservation of the donor, with the ultimate purpose to increase donation and transplantation.
	●	The trainings have not yet been tested for effectiveness.
	+	Greece uses an accreditation scheme to qualify transplant donor coordinators: TPM training course and 1 year training course in Greece (6 month in the ICU and 6 months in the Hellenic Transplant Organization.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: To create regional branches and, in a local level, teams in the ICU. Educate transplant donor coordinators.
	+	EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: Coordinators were trained in order to train other Coordinators. ETPOD courses are performed very often in hospitals.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process and the procurement process.
	+	The national policy on Quality Improvement Programmes will be influenced by the EU Action Plan.
	●	EU supported[241] activities did not contribute to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Greece has directed living donation programmes. So far directly living donation is performed only for kidney transplantation.
	+	There also are undirected living donation programmes: So far undirected living donation is performed only for kidney transplantation and only after a relevant judgment decision.
	+	4 hospitals have a living donation program.

[241] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	●	There is no independent body to evaluate the living donor before the start of the procedure.
	●	There are no registers established to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Greece has not yet ratified the Council of Europe Convention.
	+	National policy on living donation programs will be influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Greece deploys programs to improve knowledge and communication skills of for all health care (hospital) personnel but not yet for patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan.
	+	The EU supported activities contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	Greece provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Greece: residents with a foreign nationality who die in Greece, and non-residents who die in Greece.
	+	Criteria required to be admitted to the waiting list: residency in Greece, local nationality and signed up with local social security or health care insurance.
	+	National policy on cross-border donation will be influenced by the EU Action Plan.
	+	EU supported activities contributed to the identification of cross-border donors: FOEDUS (exchanging surplus organs from our donors and from donors abroad).
Priority Action 6: Enhancing organisational models	+	Greece is involved in twinning projects, as member of two bilateral collaborations. Topics are: Exchange organs, Transplantation of urgent and paediatric patients (liver, heart) and patients who require lung transplantation in collaboration with Italy and Vienna.
	+	These projects lead to changes: Organ transplantation of urgent and paediatric patients (liver, heart) and patients who require lung transplantation.
	●	Greece has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.

	+	Transplantation centres or hospitals participate in networks of reference: For liver transplantation (especially for patients who need an urgent transplantation and for paediatric liver transplantation from a living or deceased donor) with CNT - Italy and lungs with Eurotransplant-Vienna (our Lungs Transplant Centre is not yet in operation).
	+	The organisational model of the donation and transplantation system will be influenced by the EU Action Plan.
	+	EU supported activities, especially ACCORD, contributed to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Greece has agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, and training/certifying health care professionals (surgeons, coordinators).
	●	Greece does not have agreements with other countries to prevent and address organ trafficking.
	+	Future research programs should focus on: - Training - Increase number of donors - Family Approach - Communication skills.
	+	The development of EU-wide agreements is influenced by the EU Action Plan.
	+	EU supported activities contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Greece has bilateral agreements / collaborations with Eurotransplant (for lung transplantation) and with Italy (for urgent liver / paediatric liver and paediatric heart transplants). Patient groups involved are: Patients with urgent needs for transplantation and paediatric patients.
	+	In 2015 2 organs came from abroad, 9 organs left the country.
	+	Greece has offered non-allocated organs to other countries, 12 lungs, 4 hearts, 5 kidneys, 4 livers (during 2015).
	●	Procedures for offering non-allocated organs are not yet evaluated.
	+	Greece has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, heart and lung. 9 (2013-today) organs have been exchanged.
	●	Greece does not yet participate in the use of an IT-tool for the facilitation of cross-border exchange, but participation in FOEDUS is planned in 2016.
	+	The national policy on the interchange of organs is influenced by the EU Action Plan.
	+	EU activities FOEDUS and ACCORD contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at national level.

	+	Results are measured 12 months after transplantation.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors older than 60 years.
	+	The national policy on the evaluation of post-transplant results will be influenced by the EU Action Plan.
	+	EU supported activities contributed to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	●	Greece does not yet promote an accreditation system for procurement organisations and transplantation centres.
	+	National policy on the promotion of accreditation systems is influenced by the EU Action Plan.
	+	EU supported activity ACCORD contributed to the promotion of accreditation systems through a training course in transplant donor coordination.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects Greece is horizontal work package leader in the EU funded project FOEDUS[242] (work package on evaluation). Greece withdrew from participation in COORENOR. In addition it was a partner in ETPOD, EFRETOS and ODEQUS and is a partner in ACCORD.

In 2011, the country participated in the annual data collection launched by the working group on indicators[243] 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[244]).

The Action Plan contributed at the benchmarking of the donation activity (detect problems and find a solution, opinion exchange), the study of best practices, the prioritization of goals, and at making an effort to adopt and adapt all the necessary practices.
Priorities of Greece for the next 5 years are: to increase the donors pools, to create more transplant structures, to educate the appropriate personnel, to establish branches and to increase public awareness.
From the Greek point of view the EU could be helpful to deal with organ and patient exchange, to create registries that may communicate and establish a better legal frame for the living donation from unrelated or non-resident donors.

Conclusions
Greece was among those countries with good levels of deceased donations. However, these rates decreased since 2008. Also the living donation rate slightly decreased during the timeframe of the Action Plan. A key goal for Greece should be to come to and stabilize the transplant numbers of 2008.

[242] For more information about EU-funded projects, see chapter 3.
[243] For more information about the working groups, see chapter 3.
[244] For more information about CD-P-TO, see Annex 3.

13. Hungary

Background information[245]

In Hungary the first human kidney transplantation was performed in 1962. With a deceased donation rate PMP of above 20 in 2015, Hungary belongs to the countries with a higher deceased donation rate in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, hearts, lungs and pancreases.
With a living kidney donation rate PMP of less than 5 in 2015, Hungary's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.
Donor organs are allocated at national level. Since 2012, Hungary is officially part of Eurotransplant (R. Langer, 2011; RM Langer, Cohen, & Rahmel, 2012; R. M. Langer, 2012).

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

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

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.

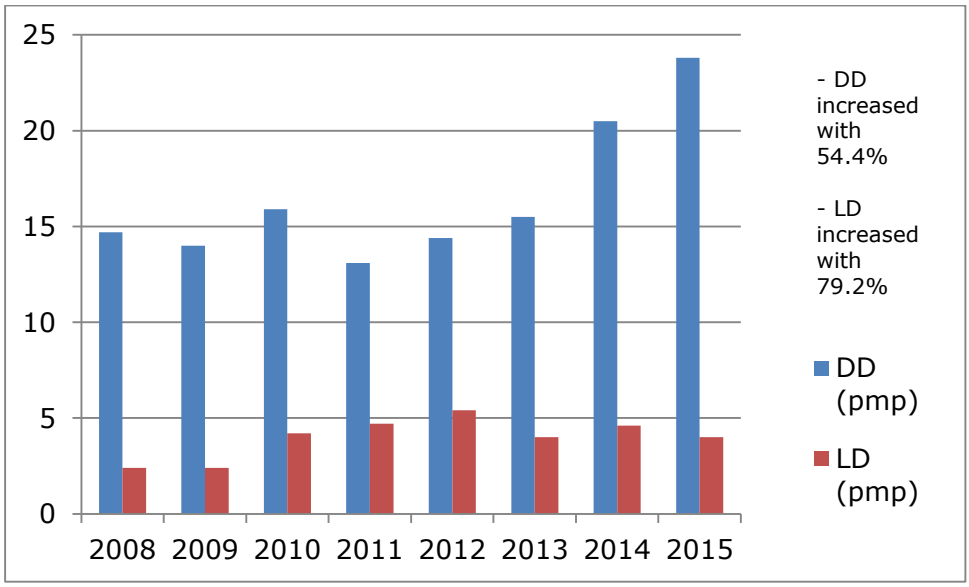
[245] Sources: FACTOR survey filled in by national Competent Authority, and information additionally provided; Borsi, J. D., Borka, P., Tornai, E., Mihaly, S., Deme, O., & Mina, A. (2005). Results of a multilateral approach to donation-transplantation process in Hungary in the past 2 years. Transplant 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., Bešireviæ, 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.

Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	10.1	10.0	10.0	10.0	9.9	10	9.9	9.9
Family refusal rate (refusals/times asked)	11/148	11/222	14/243	11/209	12/195	12/212	-	-
Actual deceased donation rate (total/per million population, pmp)	148/ 14.7	140/ 14.0	159/ 15.9	131/ 13.1	143/ 14.4	155/ 15.5	203/ 20.5	236/ 23.8
Multi-organ donation rates (% of total)	41.2	42.8	43.4	41.2	52.4	67.1	70.4	55.5
Number of utilised donors (total/per million population)	134/ 13.3		151/ 15.1	-	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	0	0	0	0	0
Number of donors older than 60	6		7	-	-	-	42	
Number of transplant centres								
Kidney	4	4	4	4	4	4	4	4
Liver	1	1	1	1	1	1	1	2
Heart	2	2	2	2	2	2	2	2
Lung	0	0	0	0	0	0	-	1
Pancreas	2	2	2	2	2	2	1	2
Bowel	-	0	-	-	0	0	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	235/ 23.3	250/ 25.0	265/ 26.5	204/ 20.4	223/ 22.5	251/ 25.1	341/ 34.4	303/ 30.6
Liver	36/ 3.6	40/ 4.0	43/ 4.3	41/ 4.1	41/ 4.1	45/ 4.5	-	89/ 9
Heart	22/ 2.2	24/ 2.4	20/ 2	14/ 1.4	33/ 3.3	45/ 4.5	58/ 5.9	51/ 5.2
Lung	-	-	-	-	-	-	-	1/0.1
Pancreas	5/0.5	9 /0.9	9/0.9	10/1	6/0.6	14/ 1.4	14/ 1.4	13/ 1.3
Bowel	-	-	-	-	-	-	-	0
Number of living donor transplant procedures (total/pmp)								
Kidney	24/ 2.4	24/ 2.4	42/ 4.2	47/ 4.7	53/ 5.4	40/ 4	46/ 4.6	40/ 4
Liver	0	0	0	0	0	0	0	0

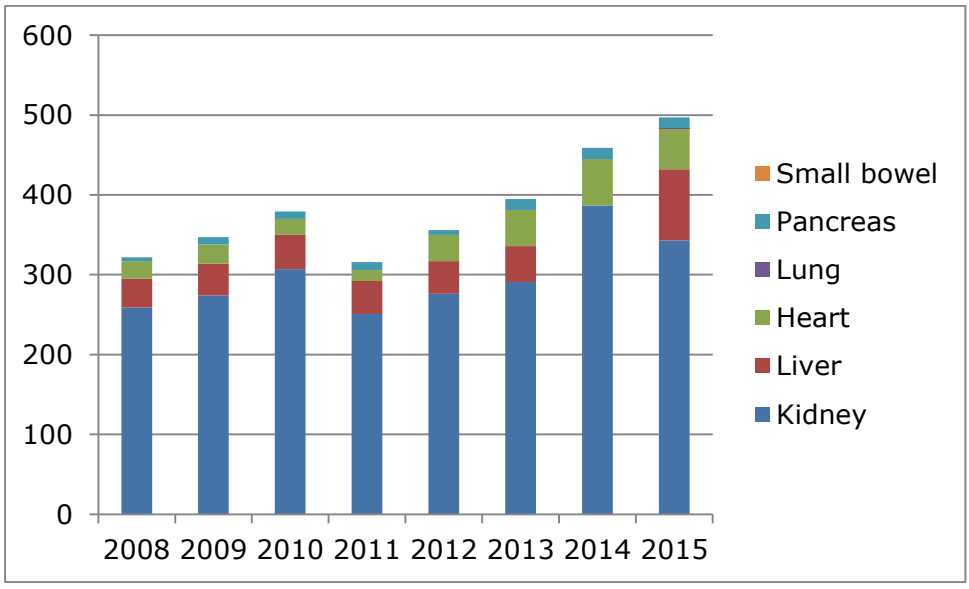
- = not known to the research team

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Hungary*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 18 at the local/hospital level, 10 at the regional level and 6 at the national level.
	+	Transplant donor coordinators receive initial training.
	+	The trainings have been tested for effectiveness.
	●	Hungary uses no accreditation scheme to qualify transplant donor coordinators.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: - Priority action 1 was implemented in 18 hospitals until now - Priority action 2 was implemented in all hospitals with local coordinators - Priority action 3: national living donor register is under construction - PA4: Hungary has national training program for MDs involved in donor procedures - PA6: after a long lasting twinning program for lung transplant, Hungary started the national lung TX program in close collaboration with Vienna - PA7-8. Hungary became Eurotransplant member state in 2013.
	+	EU supported activities contributed to the promotion of the role of the transplant donor coordinators: The national training program was modified after the Hungarian participation at the European Training Course.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process and the transplantation process.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: The Hungarian proposal to have QAP for organ donation was based on the Action Plan.
	●	EU supported activities did not contribute to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Hungary has directed[246] living donation programmes Hungary requires the consent of the donor to be approved by a public authority. Hungary explicitly requires the recipient to consent as well. Hungary prefers to perform transplant from deceased donor if suitable organ is available. In Hungary, LOD may be possible if the donor is a lineal kin of the recipient, a sibling of a lineal kin of the recipient, a sibling of the recipient, a lineal kin of a sibling of the recipient. LOD is also possible for

[246] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		exceptional cases, however, LOD is only permitted after a hospital ethics committee has established that the donation has taken place with consideration, without force, duress, coercion or deception. Paired exchange donation is also allowed.
	+	There also are undirected living donation programmes, but only in case of paired exchange donation.
	+	4 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Hungary has not ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan: through establishment of the national living donor register.
	●	No information whether EU supported activities contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Hungary deploys programs to improve knowledge and communication skills of for healthcare professionals involved in transplant program and patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public and to improve knowledge and skills of health professionals.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: Hungary organized the Council of Europe European Organ Donation Day in 2012. Hungary organizes this annual celebration for ca. 8 years.
	●	No information whether The EU supported activities contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	Hungary provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU: Via our official webpage.
	+	People from outside Hungary cannot legally be donors in Hungary.
	+	Criteria required to be admitted to the waiting list: being signed up with local social security or health care insurance.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational	+	Hungary is involved in twinning projects, in a teaching role. These projects did not yet lead to

models		changes.
	●	Hungary is interested in structural funds for the purpose of the development of transplantation systems, but has not used them yet.
	+	Transplantation centres or hospitals participate in networks: Semmelweis University; Transplantation and Surgical Dept. acquired UEMS joint accreditation with Oslo and Groningen.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: We recently renewed our donor coordination network. HNBTS established new type of position for coordinators, as procurement coordinator, and new lung transplant center coordinator positions.
	●	No information whether EU supported activities contributed to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Hungary has agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, training/certifying health care professionals (surgeons, coordinators) and collecting data. Hungary is a Eurotransplant full member since 2013. The Hungarian lung transplant programme is maintained with close collaboration with Vienna. We have national training programme for donor coordinators and procurement surgeons. HNBTS provide data for international registries.
	●	Hungary does not have agreements with other countries to prevent and address organ trafficking: the main challenges are Hungary could theoretically and possibly be involved in organ tourism.
	+	HNBTS started to collect center specific data in order to measure and identify possible cases.
	+	Future research programmes should focus on Machine perfusion.
	●	The EU Action Plan has not influenced the development of EU-wide agreements.
	●	EU supported activities have not contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Hungary is part of a fixed collaboration: a multilateral collaboration, namely Eurotransplant and of bilateral collaborations with Austria.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	In 2015 102 organs came from abroad, 185 organs left the country.
	+	Hungary has not offered non-allocated organs to other countries, there were no 'non allocated' organs.
	●	Procedures for offering non-allocated organs are not evaluated.
	+	Hungary has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, kidney, heart, lung and

		pancreas. A total of 16 organs were exchanged.
	+	Hungary participates in the ET IT-tool for the facilitation of cross-border exchange.
	●	The EU Action Plan has not influenced the national policy on the interchange of organs.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	●	Post-transplant results of organ recipients are not yet evaluated on a national level.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency and from donors older than 60 years.
	●	The EU Action Plan did not influence the national policy on the evaluation of post-transplant results.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	●	Hungary not yet promotes an accreditation system for procurement organisations and transplantation centres.
	●	The EU Action Plan did not influence national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Hungary is horizontal work package leader in the project FOEDUS[247] (work package on dissemination) and was core work package leader in COORENOR, DOPKI and MODE. Hungary was a partner in Alliance-O, EUROCET and ODEQUS and is a partner in ACCORD.

In 2010, 2011 and 2012, the country participated in the working group on indicators[248] and in the annual data collection exercise launched by the working group. Hungary 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[249]).

Conclusion

Both Hungary's deceased donor rate and living donor rate increased since 2008. This is very positive. The challenge for Hungary will be to maintain this development. Also Hungary could consider taking up the evaluation of post transplant results, to be able to further steer the effectiveness of their transplantation efforts. An area to explore for Hungary may be DCD.

[247] For more information about EU-funded projects, see chapter 3.
[248] For more information about the working groups, see chapter 3.
[249] For more information about CD-P-TO, see Annex 3.

14. Iceland

Background[250]
With a deceased donation rate PMP of 40 in 2015, Iceland's deceased donation rate PMP is amongst the highest of the countries included in this study. In 2015, it is not known to the research team if deceased donor transplant procedures were carried out involving livers, hearts, lungs and pancreases.

With a living kidney donation rate PMP of above 10 in 2015, Iceland's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.

Iceland is part of Scandiatransplant[251] and donor organs are allocated through Scandiatransplant.

An opt-in system is in place.

[250] 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.

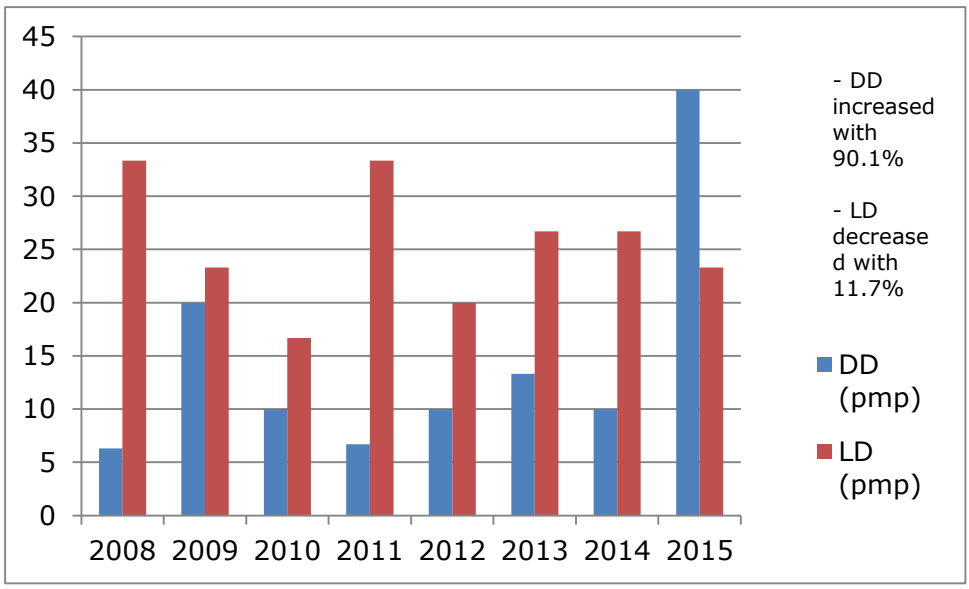
[251] Regarding EU-funded projects, Scandiatransplant participated as a partner in EFRETOS.

Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Family refusal rate (refusals/times asked)	-	2/8	-	-	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	2/6	5/20.0	3/10	2/6.7	3/10	4/13.3	3/10	12/40
Multi-organ donation rates (% of total)	100	50	100	100	66.7	100	-	91.7
Number of utilised donors (total/per million population)	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	0	0	-	-	0
Number of donors older than 60	-		-	-	-	-	1	
Number of transplant centres								
Kidney	1	1	1	1	1	1	-	1
Liver	0	0	-	-	0	0	-	0
Heart	0	0	-	-	0	0	-	0
Lung	0	0	-	-	0	0	-	0
Pancreas	0	0	-	-	0	0	-	0
Bowel	0	0	-	-	0	0	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	-	0	0	0	0	0	-	0
Liver	-	-	0	0	0	0	0	0
Heart	-	-	0	-	0	-	-	0
Lung	-	-	0	-	0	-		0
Pancreas	-	-	0	-	0	-	-	0
Bowel	-	-	-	-	0	-	-	0
Number of living donor transplant procedures (total/pmp)								
Kidney	5/ 16.7	7/ 23.3	5/ 16.7	11/ 36.7	6/ 20	8/ 26.7	8/ 26.7	7/ 23.3
Liver	5/16.7	-	0	-	0	-	-	0

- = not known to the research team

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Iceland*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Implementation Action Plan
Iceland did not provide data for 2012 and 2016.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects Iceland is an associated partner in the Joint Action project FOEDUS[252].

Iceland is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[253]).

Conclusions
Iceland's deceased donor rate increased since 2008 and its living donor rate decreased since 2008. An area to explore for Iceland may be DCD.

Regarding the implementation of the Action Plan, Iceland did not provide data for 2012 and 2016. It is not known to the research team what the status is of the implementation of the Action Plan in Iceland.

[252] For more information about EU funded projects, see §3.
[253] For more information about CD-P-TO, see Annex 3.

15. Ireland

Background information[254]
With a deceased donation rate PMP above 20 in 2015, Ireland belongs to the highest countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, and lungs.
With a living kidney donation rate PMP of less than 10 in 2015, Ireland's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.
Donor organs are allocated at national level.

Ireland has an **opt-in system**. The system requires express consent from the donor but allows the donation with the consent of the next of kin when no express consent from the deceased donor has been given during their life time.

Financing of organ donation
There is no protocol in place.

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

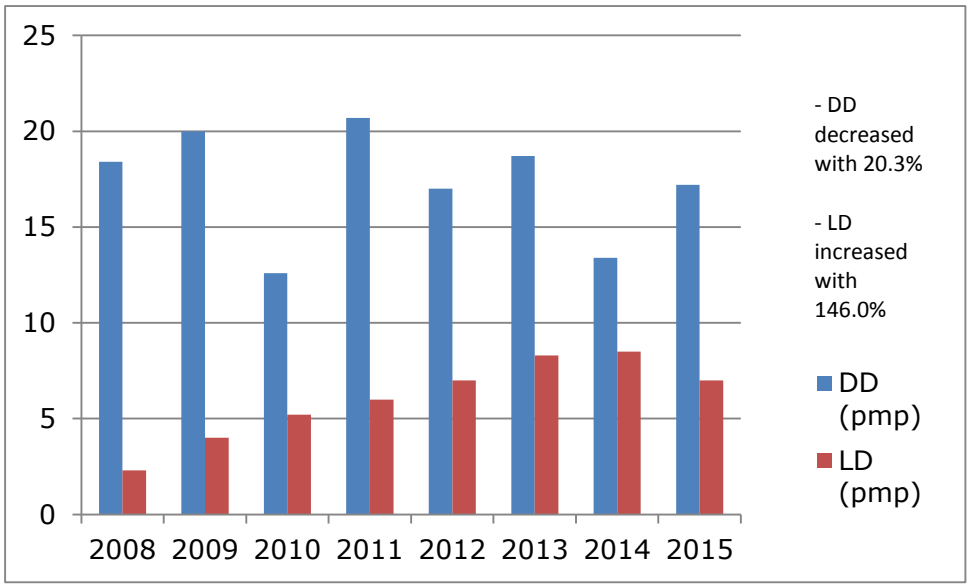
Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	4.4	4.5	4.4	4.5	4.6	4.6	4.7	4.7
Family refusal rate (refusals/times asked)	24/ 105	22/ 127	23/ 119	19/-	-	21/-	-	20/ 154
Actual deceased donation rate (total/per million population, pmp)	81/ 18.4	90/ 20.0	58/ 12.6	93/ 20.7	78/ 17	86/ 18.7	63/ 13.4	81/ 17.2
Multi-organ donation rates (% of total)	-	80	-	92.5	83.3	73.3	82.5	76.5
Number of utilised donors (total/per million population)[255]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	1	3	6	4	4
Number of donors older than 60	9		6	-	-	-	7	
Number of transplant centres								
Kidney	1	1	1	1	1	1	1	1
Liver	1	1	1	1	1	1	1	1
Heart	1	1	1	1	1	1	1	1
Lung	1	1	1	1	1	1	1	1
Pancreas	1	1	1	1	1	1	-	1
Bowel	0	0	-	-	1	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	136/ 30.9	154/ 34.2	151/ 34.3	165/ 36.7	131/ 28.5	147/ 31.9	112/ 23.8	120/ 25.5
Liver	58/ 13.2	64/ 14.2	38/ 8.6	61/ 13.6	50/ 10.9	55/ 11.9	44/ 9.4	61/ 13
Heart	4/0.9	11/2.4	3/0.7	6/1.3	10/2.2	11/2.4	18/3.8	16/3.4
Lung	4/0.9	5 /1.1	4/0.9	8/1.8	14/3	32/7	31/6.6	36/7.7
Pancreas	12/2.7	9 /2.0	8/1.8	8/1.8	1/0.2	11/2.4	6/1.3	0
Bowel	0	0	0	-	-	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	10/2.3	18/4.0	23/5.2	27/6	32/7	38/8.3	40/8.5	33/7
Liver	-	-	0	0	0	0	0	0

- = not known to the research team

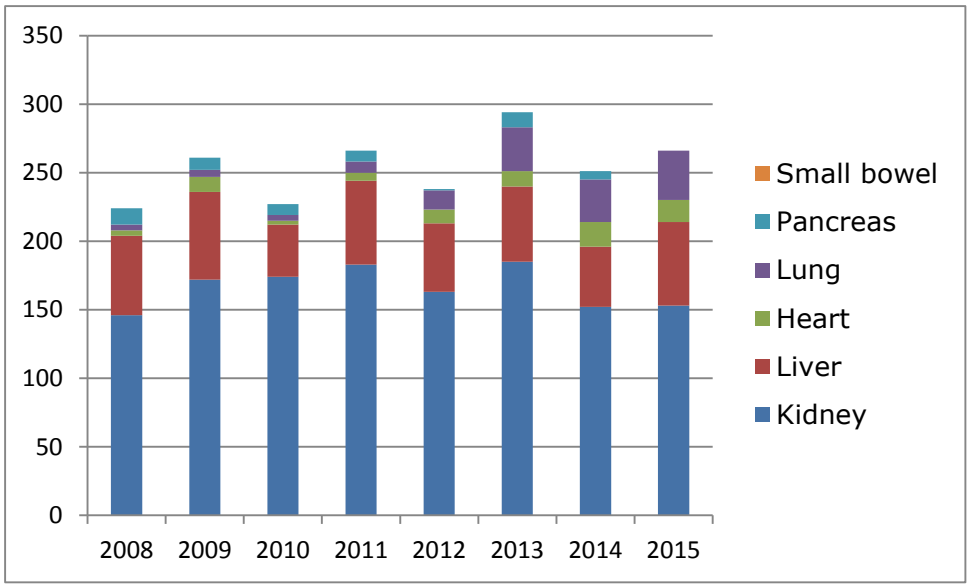
[255] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Ireland*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators appointed, 6 at national level.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: Local induction programme. This includes modules from tissue typing, virology, surgeons, recipient coordinators, coroner and organ donor nurse manager. On-going regular updates are given on new techniques, refresher courses, etc. Attendance at Transplant Procurement Management training in Barcelona.
	●	The local training has not yet been tested for effectiveness, TPM course has been tested.
	+	Training is arranged as part of the personnel training programmes of hospitals and professional networks.
	●	Ireland does not use national or international accreditation schemes to qualify transplant donor coordinators. After initial local induction our coordinators attend TPM training in Barcelona. Two of our coordinators have received this training. We intend to send the other four coordinators in November. We are also in consultation with Spain to develop a bespoke package of training that will meet national accreditation standards and will train future trainers in Ireland.
	+	The EU Action Plan influenced policy on transplant donor coordinators: As a result of the EU Action Plan and Directive, Ireland made a business case to enhance and restructure organ procurement services in Ireland. A national organ procurement service was established and the service moved from being based in a transplant centre to the national office, Organ Donation and Transplant Ireland. A new organ procurement team was recruited. Standards were produced and implemented based on the EU directive, including use of the health and lifestyle questionnaire. This commenced in April 2015.
	+	The EU supported activities contribute to the promotion of the role of transplant donor coordinators in Ireland: TPM course is a part of ETPOD.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process and the transplantation process.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: The EU Action plan led to the introduction of regional hospital teams consisting of an Organ Donation Nurse Manager and an Intensive Care Consultant with special interest in Organ Donation. This has aided the identification of potential donors with increased referrals. Audit of these referrals is planned. The procurement process has also been

		enhanced, with the establishment of a national office and appointment of a national team with new guidelines that comply with the EU directive.
	+	EU supported activities have contributed to the promotion of Quality Improvement Programmes: The ACCORD project on end of life care pathways was useful as a basis to design our own audit of end of life care pathways which is under development and planned for use in 2016 / 2017.
Priority Action 3: Exchange of best practices on living donation programmes among EU MS	+	Ireland has directed[256] living donation programmes: Since LOD has an impact on the donor and the recipient, Ireland considers it a reciprocal duty to provide disclosure to both parties. Ireland does not explicitly require the recipient's consent. However, due to the principle of autonomy, in normal cases, irrespective of the state of emergency, no one can get an organ implantation without consenting to this surgery. (Lopp, 2012). Generally, a close relative, spouse, partner, or close friend who has demonstrated a longstanding emotional relationship can consider becoming a donor. Donors are usually brothers, sisters or parents of the patient. Less often donors are other close relatives such as uncles, aunts, grandparents, sons or daughters. A donor must be over 18 years of age. Prior to consideration for live donation the potential recipient must be approved and deemed fit for transplant surgery.
	●	Ireland does not have undirected living donation programmes.
	+	There is 1 hospital with a living donation program.
	+	There is an independent body that evaluates the living donor, before the start of the procedure.
	●	There are not yet registers established to evaluate and guarantee the health and safety of living donors.
	●	Organ trafficking is not prohibited by law and the Council of Europe Convention on Action against Trafficking in Human Organs is not yet ratified.
	+	The EU Action Plan has influenced national policy on living donation programmes: A quality system has been introduced and a living donor follow up register is in progress.
	●	It is not known whether or not the EU supported activities have contributed to the promotion of living donation programmes.
Priority Action 4: Improve the knowledge and communication skills of	●	There are not yet communication guidelines for informing the public about organ donation and transplantation.

[256] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

health professionals and patient support groups	+	Programmes are deployed to improve knowledge and communication skills of health professionals dealing with organ transplantation and local hospital training is delivered by organ procurement coordinators and organ donor nurse managers.
	+	Programmes are deployed to improve knowledge and communication skills of patient support groups on organ transplantation.
	+	Periodic meetings with journalists were organized since the EU Action Plan was implemented but not on a regular basis.
	+	Guidelines and deliverables developed by EU supported activities are used or will be used to inform the public, to improve knowledge and skills of health professionals, to improve knowledge and skills of patient support groups, and to organise periodic meetings with journalists.
	+	The EU Action Plan has influenced national policy on public awareness of organ donation: We intend to consider the contents of the communication guidelines from FOEDUS for national purposes. While our approach to organ donation has not changed, we have sent a number of journalists to the EU workshops and consider that we have the support from journalists to promote organ donation and that they are better informed. As a result, our public are better informed. Our 2015 national survey showed that, in comparison to Eurobarometer 2009 figures, there has been a 17% increase in people's willingness to donate one of their organs (now at 81%).
	+	EU supported activities have contributed to the promotion of public awareness through Journalists Workshops and as above.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Ireland does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Ireland: residents with a foreign nationality who die in Ireland, non-residents who die in Ireland and illegal persons who die in Ireland.
	+	Criteria required to get admitted to the waiting list are: residency in Ireland and being signed up with local social security or health care insurance.
	+	100% of transplanted patients are local residents.
	+	The EU Action Plan has influenced national policy on cross border donation: Service Level Agreements and cross border exchange programmes will be put in place that are compliant with the EU Directive and its amendments.
	●	EU supported activities have not contributed to the identification of cross border donors.
Priority Action 6: Enhancing the organisational models of organ donation	+	Ireland has been involved in twinning projects, in a learning role.
	+	Topics were: End of Life Care Pathways, work package 5, ACCORD; Living Donor Registries, work

and transplantation		package 4, ACCORD
	+	Cooperating countries were: Work Package 5 was led by the UK. Fourteen other EU Member States took part in the Project: Croatia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Slovenia and Spain.
	●	These projects did not yet lead to changes.
	●	Ireland has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.
	+	Transplant centres in Ireland acts participate in the following networks: Transplant Advisory Networks, Statistical; registries / networks, national Organ Donation Network, ODTI.
	+	The EU Action Plan has influenced the organisational model of your donation and transplantation system: The EU Action plan led to the introduction of regional hospital teams consisting of an Organ Donation Nurse Manager and an Intensive Care Consultant with special interest in Organ Donation. This has aided the identification of potential donors with increased referrals. Audit of these referrals is planned. The procurement process has also been enhanced as a result with the establishment of a national office and appointment of a national team with new guidelines that comply with the EU directive.
	+	EU supported activities have contributed to enhancing the organisational model of the donation and transplantation system: Ireland participated in WP 5 ACCORD on End of Life Care Pathways. The pathway model developed is being used as a basis to plan our audit of the care pathway.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Ireland has agreements with other countries in place regarding: Exchanging organs and treating each other's patients.
	●	Ireland does not have agreements with other countries to prevent and address possible cases of organ trafficking.
	+	Future research programmes should ideally focus on Organ Support Systems (e.g., EVLP) and Meaningful SAE reporting and learning.
	+	The EU Action Plan has influenced the development of EU-wide agreements: Legislation requires EU countries to have standardized approaches to Quality and Safety of organ transplantation, thereby facilitating agreements between countries that incorporate quality and safety standards.
	+	EU supported activities have not contributed to the development of EU-wide agreements.
Priority Action 8: Facilitate the interchange of organs between national	+	For the interchange of organs between national authorities, Ireland is part of bilateral collaborations. There is an organ sharing arrangement with the UK.

authorities	+	Patient groups involved are: patients with urgent needs for transplantation and paediatric patients.
	+	Organs that are involved: liver, kidney, heart and lung.
	+	In 2015 1 organ came from abroad, 10 organs left the country.
	+	Ireland has offered 27 'non allocated' organs in 2015.
	+	Organs involved were: liver, kidney, heart and lung.
	●	Ireland does not evaluate procedures for offering non allocated organs to other countries.
	+	Ireland has procedures in place for the exchange of organs of urgent and difficult-to-treat patients.
	+	Organs involved are: liver. One organ (imported) crossed the border.
	●	Ireland does not participate in the use of an IT-tool for the facilitation of cross border exchange.
	●	The EU Action Plan has not influenced national policy on the interchange of organs between countries. Sharing of organs is already established between Ireland and the U.K. The EU action plan has provided a framework to progress interchange of organs throughout Europe via Eurotris which may be considered in the future as a method for organ sharing.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, but not in a systematic way.
	+	Transplant results are measured 12 months after transplantation.
	●	The evaluation of post-transplant results is not supported by a vigilance system.
	+	Ireland accepts donor organs from donors with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, HIV and donors aged over 60.
	●	No information about the influence of the EU Action Plan on national policy regarding the evaluation of post-transplant results.
	●	No information about the contribution of EU supported activities on national policy regarding the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	Ireland promotes an accreditation system for procurement organisations and transplantation centres. For donation (coordinators): competency based training for procurement coordinators. TPM (EU) accredited training. National accreditation planned. For other staff involved in donation and transplantation: Organ Donation is incorporated in to the training required to qualify as an Intensive Care Medical Consultant.
	+	The EU Action Plan influenced national policy on the promotion of accreditation systems: The EU Action

		Plan led to the EU Directive which required a Quality and Safety Framework. This has been implemented in Ireland and requires that all staff involved in the process is appropriately trained. Procurement and transplant centres are authorized and regularly inspected by the Health Products Regulatory Authority in Ireland.
	+	EU supported activity Transplant Procurement Management (TPM) for procurement coordinators (ETPOD), contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Ireland participates as partner in the Joint Action ACCORD[257].

In 2010 the country participated in the working group on indicators[258]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[259]).

Ireland's deceased donor rate decreased since 2008, and its living donor rate increased since 2008. An area to explore for Ireland might be small bowel transplantation. Furthermore, Ireland could consider the possibility to appoint transplant donor coordinators at hospital level, and to further improve quality management in this area.

According to the Irish CA the action plan has provided a framework that supports action taken in Ireland to increase organ donation.

Ireland will prioritize the implementation of enhanced organ donation staff structures nationally. Accredited organ donation training is being developed for organ donation personnel. Audit of end of life care pathway will be prioritized to identify where the most effective improvements can be made. The further development of DCD will be explored.

EU cooperation should continue according to Ireland in this area and facilitate engagement with third countries, e.g., UK. Essential topics are the improvement of financial resources for organ donation and transplant and continual development of quality and standards guidelines that are adaptable for national use.

[257] For more information about EU-funded projects, see chapter 3.
[258] For more information about the working groups, see chapter 3.
[259] For more information about CD-P-TO, see Annex 3.

16. Italy

Background information[260]

With a deceased donation rate PMP of above 20 in 2015, Italy's deceased donation rate PMP is amongst the highest of the countries included in this study.
In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.
With a living kidney donation rate PMP of less than 10 in 2015, Italy's living kidney donation rate PMP is among the lowest of the countries included in this study. In 2015 living donor transplant procedures were carried out involving 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. Together with France and Spain, Italy formed a new cooperation agreement, the South Transplant Alliance (SAT) (SAT, 2013).

Since April 1st 1999 an **opt-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 not known. The will (consent/refusal) is **collected** in a national database system.

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.

[260] Sources: FACTOR 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.

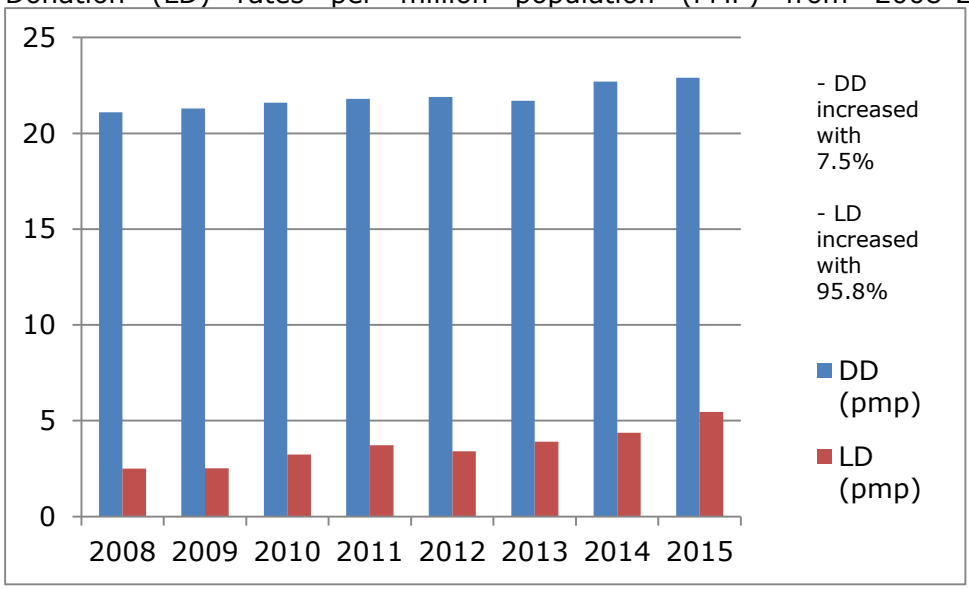
Key figures[261]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	56.9	59.9	60.1	60.8	61	61	61.1	59.8
Family refusal rate (refusals/times asked)	749/ 2299	707/ 2328	722/ 2289	651/ 2271	592/ 2271	668/ 2270	728/ 2349	707/ 2333
Actual deceased donation rate (total/per million population, pmp)	1201/ 21.1	1273/ 21.3	1298/ 21.6	1325/ 21.8	1337/ 21.9	1323/ 21.7	1384/ 22.7	1369/ 22.9
Multi-organ donation rates (% of total)	80.3	81.1	75.4	69.8	57	-	57.1	59.9
Number of utilised donors (total/per million population)	1094/ 19.2		1095/ 18.2	-	-	-	-	
Number of donors after circulatory death - DCD	3	2	3	6	5	3	2	8
Number of donors older than 60	345		408	-	-	-	794	
Number of transplant centres								
Kidney	43	43	43	43	41	41	41	42
Liver	22	22	22	22	22	22	21	21
Heart	19	19	19	19	16	16	17	17
Lung	13	13	13	13	11	11	11	11
Pancreas	13	13	13	13	17	17	17	17
Bowel	3	3	3	3	3	3	3	3
Number of deceased donor transplant procedures (total/pmp)								
Kidney	1533/ 26.9	1650/ 27.5	1694/ 28.2	1540/ 25.3	1593/ 26.1	1498/ 24.6	1589/ 26	1578/ 26.4
Liver	996/ 17.5	1061/ 17.7	1002/ 16.7	1019/ 16.7	986/ 16.2	992/ 16.3	1059/ 17.3	1071/ 17.9
Heart	326/ 5.7	355/ 5.9	273/ 4.5	278/ 4.6	67/ 1.1	59/ 1	43/ 0.7	245/ 4.1
Lung	94/ 1.7	112/ 1.9	107/ 1.8	120/ 2.0	114/ 1.9	141/ 2.3	126/ 2.1	112/ 1.9
Pancreas	61/1.1	72 /1.2	47/0.8	58/1.0	67/1.1	59/1	43/0.7	50/0.8
Bowel	3/0.1	4 /0.7	6/0.1	4/0.1	0	0	0	1/0
Number of living donor transplant procedures (total/pmp)								
Kidney	123/ 2.2	136/ 2.3	182/ 3.0	211/ 3.5	193/ 3.2	217/ 3.6	251/ 4.1	303/ 5.1
Liver	19/0.3	15 /0.3	12/0.2	15/0.2	15/0.2	21/0.3	16/0.3	23/0.4

- = not known to the research team

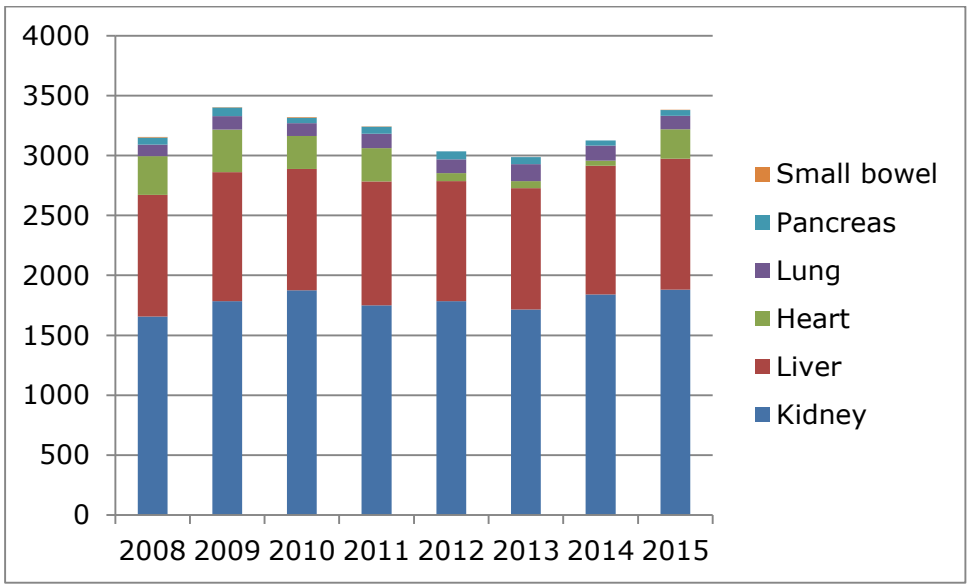
[261] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Italy*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level 292, at the regional level 19, at the national level 1.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: National and regional transplant procurement management courses are organized yearly, and in addition a national course for clinical transplant coordinators, especially addressed to nurses. Additionally, on a regional basis, skill communication courses are offered, whereas at national level devoted courses are addressed to emergency room and ICU doctors.
	●	The trainings have not been tested for effectiveness.
	●	Italy does not use an accreditation scheme. – In 2009 and 2011 national accreditation was organized, coordinators had to prove to have definite prerequisite: attendance of Transplant procurement management course, coordination of a given number of procurement processes, a minimum number of years of experience. Such national accreditation scheme will probably be relaunched in the near future.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	+	The EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: ETPOD courses were organized in two regions, Puglia and Calabria.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	●	EU Action Plan has not influenced national policy on Quality Improvement Programmes.
	+	EU supported activities have contributed to the promotion of Quality Improvement Programmes: Italy has planned to initiate use of indicators developed by ODEQUS project in its national donation programme and ACCORD PSDA cycle for improving procurement processes.
Priority Action 3: Exchange of best practices	+	Italy has directed[262] living donation programmes. In Italy, living donation is allowed from first grade

[262] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

on living donation		relatives, i.e. fathers or mothers, brothers and sisters, and children. However, other donors (including distantly genetically related and non-genetically related donors) can be taken in to account if no first grade relative is available. Living donation is ruled by Law June 26, 1967, Law Dec 16, 1999 and national guidelines.
	+	There are undirected living donation programmes In Italy, unspecified LOD is allowed by law and is also actually carried out, since anonymous undirected donation has been explicitly allowed by decision of the Health minister. Under a special protocol drawn by national CA, organs from Samaritan donors are allocated to crossover program, in 2015 a chain of six transplants (six couples through crossover program) started by a Samaritan donor was identified and carried out.
	+	At present (January 2016) 33 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not yet ratified by Italy, but is planned by June 2016.
	+	National policy on living donation programs is influenced by the EU Action Plan: Prospective improvement of data collection for living donor follow-up.
	+	EU supported activities EULID and ACCORD contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Italy deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation, but not patient support groups.
	●	No periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used for informing the public, improving knowledge and skills of health professionals and to improve knowledge and skills of patient support groups.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan, there were actions at the time of the European Donor Day.
	+	EU supported activities contributed to the promotion of public awareness: Italy organized EODD in 2014 for the first time in Italy, and we plan to make use at national level of all communication tools developed by FOEDUS (manual and videos).
Priority Action 5: Facilitate the identification of organ	●	Italy does not provide easily accessible information to its citizens about their legal position as a

donors across Europe		possible donor in other countries across the EU.
	+	The following people can legally be donors in Italy: residents with a foreign nationality who die in Italy, non-residents who die in Italy, and illegal persons who die in Italy.
	+	Criteria required to be admitted to the waiting list: residency in Italy, people signed up with local social security or health care insurance, illegals in urgent condition, foreign patients under special agreements.
	+	Transplanted patients are local residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Italy is involved in twinning projects in both a learning and a teaching role. Italy has been involved in twinning projects with Slovakia, the Czech Republic, Lithuania, Malta and Cyprus. They ran a PHARE twinning program with Slovakia for improving safety and quality of organ and tissue donation and transplantation systems. 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.
	+	These projects led to the following changes: Improvement multi-organ retrievals (MODE), increase organ exchanges (twinning agreements), development of international collaborations in transplant centre quality assurances.
	+	According to the CA, Italy has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.
	+	Transplantation centres or hospitals participate international registries.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	+	EU supported activities contributed to enhancing the organisational model of the donation and transplantation system: Improvement multi-organ retrievals (MODE), development of international collaborations in transplant centre quality assurances.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Italy has agreements with other countries for exchanging organs, treating each other's patients, and other aspects of transplant medicine (support to immunological testing in other country).
	+	Italy has agreements with other countries to prevent and address organ trafficking: the main challenges are: 1. Achieving for self-sufficiency in organ donation would be pivotal in order to dwarf the risk of organ trafficking; 2. Due information

		should be spread concerning the risks for donors in case of organ trafficking; 3. Due information should be spread concerning the necessity for post-transplant treatment.
	+	Future research programmes should ideally focus on Quality assurance programs for transplant centres and Common evaluation criteria for DCD organs.
	+	The development of EU-wide agreements is influenced by the EU Action Plan: in 2012, Italy, France and Spain started South Alliance for Transplant cooperation agreement.
	+	EU supported activities contributed to this development: they all contributed to built a common forum for discussions from which several common activities were born.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Italy is part of a fixed collaboration: a multi-lateral collaboration, namely the South Alliance for Transplants (SAT), and of bilateral collaborations, with European countries such as Malta, Greece and Slovak Republic. Furthermore, Italy, France and Spain have constituted the South Alliance for transplantation.
	+	Patient groups involved are: patients with urgent needs for transplantation, Paediatric patients.
	+	Organs involved are liver, heart, lung.
	+	In 2015 16 organs came from abroad, 11 organs left the country.
	+	Italy has offered non-allocated organs to other countries, the organs involved were liver (3), kidney (2), heart (3), lung (3), small bowels (2).
	+	Procedures for offering non allocated organs to other countries are evaluated, meaning that surplus organs are offered to other countries in order to avoid they can be wasted.
	•	Italy has no procedures yet for the exchange of organs of urgent and difficult-to-treat patients. Organs involved are liver and kidney.
	+	Italy participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs is influenced by the EU Action Plan: Action Plan and Directive 25/2012 gave a sound framework to international exchanges, thus supporting the identification of a national competent authority in this specific field.
	+	All EU activities contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 12 months after transplantation, indicators adopted for transplant outcome evaluation, are analysed at 12 months and 5 years.

	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute, to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis and Italy promotes an accreditation system for this.
	+	This system is used for donation (coordinators) at the regional level, for procurement (hospitals, not surgeons) at the regional level (hospitals can be either private or public) and for transplantation (including teams of surgeons) at the regional level, all public.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	It is unclear whether EU supported activities contributed to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU funded projects Italy is horizontal work package leader of the EU funded project ACCORD[263] 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[264]. 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[265]).

Conclusion

Both Italy's deceased donor rate and living donor rate increased since 2008. This is very positive.

From an overall point of view, Italy's CA reports that the Action Plan gave a great contribution to safety improvement and organ utilization. Italy had already a rather developed system both on donation and transplantation side. Improvement is still possible and the tools developed under some Joint actions will certainly contribute to this progress. In particular, with reference to Quality Improvement Programmes for organ donation (Priority Action 2) and taking advantage of the results of ODEQUS project and ACCORD Joint action, national organ donation plan for the years 2017-2019 that has been recently approved by the National Transplant Council. This plan aims at supplying homogenous clinical and organisational guidelines in this field, with

[263] For more information about EU funded projects, see chapter 3.
[264] For more information about the working groups, see chapter 3.
[265] For more information about CD-P-TO, see Annex 3.

the final goal of optimizing quality and safety of available organs on one hand and increasing their number on the other hand.

As far as Transplantation is concerned, Italy indicated Priority Actions 6 , 7 and 8 were also most useful. In this field, Italy had already started several activities that found a proper reference framework in the Action Plan that therefore allowed to consolidate them all, namely twinning with other countries, cross border exchange of organ, bilateral agreements on different aspects of transplantation medicine.

CA's indicate that the priorities in the field of organ donation in the next five years in Italy are:

1. Implementing the consolidated use of quality indicators for assessment of donation and transplantation programs in all involved facilities. The Italian Ministry of Health has recently inserted such indicators in the list of the Italian Essential Healthcare Assistance Services, i.e. the services that have to be delivered by Italian National Health System to all citizens.
2. Fostering DCD.
3. Defining a common national framework for organ donation with homogenous monitoring systems and identifying organisational, clinical and administrative "good practices", also implementing national and regional auditing systems and homogenous continuous training programs.

From a general organisational point of view:

- Consolidating authorization and auditing programs for transplant centres.
- Revising and updating existing national protocols and guidelines for the different aspects of quality and safety.
- Making an effort towards homogeneity of regional approaches to the management of organ donation and transplant processes.

The next step for the EU as a whole, according to Italy, should be an active EU surveillance network to prevent organ trafficking should be established. Prospective clinical research on DBD and DCD donation should be jointly conducted and standardized protocols for the management of potential DBD and DCD donors should be developed. Development of an agreed methodology for auditing donation and transplantation centres as well as hospital and regional coordinating units.

17. Latvia

Background information[266]

With a deceased donation rate PMP between 10 and 20 in 2015, Latvia belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys and hearts.

With a living kidney donation rate PMP of less than 10 in 2015, Latvia's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.

Since September 29th 1995 **an opt-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.

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.

[266] Sources: FACTOR 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.

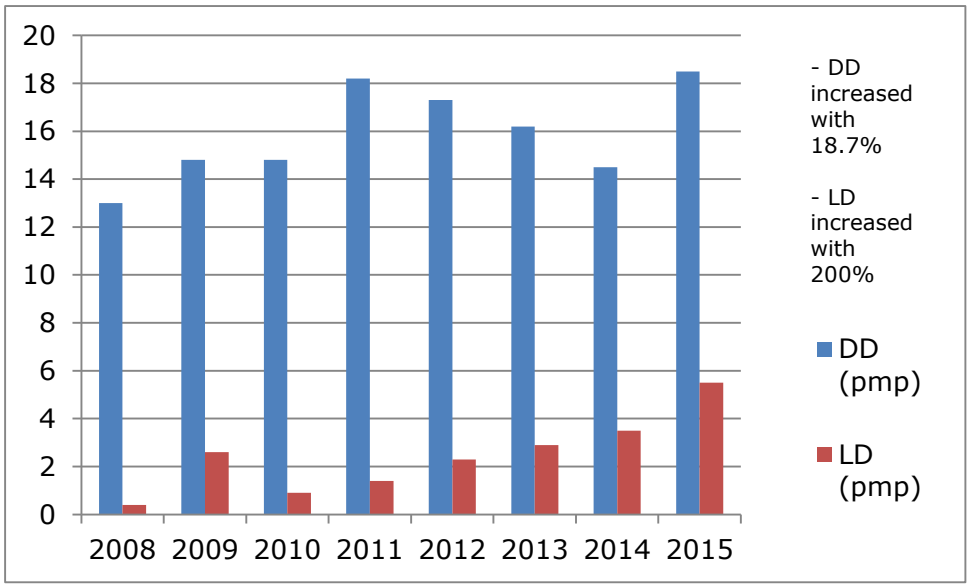
Key figures[267]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	2.3	2.3	2.3	2.2	2.2	2.1	2	2
Family refusal rate (refusals/times asked)	13/24	11/24	9/19	6/25	10/30	6/23	7/24	9/29
Actual deceased donation rate (total/per million population, pmp)	30/ 13.0	34/ 14.8	34/ 14.8	40/ 18.2	38/ 17.3	34/ 16.2	29/ 14.5	37/ 18.5
Multi-organ donation rates (% of total)	-	3	-	10	2.6	11.8	6.9	8.1
Number of utilised donors (total/per million population)	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	11	13	11	13	15	13	9	11
Number of donors older than 60	-		-	-	-	-	10	
Number of transplant centres								
Kidney	1	1	1	1	1	1	1	1
Liver	0	0	1	0	0	-	-	0
Heart	1	1	1	1	1	1	1	1
Lung	0	0	0	0	0	-	-	0
Pancreas	1	0	0	0	0	-	-	0
Bowel	0	0	0	0	1	-	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	53/ 23.0	64/ 27.8	64/ 27.8	74/ 33.6	65/ 29.5	66/ 31.4	52/ 26	66/ 33
Liver	0	0	0	1/0.5	0	0	0	0
Heart	0	1 /0.4	0	3/1.4	1/0.5	4/1.9	2/1	2/1
Lung	0	0	0	0	0	0	0	0
Pancreas	1/0.4	0	0	0	0	0	0	0
Bowel	0	0	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	1/0.4	6 /2.6	2/0.9	3/1.4	5/2.3	6/2.9	7/3.5	11/5.5
Liver	0	0	0	0	0	0	0	0

- = not known to the research team

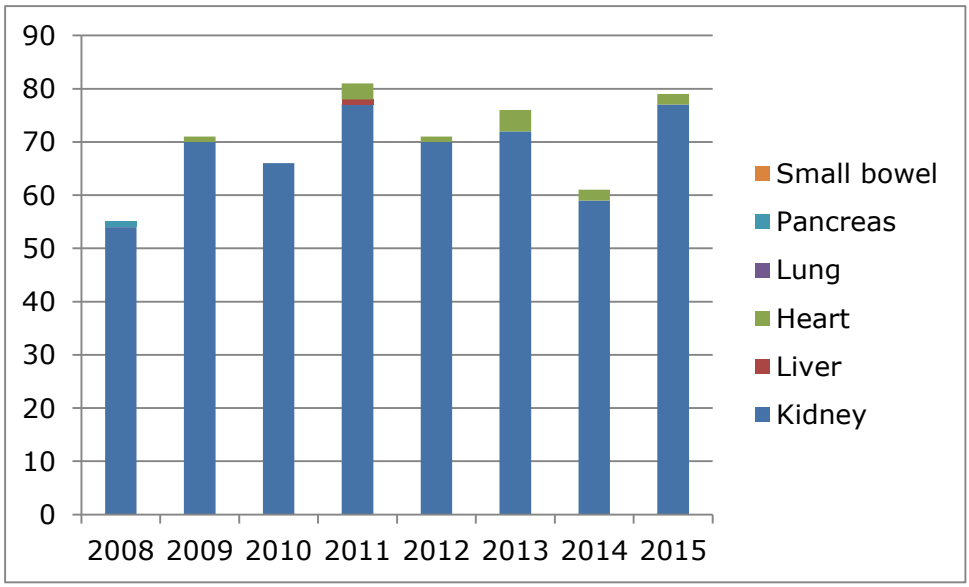
[267] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Latvia*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the regional level 3.
	+	Transplant coordinators receive both initial and regular training.
	+	Summary of the training: Initial training – information on legislation, potential donors, donation procedures, multi-organ donation, donor management, explantation operation, family approach. Regular training – two times per year pass seminars on organ donation and transplantation, news in transplantation.
	●	The trainings have not yet been tested for effectiveness.
	●	Latvia does not yet use an accreditation scheme, but that is intended: Transplant coordinators pass TPM training. After this training they have the possibility to get UEMS-CETC exam certification (EDTCO). In the future it is planned that education could be passed locally based at Riga Stradins University.
	+	The EU Action Plan has probably influenced national policy on transplant donor coordinators, process is limited due to limited financing.
	+	EU supported activity ETPOD has contributed to the promotion of the role of the transplant donor coordinators, but also limited due to limited financing.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the procurement process, the transplantation process, and the follow-up care.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: Quality Improvement Programmes will be influenced by the EU Action Plan in the future - according to available financial resources.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Latvia has directed[268] living donation programmes. Living donor program is active and the number of donors grows each year.
	●	Latvia does not yet have undirected living donation programmes. Unspecified LOD is legal in countries that do not restrict the donor-recipient relationship at all - Belgium, Denmark, England, Latvia, the Netherlands, Portugal, Scotland, Spain and Switzerland. In medical practice, it seems to be rather rare. The Latvian law does not explicitly state that no special relationship between donor

[268] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		and recipient is required, but addresses the issue by requiring the medical staff to ensure anonymity between donor and recipient if they are not next of kin. The implication of this requirement is that donor and recipient must not know one another. Latvian law does not contain any further specific instructions for cases of unspecified LOD.
	+	At present (January 2016) 1 hospital has a living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	Registers are established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not yet ratified by Latvia.
	+	National policy on living donation programs is influenced by the EU Action Plan: During the last few years the rate of living donor kidney transplantation has increased significantly. We will work out a proposal how to establish national level (national database) living donor register, but in a meantime we use the centre/hospital LD Register (there is only one transplant centre in Latvia).
	+	EU supported activities COORENOR, ACCORD, ELPAT have contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public.
	+	Latvia deploys programs to improve knowledge and communication skills for personnel that deals with organ transplantation, but not yet for patient support groups.
	●	Periodic meetings with journalists have not yet been organised.
	+	Guidelines and deliverables developed by EU supported activities are used for informing the public, improving knowledge and skills of health professionals, improving knowledge and skills of patient support groups and organising periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: We have organized special public awareness conference in November 2014 and also a special video was published to increase public awareness in respect to willingness to donate (ACCORD), and we also plan to continue those activities in future, if financial resources will be available.
	●	EU supported activities have not contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Latvia does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.

	+	The following people can legally be donors in Latvia: residents with a foreign nationality who die in Latvia and non-residents who die in Latvia.
	+	Criteria required to be admitted to the waiting list in Latvia: Being a resident in Latvia.
	+	90% of transplanted patients are local residents, 10% of transplanted patients are non-residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Latvia is not involved in twinning projects.
	●	CA is not aware that Latvia has used structural funds or other community instruments for the purpose of the development of transplantation systems but is interested.
	●	Transplantation centres or hospitals do not participate international registries.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Latvia has agreements with other countries for exchanging organs. On 21 May 2013, Declaration on cooperation of the Baltic States in exchange of organs for transplantation was signed.
	●	Latvia has no agreements with other countries to prevent and address organ trafficking. Main challenges are: How to detect in national health care system living donors who have had illegal donation in another country.
	+	Suggestions for future research programmes: Suboptimal donors and organ donation.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Latvia is part of bilateral collaborations, with next countries Estonia, Lithuania.
	+	All patient groups are involved.
	+	Organs involved are liver, kidney, heart and lung.
	+	In 2015 3 organs came from abroad and 3 organs left the country.
	+	Latvia has offered 3 non-allocated organs to other countries, the organs involved were kidney and heart.
	+	There are evaluation procedures for offering non allocated organs to other countries.
	+	There are procedures in place for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, kidney, heart and lung.
	+	Latvia does not yet participate in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.

	●	National policy on the interchange of organs is not influenced by the EU Action Plan.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, but only at a regional or local level.
	+	Results are measured 3, 6 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	The accreditation system used for donation (coordinators) is UEMC CETC-EDTCO, for procurement (surgeons) and for transplantation national accreditation systems are used.
	+	The EU Action Plan has influenced national policy on the promotion of accreditation systems: we will promote accreditation of transplantation coordinator in EU level.
	+	EU supported activity TPM -Transplant Procurement Management- contributed to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)
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[269]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[270]).

Conclusion
Both Latvia's deceased donation rate and living donation rate increased since 2008. This is positive. An opportunity could be to explore possibilities to increase multi organ donation rates, especially for bowel and pancreas donors, and evaluate the exchange programmes, which could increase the efficient use of organs across Europe. Furthermore, Latvia could consider the possibility to appoint transplant donor coordinators at hospital level and to invest more in quality assurance for transplant coordinators.

[269] For more information about the working groups, see chapter 3.
[270] For more information about CD-P-TO, see Annex 3.

18. *Liechtenstein*

Background information[271]

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 (36.300 inhabitants in 2010), for the same reasons.

Implementation Action Plan[272]

Priority Action 1: Promote the role of transplant donor coordinators	•	Not applicable for Liechtenstein.
Priority Action 2: Promote Quality Improvement Programmes	•	Not applicable for Liechtenstein.
Priority Action 3: Exchange of best practices on living donation	•	Liechtenstein has no directed[273] living donation programmes.
	•	There also are no undirected living donation programmes.
	•	There is no independent body to evaluate the living donor before the start of the procedure.
	•	A register is not yet established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	•	Organ trafficking is prohibited by law, but Liechtenstein has not ratified the Council of Europe Convention.
	•	Influence on the national policy on living donation programs by the EU Action Plan is not applicable.
	•	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and	•	There are no communication guidelines for informing the public.
	•	The EU supported activities did not contribute to the promotion of public awareness.

[271] Sources: FACTOR 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.

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

[273] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

patient support groups		
Priority Action 5: Facilitate the identification of organ donors across Europe	•	Liechtenstein does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	•	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	•	Liechtenstein is not involved in twinning projects. There are no transplantation centres in Liechtenstein.
	•	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	•	Liechtenstein has agreements with other countries for treating each other's patients.
	•	Liechtenstein has no agreements with other countries to prevent and address organ trafficking.
	•	The development of EU-wide agreements is not influenced by the EU Action Plan.
	•	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	•	Liechtenstein is part of a fixed collaboration: Liechtenstein has a bilateral collaboration with Switzerland.
	•	Patient groups involved are: all patients.
	•	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	•	Liechtenstein has not offered 'non allocated' organs to other countries in 2015: there were no 'non allocated' organs.
	•	Liechtenstein has no procedures for the exchange of organs of urgent and difficult-to-treat patients.
	•	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	•	Not applicable for Liechtenstein.
Priority Action 10: Promote a common accreditation system	•	Not applicable for Liechtenstein.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Not applicable.

Conclusions
No organ donation and transplantation is performed in Liechtenstein. No transplants 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 Liechtenstein 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[274]
With a deceased donation rate PMP between 10 and 20 in 2015, Lithuania belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases.
With a living kidney donation rate PMP of less than 5 in 2015, Lithuania's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.

In Lithuania an **opt-in system** is in place. People can register their consent and dissent for organ donation. If people have not registered this, then consent is requested from next-of-kin. If the next-of-kin cannot be contacted, donation is not possible. If there is no next-of-kin 12 hours after brain death confirmation hospitals ethics commission of 3 persons can decide whether potential donor organs can be taken for transplantation. In all other cases consent is required from either the deceased or their next-of-kin.

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.

[274] Sources: FACTOR 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.

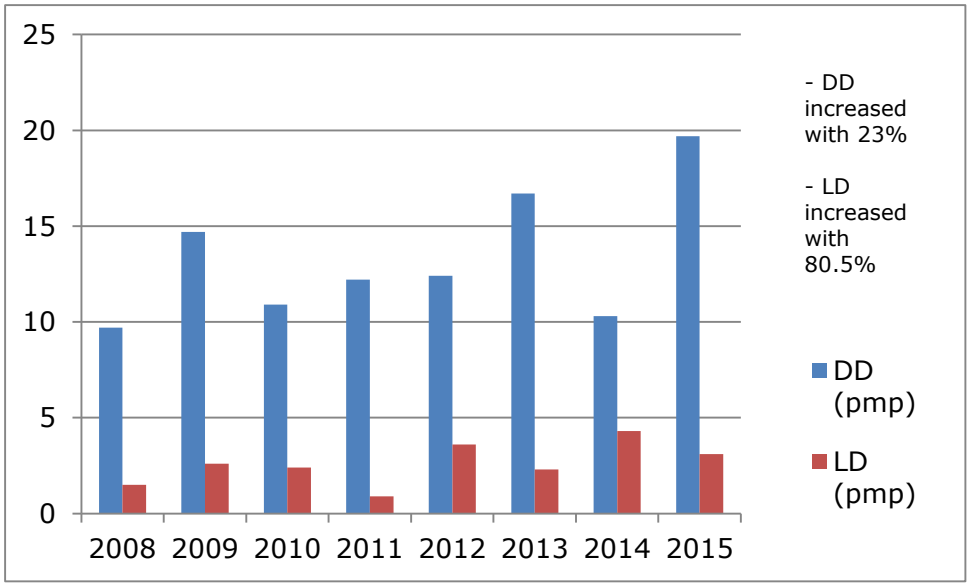
Key figures[275]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	3.4	3.4	3.3	3.2	3.3	3	3	2.9
Family refusal rate (refusals/times asked)	19/61	24/79	25/75	34/89	35/87	29/92	37/86	30/ 105
Actual deceased donation rate (total/per million population, pmp)	33/9.7	50/ 14.7	36/ 10.9	39/ 12.2	41/ 12.4	50/ 16.7	31/ 10.3	57/ 19.7
Multi-organ donation rates (% of total)	30.3	30	58.3	40.0	53.7	42	61.3	47
Number of utilised donors (total/per million population)	33/ 9.7	49/ 14,4	34/ 10.3	38/ 11.8	41/ 12,4	49/ 16,3	31/ 10,3	56/ 19.3
Number of donors after circulatory death - DCD	0	-	0	0	0	0	0	0
Number of donors older than 60	3	8	10	11	6	15	6	11
Number of transplant centres								
Kidney	2	2	2	2	2	2	2	2
Liver	2	2	2	2	2	2	2	2
Heart	2	2	2	2	2	2	2	2
Lung	2	2	1	1	1	1	1	2
Pancreas	1	1	1	1	1	1	1	1
Bowel	-0	-0	0	-0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	42/ 12.3	75/ 22.1	63/ 19.1	69/ 21.6	76/ 23.0	78/ 26	59/ 19.7	106/ 36.6
Liver	6/1.8	7 /2.1	13/3.9	12/3.8	15/4.5	13/4.3	12/4	14/4.8
Heart	5/1.5	8 /2.4	10/3	5/1.6	9/2,7	10/3	11/3,7	17/5.9
Lung	2/0.6	3 /0.9	0	1/0.3	2/0,7	1/0,3	1/0,3	2/0.7
Pancreas	4/1.2	4 /1.2	0	3/0.9	0	1/0.3	2/0.7	1/0.3
Bowel	-0	-0	0	-0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	5/1.5	9 /2.6	8/2.4	3/0.9	12/3.6	7/2.3	13/4.3	9/3.1
Liver	0	-0	0	0	0	0	0	0

- = not known to the research team

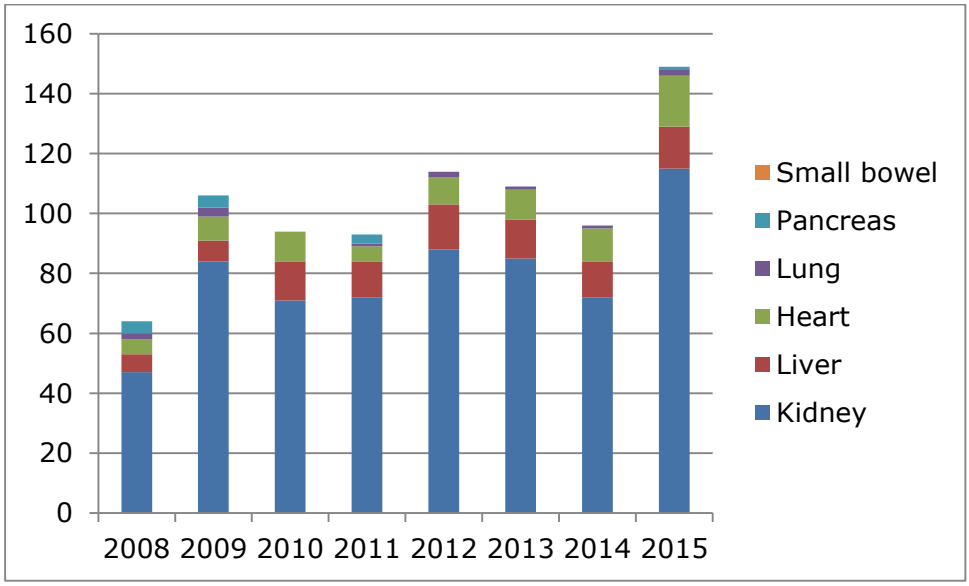
[275] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Lithuania*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 11 at the local/hospital level and 7 persons (5 posts) at the national level.
	+	Transplant donor coordinators receive initial training.
	+	Summary of the training: 2016 – "Lietuvos sveikatos mokslų universiteto Kauno klinikos" hospital has established a training course about organ donation and transplantation in national level. Frequency of training courses depends on financial situation. For National transplant coordinators we have training courses before starting work in National transplant bureau. Knowledge test after courses is written.
	+	The trainings have been tested for effectiveness.
	●	Lithuania does not yet use an accreditation scheme to qualify transplant donor coordinators.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: National transplant bureau appealed to the Ministry of Health in 2013 because of donation coordinator adoption in regulation act, but was rejected. 2016 applied one more time -results will be seen in near future.
	+	EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: ETPOD project lectures listened a wide audience of people (health care professionals), which met with a good experience, and some hospitals as a result set up a donation coordinator.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process and the transplantation process.
	●	The EU Action Plan has not influenced the national policy on Quality Improvement Programmes.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Lithuania has directed[276] living donation programmes: in Lithuania living donation can be only in close relatives or spouses. Also paired kidney donation enshrined in legal act, but still there has been no single case.
	●	There are no undirected living donation programmes.

[276] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	2 hospitals have a living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Lithuania has not ratified the Council of Europe Convention.
	●	National policy on living donation programs is not influenced by the EU Action Plan.
	+	EU supported activities contributed to the promotion of living donation programs: we gave data about living donation in ACCORD project and in the future we will follow by international recommendations which data to about living donors in National register.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Lithuania deploys programs to improve knowledge and communication skills of for all health care (hospital) personnel and patient support groups.
	●	Periodic meetings have not yet been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of patient support groups and to organise periodic meetings with journalists.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.
	+	EU supported activities contributed to the promotion of public awareness: Lithuanian journalists participate in the European Commission organized Journalist Workshops. After returning they share information with the public in their media.
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: Dissemination to the public messaging support. Or, to every citizen's request is answered personally. More information is hosted in www.transplantacija.lt.
	+	The following people can legally be donors in Lithuania: residents with a foreign nationality who die in Lithuania, and non-residents who die in Lithuania.
	+	Criteria required to be admitted to the waiting list: residency in Lithuania, local nationality and signed up with local social security or health care insurance.
	+	100% of transplanted patients are local residents.
	●	The EU Action Plan has not influenced national policy on cross-border donation is influenced.
	●	EU supported activities did not contribute to the identification of cross-border donors.

Priority Action 6: Enhancing organisational models	+	Lithuania is involved in twinning projects, in a learning role.
	+	Cooperation countries are Czech Republic, Cyprus, Malta, France and Italy.
	+	Lithuania has been cooperating with SEEHN countries: Romania (February 2014) - FYR of Macedonia (February 2014) - Montenegro (June 2014) - Albania (June 2014) - Serbia (November 2014) - Federation of Bosnia and Herzegovina (November 2014) and Austria. This has led to Progress of transplant activities in SEEHN countries.
	+	These projects led to the following changes: The legal framework created and pilot inspections in Lithuanian transplantation centres were carry out. Also international team of auditors was initiated by this project and Lithuania is a part of it.
	●	Lithuania is interested to use structural funds.
	●	Transplantation centres or hospitals do not participate in networks.
	●	The EU Action Plan did not influence the organisational model of the donation and transplantation system.
	●	No information whether EU supported activities contributed to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Lithuania has agreements with other countries for exchanging organs, training/certifying health care professionals (surgeons, coordinators) and collecting data. Lithuania has two agreements with Eurotransplant (2010, November) and Baltic state countries (Cooperation declaration between Baltic States Health ministers exchange of organs for transplantation, 2013, May 21.) "Lietuvos sveikatos mokslų universiteto Kauno klinikos" hospital has established a training course about organ donation and transplantation in national level (for surgeons and other doctors who are involved in donation and transplantation process, donor coordinators, tissue bank specialists). In 2016 Vilniaus Universiteto ligoninės Sanatriskiu Klinikos became a part of ELTR.
	+	Lithuania has agreements with other countries to prevent and address organ trafficking
	+	Future research programmes should focus on National - NHBD and paired kidney donation.
	●	The EU Action Plan has not influenced the development of EU-wide agreements.
	+	EU supported activities COORENOR and FOEDUS. contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Lithuania collaborates with the Eurotransplant (not associated partners); Baltic states cooperation declaration (declaration written by Health ministers); Foedus planned to be signed.
	+	Patient groups involved are: Patients with urgent needs for transplantation and Paediatric patients

	+	Organs involved are liver, kidney, heart and lung.
	+	In 2015 2 organs came from abroad, 6 organs left the country.
	+	Lithuania has offered 6 non-allocated organs to other countries, organs involved are liver and heart.
	+	Procedures for offering non-allocated organs are evaluated.
	+	Lithuania has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, kidney, heart and lung.
	+	Lithuania participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The EU Action Plan has not influenced national policy on the interchange of organs.
	+	EU activities contributed to the interchange of organs between countries: Coorenor and Foedus have established contacts with other countries, to receive as well as to offer donor organs. Accord project - twining working group for a system for accreditation and audit of donation and transplantation activities helped to prepare national legal acts for auditing process in transplantation centres and donor hospitals.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, but only at the local level.
	+	Results are measured 3, 6 and 12 months after transplantation.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency and from donors aged over 60.
	●	The EU Action Plan has not influenced national policy on the evaluation of post-transplant results.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	In Lithuania transplantation centres (in Lithuania there are 2) get licenses for organ transplantation, but not for procurement organization. These licences are at national level (issues State Health Care Accreditation Agency under the Ministry of Health).
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	+	EU supported activities contributed to the promotion of accreditation systems: ACCORD acquainted with the best practices applicable in the Member States.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Lithuania was core work package leader of the Joint Action MODE[277] 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[278].

Conclusions

Both Lithuania's deceased donation rate and living donation rate increased since 2008. This is positive. Areas to explore for Lithuania may be DCD and small bowel transplantation.

The implementation of the international projects, with many European countries participating was very useful according to the Lithuanian CA. Concerning the legal acts: at national level the auditing system was very useful. First steps have been made in new models in the non-beating heart donation. As well as the cross border exchange. Lithuania has now agreements with for example Eurotransplant and joined the platform for organ exchange. And last, a lot of work has been done in the field of communication with the public. This increased the knowledge of the public.

Next steps in the common five years for Lithuania:

(1) to have coordinators in all donor hospitals.
(2) more work in the field of living donation, also by involving doctors more so they are able to inform families about the possibilities of living donation.

Change in accreditation system is desirable. Now only transplant centres are granted accreditation, but in the future this should be wider and also hospitals should be able to receive accreditation.

For future cooperation with EU:

Lithuania thinks it should be continued.

(1) Small countries could use the help from national experts from other countries. For example national experts from other EU countries could help with audits because small countries only have a limited number of doctors and experts to perform the audits.
(2) A continuation of knowledge exchange between EU countries through the international projects. For example twinning is a very useful way to exchange knowledge.
    More uniform recommendations concerning standards for transplantation and donation. There are now many differences between countries in standards and regulations and it is desirable that this becomes more similar in the future.

[277] For more information about EU-funded projects, see chapter 3.
[278] For more information about the working groups, see chapter 3.

20. Luxembourg

Background information[279]

With a deceased donation rate PMP between 10 and 20 in 2015, Luxembourg belongs to the majority of the countries included in this study. In 2015, there were neither living nor deceased donor transplant procedures in Luxembourg. Only organ procurement procedures were carried out since 2011.

Luxembourg is part of Eurotransplant[280] 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). Kidney transplants were stopped since 2011.

Since November 25th 1982 an **opt-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.

[279] Sources: FACTOR 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.

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

Key figures[281]

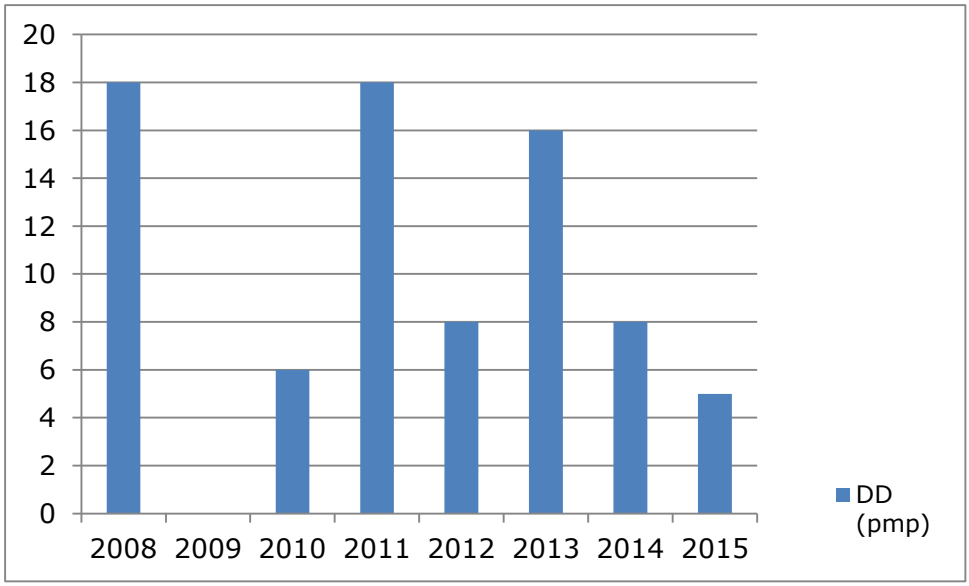
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.6
Family refusal rate (refusals/times asked)	-	-	3/7	-	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	9/18	-	3/6	9/18	4/8	8/16	4/8	3/5
Multi-organ donation rates (% of total)	100	-	100	88.9	75	87.5	75	100
Number of utilised donors (total/per million population)[282]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	-	-	0	-	0	0	-	0
Number of donors older than 60	-		-	-	-	-	1	
Number of transplant centres								
Kidney	-	-	0	0	-	-	-	0
Liver	-	-	0	0	-	-	-	0
Heart	-	-	0	0	-	-	-	0
Lung	-	-	0	0	-	-	-	0
Pancreas	-	-	0	0	-	-	-	0
Bowel	-	-	0	0	-	-	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	3/6	2 /4.0	6/12	0	-	-	-	0
Liver	0	0	0	0	-	-	-	0
Heart	0	-	0	-	-	-	-	0
Lung	0	-	0	-	-	-	-	0
Pancreas	0	-	0	-	-	-	-	0
Bowel	0	-	1/2.0	-	-	-	-	0
Number of living donor transplant procedures (total/pmp)								
Kidney	0	0	0	0	-	-	-	0
Liver	0	0	0	0	-	-	-	0

- = not known to the research team

[281] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

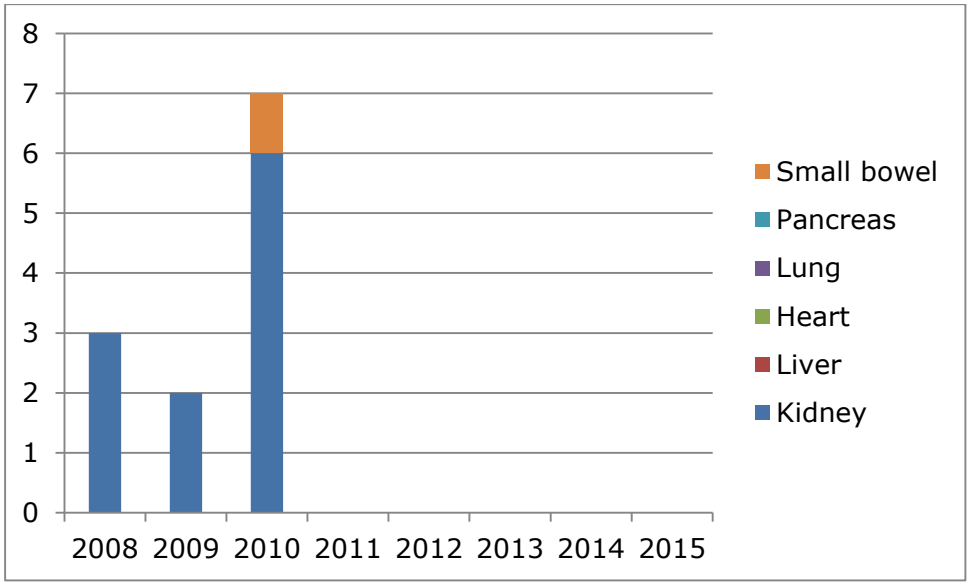
[282] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) from 2008-2015 in Luxembourg*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. There were no living donations in Luxembourg these years.

Figure 2: total number of transplants* per organ per year (2008-2015)



Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the national level 3.
	+	Transplant coordinators receive initial training at moment of appointing.
	+	The trainings have not been tested for effectiveness.
	●	Luxembourg does not use an accreditation scheme.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators, but no explanation is given.
	●	CA does not know whether EU supported activities have contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes, but no explanation is given.
	●	CA does not know whether EU supported activities have contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Luxembourg has directed[283] living donation programmes and undirected living donation programmes. A relationship between donor and recipient must exist in most countries, but this relationship does not need to be genetic. Countries such as Austria, Belgium, the Czech Republic, Finland, Germany, Latvia, Luxembourg, Norway, The Netherlands, Poland, Sweden, Spain and the UK do not require a genetic relationship between the donor and the recipient.
	+	At present (January 2016) no hospital has a living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not ratified by Luxembourg.
	●	No information is provided on the influence of the EU Action Plan on the national policy on living donation programs.
	●	CA does not know whether EU supported activities have contributed to the promotion of living donation programs.
Priority Action 4:	●	There are no communication guidelines for

[283] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

Improve the knowledge and communication skills of health professionals and patient support groups		informing the public.
	+	Luxembourg deploys programs to improve knowledge and communication skills for all health care (hospital) personnel and for patient support groups.
	●	Periodic meetings with journalists have not been organised.
	●	No information is given on the use of guidelines and deliverables developed by EU supported activities.
	●	No information is provided on the influence of the EU Action Plan on the national policy on public awareness of organ donation.
	●	CA does not know whether EU supported activities have contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Luxembourg does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Luxembourg: residents with a foreign nationality who die in Luxembourg.
	+	Criteria required to be admitted to the waiting list in Luxembourg are: criteria are those of Eurotransplant who is in charge of a centralized waiting list.
	●	No information about how many of transplanted patients are local residents.
	●	No information is provided on the influence of the EU Action Plan on the national policy on cross-border donation.
	●	CA does not know whether EU supported activities have contributed to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Luxembourg is not involved in twinning projects.
	●	Transplantation centres or hospitals do not participate international registries.
	●	No information is provided on the influence of the EU Action Plan on the organisational model of the donation and transplantation system).
	●	CA does not know whether EU supported activities have contributed to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	●	Luxembourg has provided no information about Priority Action 7.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Luxembourg is part of a multi-lateral collaboration, Eurotransplant.
	+	Patient groups involved in this collaboration are: all patients.
	+	Organs involved are liver, kidney, heart, lung and other, pancreas, small bowel.
	+	0 organs came from abroad, 79 (16 organs + 63 tissues and cells) left the country.

	●	Luxembourg has not offered non-allocated organs to other countries, there were no 'non allocated' organs.
	●	Procedures for offering non allocated organs to other countries are not evaluated.
	●	Luxembourg has no procedures for the exchange of organs of urgent and difficult-to-treat patients.
	●	Luxembourg does not participate in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	No information is provided on the influence of the EU Action Plan on the national policy on the interchange of organs.
	●	CA does not know whether EU activities have contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are not evaluated on a national level.
	●	There is no information on the existence of a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency and from donors aged over 60.
	●	No information is provided on the influence of the EU Action Plan on the national policy on the evaluation of post-transplant results.
	●	CA does not know whether EU supported activities have contributed to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Luxembourg has provided no information about Priority Action 10.

Participation in EU-funded projects during the Action Plan period (2009-2015)

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[284]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[285]).

Luxembourg's deceased donation rate decreased since 2008. No living donations were performed since 2008. This might be an area to gain benefits from. Possible benefits of participating in EU-funded projects could be explored by Luxembourg. Furthermore, Luxembourg could consider the possibility to appoint transplant donor coordinators at hospital level.

[284] For more information about the working groups, see Annex 3.
[285] For more information about CD-P-TO, see Annex 3.

The most valuable contribution of the Action Plan to Organ Donation in Europe is:

- Strengthening cooperation between Member States (mainly with cross-border countries, Luxembourg is a member of EUROTRANSPLANT in terms of organ donation and transplantation.
- Improving quality and safety in organ donation and transplantation.
- One priority is to designate a national coordination body (delegated body) according to the art. 17 (1) of the DIRECTIVE 2010/45/EU and to the 2015 national law on organ donation and transplantation. Last year only 3 organs procurements were made in Luxembourg. A second priority is to raise public awareness in order to increase organ donation. A third priority is the development of medicine in the field of organ transplantation.

Luxembourg indicated that European cooperation should continue in this area. One essential topic is inspection. Luxembourg is a small country (500 000 inhabitants) and this means less human resources to organize inspection training sessions.

21. Macedonia (former Yugoslav Republic of Macedonia)

Background information[286]
In Macedonia in 2015, 3 transplants were carried out from deceased donors.

With a living kidney donation rate PMP of less than 5 in 2015, Macedonia's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015, 9 kidney transplants were carried out from living donors.

Explicit written consent is required for organ retrieval.

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.

[286] Sources: FACTOR 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

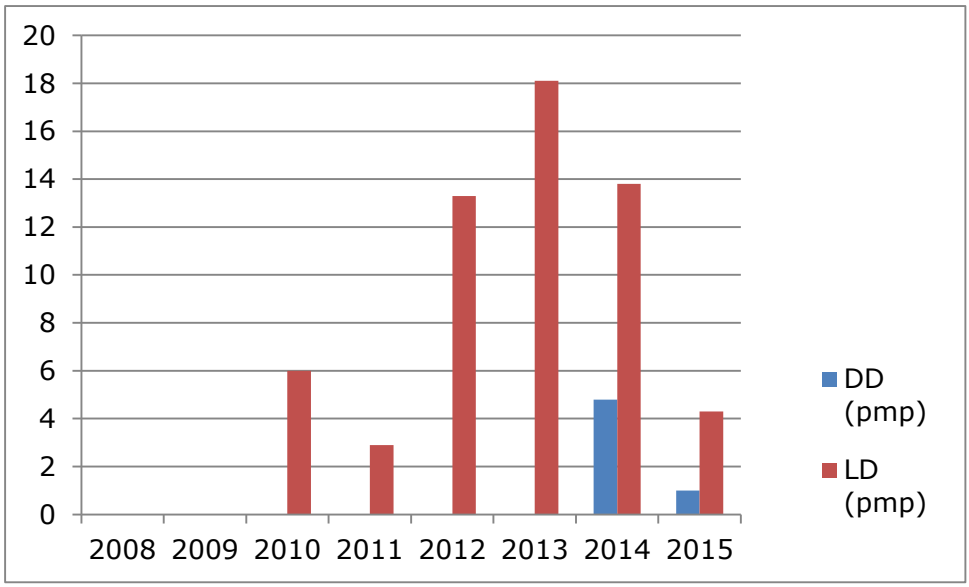
Key figures[287]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	2.1		2.0	2.1	2.1	2.1	2.1	2.1
Family refusal rate (refusals/times asked)	-		-	2/2	-	-	-	4/6
Actual deceased donation rate (total/per million population, pmp)	-		0	0	0	0	10/4.8	2/1
Multi-organ donation rates (% of total)	0		0	0	-	-	-	-
Number of utilised donors (total/per million population)	0		0	-	-	-	-	1
Number of donors after circulatory death - DCD	0		0	0	0	0	0	0
Number of donors older than 60	-		-	-	-	-	-	
Number of transplant centres								
Kidney	-		1	1	1	1	1	1
Liver	-		0	0	0	0	0	0
Heart	-		0	0	0	-	-	-
Lung	-		0	0	0	-	-	-
Pancreas	-		-	0	0	-	-	-
Bowel			0	0	0	-	-	-
Number of deceased donor transplant procedures (total/pmp)								
Kidney	-		0	0	0	0	12/5.7	3/1.4
Liver	-		0	0	0	-	-	0
Heart	-		0	-	0	-	-	0
Lung	-		0	-	0	-	-	0
Pancreas	-		0	-	0	-	-	0
Bowel			0	-	0	0	-	0
Number of living donor transplant procedures (total/pmp)								
Kidney	-		12/6	6/2.9	28/ 13.3	38/ 18.1	29/ 13.8	9/4.3
Liver	-		0	0	0	-	-	0

- = not known to the research team

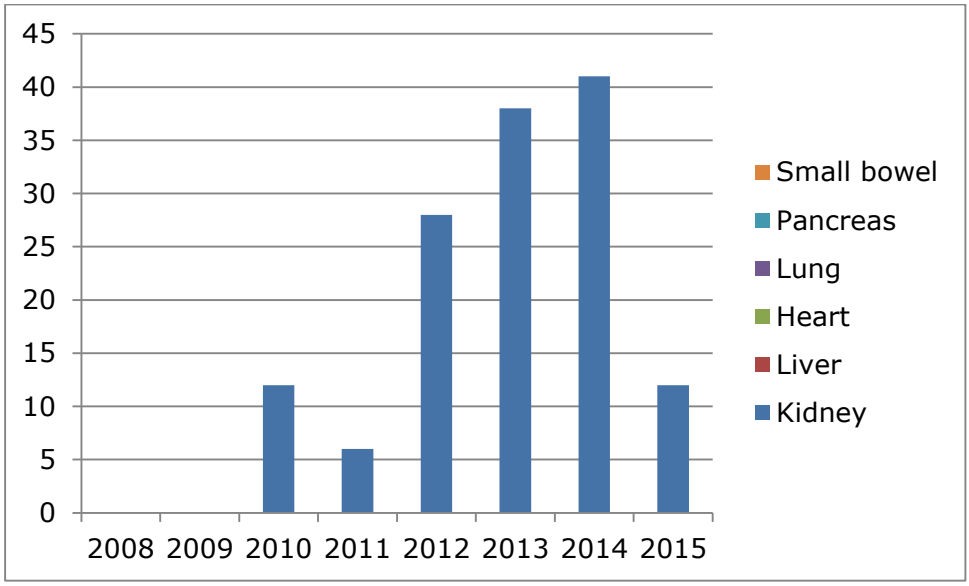
[287] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Macedonia*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 5 at the local/hospital level and 1 at the national level.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: • The donor coordinators have undertaken and/or attended training programme for donor management in Zagreb, Croatia. In addition, one donor coordinator from Macedonia attended the Advanced International Training Course in Transplant Procurement Management (TPM) - Barcelona 2015.
	●	The trainings have not been tested for effectiveness.
	●	Macedonia does not use an accreditation scheme.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the transplantation process, and the follow-up care.
	●	The EU Action Plan has not influenced the national policy on Quality Improvement Programmes through National audits.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Macedonia has directed[288] living donation programmes.
	●	There are no undirected living donation programmes.
	+	1 hospital has a living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	●	There are no registers to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, and Macedonia has ratified the Council of Europe Convention.
	●	National policy on living donation programs is not influenced by the EU Action Plan through the living

[288] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		donor register.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Macedonia deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation.
	●	Periodic meetings with journalists have not yet been organised.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public and improve knowledge and skills of health professionals.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan, there were actions at the time of the European Donor Day.
	●	It is not known whether the EU supported activity EDD contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Macedonia does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	Criteria required to be admitted to the waiting list: residency in Macedonia, local nationality or being signed up with local social security or health care insurance.
	+	All transplanted patients are local residents.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Macedonia is not involved in twinning projects.
	●	Transplantation centres or hospitals do not participate in any networks.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Macedonia has agreements with other countries for supporting the development of new transplantation programmes, training/certifying health care professionals (surgeons, coordinators) and other aspects of transplant medicine.
	+	Macedonia has agreements with other countries to prevent and address organ trafficking
	●	It is not known whether EU supported activities contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	●	Macedonia is not yet part of a fixed collaboration: a multilateral collaboration.
	●	Macedonia does not yet evaluate procedures for offering non allocated organs to other countries.
	●	Macedonia does not have procedures in place for the exchange of organs of urgent and difficult-to-treat patients.
	●	Macedonia does not participate in the use of an IT-tool for the facilitation of cross border exchange.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9:	+	Post-transplant results of organ recipients are

Evaluation of post-transplant results		evaluated, but not in a systematic way.
	+	Results are measured 3 and 12 months after transplantation.
	●	The evaluation of post-transplant results is not supported by a vigilance system.
	+	Donor organs are accepted from patients with hypertension and from donors aged over 60.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not controlled or audited on a regular basis.
	●	Macedonia not yet promotes an accreditation system for procurement organisations and transplantation centres.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

As it is not an EU Member State, the country does not participate in EU-funded projects, but as a candidate country[289], 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. The University of St. Cyril and Methodius of Macedonia is an associated partner in the HOTT-project.[290]

Conclusions

Macedonia's living donation rates increased since 2008, but have fallen back in 2014 and 2015. Macedonia could try to come back to their numbers of 2014 and stabilize them.

Macedonia could invest in quality measures to improve the effectiveness of transplant coordinators.

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

[290] HOTT-project.com

22. Malta

Background information[291]

With a deceased donation rate PMP between 10 and 20 in 2015, Malta's deceased donation rate PMP belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys.
In 2015 no living donor transplant procedures were carried out.
Donor organs are allocated at national level and through cooperation with other EU countries.
Organ donor registration in Malta has always been in the hands of a NGO, who managed to register about 25000 people. In spite of the fact that all these people were issued with a donor card, their personal data could not be stored because of Data protection issues and so could not be referred to in the event of death. In December 2016 the Government of Malta enacted the Human Organs, Tissues, and Cells Donation Act Chapter 558. This Legislation followed a White paper carrying a two month Consultation period. The new Legislation provides for Malta to adopt the hard Opt-In system thus no one can overturn the person's decision with regards to Organ Donation after death. In case a potential donor is not registered, the relatives are consulted to obtain consent for organ donation. Amongst other provisions this Legislation states that any person who has attained the age of sixteen may register his/her wish to donate or not to donate his/her organs after death. Malta now has a National Organ donor register where people residing in Malta can register his/her wish regarding organ donation after death. Anyone wishing to donate an organ (a kidney) while he/she is alive is referred to the Committee of professionals taking care of this sensitive area of organ donation. People can access the Organ Donation Registration website on www.organdonation.gov.mt.

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.

[291] Sources: FACTOR survey filled in 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.

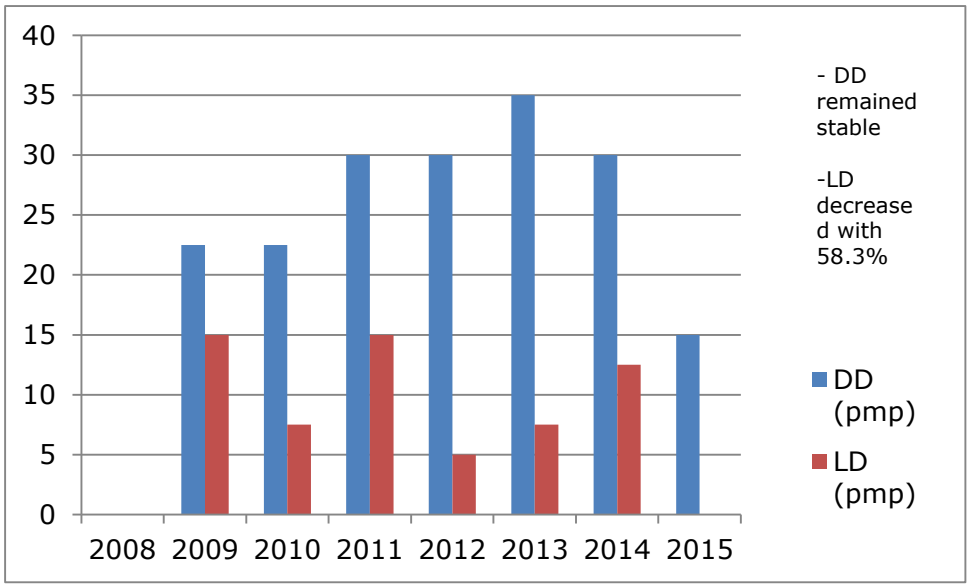
Key figures[292]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Family refusal rate (refusals/times asked)	-	1/10	1/10	2/18	-	1/15	1/13	0/6
Actual deceased donation rate (total/per million population, pmp)	-	9 /22.5	9/22.5	12/30	12/30	14/35	12/30	6/15
Multi-organ donation rates (% of total)	-	100	100	66.7	100	-	-	100
Number of utilised donors (total/per million population)	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	-		0	0	0	0	0	0
Number of donors older than 60	-		-	-	-	-	6	
Number of transplant centres								
Kidney	-	1	1	1	1	1	1	1
Liver	0	0	0	0	0	0	0	0
Heart	1	1	1	1	1	1	1	1
Lung	0	0	0	0	0	0	0	0
Pancreas	0	0	0	0	0	0	0	0
Bowel	0	0	0	0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	-	6 / 15.0	11/ 27.5	12/ 30	8/ 20	10/ 25	15/ 37.5	8/ 20
Liver	-	9 /22.5	0	-	-	0	0	0
Heart	-	1 /2.5	1/2.5	1/2.5	0	0	1/2.5	0
Lung	-	0	0	-	-	0	0	0
Pancreas	-	0	0	-	-	0	0	0
Bowel	-	0	0	-	-	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	-	6 /15.0	3/7.5	6/15	1/2.5	3/7.5	5/12.5	0
Liver	-	-	0	-	1/2.5	0	0	0

- = not known to the research team

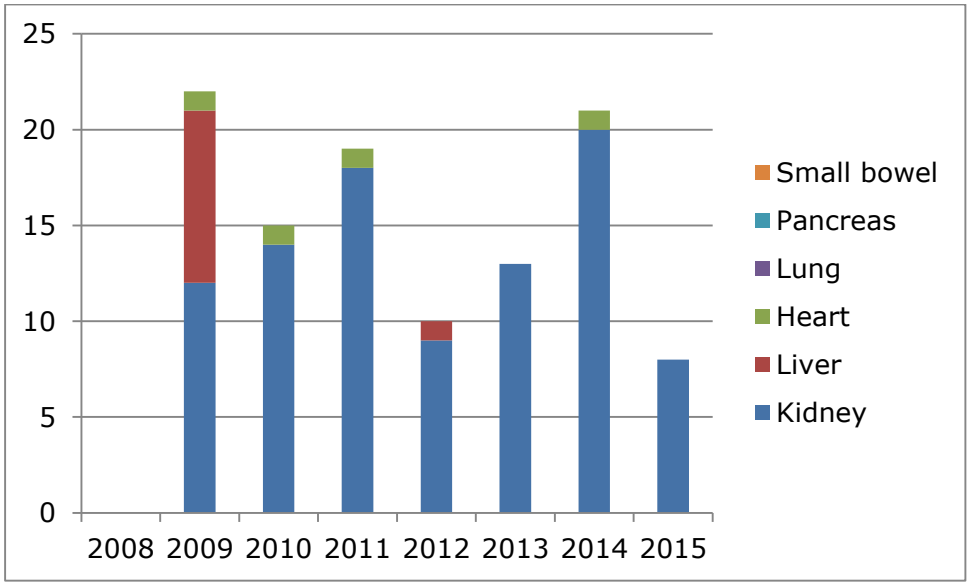
[292] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Malta*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the rate 2009 and for 2014 and 2015. This means that the years in between are not taken into account. No numbers on deceased and living donation rates were available for year 2008.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 3 at the national level.
	+	Transplant donor coordinators receive regular training.
	+	Summary of the training: Training consists of accredited courses abroad specifically for Transplant coordinators. Participation in EU funded work packages meant for Transplant coordinators. Job shadowing with other countries.
	●	The trainings have not been tested for effectiveness.
	●	Malta does not yet use an accreditation scheme to qualify transplant donor coordinators.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programme: new systems are in place to ascertain that all patients after organ donation are followed up and records are kept. New plans are in place to introduce HLA testing for all deceased donors. Kidney transplant lists are also updated regularly. All living donors are being formally reviewed by physicians.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Malta has directed[293] living donation programmes. The Public Health System in Malta has a program meant for living organ donations. If an organ donation is not by a blood related patient, a compulsory psychological assessment is performed, moreover, the go ahead is given afterwards by the Ethics committee (a committee that decides. Characterisation of donor and recipient which includes investigations, blood and imaging about the allocation of the organ donation) together with HLA/XM cross matching is carried out. CT abdomen Aorta CTA is also performed. This is followed by a consultation with the surgeons involved to plan for the actual transplantation. The final Confirmatory Cross match will lead to the actual transplantation.

[293] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		In Malta there is a Moral Obligation to regularly follow up the living donor.
	+	There also are undirected living donation programmes: Unrelated Living Donation can be direct, like for example between spouses or friends or Samaritan undirected Donors. Basically they go through the same program as above and are HLA/XM with the first 5 recipients on the waiting list. Obviously they have to go through the Psychological assessment and have to appear in front of the Ethics committee.
	+	1 hospital has a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law: So Far, Article 248C of the Criminal Code, Cap 9 of the Laws of Malta provides that "whosoever, by any means mentioned in article 248 A(2), traffics a person of age for the purpose of exploiting that person in the removal of any organ of the body shall on conviction be liable to the punishment of imprisonment for a term from six to twelve years. Punishment is increased by one degree if the person is a minor." The Human Bloods and Transplants Act, Cap 483 of the Laws of Malta also provides for regularisation on related matters.
	+	The recently enacted Human Organs, Tissues and Cells Donation Act, Cap 558 provided for an amendment in the Criminal Code Cap 9 to provide for 'Trafficking in human organs'.
	●	Malta has not yet ratified the convention because National Legislation needed to be amended.
	●	National policy on living donation programs was not influenced by the EU Action Plan through the living donor register.
	+	EU supported activities contributed to the promotion of living donation programs: improvement in the follow up of living donors.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Malta deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation and of patient associations.
	●	Periodic meetings with journalists have been organised to increase social awareness regarding organ donation registration and the newly enacted legislation.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.

	●	The EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Malta provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Malta: residents with a foreign nationality who die in Malta.
	+	Criteria required to be admitted to the waiting list: residency in Malta and being singed up with local transplant list found within the public hospital.
	+	100% of transplanted patients are local residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Malta is involved in twinning projects in a learning role. Cooperating country is Italy.
	+	These projects led to the following changes: Improved local processes and being in the process of licencing the organ transplant facility /organization.
	●	Malta has not used structural funds and/or other community instruments (EU funding) for this purpose.
	●	Transplantation centres or hospitals do not participate in any networks.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan.
	+	EU supported activities contributed to enhancing the organisational model of the donation and transplantation system: ACCORD helped us - to accept Extended Criteria Donors, - in the creation of a Living Donor Register soon - in the creation of a Donor and Non Donor register - in accreditation and Licencing.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Malta has agreements with other countries for exchanging organs, treating each other's patients and training/certifying health care professionals (surgeons, coordinators).
	●	Malta has no agreements with other countries to prevent and address organ trafficking. So far Malta has no practical experience of this crime hence it cannot provide information in this regard.
	+	Future research programmes should focus on - Better graft survival - upgrading our coordinators skills - providing better quality service –improve our immunological expertise.
	+	The development of EU-wide agreements will be influenced by the EU Action Plan.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Malta is part of a fixed collaboration: a multilateral collaboration, namely the South Alliance for Transplants (SAT).
	+	Patient groups involved are: all patients, patients with urgent needs for transplantation, paediatric

		patients and older patients.
	+	Organs involved are kidney and heart.
	+	In 2015 no organs came from abroad, 3 organs left the country.
	●	Malta has not offered 'non allocated' organs to other countries in 2015: there were no 'non allocated' organs.
	●	Malta has no procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Malta participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3 and 6 months after transplantation.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, infectious diseases such as hepatitis, HIV, and from donors aged over 60.
	+	National policy on the evaluation of post-transplant results is influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	●	Malta not yet promotes an accreditation system for procurement organisations and transplantation centres.
	+	The EU Action Plan has influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

With regard to EU-funded projects, Malta was an associated partner in ODEQUS (M. Manyalich et al., 2013). Malta is a partner in the Joint Action project FOEDUS[294] 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[295]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[296]).

[294] For more information about EU-funded projects, see chapter 3.

Conclusion

Both Malta's deceased donation rate is on average stable and its living donation rate decreased since 2008.

Organ donor registration in Malta has always been in the hands of a NGO (non governmental organization), first the Lions Club and then the Transplant Support group. Following a White paper which carried a Public Consultation period of two months, organ donation registration in Malta was given a legal framework through the Human Organs, Tissues, and Cells Donation Act Chapter 558. Through this legislation Malta now adopted the Hard –Opt –In approach, thus the registered wish cannot be overturned by anyone. Amongst other provisions this Legislation states that any person who has attained the age of sixteen may register his/her wish to donate or not to donate his/her organs after death.

In view of this Act, Malta appointed five organ transplant coordinators working within the only public hospital in Malta- Mater Dei Hospital, at which till now is the only hospital carrying out organ transplantation. All these coordinators were given access to the National Organ donor register. All those people residing in Malta can access our website on www.organdonation.gov.mt and register his/her wish regarding Organ Donation.

Maltese CA's state that the most valuable contribution is the continued practice of altruistic donation programs.

The priorities in the field of organ donation in Malta are:

- To increase donation both DBDs and living.
- To establish allocation of deceased donation on HLA typing in collaboration with San Camillo Laboratory in Rome.
- To seek help from other countries in helping us in our Sensitised Recipients on our waiting list.

The next step in the EU as a whole should be:

- Collaboration between EU member states should continue since this is beneficial for all states.
- Surplus organs in one country can be utilised in other countries.
- Recipients from small member states can benefit from wider pool of larger member states.
- Expertise can be shared.
- Bilateral collaboration between member states will enable residents to undergo transplants which are not performed in their respective country.

[295] For more information about the working groups, see chapter 3

[296] For more information about CD-P-TO, see Annex 3

23. Montenegro

Background information[297]
In 2015, no deceased donor transplants have been carried out in Montenegro. With a living kidney donation rate PMP of above 10 in 2015, Montenegro's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidneys and livers.

First kidney transplants 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.

Explicit written consent is needed for organ retrieval.

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.

[297] Sources: 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.

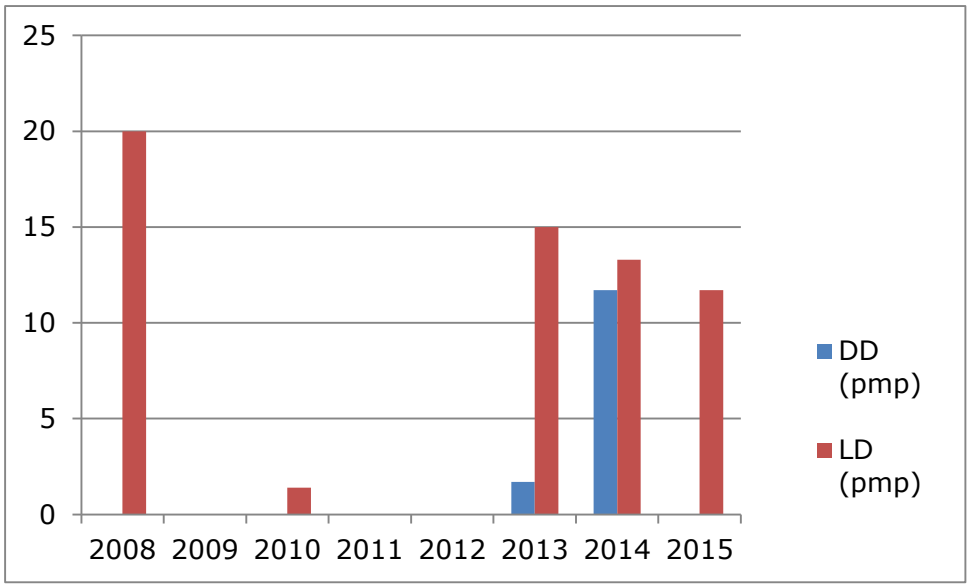
Key figures[298]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	0.7		0.7	-	-	0.6	0.6	0.6
Family refusal rate (refusals/times asked)	0/0		0/0	-	-	-	7/7	23/23
Actual deceased donation rate (total/per million population, pmp)	-		0	-	-	1/1.7	7/11.7	0
Multi-organ donation rates (% of total)	0		0	-	-	100	14.3	0
Number of utilised donors (total/per million population)	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	0		0	-	-	0	0	0
Number of donors older than 60	0		0	-	-	-	-	
Number of transplant centres								
Kidney	-		-	-	-	1	1	1
Liver	-		-	-	-	0	-	0
Heart	-		-	-	-	0	0	0
Lung	-		-	-	-	0	0	0
Pancreas	-		-	-	-	0	0	0
Bowel					-	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	0		0	-	-	1/1.7	1/1.7	0
Liver	0		0	-	-	-	2/3.3	0
Heart	0		0	-	-	-	0	0
Lung	0		0	-	-	-	0	0
Pancreas	0		0	-	-	-	1/1.7	0
Bowel					-	-	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	14		1	-	-	9/15	8/13.3	6/10
Liver	0		0	-	-	-	0	1/1.7

- = not known to the research team

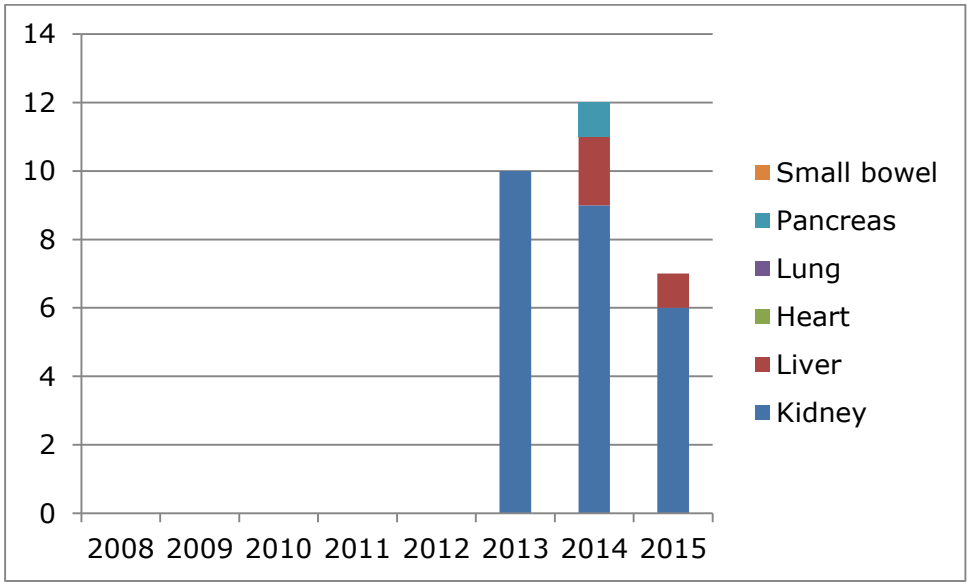
[298] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Montenegro*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. No numbers on deceased donation rates were available for year 2008, 2009, 2010, 2011, and 2012, and living donation rates for year 2009, 2011, and 2012.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan BASED ON 2012 DATA

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed at the local/hospital level. These transplant donor coordinators receive regular training.
Priority Action 2: Promote Quality Improvement Programmes	+	Montenegro 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	●	There are no directed[299] or undirected living donation programmes. 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	●	There are no programmes deployed to improve knowledge and communication skills of health professionals and patient support groups. No efforts have been made with regard to setting up of 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 provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. 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 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	+	There are agreements in place about organ trafficking and common priorities and strategies for future research programmes. 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 has a bilateral agreement with Croatia.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, 3, 6 and 12 months after transplantation.

[299] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

Priority Action 10: Promote a common accreditation system	•	There are no additional plans undertaken regarding promoting a common accreditation system for organ donation/ procurement and transplantation programmes.

Participation in EU-funded projects during the Action Plan period (2009-2015)

As it is not an EU Member State, the country does not participate in EU-funded projects, but as a candidate country[300], 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.

Conclusions

Montenegro's deceased donation rate increased since 2008 and its living donation rate decreased since 2008.

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

24. The Netherlands

Background information[301]

With a deceased donation rate PMP between 10 and 20 in 2015, the Netherlands belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.

With a living kidney donation rate PMP of above 10 in 2015, the Netherlands' living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver.

The Netherlands is part of Eurotransplant[302] and donor organs are allocated through Eurotransplant.

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.

Since May 24th 1996, an **opt-in system** is in place, combined with elements of a **less strict opt-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. People can also register from the age of 12. An element of a less strict opt 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.

In the time of writing, the Dutch Second Chamber voted for a draft bill to change the system into an opt-out system. This still has to be approved by the First Chamber.

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.

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[301] Sources: FACTOR 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/

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

Key figures[303]

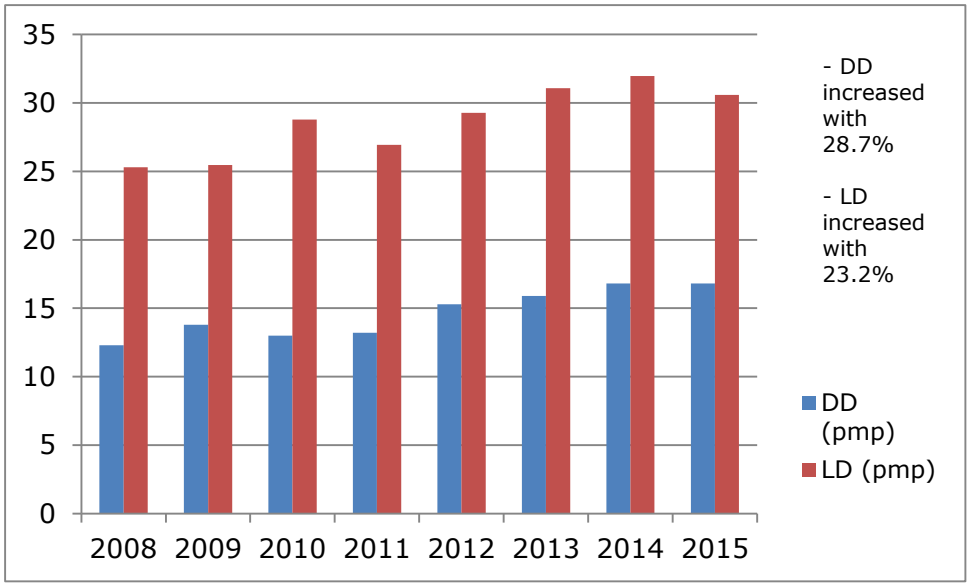
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	16.4	16.5	16.6	16.7	16.7	16.8	16.8	16.9
Family refusal rate (refusals/times asked)	250/ 456	274/ 518	257/ 495	286/ 549	327/ 630	366/ 702	347/ 703	397/ 775
Actual deceased donation rate (total/per million population, pmp)	201/ 12.3	227/ 13.8	216/ 13.0	221/ 13.2	256/ 15.3	267/ 15.9	282/ 16.8	284/ 16.8
Multi-organ donation rates (% of total)	69	73.6	69	71	82	74.5	78.4	76.8
Number of utilised donors (total/per million population)	201/ 12.3	215/ 13.0	216/ 13.0	221/ 13.2	252/ 15.1	255/ 15.2	271/ 16.1	265/ 15.7
Number of donors after circulatory death - DCD	82	96	73	111	128	160	132	156
Number of donors older than 60	24	-	28	41	-	-	-	-
Number of transplant centres								
Kidney	8	10	8	8	9	10	11	11
Liver	3	3	3	3	3	3	3	3
Heart	3	3	3	3	3	3	3	3
Lung	3	3	3	3	3	3	3	3
Pancreas	2	2	2	2	5	3	6	7
Bowel	0	1	0	1	1	0	0	0
Number of deceased donor transplant procedures (total/pmp)[304]								
Kidney	351/ 21.4	397/ 24.1	388/ 23.4	420/ 25.1	476/ 28.5	434/ 26.0	470/ 28.0	470/ 27.8
Liver	129/ 7.9	129/ 7.8	131/ 7.9	125/ 7.5	141/ 8.4	138/ 8.3	169/ 10.1	148/ 8.8
Heart	25/1.5	36 /2.2	48/2.9	44/2.6	37/2.2	37/2.2	51/3	54/3.2
Lung	81/4.9	67 /4.1	66/4.0	68/4.1	80/4.8	88/5.3	91/5.4	77/4.6
Pancreas	16/1	20 /1.2	17/1	36/2.2	37/2.2	32/1.9	35/2.1	35/2.1
Bowel	1/0.1	1 /0.1	3/0.1	1/0.1	2/0.1	0	0	3/0.1
Number of living donor transplant procedures (total/pmp)								
Kidney	413/ 25.2	417/ 25.3	473/ 28.0	440/ 26.3	485/ 29	520/ 31	534/ 31.8	514/ 30.4
Liver	2/0.1	3 /0.2	5/0.3	10/0.6	4/0.2	2/0.1	3/0.2	3/0.2

- = not known to the research team

[303] Numbers are based on Statistics of Eurotransplant and the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

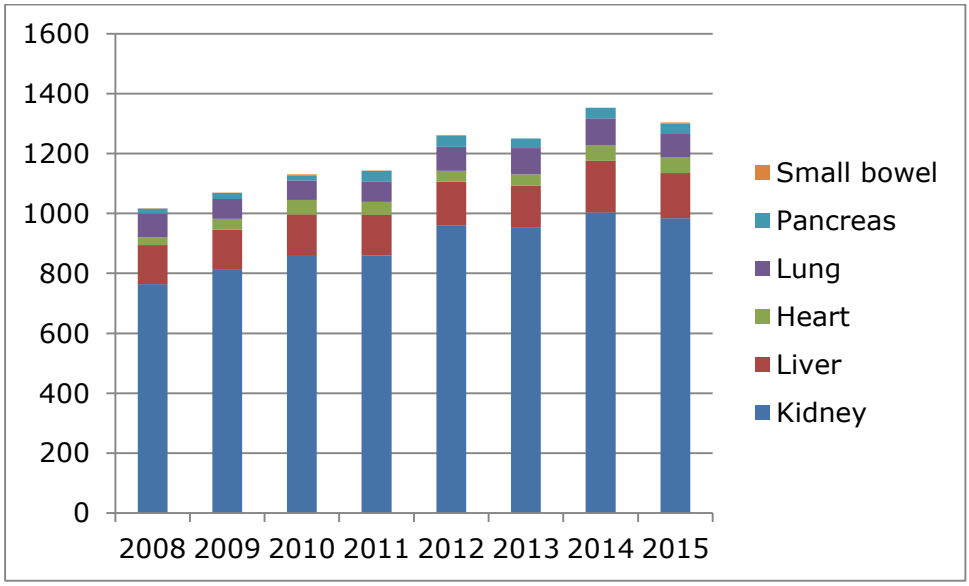
[304] Figures are actual transplantations, failed procedures are not taken into account.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in the Netherlands*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Donor coordinators have been appointed: 80 at the local/hospital level and circa 30 transplant coordinators at the regional level.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: The basic course consists of a manual that can be worked with independently. The manual provides the information needed to start the work, and where necessary refers to other important information. The Regional Team Leader (RTL) accompanies the DF(Donation Functionary) where necessary in the implementation of the Basic Course. Another course is about communication with next of kin. This training is specifically aimed at donation coordinators, (IC nurses) in donor hospitals whose main task is to enhance awareness and train professionals within their hospital and support the professionals in their donor hospital or region with regard to administrative and communicative aspects of (organ) donation. The transplant coordinators are healthcare professionals (mostly IC nurses) who actually play an active part in the donation procedure. Besides the already mentioned basic course, there is no formal training for these professionals. They do need to have extensive experience in the field of healthcare, preferably on IC, SEH or OR. They are being trained on the job by their peers.
	●	The trainings have not been tested for effectiveness.
	●	The Netherlands does not use an accreditation scheme for transplant donor coordinators.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators, because Netherland did that already.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	●	The EU Action Plan has not influenced the national policy on Quality Improvement Programmes, because the government already had a national action plan in place ('Masterplan orgaandonatie).
Priority Action 3: Exchange of best practices	+	The Netherlands has directed[305] and undirected living donation programmes. More than 50 % of

[305] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed

on living donation		the kidney transplants are performed with a kidney from a living donor. 85-90 % of the living kidney transplants are direct living donations, 10-15% indirect living donations. Because of differences in the definition of direct and indirect donation, numbers are not exact. Living kidney donation is actively promoted by patients and donors in the Netherlands and not so much by the government. Living liver donation is mostly considered in cases where the patient suffering from liver failure is in imminent danger of dying before a suitable organ donated by a deceased donor can be found. It is also prominent for paediatric recipients because a child can be at acute risk of dying and the risk for the living donor, who is usually a parent of the sick child, when removing a small left lateral segment, is modest and the liver will regenerate in the long run. Health consequences for the living liver donor are temporary (perioperative), not permanent. As a result, it can be observed that LOD, especially living kidney donation, is a rather common procedure. • CA provides objective information on all aspects of living donation for patients and (potential) donors • CA maintains a living donor register. • Kidney and liver donors are granted a compensation for expenses which are not covered by their insurance company. NTS is responsible for this agreement.
	+	There also are undirected living donation programmes: 1) Altruistic donation is legally possible in the Netherlands and occurs regularly. All 8 transplant centres offer this possibility. Altruistic donors are preferably used nationally to create better chances in the domino paired exchanges and help more patients. Awareness of undirected living donation is provided by the transplant centres as well as nationally. 2) Living donor kidney paired exchange programme for recipients with a blood type or cross-match incompatible donor consisting of: - Independent allocation organization (CA) - Hierarchical computer matching program with minimum criteria - Centralized cross match facility - National Reference Laboratory of Histocompatibility - Donor travels. Furthermore: all kidney donors are granted 500 bonus points if at some point after donation the donor is put on the waiting list in case of end-stage renal failure. Kidney and liver donors are granted a compensation for part of their expenses, which are not covered by their insurance company. NTS is responsible for this arrangement.

living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	8 hospitals have a living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but The Netherlands has not ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan: The Netherlands has promoted the development of a national register for living donors.
	+	EU supported activities contributed to the promotion of living donation programs: NL was WP leader of ACCORD LDR and will adapt her own register (data-dictionary) accordingly: exchange of best practices in ELPAT, EULID, LIDOBS.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. The Netherlands deploys programs to improve knowledge and communication skills of all health care (hospital) personnel and patient associations.
	●	Periodic meetings with journalists have not been organised.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan, there were actions at the time of the European Donor Day.
	●	The EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	The Netherlands provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU. See: http://www.transplantatiestichting.nl/donor-worden. On the website of the Dutch Transplant Foundation citizens can find information about becoming a donor.
	+	The following people can legally be donors in The Netherlands: residents with a foreign nationality who die in The Netherlands, non-residents who die in The Netherlands and Illegal persons who die in The Netherlands.
	+	Criteria required to be admitted to the waiting list: residency in The Netherlands, although exceptions can be made in specific cases, for example asylum seekers of neighbouring countries and being signed up with local social security or health care insurance.
	+	97% of transplanted patients are local residents, 1% are foreign residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan. The Dutch Transplant Foundation is working with

		EUROTRANSPLANT.
	●	Not clear whether EU supported activities contributed to the identification of cross-border donors: this is organized through Eurotransplant (ET). Organs not suitable for ET patients (8 countries) will be offered outside ET and vice versa.
Priority Action 6: Enhancing organisational models	+	The Netherlands is involved in twinning projects in a teaching role. Collaborating country is Hungary. This project led to the following changes: more trained surgeons in Hungary.
	●	The Netherlands has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	The Netherlands has agreements with other countries for exchanging organs, training/certifying health care professionals (surgeons, coordinators), collecting data and research activities. a) The Netherlands is part of Eurotransplant and has a collaboration agreement with Eurotransplant. b) The Dutch Transplant Foundation has an agreement with England to promote and further develop the e-learning module for professionals. Also the Dutch Transplant Foundation has an agreement with ESOT. c) As a part of ACCORD the Dutch Transplant Foundation had/have agreement(s) with other countries d) In the Netherlands there is now a trial going on with machine perfusion of kidneys.
	●	The Netherlands has no agreements with other countries to prevent and address organ trafficking.
	+	Future research programmes should focus on quality improvement of organs: procurement techniques, preservation techniques.
	+	The development of EU-wide agreements is influenced by the EU Action Plan: Foedus, international exchange platform, ACCORD: international data-dictionary living donation, but no formal agreements.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	The Netherlands is part of a fixed collaboration: a multilateral collaboration, namely Eurotransplant.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	In 2015 151 organs came from abroad, 172 left the country.
	●	The Netherlands has not offered 'non allocated' organs to other countries, because there were no 'non allocated' organs. These are allocated via Eurotransplant.

	+	The Netherlands evaluates the procedures for offering non allocated organs to other countries.
	+	The Netherlands has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	The Netherlands participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at national level.
	+	Results are measured 3 and 12 months after transplantation and yearly.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis (For selected recipients only), HIV (For selected recipients only!), and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	The Netherlands promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation systems used are: for procurement (surgeons): It is nationally done by the Dutch Transplant Foundation; for other staff involved in donation and transplantation: Nationally by the professionals associations.
	+	The EU Action Plan has influenced national policy on the promotion of accreditation systems: In General the need for accreditation has been promoted by EU Action Plan.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, the project EULOD[306] 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. The Netherlands is associated partner in the Joint Action FOEDUS. The ERASMUS Medical Centre in Rotterdam, the Netherlands is coordinator of the HOTT-project.[307]

[306] For more information about EU funded projects, see chapter 3.
[307] Hottproject.com

In 2010, 2011 and 2012, the country participated in the working group on indicators[308] 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[309]).

Conclusions

Both the Dutch deceased donation rate and living donation rate increased since 2008. This is very positive. Further developing in the area of small bowel transplantation may be an opportunity for the Netherlands.

The Netherlands indicated that the Action Plan was useful in the sense that it encouraged them to critically assess their own national program. In The Netherlands, many things in the field of organ donation and transplantation were already there at the start of the Action Plan.

According to the Dutch CA, the advantages of the action plan are: it gives the ingredients, it sustained the EU directive 2010/45/EU and it is a good way to learn from each other and critically assess the country's own performance.

What are the priorities for The Netherlands:

- bringing down the refusal rates;
- developing transplantation with organs from a living donor;
- data collection on performance, waiting lists and preferences;
- development of new technologies to improve quality and utility of organs.

According to The Netherlands, essential topics to address in the future are:

- quality of life, aftercare, effects of transplant patients;
- prevention of medical tourism;
- protection of the donor, prevent forced donation;
- develop medical technologies to increase the quality of organs;
- exchange of knowledge, training, standardization of knowledge and skills;
- establish transplantation programs;
- develop self-support of donation and transplantation;
- use existing knowledge.

[308] For more information about the working groups, see chapter 3.

[309] For more information about CD-P-TO, see Annex 3.

25. Norway

Background information[310]

With a deceased donation rate PMP of above 20 in 2015, Norway's deceased donation rate is amongst the highest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases. With a living kidney donation rate PMP of above 10 in 2015, Norway's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver. Norway has a relatively high number of pancreas transplants. Norway is part of Scandiatransplant[311] and donor organs are allocated through Scandiatransplant.

Since January 1st 1974 an **opt-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 not be removed. There is no **register** in place.

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.

[310] Sources: FACTOR survey filled in by national Competent Authority, 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; FACTOR 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.

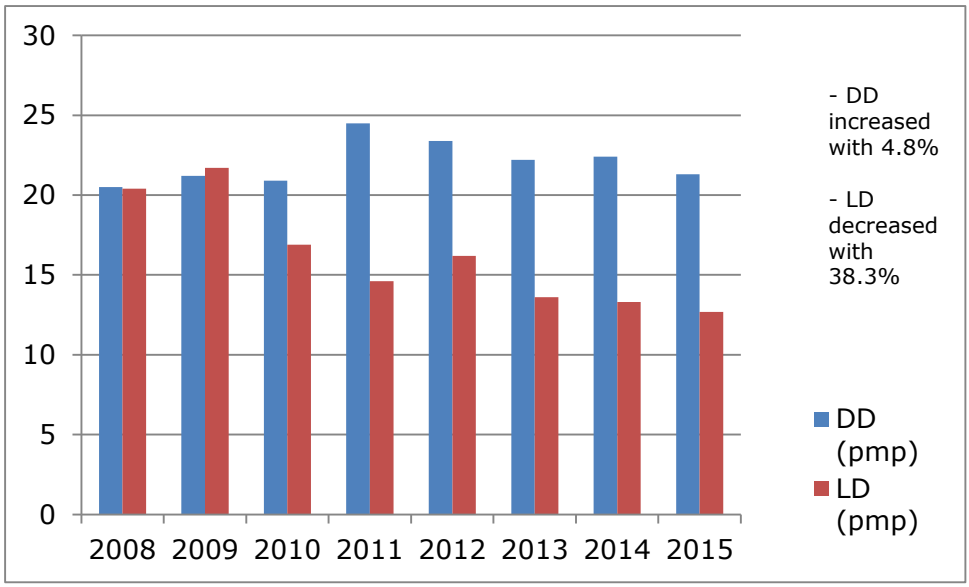
[311] Regarding EU-funded projects, Scandiatransplant participated as a partner in EFRETOS.

Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	4.8	4.8	4.9	5.0	5.0	5.0	5.1	5.2
Family refusal rate (refusals/times asked)	42/143	-	42/149	35/162	21/117	-	-	-
Actual deceased donation rate (total/per million population, pmp)	98/ 20.5	102/ 21.2	102/ 20.9	127/ 24.5	117/ 23.4	111/ 22.2	114/ 22.4	111/ 21.3
Multi-organ donation rates (% of total)	90.0	81	92.0	88.2	82.1	91	-	83.8
Number of utilised donors (total/per million population)	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	0	0	-	2	6
Number of donors older than 60	15		17	-	-	-	61	
Number of transplant centres								
Kidney	1	1	1	1	1	1	1	1
Liver	1	1	1	1	1	1	1	1
Heart	1	1	1	1	1	1	1	1
Lung	1	1	1	1	1	1	1	1
Pancreas	1	1	1	1	1	1	1	1
Bowel	0	0	-	-	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	180/ 37.5	188/ 39.2	180/ 36.7	229/ 45.8	218/ 43.6	201/ 40.2	206/ 40.4	191/ 36.7
Liver	79/ 16.5	82/ 17.1	89/ 18.2	89/ 17.8	100/ 20	110/ 22	100/ 19.6	83/ 15.9
Heart	39/8.1	27/5.6	32/6.5	30/6	32/6.4	37/7.4	34/6.7	37/7.1
Lung	30/6.3	24/5.0	32/6.5	28/5.6	28/5.6	33/6.6	33/6.5	34/6.5
Pancreas	10/2.1	16/3.3	15/3.1	20/4	28/5.6	39/7.8	31/6.1	31/6
Bowel	-	-	-	-	0	-	-	0
Number of living donor transplant procedures (total/pmp)								
Kidney	98/ 20.4	104/ 21.7	83/ 16.9	73/ 14.6	81/ 16.2	68/ 13.6	68/ 13.3	63/ 12.1
Liver	0	0	0	0	0	0	0	3/0.6

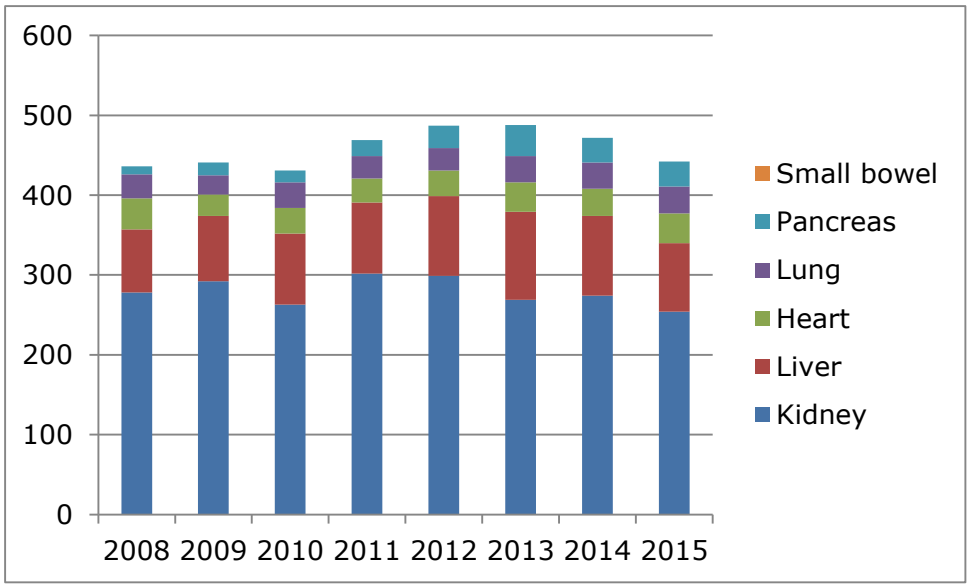
- = not known to the research team

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Norway*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level 26, at the national level 1.
	+	Transplant coordinators receive regular training.
	+	Summary of the training: Transplantation-indication, results. Law and regulations. Ethical themes with discussion, Communication theory and practise. Identification of potential donors, Organ preservation, Clinical diagnosis. Organ donation procedure. Religion. Follow-up -Next of kin. Transplant coordination.
	●	The trainings have not been tested for effectiveness.
	+	Norway uses an accreditation scheme.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors.
	●	The EU Action Plan has not influenced national policy on Quality Improvement Programmes.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Norway has directed[312] living donation programmes. When a patient becomes uremic, the nephrologist explains the treatment options including the possibility of a living donor. If affirmative about a LD, the nephrologist approaches the potential donor. A potential donor is always handled by another nephrologist than the one in charge of the patient. If there is no chance of a LD, the patient goes on the waiting list for an organ from a DD (Jakobsen, 2011).
	●	There are no undirected living donation programmes Norway.
	+	At present (January 2016) 1 hospital has a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.

[312] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	Organ trafficking is prohibited by law, the Council of Europe Convention is ratified by Norway.
	+	National policy on living donation programs is influenced by the EU Action Plan: Intensified follow-up programmes and research on living donors are implemented as a part of quality control measures.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public.
	+	Norway deploys programs to improve knowledge and communication skills for personnel that deals with organ transplantation and for patient support groups.
	●	Periodic meetings with journalists have not been organised.
	●	Guidelines and deliverables developed by EU supported activities are not used.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan. As to public awareness, the Action Plan contains many good points. Nevertheless most of these points have been implemented in our work for years – even before the AP was made.
	●	EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Norway does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Norway: residents with a foreign nationality who die in Norway, non-residents who die in Norway and illegal persons who die in Norway.
	+	Criteria required to be admitted to the waiting list in Norway are: Residency in Norway and being signed up with local social security or health care insurance.
	+	95 % of transplanted patients are local residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Norway is involved in twinning projects in a learning role, through participation in the ACCORD "Achieving comprehensive coordination on organ donation throughout the EU-ACCORD" and as collaborating partner in FOEDUS Facilitating exchange of organs donated in EU member states.
	+	Following countries are involved: Estonia, Moldova, The Netherlands, Spain, Cyprus, Iceland, UK, France, Portugal.
	+	These projects led to the following changes: Using FOEDUS IT –Tools.
	●	Norway has not used structural funds and/or other community instruments (EU funding) for the

		purpose of the development of transplantation systems, but is interested to do so.
	●	Transplantation centres or hospitals do not participate international registries.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan).
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	●	Norway has no agreements with other countries: Exchanging organs through Scandiatransplant.
	●	Norway has no agreements with other countries to prevent and address organ trafficking. No relevant issue at the time.
	●	No suggestions are given for future research programmes.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Norway is part of a multi-lateral collaboration, Scandiatransplant.
	+	Patient groups involved in this collaboration are: all patients.
	+	Organs involved are liver, kidney, heart, lung and other, being pancreas, small bowel.
	+	47 organs came from abroad, 68 left the country.
	●	Norway has not offered non-allocated organs to other countries, there were no 'non allocated' organs.
	+	Procedures for offering non allocated organs to other countries are evaluated.
	+	Norway has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Organs involved are liver, kidney, heart and lung.
	+	Norway participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange and in Scandiatransplant.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level: results are systematically collected in a database/register at national level.
	+	Results are measured 3, 6 and 12 months after transplantation.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors aged over 60.

	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis, Norway promotes an accreditation system for transplantation centres.
	+	The following accreditation systems are used: - for donation (coordinators): 26 donor hospitals approved by the authorities - for procurement (surgeons): 26 donor hospitals approved by the authorities - for transplantation: 1 national transplant center approved - for other staff involved in donation and transplantation: health staff involved in the donation process in all donor hospitals approved by NOROD Norwegian Resource group on competence in organ donation.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects, Norway was core work package leader of the EU funded project EULID[313] 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[314]. 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[315]): in 2010/2012, the CD-P-TO had even a Norwegian Chairman.

Conclusion
Norway's deceased donation rate increased since 2008, and its living donation rate decreased since 2008.

From Norway's CA perspective, the most valuable contribution of the Action Plan is the possibility for increased cooperation within all EU/EEA countries through the organizing of Competent Authority meetings. Incidentally, it is to say that Norway basically had all the most important aspects of the Action Plan in place before this was initiated.
Norway's priority in the nearest future is based on a new set of regulations based on the Directive 2010/53 / EU. In addition, a new transplantation law is developed which came into force on 01.01.2016. In the wake of this, further work mostly consists of implementation issues.
Norway is not an EU member, but invited to the CA meetings as an EEA member and the participation of this community is appreciated. To Norway, these meetings provide a valuable exchange of experience, conversations with key executives in other countries and also opportunities for new venues of cooperation across national borders.

[313] For more information about EU funded projects, see chapter 3.
[314] For more information about the working groups, see chapter 3.
[315] For more information about CD-P-TO, see Annex 3.

26. Poland

Background information[316]

With a deceased donation rate PMP between 10 and 20 in 2015, Poland belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases.
With a living kidney donation rate PMP of less than 5 in 2015, Poland's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver.
Donor organs are allocated at national level only.

[316] Sources: FACTOR survey filled in by national Competent Authority; Competent Authority Poland. (2011). Presentation National Action Plan Poland, 27 September 2011. Present data on organ donation and transplantation in Poland. Transpl Proc 2009, 41, 2955-2958; 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. System of donor hospital transplant coordinators maintained and financed by national transplant organization improves donation rates, but it is effective only in one half of hospitals. Transplant Proc. 2014; 46(8): 2501-4. Profiles of All 550 Procurements and Transplantations of Kidneys From Living Donors in Poland, 1967–2012. Transplant Proc. 2014;46(8): 2496-2500. Central Register of Objections for Deceased Donation in Poland 1996 to 2014; Country With an Opting-Out System. Transplant Proc. 2016; 48(8): 1337-40. Effective Application of a Quality System in the Donation Process at Hospital Level. Transplant Proc. 2016; 48(8): 1387-9. Evolution of Organ Transplantation in Poland 1966 to 2014: Dates and Numbers. Transplant Proc. 2016; 48(8): 1423-6. National Transplants Registry in Poland: Early and Long-term Results of Organ Transplantation in the Years 1998 to 2014. Transplant Proc. 2016; 48(8): 1407-10.

Key figures[317]

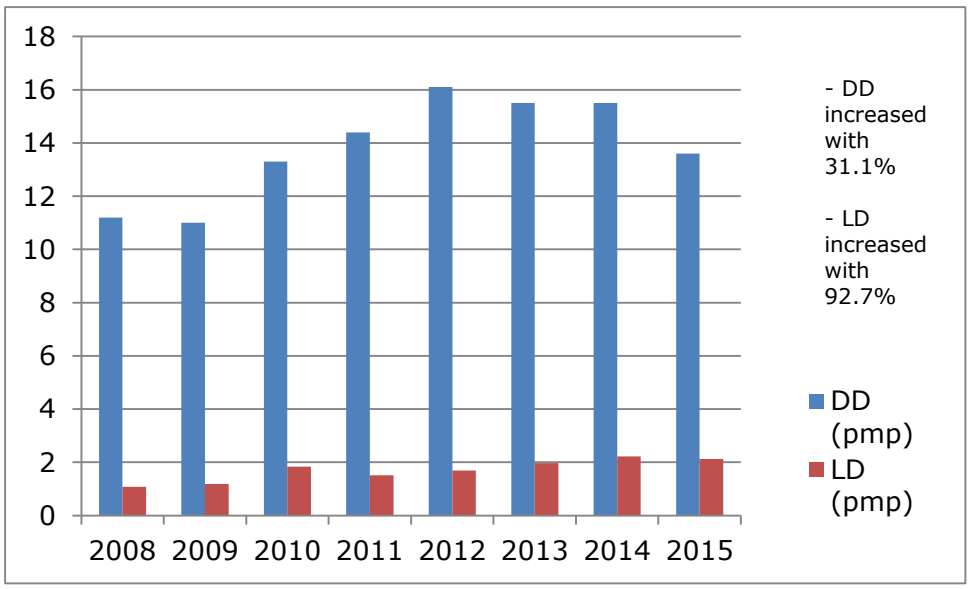
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	38.1	38.1	38.1	38.3	38.3	38.2	38.2	38.6
Family refusal rate (refusals/times asked)	54/497	56/500	51/587	68/641	73/699	89/698	103/ 719	100/ 643
Actual deceased donation rate (total/per million population, pmp)	427/ 11.2	420/ 11.0	509/ 13.3	553/ 14.4	615/ 16.1	593/ 15.5	594/ 15.5	526/ 13.6
Multi-organ donation rates (% of total)	56.0	56	47.0	58.4	56.6	62.6	63.8	66.3
Number of utilised donors (total/per million population)	422/ 11.1	410/ 10.8	497/ 13.0	541/ 14.1	595/ 15,5	574/ 15.0	572/ 15.0	510/ 13.2
Number of donors after circulatory death - DCD[318]	0	0	0	0	0	0	0	3
Number of actual donors older than 60	47	51	71	84	116	122	140	115
Number of utilised donors older than 60	46	50	68	82	102	111	129	107
Number of transplant centres								
Kidney	18	17	18	18	20	20	21	21
Liver	5	6	5	6	6	6	6	8
Heart	4	4	5	5	6	6	6	6
Lung	1	2	2	2	4	5	5	6
Pancreas	4	3	4	4	4	5	5	5
Bowel	0	0	1	1	1	1	1	1
Number of deceased donor transplant procedures (total/pmp)								
Kidney	790/ 20.7	762/ 20.0	949/ 24.9	1035/ 27.0	1094/ 25.6	1105/ 28.9	1094/ 28.6	987/ 25.6
Liver	224/ 5.9	224/ 5.6	217/ 5.7	282/ 7.4	314/ 8.2	318/ 8.3	336/ 8.8	310/ 8
Heart	61/1.6	71 /1.9	79/2.1	80/2.1	79/2.1	87/2.3	76/2	99/2.6
Lung	11/0.3	10 /0.3	12/0.3	15/0.4	16/0.4	17/0.4	19/0.5	24/0.6
Pancreas	20/0.5	20 /0.5	20/0.5	34/0.9	43/1.1	35/0.9	37/1	41/1.1
Bowel	0	0	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	20/0.5	23 /0.6	50/1.3	40/1.0	51/1.3	57/1.5	55/1.4	60/1.6
Liver	21/0.6	22 /0.6	20/0.5	18/0.5	14/0.4	18/0.5	30/0.8	22/0.6

- = not known to the research team

[317] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

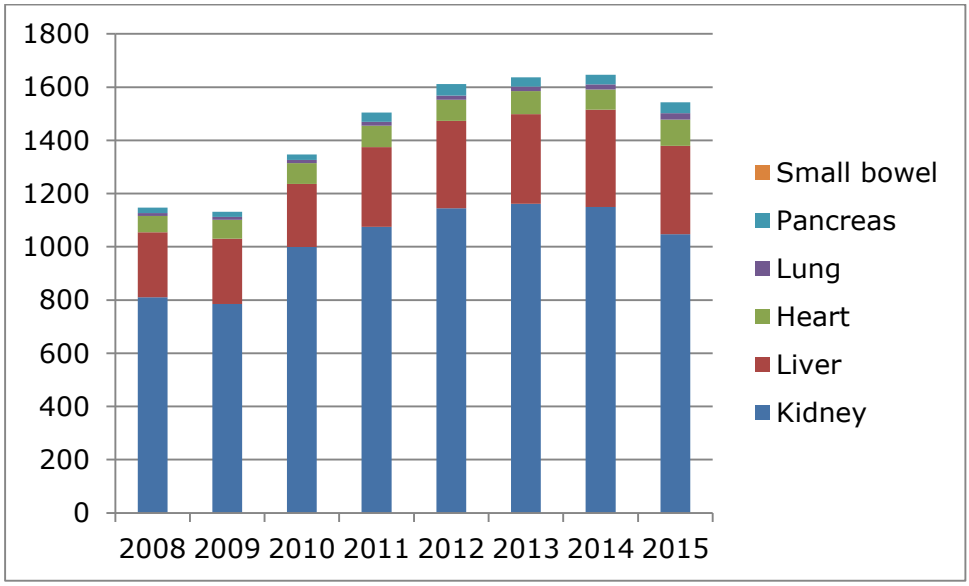
[318] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Poland*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 276 at the local/hospital level, 42 at the regional level and 7 at the national level.
	+	Transplant donor coordinators receive both initial training at the moment of appointing and regular training.
	+	The trainings have been tested for effectiveness.
	+	Poland uses an accreditation scheme, consisting of: 1. medical education, 2. advanced course for transplant coordinator, 3. agreement of the hospital's director.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: At the end of 2015: transplant coordinators appointed in 231 hospitals where there is potential for organ donation. Compared with 2010 when 123 hospital transplant coordinators worked in the field. Improvement in organization and information flow in process of coordination.
	+	Of the EU supported activities ETPOD has contributed to the promotion of the role of the transplant donor coordinators: 18 courses in 2015 with 1950 persons trained.
	+	The system of donor hospital transplant coordinators is maintained and financed by national transplant organization
Priority Action 2: Promote Quality Improvement Programmes	+	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.
	+	The EU Action Plan influences the national policy on Quality Improvement Programmes: DOPKI based procedures (monitoring of hospital potential of DBD donation) are being introduced in donor hospitals. At the national level transplant coordinators activities are being reported through the web net tool (koordynator.net) and analysed.
	+	Of the EU supported activities, ODEQUS has contributed to the promotion of Quality Improvement Programmes. ODEQUS based procedures are being introduced in some donor hospitals (in DBD and DCD programs), this process will continue in the years to come.
Priority Action 3: Exchange of best practices	+	Directed[319] living donation programmes exist: Living kidney and liver (part) donation is performed in most experienced transplant centres. There is a

[319] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

on living donation		special programme aimed to increase living donation (professionals training, families and recipients training). Pair exchange transplantation of kidneys was introduced.
	●	There are no unspecified (anonymous) living donation programmes, specified undirected (pair exchange) promes exist.
	+	15 hospitals have living donation program.
	●	There is no independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Poland has not yet ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan through development of a national register of living donors, available through the Internet for transplant centres. The Transplantation Act forces obligatory living organ donors medical check-ups up until 10 years after the donation. Development of pair exchange programme.
	+	Poland took part in COORENOR, EULID, ACCORD, ELPAT and LIDOBS and adopted its results. Materials and experience from these programmes are still in use.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	Communication guidelines for informing the public exist in Poland.
	+	Poland deploys programs to improve knowledge and communication skills of health professionals and of patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities will be used to inform the public, improve knowledge and skills of health professionals and of patient support groups and organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: In 2015-2016 the Ministry of Health launched a national campaign (TV-commercials, events, opinion polls) called "Yes for life" which promotes deceased donor organ donation. In recent years a living related kidney donation public campaign was and is being conducted.
	+	Of the EU supported activities, materials developed by FOEDUS are being used.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Poland does not yet provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can be legally donors in Poland: residents with a foreign nationality who die in Poland, non-residents who die in Poland, illegal

		persons who die in Poland (although there is no experience with this situation).
	+	Criteria required to be admitted to the waiting list: residency in Poland, local nationality, and signed up with local social security or health care insurance.
	+	99% of transplanted patients are local residents, 1% are non-residents.
	+	National policy on cross-border donation is influences by the EU Action Plan: Poland took part in COORENOR organ exchange and now in FOEDUS organ exchange through web-based application. In 2015 6 pairs of lungs donated in Poland were transplanted in Austria, Germany and France.
	+	EU supported activities contribute to the identification of cross-border donors: Poland takes active part in both programmes.
Priority Action 6: Enhancing organisational models	●	Poland is not officially involved in any twinning projects yet.
	+	Transplantation centres or hospitals do not yet participate in any network, but there is a need to cooperate with other Lung transplantation programmes, especially for patients with cystic fibrosis.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan through development of transplant coordinators network; more efficient cooperation between transplant donor coordinators and intensive care units; a living kidney donation awareness programme conducted for nephrologists, dialysis stations staff, patients as well as for general public; and further development of national registries (waiting lists, transplant coordination, living donor register, transplant follow-up register).
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Poland has agreements with other countries for exchanging organs and for collecting data: Poland actively participates in FOEDUS agreement and organ exchange platform established in this programme. Poland takes part international transplant registries for liver, pancreas, heart and lungs – reported by transplant centres and in data reporting for EU Newsletter Transplant and IRODAT. Research and training activities conducted at the transplant centre level.
	●	Poland has no agreements with other countries to prevent and address organ trafficking: the main challenges are: possible (not existing) Organ Trade - Transplant Tourism.
	+	Future research programs should ideally focus on transplant registries (National and at the EU level) and organ exchange at the regional level.
	+	The development of EU-wide agreements is influenced by the EU Action Plan because of the FOEDUS organ exchange agreement.
	+	EU supported activities contribute to this development: Poland is actively participating in FOEDUS agreement and organ exchange platform.

Priority Action 8: Facilitate the interchange of organs between national authorities	+	Poland is part of a fixed collaboration: FOEDUS.
	+	Patient groups involved are patients with urgent needs for transplantation.
	+	Organs involved are liver, heart and lung.
	+	In 2015 0 organs came from abroad, 6 organs left the country.
	+	Poland has offered 6 'non-allocated' organs (lungs) to other countries.
	+	The procedure for non-allocated organs is evaluated.
	●	Poland has no procedure for the exchange of organs of urgent and difficult-to-treat patients.
	+	Poland participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs is influenced by the EU Action Plan. Poland is using FOEDUS application for organ exchange.
	+	EU activities contributed to the interchange of organs between countries: Poland is an active participant in COORENOR and now FOEDUS.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3, 6 and 12 months after transplantation and every 12 months thereafter and published in open manner.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors aged over 60.
	+	National policy on the evaluation of post-transplant results will be influenced by the EU Action Plan through further development of transplant registries. Living donors register data are ready for implementation of European register of registries.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	Poland promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation system used is: a) for donation (coordinators): preliminary, complementary and continuous training every 2 years at the national level; b) for procurement (surgeons): board exam after 4 years of training in clinical transplantology national level; c) for transplantation: board exam after 4 years of training in clinical transplantology national level.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	+	EU supported activities contribute to the promotion of accreditation systems: Accreditation systems are to be implemented on a broader scale in the future.

		Currently in several hospitals accreditation programmes (ODEQUS like) are implemented.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Poland was core work package leader in the COORENOR[320] 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[321] and in the annual exercises. Poland also participated in the living donation working group. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[322]).

Conclusion

Both Poland's deceased donation rate and living donation rate increased since 2008. This is very positive.

The Polish CA stated that every one of the priority action points is important, for the EU and for Poland. International contacts are very important to create a platform to share experiences from different countries. As an example: Poland has good experience with the living kidney donor program and learns from others about how to construct a register for this. Also the ACCORD project has been very helpful, but these are examples, the whole program is very valuable.

Poland's priorities are to have a deceased donation system in 400 hospitals; a web-based tool for monitoring this system; to include the criteria for living and deceased donation into the hospital quality system and into the rules for accreditation; and to educate professionals in this hospital quality system.

The next step in the EU as a whole should be to continue with meetings, according to Poland, but focus more on meetings between specialists. Lately the value and quality of the international meetings have changed, because there are more non-specialists attending, who are not always as enthusiastic as the specialists, maybe because they are more concerned with organisations and regulations. Another thing is the need to improve the system's capacity to disseminate the results and the need to focus on how to share results of different projects in Europe. For instance, the DOPKI-project finished five years ago, but no-one knows about it.

[320] For more information about EU-funded projects, see chapter 3.
[321] For more information about the working groups, see chapter 3.
[322] For more information about CD-P-TO, see Annex 3.

27. Portugal

Background information[323]

With a deceased donation rate PMP of above 20 in 2015, Portugal's deceased donation rate is amongst the highest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases.

Portugal has a relatively high number of liver transplants. With a living kidney donation rate PMP of less than 10 in 2015, the Portugal's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver.

Donor organs are allocated on the regional level.

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

Since September 26th 1994 an **opt-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 Register (RENNDA).

Financing of organ donation

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

[323] Sources: FACTOR 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.

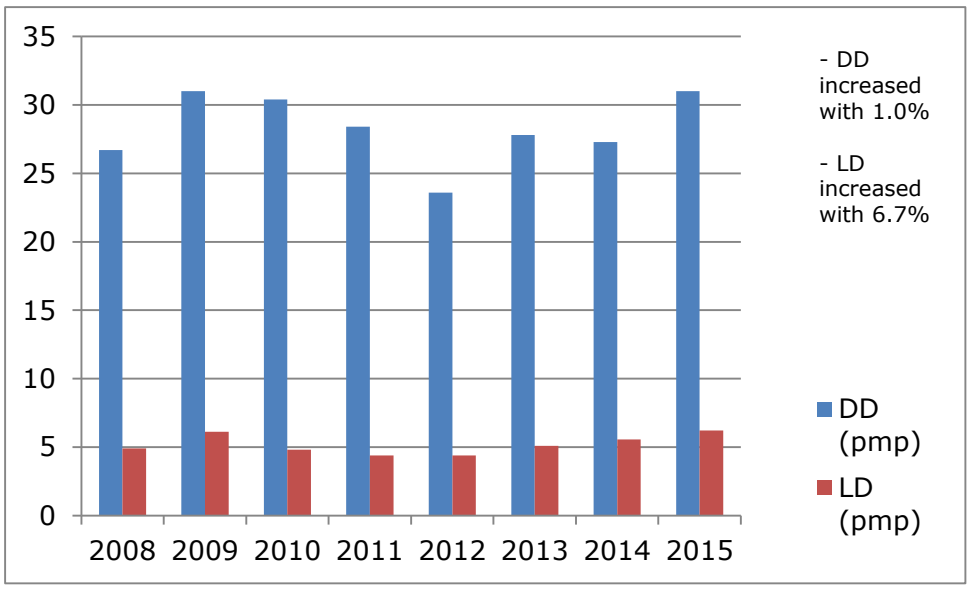
Key figures[324]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	10.6	10.6	10.6	10.6	10.7	10.6	10.6	10.3
Family refusal rate (refusals/times asked)	NA	-	NA	NA	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	283/ 26.7	329/ 31.0	323/ 30.4	301/ 28.4	252/ 23.6	295/ 27.8	289/ 27.3	319/ 31
Multi-organ donation rates (% of total)	73.9	68.1	69.0	71.1	71.0	72.9	67.1	69
Number of utilised donors (total/per million population)	-		320/ 30.2	286/ 27	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	0	0	0	0	0
Number of donors older than 60	-		63	68	-	-	119	
Number of transplant centres								
Kidney	8	8	8	8	8	8	8	8
Liver	3	3	3	3	3	3	3	3
Heart	4	4	4	4	4	4	4	4
Lung	1	1	1	1	1	1	1	1
Pancreas	1	1	2	2	2	2	2	2
Bowel	0	0	0	0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	476/ 44.8	531/ 50.0	522/ 49.1	483/ 45.1	382/ 35.7	399/ 37.6	394/ 37.2	421/ 40.9
Liver	200/ 18.8	254/ 23.9	208/ 19.6	193/ 18.2	140/ 13.1	238/ 22.5	197/ 18.6	247/ 24
Heart	42/4.0	47 /4.4	50/4.7	46/4.3	30/2.8	55/5.2	43/4.1	50/4.9
Lung	4/0.4	11 /1.0	10/0.9	18/1.7	14/1.3	16/1.5	19/1.8	15/1.5
Pancreas	14/1.3	20 /1.9	15/1.4	25/2.3	20/1.9	25/2.4	27/2.5	27/2.6
Bowel	0	0	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	51/4.8	64 /6.0	51/4.8	47/4.4	47/4.4	51/4.8	54/4.1	62/6
Liver	1/0.1	1 /0.1	0	0	0	3/0.3	5/0.5	2/0.2

- = not known to the research team

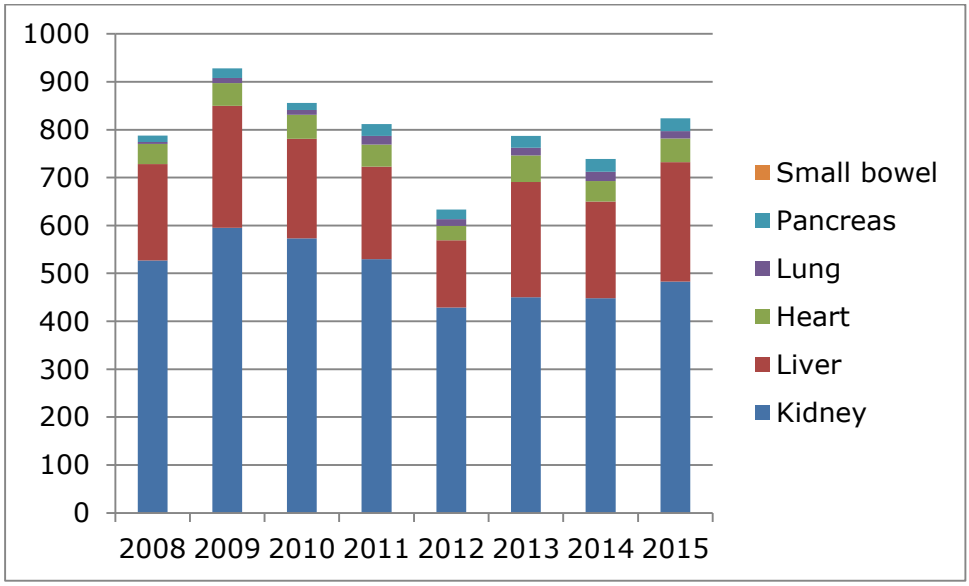
[324] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Portugal*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 50 at the local/hospital level, 5 at the regional level and 1 at the national level.
	+	Transplant donor coordinators receive initial training.
	+	Summary of the training: all the Hospital Donor Coordinators were trained by the "Transplant Procurement Management" course in cooperation with the University of Barcelona, supported by the National Competent Authority. These training courses have been organized in 2008, 2009, 2011 and 2014; in 2013, training in leadership all donor coordinators in functions; in 2015 training in tissue donation and procurement.
	+	Portugal uses an accreditation scheme. At present time, 53 Donor Hospital Coordinator officially nominated and also 53 substitutes, in the 45 authorized hospitals; all these professionals have national and international accreditation.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: Since 2008, all hospitals with intensive care services have nominated an in-hospital donor coordinator, responsible for identifying, evaluating and maintaining potential organ donors.
	+	The EU supported activities ETPOD, ODEQUS and ACCORD have contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: Participation in ODEQUS and ACCORD helped us to develop an Auditing system for the donation process, which is going on.
	+	EU supported activities ODEQUS, MODE and ACCORD have contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Portugal has directed[325] living donation programmes. Since 2007 living donation between genetically unrelated people is allowed and in 2009 started the cross kidney program.
	+	There also are undirected living donation programmes: Undirected living donation is currently included in the legislation, as well as

[325] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		altruistic donation; nevertheless, altruistic donation has no results until de moment.
	+	6 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level, at the regional level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Portugal has not yet ratified the Council of Europe Convention.
	+	National policy on living donation programs is influenced by the EU Action Plan: - Awareness for living organ donors (media and general public) - Whenever a patient with end stage renal disease starts dialysis program, all treatment possibilities are acknowledged, including living donor transplantation.
	+	EU supported activities ACCORD, LIDOBS and EULID contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public.
	+	Portugal deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation and of all health care (hospital) personnel and of patient associations.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: General public awareness is very important and is developed through media (TV, newspapers, internet,…) and through the organization of EODD in 2015.
	+	The EU supported activities EODD and FOEDUS contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Portugal does not yet provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Portugal: residents with a foreign nationality who die in Portugal, and non-residents who die in Portugal.
	+	Criteria required to be admitted to the waiting list: residency in Portugal, local nationality and being signed up with local social security or health care insurance.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.

	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Portugal is not involved in twinning projects.
	+	Portugal has used or plans to use structural funds and/or other community instruments for the purpose of the development of transplantation systems.
	●	Transplantation centres or hospitals do not participate in any networks. National Transplant Centres were elected as centres of reference having in consideration the need of such network for the following topics (examples): - sharing knowledge and investigation - sharing experiences - promoting healthcare professionals training and skills. Regarding patients treatment, the participation of transplant centres in the network of centres of reference is not allowed according to legislation.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: All Hospitals with intensive care like facilities were defined has "Potential Donor Hospitals" and therefore, according to the legislation, were obliged to give their feedback regarding the capacity and availability to became a Donor Hospital; in all Donor Hospitals it was created, by law, the role of the Hospital Donor Coordinator, which must be a medical doctor.
	+	EU supported activities DOPKI, MODE, ODEQUS and ACCORD contributed to enhancing the organisational model of the donation and transplantation system through the development of a tool to evaluate efficacy and efficiency of the organisational model and defining corrective measures.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Portugal has agreements with other countries for exchanging organs, treating each other's patients, collecting data and research activities. There is a bilateral agreement between Portugal and Spain that states that whenever there is an organ from a Portuguese donor for which there is no suitable recipient in Portugal, the organ is offered to Spain; whenever there is a very urgent request for a liver in Portugal, that is not resolved in 24 hours, the request is extended to Spain and the Portuguese patient is in the same "allocation conditions" as a Spanish patient; also Portuguese patients are admitted in the Spanish waiting list for lung.
	●	Portugal does not yet have agreements with other countries to prevent and address organ trafficking: the main challenges are: to implement a detection system for potential trafficking situation, with a timely responsiveness and effective punishment.
	+	Future research programmes should focus on: - To study survival and quality of life of transplanted patients, after 1 year, 5 years and 10 years post transplantation (by organ). - To study the impact of

		the different waiting lists criteria of each Member State and design a harmonized network to organize these waiting lists.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	+	EU supported activities ACCORD, FOEDUS, HOTT project, ELPAT and LIDOBS contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Portugal is part of a fixed collaboration: a multilateral collaboration, namely South Alliance for Transplants (SAT) and bilateral collaborations, with next countries Spain.
	+	Patient groups involved are: patients with urgent needs for transplantation, paediatric patients and patients in need of lung and small bowel.
	+	Organs involved are liver, heart, lung and small bowel.
	+	Portugal has offered 'non allocated' organs to other countries.
	+	Organs involved are liver, kidney, heart and lung.
	●	Portugal does not evaluate procedures for offering non allocated organs to other countries.
	+	Portugal has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Organs involved are liver.
	●	Portugal does not yet participate in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs will be influenced by the EU Action Plan: In the future, interchange of organs between countries, other than Spain, will be possible through the FOEDUS portal.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, but only at a regional or local level.
	+	Results are measured 3, 6 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	●	Portugal does not yet promote an accreditation system for procurement organisations and transplantation centres.

	+	The EU Action Plan has influenced national policy on the promotion of accreditation systems: A special program of CHKS is being developed to accredit organ donation and cornea transplantation.
	•	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Portugal was core work package leader in EULID and ELIPSY[326] 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[327] 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[328]).

Conclusions

Both Portugal's deceased donation rate and living donation rate slightly increased since 2008. This is positive.

According to the Portuguese CA, the Action Plan on Organ Donation in Europe strengthens national donation country, supporting them to develop new strategies for organ donation and transplantation increase.

The priorities of Portugal are to implement a quality assurance program for organ donation and transplantation, increase living donation and develop Donation After Circulatory Death Program, allowing Maastricht type III.

For Portugal, European cooperation is essential, all countries face lack of organs and therefore joint efforts to improve transplantation programs benefit all European citizens. Organ and human trafficking and quality indicator for transplantation are essential topics.

[326] For more information about EU-funded projects, see chapter 3.
[327] For more information about the working groups, see chapter 3.
[328] For more information about CD-P-TO, see Annex 3.

28. Romania

Background information[329]

With a deceased donation rate PMP between 5 and 10 in 2015, Romania's deceased donation rate PMP is amongst the lower of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts and pancreases.

With a living kidney donation rate PMP of less than 5 in 2015, Romania's living kidney donation rate PMP is among the lower of the countries included in this study. In 2015 living donor transplant procedures were carried out involving 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.

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

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

Financing of organ donation

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

[329] Sources: FACTOR survey filled in by national Competent Authority, 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.

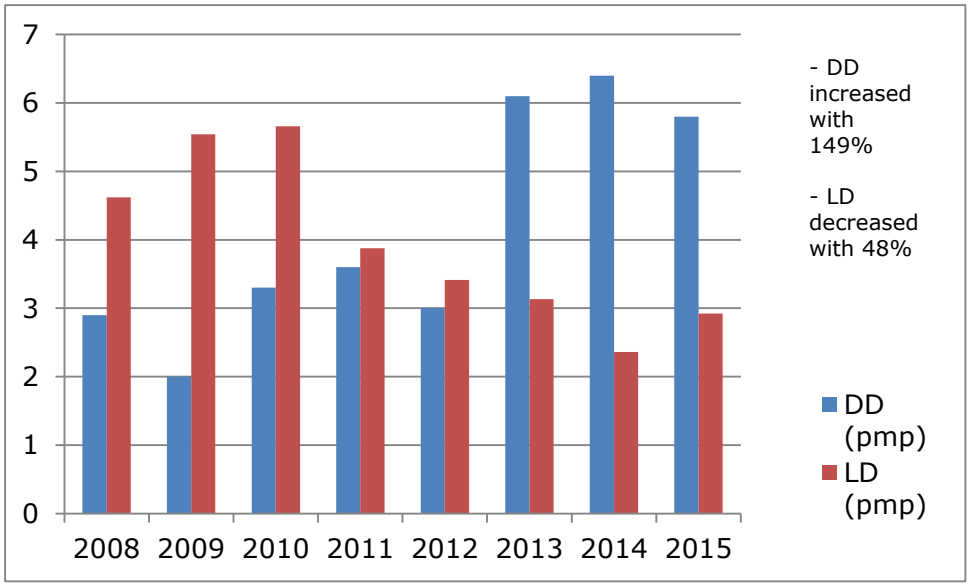
Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	21.0	21.3	21.2	21.4	21.4	21.7	21.6	19.5
Family refusal rate (refusals/times asked)	-	70/112	-	45/159	45/154	-	83/284	67/370
Actual deceased donation rate (total/per million population, pmp)	60/2.9	42 /2.0	70/3.3	77/3.6	65/3	132/ 6.1	138/ 6.4	113/ 5.8
Multi-organ donation rates (% of total)	60	75	75	75.3	100	100	77.5	80.5
Number of utilised donors (total/per million population)[330]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	1	0	1	-	1	0	0	0
Number of donors older than 60	-		-	-	-	-	28	
Number of transplant centres								
Kidney	5	5	5	3	5	3	4	4
Liver	1	1	1	1	1	2	2	2
Heart	2	2	2	2	2	2	3	3
Lung	2	0	0	0	1	0	0	0
Pancreas	3	1	1	1	2	2	2	2
Bowel	0	0	0	0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	115/ 5.5	83 /3.9	124/ 5.8	144/ 6.7	124/ 5.8	240/ 11.1	273/ 12.6	199/ 10.2
Liver	35/1.7	29 /1.4	42/2.0	57/2.7	55/2.6	108/ 4.9	108/5	85/4.3
Heart	6/0.3	10 /0.5	7/0.3	7/0.3	2/0.1	1/0	4/0.2	4/0.2
Lung	0	0	0	0	0	0	0	0
Pancreas	0	0	0	0	0	0	12/0.6	1/0.1
Bowel	0	0	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	88/4.2	113/ 5.3	112/ 5.3	75/3.5	53/2.5	54/2.5	37/1.7	46/2.4
Liver	9/0.4	3 /0.1	8/0.4	8/0.4	20/0.9	14/0.6	14/0.6	11/0.6

- = not known to the research team

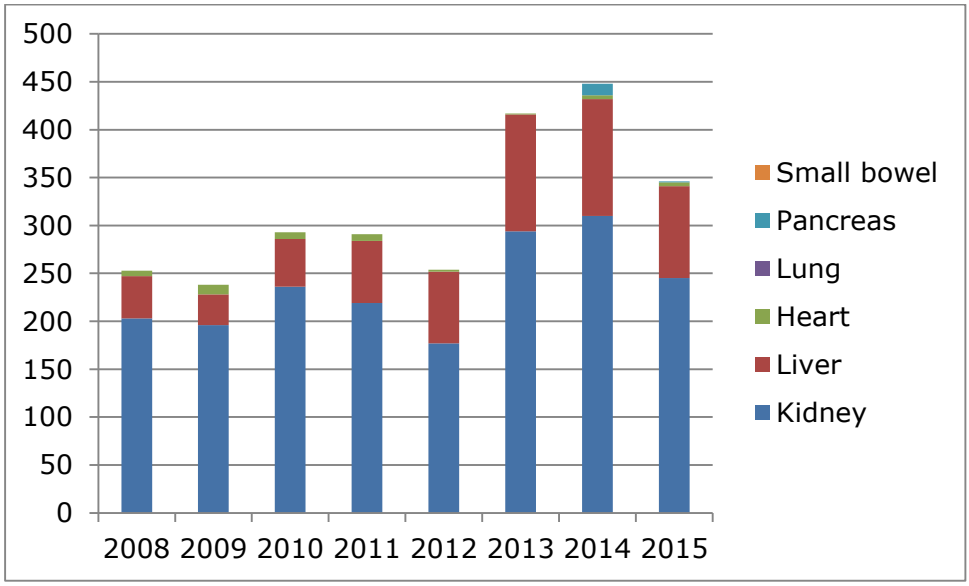
[330] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Romania*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level 41, at the regional level 6, at the national level 1.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: Initial training at the moment of appointing and 2 regular bi-annual meetings of the Romanian transplant coordinators. Many of the Romanian coordinators have attended international transplant coordination trainings/ courses (e.g. TPM).
	●	The trainings have not been tested for effectiveness.
	●	Romania does not use an accreditation scheme.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: The implementation of in house transplant coordinators has doubled the number of donors and transplant procedures in Romania.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: Audit of the 40 county hospitals performed by the ICU specialists commission - ICU's are accredited as part of the national transplant program - ICU's receive reimbursement from the Ministry of Health (3000 EUR/declared deceased donor) - A better use of the marginal donors - Implementing a DCD program - Common criteria of accreditation of the procurement and transplant centres – according to the requirements of Directive 2010/53/EC; - Brain death diagnosis protocol established by law (whole brain death concept) - Guides of good medical practices concerning the maintenance of the donors - Regular meetings with the hospital staff, head of ICU departments and transplant coordinators - Applying the national legislation provisions – MoH's Order nr. 1246/2012.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices	+	Romania has directed[331] living donation programmes. According to the Romanian transplant

[331] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed

on living donation		law, all living organ donations are allowed only after the approval by an "ethical commission".
	+	There are undirected living donation programmes Romania, In Romania there is no regulatory or legal limitation in the donor - recipient relationship. The living organ donation from minors is forbidden. Truly altruist donors ("good Samaritans") are accepted for anonymous donation in Romania. According to the Romanian transplant law, all living organ donations are allowed only after the approval by an "ethical commission".
	+	At present (January 2016) 3 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not yet ratified by Romania.
	●	National policy on living donation programs is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Romania does not yet deploy programs to improve knowledge and communication skills of personnel that deal with organ transplantation, but deploys some for patient support groups.
	+	Periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used for informing the public and improving knowledge and skills of health professionals, but not to improve knowledge and skills of patient support groups.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Romania does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Romania: residents with a foreign nationality who die in Romania and non-residents who die in Romania.
	+	Criteria required to be admitted to the waiting list: residency in Romania.
	+	All transplanted patients are local residents.

living donation means that the donor and recipient have a social relationship (partner, family or friend).

	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Romania is involved in twinning projects in a teaching role. Cooperation with the Republic of Moldova in BSA Project - Romanian specialists (coordinators, ICU doctors, surgeons) are involved in a twinning European project for technical support to develop the transplant activity in Moldavia - "Strengthening the Transplant Agency of the Republic of Moldova and support in legal approximation in the area of quality and safety of substances of human origin" - The first 3 liver transplants from BDD in the Republic of Moldova were performed with the cooperation of the Romanian specialists (Prof. Dr. Irinel Popescu, Dr. Vlad Brasoveanu)".
	+	These projects led to the following changes: The start of the BDD donation and liver transplant program in the Republic of Moldova.
	●	According to the CA, Romania has not yet used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems, but they are interested.
	●	Transplantation centres or hospitals do not yet participate international registries.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Romania has agreements with other countries for exchanging organs, treating each other's patients, and for supporting the development of new transplantation programmes, including an agreement with AKH for lung transplant and training of Romanian specialists for lung donor evaluation and lung transplantation.
	●	Romania has no agreements with other countries to prevent and address organ trafficking: the main challenges are: Transplant tourism encouraged by rich countries for their own citizens.
	●	No suggestions for future research programmes.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	●	Romania is not yet part of a multi-lateral collaboration, but has a bilateral collaboration with Austria.
	+	Patient groups involved in this collaboration are: patients in need of lung transplant.
	+	Organs involved are lung.

	●	In 2015 no organs came from abroad, no organs left the country.
	●	Romania has not offered non-allocated organs to other countries, because there are no agreements with other countries.
	●	Procedures for offering non allocated organs to other countries are not evaluated.
	●	Romania has no procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Romania participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a regional/local level.
	+	Results are measured 3, 6 and 12 months after transplantation and then every 6 months.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute, to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis and Romania promotes an accreditation system for this.
	+	This system is used for donation at the national level, for procurement at the national level and for transplantation at the national level. Centres are accredited, not staff.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Romania participated as a partner in ETPOD[332], COORENOR, EULID, ODEQUS and FOEDUS. It participates as a partner in the Joint Actions ACCORD and FOEDUS. The Academic Society for the Research of Religions and Ideologies (SACRI) of Romania participates as a co-beneficiary in the HOTT-project.[333]

[332] For more information about EU funded projects, see chapter 3.
[333] Hottproject.com

In 2011 and 2012, the country participated in the data collection launched at European level by the working group on indicators[334]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[335]).

Conclusion

Romania's deceased donation rate increased since 2008, and its living donation rate decreased since 2008. An opportunity for Romania may be to form agreements with other countries, to exchange surplus organs and to contribute to the efficient use of organs across Europe.

According to the Romanian CA, the most valuable contribution of the Action Plan to Romania was the focus on the importance of the in house transplant coordinators. This priority of the Action Plan was very helpful for me to convince the authorities about the essential role of the in house transplant coordinators in order to develop a very efficient transplant system.

Romania has 2 priorities for the next years:

- to consolidate the achievements that we have reached considering the number of the hospitals involved in brain death declaration and if it is possible to increase this number.
- to increase the number of organ transplant centres for liver and kidneys and to develop the lung transplant program.

The very important step in the next period must be the establishment of the same level of the quality standards in transplant activity for all EU Member States. For this reason, the essential topics must be the cooperation and exchange of experience between the experts of the Member States. In my opinion, it is the unique possibility to explain and to convince the authorities to create all the conditions for the development of the transplant activity at high level.

[334] For more information about the working groups, see chapter 3.
[335] For more information about CD-P-TO, see Annex 3.

29. Serbia[336]

In Serbia, an **opt in** consent system is in place[337].

No further background information available for Serbia.

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	-	-	-	-	-	9.5	-	-
Family refusal rate (refusals/times asked)	-	-	-	-	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	-	-	-	-	-	41/4.3	-	-
Multi-organ donation rates (% of total)	-	-	-	-	-	41.5	-	-
Number of utilised donors (total/per million population)[338]	-		-	-	-	-	-	-
Number of donors after circulatory death - DCD	-	-	-	-	-	0	-	-
Number of donors older than 60	-		-	-	-	-	-	-
Number of transplant centres								
Kidney	-	-	-	-	-	5	-	-
Liver	-	-	-	-	-	3	-	-
Heart	-	-	-	-	-	2	-	-
Lung	-	-	-	-	-	0	-	-
Pancreas	-	-	-	-	-	0	-	-
Bowel	-	-	-	-	-	0	-	-
Number of deceased donor transplant procedures (total/pmp)								
Kidney	-	-	-	-	-	74/7.8	-	-
Liver	-	-	-	-	-	17/1.8	-	-
Heart	-	-	-	-	-	4/0.4	-	-
Lung	-	-	-	-	-	0	-	-
Pancreas	-	-	-	-	-	0	-	-
Bowel	-	-	-	-	-	0	-	-
Number of living donor transplant procedures (total/pmp)								
Kidney	-	-	-	-	-	30/3.2	-	-
Liver	-	-	-	-	-	0	-	-

- = not known to the research team

[336] Source: FACTOR survey filled in by national Competent Authority.
[337] http://budidonor.kgv-projekt.hr/legislation/
[338] No separate information was given for the number of utilised donors.
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Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Priority Action 1: Promote the role of transplant donor coordinators
	●	Serbia does not use an accreditation scheme.
	●	The EU Action Plan will in the future influence national policy on transplant donor coordinators.
	●	It is not known whether the EU supported activities have contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	●	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, and the follow-up care.
	●	It is not known whether the EU supported activities have contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Serbia has directed living donation programmes. In Serbia living kidney donation means only donation from relatives.
	●	There are no undirected living donation programmes in Serbia.
	+	At present (January 2016) 5 hospitals have a living donation program, only for related donors.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not yet ratified by Serbia.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are no communication guidelines for informing the public. Serbia does deploy programs to improve knowledge and communication skills of personnel that deal with organ transplantation.
	●	Periodic meetings with journalists have not been organised.
	●	Guidelines and deliverables developed by EU supported activities are not used.
	●	EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Serbia does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Serbia: residents with a foreign nationality who die in Serbia and non-residents who die in Serbia.
	+	Criteria required to be admitted to the waiting list: Serbian nationality and being signed up with local social security or health care insurance.
	+	All transplanted patients are local residents.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6:	+	Serbia is involved in twinning projects in a learning

Enhancing organisational models		role. Serbia was involved in TAIEX workshops regarding organ donation and transplantation, financing, brain death declaration, legislation improvement, in cooperation with south eastern European countries such as Croatia, Slovenia, Macedonia and Moldova.
	●	Serbia has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems, but they are interested.
	+	Transplantation centres or hospitals participate in the RHDC network.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	●	Serbia has no agreements with other countries for exchanging organs, treating each other's patients, supporting the development of new transplantation programmes, training/certifying healthcare professionals, collecting data, research activities or other aspects of transplant medicine.
	●	Serbia has no agreements with other countries to prevent and address organ trafficking: the main challenge is: To achieve self-sufficiency in organ donation for each country.
	●	Suggestions for future research programmes: Living donation outcome, Quality of organs for transplantation.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	●	Serbia is not part of a multi-lateral collaboration.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	●	Post-transplant results of organ recipients are not evaluated.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency and from donors aged over 60.
	●	EU supported activities did not contribute, to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not controlled or audited on a regular basis.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

30. Slovakia

Background information[339]

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 PMP between 10 and 20 in 2015, Slovakia belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers and hearts.

With a living kidney donation rate PMP of less than 5 in 2015, Slovakia's living kidney donation rate PMP is among the lowest of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney.

Donor organs are allocated at national level.

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

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

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.

[339] Sources: FACTOR 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.

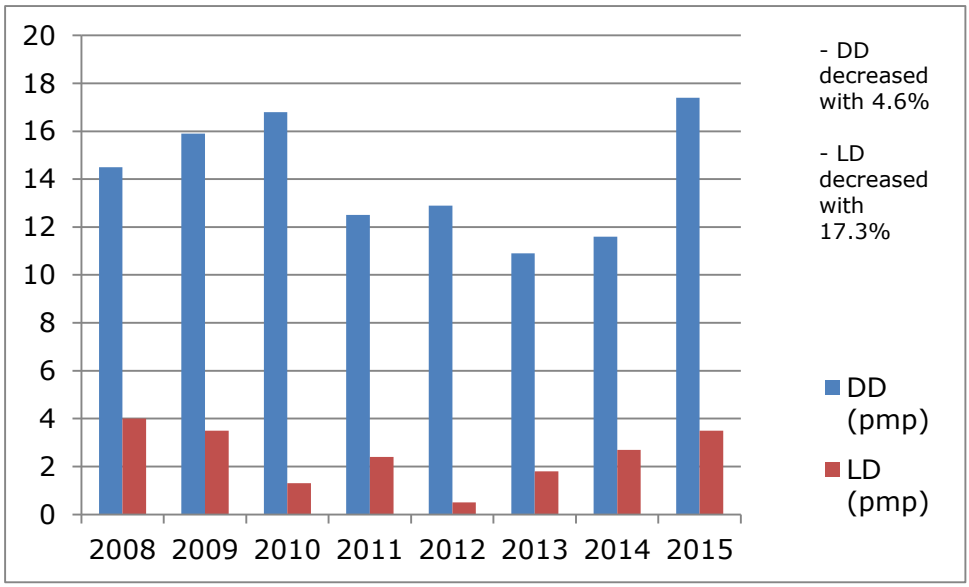
Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	5.3	5.4	5.4	5.5	5.5	5.5	5.5	5.4
Family refusal rate (refusals/times asked)	-	-/105	7/98	9/88	-	-	11/-	12/117
Actual deceased donation rate (total/per million population, pmp)	77/ 14.5	86/ 15.9	91/ 16.8	69/ 12.5	71/ 12.9	60/ 10.9	64/ 11.6	94/ 17.4
Multi-organ donation rates (% of total)	48.0	47	54.0	58.0	59.1	48.3	45.3	54.3
Number of utilised donors (total/per million population)[340]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	0	0	0	0	0
Number of donors older than 60	5		7	-	-	-	11	
Number of transplant centres								
Kidney	4	4	4	4	4	4	4	4
Liver	2	2	2	2	2	2	2	2
Heart	2	1	1	1	1	1	1	3
Lung	0	0	0	0	0	0	0	0
Pancreas	0	0	0	1	0	0	1	2
Bowel	0	0	0	0	0	0	0	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	145/ 27.4	153/ 28.3	162/ 30	116/ 21.1	130/ 23.6	109/ 19.8	110/ 20	165/ 30.6
Liver	12/2.3	24 /4.4	33/6.1	25/4.5	29/5.3	22/4	23/4.2	34/6.3
Heart	26/4.9	23 /4.2	21/3.9	19/3.5	20/3.6	14/2.5	17/3.1	27/5
Lung	0	0	0	0	0	0	0	0
Pancreas	0	0	0	0	0	0	0	0
Bowel	0	0	0	0	0	0	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	21/4.0	19 /3.5	7/1.3	13/2.4	3/0.5	10/1.8	15/2.7	19/3.5
Liver	0	-	0	0	0	0	0	0

- = not known to the research team

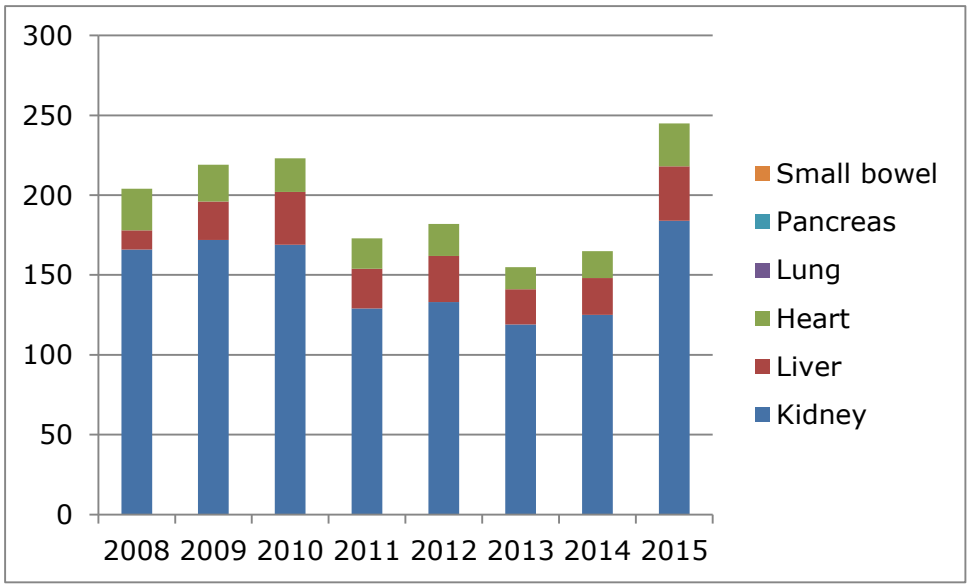
[340] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Slovakia*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Priority Action 1: Promote the role of transplant donor coordinators
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: there were two courses with practical training and lectures (3 days). Similar to TPM in collaboration with EDTCO. At present time there is once a year seminar specific for some donor management topic and one type of transplantation called Transplantforum. - Seminars about the donor management - Regular meetings and seminars about donation at regional level organized by regional coordinators with participation of medical professionals from transplant program.
	+	The trainings have been tested for effectiveness.
	+	Slovakia uses an accreditation scheme: TPM for regional coordinators. National for hospital coordinators similar to TPM. A Manual for transplant coordinators was published in Slovak language in 2010 with support of Ministry of health.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: The network of hospital coordinators was established. The system of regular education meetings was put in place. The evaluation of effectiveness of donor identification process was established.
	+	EU supported activities have contributed to the promotion of the role of the transplant donor coordinators: In 2010 the "Manual of transplant coordinator" was published in Slovak language. The manual was elaborated by medical professionals and was financially supported by Ministry of Health, Slovak Republic (CA).
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced the national policy on Quality Improvement Programmes: The national policy regarding Quality Improvement Program runs in parallel with EU Action Plan and was the part of National transplant program.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices	+	Slovakia has directed[341] living donation programmes. Criteria for a living donor: - Healthy

[341] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed

on living donation		adult blood relative, friend or partner, capable of general anaesthesia - The presence of two healthy kidneys - Match the blood group of a negative cross-examination (cross-match) - The absence of disease that can cause kidney failure recipient - Consent to the donation must be voluntary and informed.
	●	There are no undirected living donation programmes. In Slovakia there is definition of emotionally related donor. It doesn´t fully fulfil the definition of undirected LOD. But that is the altruistic donation to the known recipient. If this is counted as undirected living donor, the answer is yes.
	+	4 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Slovakia has not yet ratified the Council of Europe Convention.
	●	National policy on living donation programs is not influenced by the EU Action Plan through the living donor register.
	+	EU supported activities ACCORD, register of living donors (ROR) contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	●	There are not yet any communication guidelines for informing the public. Slovakia deploys programs to improve knowledge and communication skills of personnel that deals with organ transplantation but not yet of patient associations.
	●	No periodic meetings have been organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are used to inform the public, improve knowledge and skills of health professionals and of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation will be influenced by the EU Action Plan: Slovakia is planning to put into practice the regular periodic meetings with journalists and media.
	●	The EU supported activities did not contribute to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Slovakia does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.

living donation means that the donor and recipient have a social relationship (partner, family or friend).

	+	The following people can legally be donors in Slovakia: residents with a foreign nationality who die in Slovakia.
	+	Criteria required to be admitted to the waiting list: residency in Slovakia and being signed up with local social security or health care insurance.
	+	100% of transplanted patients are local residents.
	+	National policy on cross-border donation is influenced by the EU Action Plan: We have intended to provide information to the Slovak citizens about their legal position as a possible donor in other countries across the EU.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Slovakia is involved in twinning projects in a learning role. Cooperating countries: Italy, Czech Republic, France. These projects did not yet lead to changes.
	●	Slovakia has not used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.
	●	Transplantation centres or hospitals do not participate in any networks.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Slovakia has agreements with other countries for exchanging organs, treating each other's patients and collecting data.
	●	Slovakia has no agreements with other countries to prevent and address organ trafficking: the main challenges are: The organ trafficking is not a problem in Slovakia, because we practically do not perform transplants for patients from other countries.
	+	Future research programmes should focus on- regenerative medicine and organ transplantation - preservation of organs modification before transplantation - immune tolerance.
	+	The development of EU-wide agreements will be influenced by the EU Action Plan: The wide agreements will be helpful for special group of patients, i.e. hyper-sensitized patients, urgent patients. There are problems to treat such patients in a country with a relative small donor pool.
	+	EU supported activities ACCORD and FOEDUS contributed to this development: standardization and better quality of the donation and transplant procedures. It results in better safety of recipients.
Priority Action 8: Facilitate the interchange of organs between national	+	Slovakia is part of a fixed collaboration: a bilateral collaboration, with next countries Czech Republic, Italy, Austria and Germany.

authorities	+	Patient groups involved are: patients with urgent needs for transplantation and paediatric patients.
	+	Organs involved are liver, kidney, heart and lung.
	+	In 2015 3 organs came from abroad, 19 organs left the country.
	+	Slovakia offered 19 'non allocated' organs to other countries, Organs involved are liver, kidney, heart and lung.
	+	Slovakia evaluates the procedures for offering non allocated organs to other countries.
	●	Slovakia does not yet have procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Slovakia participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs will be influenced by the EU Action Plan: The action plan created better conditions for organ exchange between member countries and this will be help Slovakian patients. It depends on agreements between SK and the other countries.
	+	EU activity FOEDUS, for the exchange of surplus organs, contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3 and 12 months after transplantation.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency and from donors aged over 60.
	+	National policy on the evaluation of post-transplant results will be influenced by the EU Action Plan: The improvement of vigilance system and better connection with evaluation of post-transplant results.
	●	EU supported activities did not contribute to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	●	Slovakia does not yet promote an accreditation system for procurement organisations and transplantation centres.
	+	The EU Action Plan will be influenced national policy on the promotion of accreditation systems: Slovakia has started cooperation with KST, Czech Republic international auditing of transplant centres according to the methodology of ACCORD project.
	●	EU supported activity ACCORD contributed to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Slovakia participated as a partner in the projects ETPOD[342], 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[343]. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[344]).

Conclusion

Slovakia's deceased and living donation rate decreased since 2008, but 2015 shows a promising increase. An opportunity for Slovakia might be to explore the options for agreements on exchanging difficult to allocate organs such as pancreas and bowel.

According to the Slovakian CA the most valuable contribution to Slovakia of the Action Plan to Organ Donation in Europe is its support. The ideas of the Action Plan support the discussion in our country about organ donation and transplantation and the discussion resulted in considerable changes in transplant program. In addition the ACCORD and FOEDUS projects have been very helpful.

One of Slovakia's priorities is to raise the donation rate to 20 per million. Priority action 8 is very important, because Slovakia is a small country it needs to cooperate with other countries. It will be valuable to find a model for exchanging information about patients between the countries which are not in Eurotransplant to get better chances for patients, where is difficult to find a suitable donor. Improving the possibilities for exchange between neighbouring countries is one of the next steps. At the moment there are no rules for exchange.

European cooperation should definitely be continued according to Slovakia. Support of the EU is important to develop new legislation. The transplantation and further therapy is similar in EU countries but the transplant program is a very complex issue and there are large differences between countries, the EU cannot solve that, because of budget differences, but EU support will help countries to set priorities for the resources they need.

[342] For more information about EU-funded projects, see chapter 3.
[343] For more information about the working groups, see chapter 3.
[344] For more information about CD-P-TO, see Annex 3.

31. Slovenia

Background information[345]

With a deceased donation rate PMP of above 20 in 2015, Slovenia belongs to the countries included in this study with a higher deceased donation rate. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts and pancreases.

In 2015 no kidney and liver transplant procedures were carried out from living donors.

Slovenia is part of Eurotransplant[346] and donor organs are allocated through Eurotransplant.

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

Since January 27st 2000 an **opt-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.

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.

[345] Sources: FACTOR 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

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

Key figures[347]

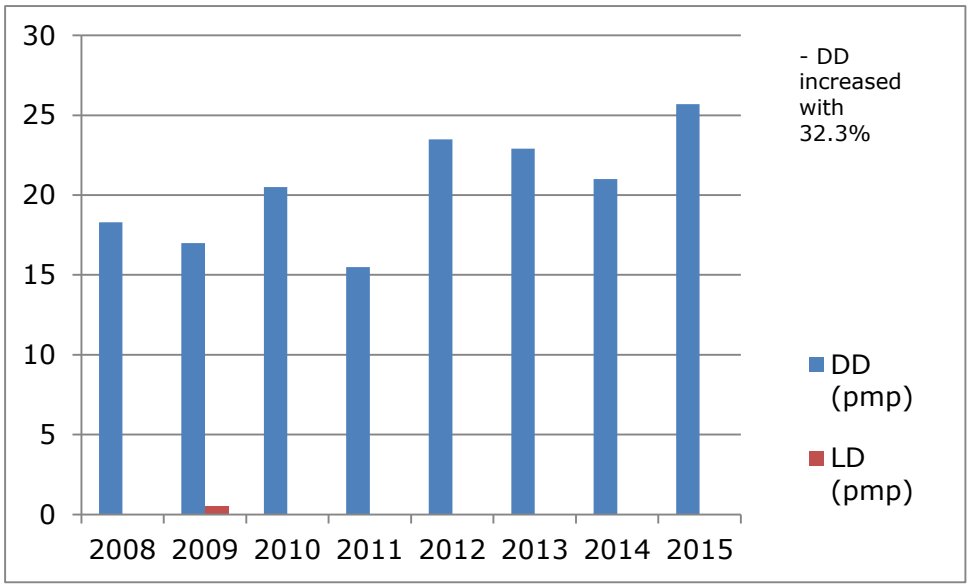
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1
Family refusal rate (refusals/times asked)[348]	23%	-	17%	5/36	-	-	-	-
Actual deceased donation rate (total/per million population, pmp)	37/ 18.3	34/ 17.0	41/ 20.5	31/ 15.5	47/ 23.5	48/ 22.9	44/ 21	54/ 25.7
Multi-organ donation rates (% of total)	81.1	79.4	87.8	77.4	91.5	85.4	84.1	74.1
Number of utilised donors (total/per million population)	36/18		41/ 20.5	-	-	-	-	
Number of donors after circulatory death - DCD	-	-	0	0	0	0	-	0
Number of donors older than 60	-		-	-	-	-	21	
Number of transplant centres								
Kidney	-	-	-	1	1	1	1	1
Liver	-	-	-	1	1	1	1	1
Heart	-	-	-	1	1	1	1	1
Lung	-	-	-	1	-	-	-	0
Pancreas	-	-	-	1	1	1	1	1
Bowel	-	-	-	0	-	-	-	0
Number of deceased donor transplant procedures (total/pmp)								
Kidney	52/26	43/ 21.5	61/ 30.5	46/ 23	62/ 31	60/ 28.6	55/ 26.2	64/ 30.5
Liver	22/11	18/9.0	23/ 11.5	20/10	27/ 13.5	21/10	31/ 14.8	24/ 11.4
Heart	6/3	18/9.0	19/9.5	14/7	28/14	30/ 14.3	33/ 15.7	24/ 11.4
Lung	-	-	-	0	0	-	-	0
Pancreas	-	2 /1.0	1/0.5	1/0.5	0	-	-	5/2.4
Bowel	-	-	-	0	0	-	-	0
Number of living donor transplant procedures (total/pmp)								
Kidney	0	1 /0.5	0	0	0	0	0	0
Liver	0	0	0	0	0	0	0	0

- = not known to the research team

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

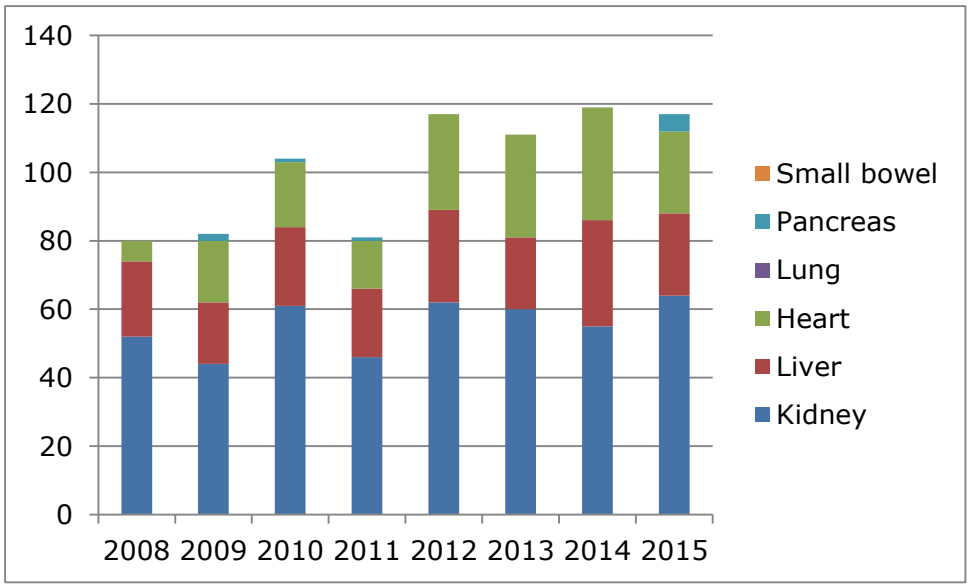
[348] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Slovenia*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level 9, at the national level 8, of whom two are on call each day.
	+	Both types of coordinator are specifically trained.
	+	Summary of the training: All central/ national coordinators are trained at least by TPM training and ETPOD program. We are organizing every year TPM training in cooperation with DTI team from Barcelona for new national coordinators and intensive care staff. Additionally, we organized the ETPOD program every year 4-6 times for different health care workers. ETPOD training covers all basic topics as referring of potential donors, maintenance and evaluation of the donor, diagnostic of brain death, allocation system in the frame of Eurotransplant, the family interview with practical cases and national transplant network. Every new candidate for the national coordinator should pass the examination carried out by the examiner who works as responsible doctor at Slovenia transplant and has knowledge of intensive care medicine and coordination of the donor program.
	+	The trainings have been tested for effectiveness.
	+	Slovenia uses an accreditation scheme: European examination for transplant coordinators and examination performed by Slovenija transplant team. In 2016 the rules of tasks and competencies of transplant coordinators have been adopted.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: EU Action plan is well-structured document, which stresses the most important parts of donor programme. Although the EU Action plan doesn't open very new issues for Slovenian donor program model, such a document is very helpful in motivating for the progress and every day work. Namely, sometimes we felt lost due to different problems and with help of an acknowledged document we are able to go on. In addition, the only thing that is really new for us, was a part about accreditation. To clarify, the EU Action plan just opens the need and does not present more data about accreditation and implementation of it for transplant activities including donor program at national level. Therefore, the task is still open for many countries, including Slovenia.
	+	The EU supported activity ETPOD has contributed to the promotion of the role of the transplant donor coordinators: We are organizing every year 4-6 courses for the doctors and nurses in donor hospitals, and for other interested groups. The content of the program is in line with the results of one of the best EU projects in the field of organ donation intended for transplantation.

Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: In Slovenia, we use the Quality Assurance Program to monitor the quality of the donor program, outcomes and the role of donor hospital management. The EU AP was not directly involved in implementing such kind of activities. As the EU document is an influential piece of work, it helps us in general to go on, to develop new strategies etc.
	+	EU supported activities have contributed to the promotion of Quality Improvement Programmes to some extent. The document will be included in the national auditing system, which will be prepared within one year.
Priority Action 3: Exchange of best practices on living donation	+	Slovenia has directed[349] living donation programmes. Donation between recipient and legally, genetically and emotionally related donors is allowed in Slovenia.
	●	There are no undirected living donation programmes Slovenia.
	+	At present (January 2016) 1 hospital has a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but the Council of Europe Convention is not yet ratified by Slovenia.
	●	National policy on living donation programs is not influenced by the EU Action Plan. Momentarily, living donation is not on the priority list in Slovenia. Namely, we prefer the transplantation of kidneys procured from deceased donors and now we are able to cover the needs. Of course, it doesn't mean that we don't have waiting lists and patient who are waiting for a longer time, but the average time of waiting is pretty short (about one year). Besides, the limited facilities as human and other resources significantly limit increase of kidney transplantation number. The quality of transplantation expressed by patients and graft survival time is among the best in Europe (one year survival of graft is more than 95%), which means that we are engaged very

[349] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		intensively in the kidney transplant program.
	●	It is not clear whether EU supported activities contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Slovenia deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation, for all health care (hospital) personnel and for open public, but not explicitly for patient support groups. Patients are invited to attend some conferences where the topic is discussed and presented to participate actively. Slovenija transplant organizes and invites the participants and the patients group to all conferences and different activities, as well.
	+	Periodic meetings have been organised with journalists, but not regularly, the topic must be connected with some special clinical achievement or some special event. This is plan for future, but we are very careful with this, because we found out in the survey in 2010, that almost half of responders are saturated with the information about organ donation and are no more interested in further information.
	+	Guidelines and deliverables developed by EU supported activities are used for informing the public, improving knowledge and skills of health professionals, improving knowledge and skills of patient support groups and organising periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: First: The Action plan presents very clearly how important is public awareness and that we should work on the issue. The previous mentioned fact was very motivating for designing new projects and preparing studies, surveys to get more results and new knowledge. Second: based on constant work we realize that the communication and public awareness may be better, when is covered with the knowledge of social marketing. Therefore, we have invited professionals from social science field to cooperate with us in the field of research. Third: Based on new cooperative partners we prepared new study, run in Slovenia hoping to come to the new recommendations with a goal to change open public behaviour and responses. Last: we realized that public awareness about organ donation and transplantation is a very complex issue and could be effectively managed by systematic approach and mainly by spreading proper information and messages. The classic advertising approach is not effective and acceptable anymore.
	+	EU supported activities contributed to the promotion of public awareness, as is mentioned in answer to previous question.
Priority Action 5:	+	Slovenia provides easily accessible information to

Facilitate the identification of organ donors across Europe		its citizens about their legal position as a possible donor in other countries across the EU. Slovenian spokes people try to stress the facts about cross border exchange of organs in the interviews with journalists. Some facts are published on the web page edited by Slovenija transplant.
	+	The following people can legally be donors in Slovenia: residents with a foreign nationality who die in Slovenia and non-residents who die in Slovenia.
	+	Criteria required to be admitted to the waiting list: residency in Slovenia and signed up with local social security or health care insurance.
	●	Not clear how many transplanted patients are local residents.
	●	Not clear whether national policy on cross-border donation is influenced by the EU Action Plan. Slovenia is full member of International foundation Eurotransplant and therefore is obliged to exchange the organs in the frame of this organization. The exception is only when procured organ is not allocated in the area of ET and we think that is good to use it. The system of allocation is published on the web, in the interviews, in the manual of Slovenija transplant Organ donation etc.
	●	Not clear whether EU supported activities contributed to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Slovenia is involved in twinning projects in a learning and teaching role for exchange of good practice and knowledge. Cooperation with Spain, Czech Republic and Italy.
	+	These projects led to the following changes: We are able to exchange good practice and improve our system.
	+	According to the CA, Slovenia has used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems, namely: EU project as FOEDUS, EUDONOR.
	●	Transplantation centres or hospitals do not yet participate international registries, but Slovenia is open to work on the basis of twinning contracts with SEEHN countries, especially Bosnia and Herzegovina, Serbia etc. in the field of different transplant programs, donor program, education, trainings.
	+	The organisational model of the donation and transplantation system is influenced by the EU Action Plan: Slovenia has improved its education system, trainings and quality assurance.
	●	Not clear whether EU supported activities contributed to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of	+	Slovenia has agreements with other countries for exchanging organs, treating each other's patients, training/certifying healthcare professionals (surgeons, coordinators), collecting data (ELTR,

transplantation medicine		ERA-EDTA registries…) and for research activities. Our cooperation with other countries is very active. The cooperation with International Foundation Eurotransplant is very fruitful and supports us to develop very efficient and good transplant medicine. The main purpose is exchange and allocation of organs. We are open to support other countries, but at the moment the cooperation in the SEEH Network countries is depressed. We are not active member due to the huge interest of Croatia to help all those countries. We are cooperating with NTI and Austria related to specific group of patients to carry out the transplantation due to limited number of procedures (liver-children under 30 kg, small children for kidney transplantation, lung transplantation).
	●	Slovenia has no agreements with other countries to prevent and address organ trafficking. There are many challenges as abuse of the rules how to put patients on the waiting lists, selling and buying the organs, unrelated living donation, national systems put in place are not transparent, the role of competent authorities is not clear enough etc.
	●	No suggestions for future research programmes.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	Not clear whether EU supported activities contributed to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Slovenia is part of a multi-lateral collaboration, Eurotransplant, and has a bilateral collaboration with Austria and Italy.
	+	Patient groups involved in this collaboration are: all patients, patients with urgent needs for transplantation and paediatric patients.
	+	Organs involved are liver, kidney, heart and lung.
	+	In 2015 58 organs came from abroad, 96 organs left the country.
	+	Slovenia has offered non-allocated organs to other countries, in 1-2 cases.
	+	Organs involved are liver, kidney, heart and lung, pancreas, small bowel.
	●	Procedures for offering non allocated organs to other countries are not yet evaluated, but that is planned in 2017.
	+	Slovenia has procedures for the exchange of organs of urgent and difficult-to-treat patients, organs involved are liver, heart and lung.
	●	Not known how many organs for difficult to treat patients exchanged across borders.
	+	Slovenia participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs is influenced by the EU Action: not so much due to our 17- year lasting cooperation with International foundation Eurotransplant. But we are open when the organs couldn’t be allocated in the area of ET.

	●	Not known whether EU activities contributed to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a regional/local level: results are systematically collected in a database/register at national level and sent to the international registries.
	+	Results are measured 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors aged over 60.
	+	National policy on the evaluation of post-transplant results is influenced by the EU Action Plan: We will collect all those data at Slovenija transplant.
	●	Not known whether EU supported activities contributed, to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis and Slovenia not yet promotes an accreditation system.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	Not known whether EU supported activities contributed to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Slovenia was coordinator of EDD[350] and participated as a partner in EFRETOS, EULID, and MODE. Slovenia was an associated partner in ODEQUS (M. Manyalich et al., 2013).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[351] and living donation. In addition, it is a member of the Council of Europe Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[352]).

Conclusions

Slovenia's deceased donation rate increased since 2008. An opportunity for Slovenia may be to explore the options for DCD or living donation.

The Slovenian CA reports that Slovenia has a national policy on organ donation since 1998 when the national transplant network was established. The most valuable contribution of the Action Plan is that the new energy and support to the national policy has been given from the EU-level, which helps Slovenia to present detailed aspects of donor and transplant program to the medical public. Action plan is well

[350] For more information about EU funded projects, see chapter 3.
[351] For more information about the working groups, see chapter 3.
[352] For more information about CD-P-TO, see Annex 3.

structured document, which defines not only specific tasks, but also the organization as a whole, which is very important for the progress in the field.

The implementation of the directive EU 53/2010 is accomplished. Two National Competent Authorities are in place. Following steps are to differentiate the tasks between these two competent authorities in practice and prepare all additional bylaws defined in the new national law named Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act (ZPPDČT) adopted in the 2015.
Next, the main and constant focus will be still on increasing the number of deceased donors, informing and educate all stakeholders and target groups including health care workers in donor hospitals and opinion makers. The main purpose is to reach changing of behaviour and develop trust in the donation procedure based on transparency of the national system, procedures and proper communication with all interested publics. Slovenia's approach is already well structured, the Action Plan of the EU will be used as supporting tool.
Furthermore, Slovenia transplant as coordinating office has to be focused more and more thoroughly in the process of evaluation of donors and organs suitable for the implantation and consequentially the selection of optimal recipient related to extended criteria organ. The cooperation between transplant coordinators and other transplant experts requires a new approach. The progress of transplant medicine pointed out that the juridical and ethical problems connected to organ donation arise. The allocation should be done in the line with the last evidence based results and the recipients should be informed about the evidence based risks, as well. The question is what is the best way of informing the recipients sufficiently and on the same time not to evoke the fear.
The focus is also on collecting useful data and improving interpersonal communication.

The European cooperation is very important for Slovenia, the Action Plan may be used as basic document for developing the donor program in all European countries, especially it is needed in supporting less developed countries. Therefore the Action Plan should be refreshed for the next period of at least five years and the topics about supporting programs should be added.
Related to the supporting program to less developed countries in Europe Slovenia would like to stress that, the existing system as TAIEX program is very good in helpful for the recipient country with sharing knowledge and money. These activities should be continued by the EU part, but there are some criticisms of it. International collaboration should be more controlled. Sometimes there are different visions and different expectations between representatives of EU as donor part and recipient country. Unfortunately, it is not always clear who is the contact person for a recipient country, not always the best experts are invited as advisors.
Related to the competent authority meetings in Brussels Slovenia would like to stress, that the meetings are very important and supportive, but the representatives who comes from smaller or less developed countries should be motivated and stimulated to be more open in discussion in order to get heard.

32. Spain

Background information[353]

With a deceased donation rate PMP (pmp) of above 40 in 2015, Spain's deceased donation rate PMP is the highest of the countries included in this study. As in previous years, in 2015 deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.

With a living kidney donation rate of less than 10 PMP, Spain's living kidney transplantation activity is in a mid-position when compared with other countries in this study. In 2015, living donor transplant procedures were carried out involving 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, as well as in collecting and sharing data for transparency and continuous improvement. Together with Italy and France, Spain formed a new international cooperation agreement, the South Alliance for Transplantation (SAT) (SAT, 2013).

Since October 27th 1979 an **opt-out system** is in place. By law, **next-of-kin** must be consulted to find out whether possible donors expressed their opposition towards donating their organs upon their death. In practice, if the family opposes organ donation, organ recovery does not proceed. The system has set down different means to express the will with regards to donation after death, including the National Advance Directives Register/Last Will Register.

Financing of organ donation

In the case of deceased donation, donation and derived transplantation activities are benefits of the National Healthcare 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.

[353] Sources: FACTOR 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.

Key figures[354]

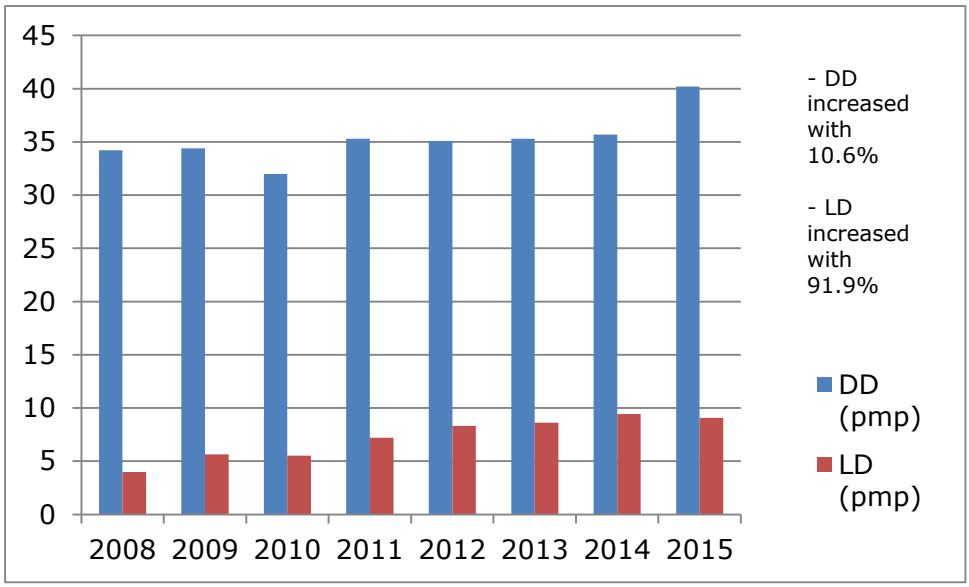
Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	46.2	46.7	47.0	47.2	46.8	46.9	47.1	46.1
Family refusal rate (refusals/times asked)	343/ 1920	316/ 1922	353/ 1855	319/ 2007	305/ 1948	313/ 1968	367/ 2049	334/ 2185
Actual deceased donation rate (total/per million population, pmp)	1577/ 34.2	1606/ 34.4	1502/ 32.0	1667/ 35.3	1643/ 35.1	1655/ 35.3	1682/ 35.7	1851/ 40.2
Multi-organ donation rates (% of total)[355]	1577/ 34.2	1606/ 34.4	1502/ 32.0	1667/ 35.3	1643/ 35.1	1655/ 35.3	1682/ 35.7	1851/ 40.2
Number of utilised donors (total/per million population)	1368/ 29.6	1400/ 30.0	1292/ 27.5	1451/ 30.8	1424/ 30.4	1455/ 31.0	1442/ 30.6	1605/ 34.8
Number of donors after circulatory death - DCD	77	107	130	117	161	159	193	314
Number of donors older than 60				896	833	868	906	989
Number of transplant centres								
Kidney	44	38	44	44	40	40	40	40
Liver	26	24	25	25	25	25	25	25
Heart	18	18	18	18	16	16	16	16
Lung	9	8	7	7	8	8	8	8
Pancreas	11	11	13	13	13	13	13	13
Bowel	3	3	2	2	3	3	3	3
Number of deceased donor transplant procedures (total/pmp)								
Kidney	2073/ 44.9	2093/ 44.8	1985/ 42.2	2186/ 46.3	2190/ 46.8	2170/ 46.3	2255/ 47.9	2517/ 54.6
Liver*	1066/ 23.1	1059/ 22.7	943/ 20.1	1103/ 23.4	1048/ 22.4	1062/ 22.6	1041/ 22.1	1127/ 24.4
Heart	292/ 6.3	274/ 5.9	243/ 5.2	237/ 5.0	247/ 5.3	249/ 5.3	265/ 5.6	299/ 6.5
Lung	192/ 4.2	219/ 4.7	235/ 5.0	230/ 4.9	238/ 5.1	285/ 6.1	262/ 5.6	294/ 6.4
Pancreas	104/2.3	97 /2.1	94/2.0	111/2.4	83/1.8	92/2	81/1.7	97/2.1
Bowel	14/0.3	11 /0.2	5/0.1	9/0.2	8/0.2	8/0.2	6/0.1	12/0.3
Number of living donor transplant procedures (total/pmp)								
Kidney	156/ 3.4	235/ 5.0	240/ 5.1	312/ 6.6	361/ 7.7	382/ 8.1	423/ 9	388/ 8.4
Liver	28/0.6	29 /0.6	20/0.4	28/0.6	28/0.6	23/0.5	21/0.4	30/0.7

* 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.

[354] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

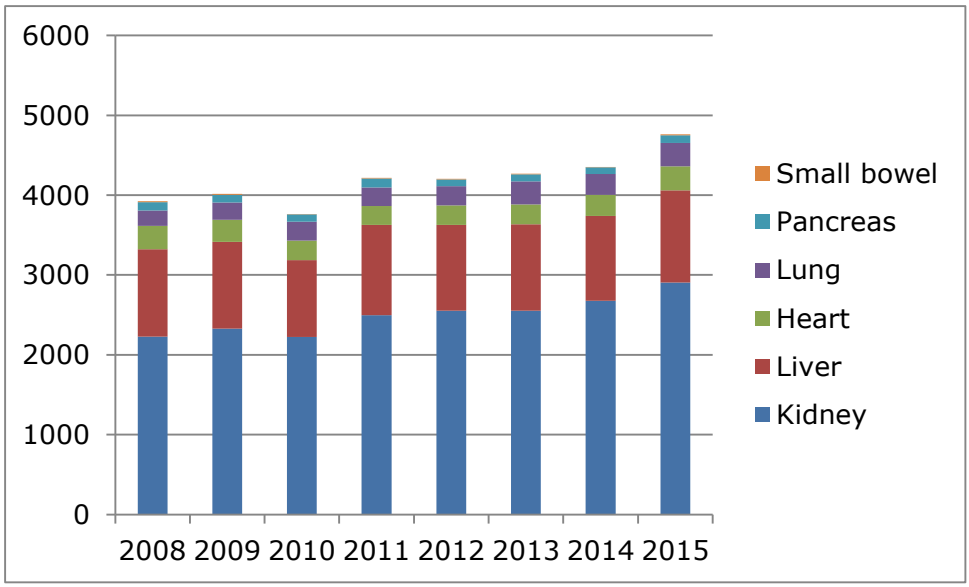
[355] Only donors after brain death (DBD) are taken into account.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Spain*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 440 at the local/hospital level in 2015.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: - Donor coordinators receive training through regular and dedicated courses promoted by the Spanish National Transplant Organization (ONT) in cooperation with the regional and hospital coordination levels and other institutions. - The basic training courses for donor coordinators cover all the stages of the process of deceased donation and procurement, with additional courses being focused on specific phases of the process, e.g. several courses are held each year on communication in critical situations. - Donor coordinators also receive regular training on particular activities, e.g. living donation, donation after circulatory death, relation with the mass media, or others, according to identified needs. This regular training is subject of ad hoc courses, symposia and an annual congress for donor coordinators.
	+	The trainings have been tested for effectiveness.
	+	Spain uses an accreditation scheme: Spanish transplant donor coordinators fulfil the national training programme specified above, and some apply (on a voluntary basis) to the UEMS Certification for European Transplant Coordinators.
	+	The EU Action Plan has helped Spain reassure the importance of its previously existing policy on donor coordinators appointed at the hospital level and their training, where there is a potential for organ donation.
	+	The EU supported activities have been led by or have received contribution from Spain. They have implied an international acknowledgement of the value of the Spanish previously existing policies on national donor transplant coordinators and their training.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve quality in the identification of potential donors, the development of the donation process, the procurement process, the transplantation process, and follow-up care of living donors and transplant recipients.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: - The experience with WP5 in the ACCORD Joint Action has helped Spain to broaden the scope of its Quality Assurance Program in Deceased Donation. This program has been in place since 1999, and has inspired national, regional and local strategies for continuous improvements. - So far focused on the process of donation after brain death (DBD), the program aims at monitoring the potential donor

		pool, evaluating performance in the DBD process and identifying areas of improvement. The program is based on a continuous audit of clinical charts of patients dead intensive care units (ICUs) to identify patients fulfilling brain death criteria and analyze the reasons why these potential DBD donors do not transition to actual DBD donors. It includes an internal audit performed by donor coordinators locally. Information compiled during the audit is reported to ONT which provides national indicators of reference to the network. The program also includes external audits that have revealed preventable losses of potential organ donors and that represent great opportunities for exchanging best practices and releasing recommendations for improvement. - The ACCORD project has provided ONT with new tools to evaluate the potential of donation outside of the ICU, identify areas for improvement in the DBD process inclusive of phases that relate to end-of-life care decisions made by the treating physician or team, estimate the potential of controlled DCD and evaluate performance in the controlled DCD process. In addition, ONT was provided with tools for the application of the PDSA methodology to deceased donation and with the training to transfer the knowledge to the network of donor hospitals. These tools were piloted in Spain (and other 14 EU Member States) during the life-time of the project. - ONT has then extended the ACCORD experience to more than 100 hospitals in the country in the framework of the ACCORD-Spain project. The tools have been refined and adapted to the Spanish needs and have been tested by the network. Based on the international and subsequent national experience, ONT is now redefining the existing Spanish Quality Assurance Program, to incorporate new modules for a more comprehensive assessment of the potential of organ donation and of performance in the deceased donation process. - The EU Action Plan (and Directive 2010/53/EU) have prompted the development of the Spanish Framework for Quality and Safety.
	+	EU supported activities have contributed to the promotion of Quality Improvement Program: The ODEQUS methodology and developed indicators have been used as a basis for monitoring practices in donation and transplantation activities as part of the Spanish Framework for Quality and Safety required by Directive 2010/53/EU. - ACCORD influence – see above.
Priority Action 3: Exchange of best practices	+	Spain has directed[356] living donation programmes. Directed living kidney and liver transplant

[356] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation

on living donation		procedures are carried out in Spain. In 2015, 351 directed living kidney donation procedures were performed in the country. According to Royal Decree 1723/2012, centers must be specifically authorized for the recovery of organs from living organ donors and for transplantation activities. Authorization criteria are detailed in the legislation. Royal Decree 1723/2012 also specifies criteria to proceed with the recovery of an organ from a living organ donor - establishing no limit of relationship and hence authorizing unrelated and undirected living transplant procedures. National recommendations on living organ donation have been released by ONT and the Spanish Society of Nephrology, which include some information relevant to the questions posed for this priority action.
	+	There are undirected living donation programmes Spain. Undirected living kidney procedures are carried out in Spain. In 2015, 37 undirected living kidney donation procedures were performed in the country. There is a national altruistic donor programme based on a specific protocol and a national cross over kidney donation program based on a specific protocol.
	+	At present (January 2016) 33 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure. Each living donation procedure needs to be evaluated by an independent doctor and an ethics committee and the procedure must be approved by the judge.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law (and it is criminalized activity). The Council of Europe Convention against Trafficking in Human Organs was signed, by Spain in March 2016. Ratification is planned by 2017-2018.
	+	National policy on living donation programs is influenced by the EU Action Plan: The data set and data dictionary for living donor registries agreed upon at the ACCORD Joint Action have inspired changes in Spain's national register. The national policy has been influenced by other best practices exchanged in living donation through projects as EULID, ELIPSY, LIDOBS and the European Commission´s Working Group on living donation.
	+	EU supported activities contributed to the promotion of living donation programs (see above).
Priority Action 4: Improve the knowledge and	+	There are communication guidelines for informing the public. Spain deploys programs to improve

(or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

communication skills of health professionals and patient support groups		knowledge and communication skills of all health care (hospital) personnel and of patient support groups.
	+	Periodic meetings are organised with journalists.
	+	Guidelines and deliverables developed by EU supported activities are intended to be used for informing the public and improving knowledge and skills of health professionals, to improve knowledge and skills of patient support groups and to organise periodic meetings with journalists.
	+	The national policy on public awareness of organ donation is influenced by the EU Action Plan: The EU Action Plan has helped reassure the value of previously existing policies on communication, particularly with the media.
	+	EU supported activities contributed to the promotion of public awareness: Tools and deliverables derived from previous and future projects under this priority action will be useful to the Spanish network and may represent appropriate material for future training.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Spain does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Spain: residents with a foreign nationality who die in Spain, non-residents who die in Spain, illegal persons who die in Spain.
	+	Criteria required to be admitted to the waiting list: people with residency in Spain, local nationality, signed up with local social security or health care insurance.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	+	Spain is involved in twinning projects in a teaching role. Spain has been involved in specific twinning activities as supporting country in the context of cooperation agreements and official visits without EU funding, and within TAIEX (Technical Assistance and Information Exchange instrument) and other EU-funded projects. - Specific reference should be made to two other EU-funded projects including twinning activities: - MODE, where Spain was a partner and contributed with training in Quality Assurance in Organ Donation. - ACCORD, with WP6 devoted to twinning, the entire Joint Action being coordinated by ONT.
	+	Countries Spain has worked with within and outside dedicated projects were Bulgaria (ACCORD, MODE), Croatia (TAIEX), Cyprus (ACCORD), Czech Republic (ACCORD), Denmark (visit of a delegation of intensive care professionals), Estonia (MODE), Germany (official visits), Hungary (ACCORD), Latvia (MODE), Lithuania (ACCORD, MODE), Malta

		(ACCORD, MODE), Portugal (MODE, bilateral cooperation), Slovenia (MODE), Sweden (official visits) and United Kingdom. (official visits).
	+	These projects led to the following changes: MODE provided participating countries with a broader knowledge of their opportunities for improvement, which has been influential to the Frameworks for Quality and Safety of participating countries. - In the ACCORD JA, development of a national curriculum for procurement surgeons in Hungary, structuring of the national transplant agency in Bulgaria, and development of national authorization/auditing systems for transplant programmes in Cyprus, Czech Republic, Lithuania and Malta.
	+	Spain used structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems: Spain has participated in a number of EU funded projects that have contributed to the development of the donation and transplantation system (although not from a structural point of view) – e.g. ACCORD, EFRETOS, MODE.
	+	Transplantation centres or hospitals participate international registries. Specialties of the networks are: Paediatric kidney transplantation; Paediatric liver transplantation; Live donor liver transplantation; Lung transplantation; Heart-lung transplantation; Paediatric heart transplantation; Pancreas transplantation; Small bowel transplantation.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Spain has agreements with other countries for exchanging organs, treating each other's patients, and for supporting the development of new transplantation programmes, training/certifying healthcare professionals (surgeons, coordinators), collecting data, research activities: Agreements with other European Organ Exchange Organization are in place, including the special agreements with SAT countries for the exchange of surplus organs. - A specific agreement exists with Portugal, as the country has been developing its own lung transplant programme, by which Portuguese lung candidates are admitted to the Spanish waiting lists and lungs from Portuguese donors are offered to the Spanish lung transplant network. - Donor coordinators and transplant professionals in Spain participate of the corresponding UEMS certification programmes (on a voluntary basis) - Spain participates in European and other international registries – ONT provides Spanish data to ERA/EDTA, ELTR and ISHLT on an annual basis. -

		Some of the Spanish centres are part of European research projects and networks (e.g. COPE).
	+	Spain has agreements with other countries to prevent and address organ trafficking: the main challenges are: Defining conditions that are consistent with ethically unacceptable travel for transplantation (transplant tourism) and deciding on common European policies to manage patients who return from transplantation abroad under suspected or proven illicit/unethical circumstances to deter these practices and protect their victims.
	+	Future research programmes should ideally focus on: Non-standard risk donors; Organ vigilance – ESSENTIAL; Donation after circulatory death; Transplant tourism.
	+	The development of EU-wide agreements is influenced by the EU Action Plan: Promoting agreements between countries (e.g. through FOEDUS) for organ exchange, facilitating research activities and exchange of best practices (e.g. LIDOBS) and progressively building international consensus on key topics (e.g. through the meetings of Competent Authorities).
	+	EU supported activities contributed to this development, see above.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Spain is part of a fixed collaboration, the South Alliance for Transplantation (SAT – founded by France, Italy and Spain and counting on the participation of additional countries).
	+	Patient groups involved in this collaboration are: recipients for otherwise surplus organs.
	+	Organs involved are surplus organs (all types).
	+	In 2015 29 organs came from abroad, 4 organs left the country.
	+	Spain has offered non-allocated organs to other countries, including liver kidney, heart and lung.
	+	Procedures for offering non allocated organs to other countries are evaluated.
	•	Spain has no procedures for the international exchange of organs of urgent and difficult-to-treat patients, at present the agreement for organ exchange is limited to surplus organs.
	+	Spain participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs is influenced by the EU Action: The experience with FOEDUS has facilitated the exchange of organs between member countries of SAT and other countries.
	+	EU activities contributed to the interchange of organs between countries, see above.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at national level.

	+	Results are measured 3, 6 and 12 months after transplantation and then depending on the organ, but usually every year.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors aged over 60.
	+	National policy on the evaluation of post-transplant results is influenced by the EU Action Plan: The experience in EFRETOS (and previously in DOPKI) has helped Spain to further develop its non-standard risk donor project, based on the prospective assessment of the outcomes of patients transplanted with organs from donors diagnosed of potentially transmissible diseases or conditions likely to impact upon the quality of the transplanted organ – donors with a past or present history of malignancy, infectious diseases, poisoning, rare diseases, and other conditions.
	+	EU supported activities contributed to the evaluation of post-transplant results, see above.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis and Spain promotes an accreditation system for this.
	+	This system is used for donation (coordinators): authorization schemes based on national criteria; for procurement (surgeons): authorization schemes based on national criteria for procurement centres; for transplantation: authorization schemes based on national criteria for transplant centres and accreditation schemes based on national criteria for centres of reference for specific transplant procedures.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Spain was coordinator of the projects DOPKI[357], ETPOD, ELIPSY, EULID, ODEQUS, and Train the Trainers, and was core work package leader in Alliance-O, EFRETOS, and MODE. The country was 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.[358] 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

[357] For more information about EU funded projects, see chapter 3.
[358] For more information about the working groups, see chapter 3.

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.[359] ONT has also chaired the ad hoc working group for the elaboration of the 6th edition of the Council of Europe Guide on Quality and Safety of Organs for Transplantation. ONT is collaborating centre of the WHO and hosts with this international organization the Global Observatory on Organ Donation and Transplantation.

Conclusions

Both Spain's deceased donation rate and living donation rate increased since 2008. This is very positive. Spain has been the leading country in the field for years now. Spain is encouraged to share its experiences and best practices with other countries.

According to the Spanish CA, the most valuable contributions of the Action Plan to Organ Donation in Europe are:

- The experience and knowledge gained during the coordination and participation in the ACCORD Joint Action, particularly WP5, has been critical to broaden the scope of the previously existing Spanish Quality Assurance in Deceased Donation. The tools developed during the life-time of the project have inspired changes in the Spanish system to monitor performance in deceased donation and has facilitated the application of the PDSA methodology to deceased donation.
- The creation of the South Alliance for Transplantation along with the tool developed in FOEDUS has provided a good basis to facilitate cross-border exchange of (surplus) organs.
- Participation in EFRETOS has been helpful in refining postransplant data collections (particularly on non-standard risk donors) and in designing the national organ-vigilance system.

Priorities in the field of organ donation in Spain for the next 5 years are:

- Increase organ availability from deceased donors, by means of the strategies that have already allowed the country to reach more than 40 donors PMP in 2015:
  - Identification of possible donors outside of the intensive care unit, particularly at the emergency departments, but also in the general hospital wards.
  - Donation after Circulatory Death.
  - Non-standard risk donors.

Linked to these strategies, the objective is also to increase the utilization of available organs.

- Wide implementation of the national Framework for Quality and Safety.

The essential topics in the EU as a whole are:

- Identification of possible organ donors within and outside of the Intensive Care Unit;

[359] For more information about CD-P-TO, see Annex 3.

- Donation after Circulatory Death;
- Expanded criteria and non-standard risk donors;
- Organ preservation strategies;
- Quality and Safety, particularly bio-vigilance and coordination of national bio-vigilance systems.

33. Sweden

Background information[360]

With a deceased donation rate PMP between 10 and 20 in 2015, Sweden belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.

With a living kidney donation rate PMP of above 10 in 2015, Sweden's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver. Sweden has a relatively high number of pancreas transplants.

Scandiatransplant[361] is an association for organ exchange between the hospitals performing organ transplants in the Nordic countries. These hospitals are co-owners of Scandiatransplant.

Since June 1st 1995 a **mixed system** is in place. Presumed consent is assumed when no information is available about the person's preference. The **next-of-kin** may refuse organ removal if the will of the deceased is not known.

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.

[360] Sources: FACTOR survey filled in by national Competent Authority, 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.

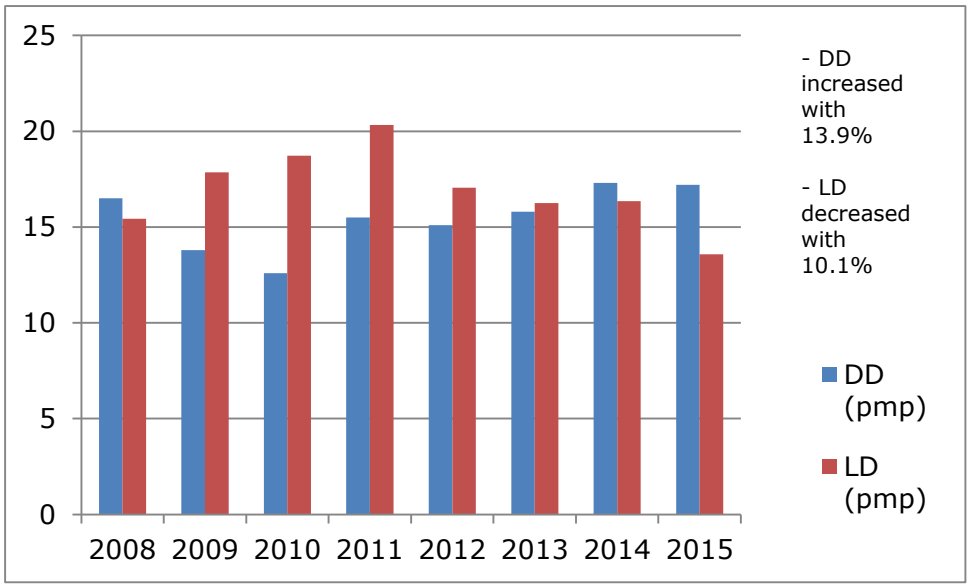
[361] Regarding EU-funded projects, Scandiatransplant participated as a partner in EFRETOS.

Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	9.2	9.3	9.4	9.4	9.5	9.6	9.6	9.8
Family refusal rate (refusals/times asked)	9.2	9.3	9.4	9.4	9.5	9.6	9.6	9.8
Actual deceased donation rate (total/per million population, pmp)	9.2	9.3	9.4	9.4	9.5	9.6	9.6	9.8
Multi-organ donation rates (% of total)	85.0		89.0	84.2	81.1	86.8	-	81.7
Number of utilised donors (total/per million population)[362]	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	-	0	-	0	0	-	-	0
Number of donors older than 60	-		-	-	-	-	74	
Number of transplant centres								
Kidney	4	4	4	4	4	4	4	4
Liver	3	3	2	2	2	2	2	2
Heart	3	3	2	2	2	2	2	2
Lung	2	2	3	2	2	2	2	2
Pancreas	3	3	1	3	3	3	3	4
Bowel	1	1	1	1	1	1	1	1
Number of deceased donor transplant procedures (total/pmp)								
Kidney	283 / 30.8	229/ 24.6	202/ 21.5	251/ 26.7	243/ 25.6	270/ 28.1	289/ 30.1	295/ 30.1
Liver	140/ 15.2	144/ 15.5	129/ 13.7	149/ 15.9	146/ 15.4	156/ 16.3	186/ 19.4	178/ 18.2
Heart	45/4.9	56/6.0	56/6.0	52/5.5	47/4.9	55/5.7	68/7.1	64/6.5
Lung	52/5.7	51/5.5	51/5.4	60/6.4	60/6.3	58/6	65/6.8	48/4.9
Pancreas	10/1.1	20 2.2	26/2.8	35/3.7	28/2.9	38/4	38 /4	30/3.1
Bowel	-	-	-	2/0.2	2 /0.2	-	2 /0.2	2/0.2
Number of living donor transplant procedures (total/pmp)								
Kidney	136/ 14.8	164/ 17.6	168/ 17.9	184/ 19.6	155/ 16.3	151/ 15.7	151/ 15.7	131/ 13.4
Liver	6 /0.7	2 /0.2	8 /0.9	7 /0.7	7 /0.7	5 /0.5	6 /0.6	2/0.2

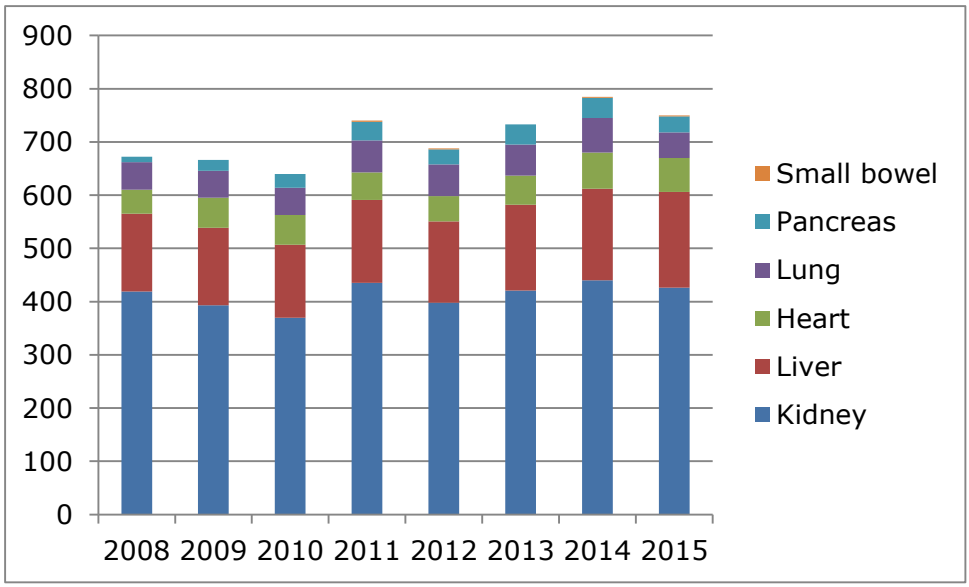
[362] No separate information was given for the number of utilised donors.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Sweden*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/hospital level, but no number is mentioned.
	+	Transplant donor coordinators have been appointed: at the local/hospital level, but no number is mentioned.
	●	Sweden does not use an accreditation scheme.
	+	The EU Action Plan will influence national policy on transplant donor coordinators.
	+	Not known whether EU supported activities have contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	●	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 the follow-up care.
Priority Action 3: Exchange of best practices on living donation	+	Sweden has directed[363] living donation programmes. In Sweden, the practice guidelines limit genetically related donors to fathers or mothers, brothers and sisters, children and grand-parents. Partners can be considered without limitation for donation in all Countries, including spouses, legally registered partners and also non registered partners. For the last category of non-registered partner, Sweden requires a minimum duration of relationship of 2 years. Legally related partners, i.e. adoptive parents, and partners of the father or the mother are also considered for donation.
	+	There also are undirected living donation programmes. Truly altruist donors ("good Samaritans") are accepted for anonymous donation.
	+	5 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Sweden has not ratified the Council of Europe Convention.
Priority Action 4: Improve the knowledge and communication skills of health professionals and	+	Sweden deploys programs to improve knowledge and communication skills of personnel that deals with organ transplantation, but not of patient associations.

[363] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

patient support groups	●	Periodic meetings with journalists have not been organised.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Sweden does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Sweden: residents with a foreign nationality who die in Sweden, and non-residents who die in Sweden.
	+	Criteria required to be admitted to the waiting list: residency in Sweden.
Priority Action 6: Enhancing organisational models	●	Sweden is not involved in twinning projects.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Sweden has agreements with other countries for exchanging organs and training/certifying health care professionals (surgeons, coordinators).
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Sweden is part of a fixed collaboration: a multilateral collaboration, namely Scandiatransplant.
	+	Patient groups involved are: all patients.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	●	No data available about number of organs that came from abroad or that left the country.
	●	In 2015 Sweden has not offered 'non allocated' organs to other countries, because there were no 'non allocated' organs.
	●	Sweden does not participate in the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated, but only at a regional or local level.
	●	The evaluation of post-transplant results is not yet supported by a vigilance system.
	+	Donor organs are accepted from patients with infectious diseases such as hepatitis and from donors aged over 60.
Priority Action 10: Promote a common accreditation system	●	Procurement organisations and transplantation centres are not yet controlled or audited on a regular basis.
	●	Sweden does not promote an accreditation system for procurement organisations and transplantation centres.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects, Sweden representatives were work package leader in the project ELIPSY[364] and participated as a partner in ETPOD, EULID, EULOD and ODEQUS. The country is also a partner in the joint action ACCORD[365]. The LUND University of Sweden participates as a co-beneficiary in the HOTT-project.[366]

In 2010, 2011 and 2012, the country was involved in the working group on indicators[367] 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[368]) of the Council of Europe.

Conclusions

Sweden's deceased donation rate increased since 2008, and its living donation rate decreased slightly since 2008. An opportunity to explore for Sweden may be DCD. Opportunities for Sweden may also be to change the decrease in the deceased and living donation rates.

A next step could also be to focus more on issues regarding education, implementation and quality assurance in the field of organ donation.

[364] For more information about EU funded projects, see chapter 3.
[365] At time of publication, Sweden withdrew from this project.
[366] Hottproject.com
[367] For more information about the working groups, see chapter 3.
[368] For more information about CD-P-TO, see Annex 3.

34. Switzerland

Background information[369]
With a deceased donation rate PMP between 10 and 20, Switzerland belongs to the majority of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs and pancreases.
With a living kidney donation rate PMP of above 10 in 2015, Switzerland's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver.
Donor organs are allocated at national level.

Since 2007 an **opt-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.

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.

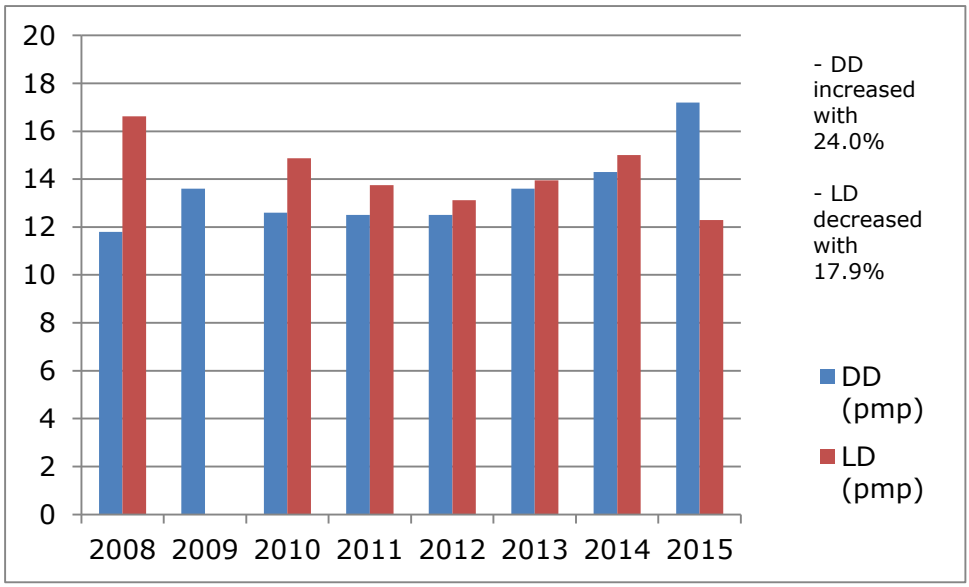
[369] Sources: FACTOR survey filled in by national Competent Authority, and information additionally provided.; Gevers, S., Janssen, A., & Friele, R. (2004). Consent Systems for Post Mortem Organ Donation in Europe. European Journal of Health Law, 11, 175-186.; Swisstransplant. (2011). Jahresbericht 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

Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	7.7	7.6	7.8	8	7.7	8.1	8.2	8.3
Family refusal rate (refusals/times asked)	56/ 160	-	102/ 207	-	-	172/ 316	175/ 303	-
Actual deceased donation rate (total/per million population, pmp)	90/ 11.8	103/ 13.6	98/ 12.6	100/ 12.5	96/ 12.5	110/ 13.6	117/ 14.3	143/ 17.2
Multi-organ donation rates (% of total)	90	84.5	98	87	92.7	69.1	100	81.8
Number of utilised donors (total/per million population)	88/ 11.4		97/ 12.4	-	-	-	-	
Number of donors after circulatory death - DCD	0	0	0	3	7	12	18	16
Number of donors older than 60	27		25	-	-	-	-	
Number of transplant centres								
Kidney	6	6	6	6	6	6	6	6
Liver	3	3	3	3	3	3	3	3
Heart	3	3	3	3	3	3	3	3
Lung	2	2	2	2	2	2	2	2
Pancreas	2	2	2	3	3	2	2	2
Bowel	1	1	1	2	2	2	2	2
Number of deceased donor transplant procedures (total/pmp)								
Kidney	170/ 22.1	189/ 24.9	180/ 23.1	181/ 22.6	155/ 20.1	169/ 20.9	181/ 22.1	222/ 26.7
Liver	83/ 10.8	95/ 12.5	98/ 12.6	100/ 12.5	95/ 12.3	105/ 12.9	108/ 13.2	134/ 16.2
Heart	29/3.8	30/3.9	35/4.5	36/4.5	35/4.5	33/4.1	36/4.4	40/4.8
Lung	40/5.2	39/5.1	49/6.3	54/6.8	52/6.8	45/5.6	56/6.8	52/6.3
Pancreas	17/2.2	10/1.3	14/1.8	28/3.5	29/3.8	29/3.6	11/1.3	8/1
Bowel	1/0.1	0	1/0.1	1/0.1	1/0.1	1/0.1	0	0
Number of living donor transplant procedures (total/pmp)								
Kidney	116/ 15.1		114/ 14.6	101/ 12.6	96/ 12.5	109/ 13.5	120/ 14.6	100/ 12
Liver	12/1.6		2/0.3	9/1.1	5/0.6	4/0.5	3/0.4	2/0.2

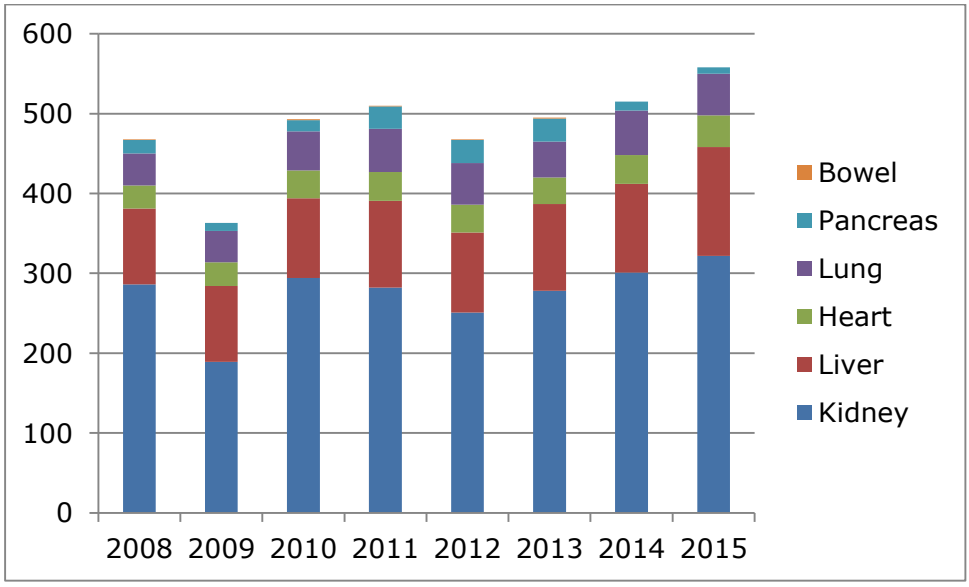
- = not known to the research team

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Switzerland*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate for 2008 and 2009 (DD) or the year 2008 (LD) and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: 165 at the local/hospital level, 10 at the regional level and 9 at the national level.
	+	Transplant donor coordinators receive a national blended learning program.
	+	Summary of the training: Communication: - 10 e-learning modules: one basic, five donation process and four communication - Two face-to-face trainings (attendance courses): communication skills, medical aspects of donation process.
	●	The trainings have not been tested for effectiveness.
	+	Switzerland uses an accreditation scheme: - National credits by medical society's -National certification - -Recommendation to pass the CETC from the UEMS.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators.
	●	The EU supported activities have not contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care (only in living donors).
	●	The EU Action Plan has not influenced the national policy on Quality Improvement Programmes.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Switzerland has directed[370] living donation programmes. The Swiss regulation that states "organs, tissues and cells may be removed from a living person if: [...] the recipient cannot be treated with any other therapeutic method with comparable benefit" should be adapted.
	+	There also are undirected living donation programmes: In the altruistic donation the donor decides to donate a kidney out of love (altruism) to a not known recipient. Altruistic liver donation is not performed in CH due to ethical constraints. In this case, donors and recipients remain anonymous and the organ is assigned to the same rules as for deceased donors. The living donor is paid in full by the insurance of the recipient. It is prohibited to provide or receive a financial gain or other benefit for the donation of human organs, tissues or cells. Available is the replacement of income lost and

[370] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		compensation for damages which the giving person suffers by the removal of organs, tissues or cells and the effort that the giving person experiences, or a subsequent symbolic gesture of gratitude rather than financial gain or other benefit.
	+	6 hospitals have a living donation program.
	+	There is an independent body to evaluate the living donor before the start of the procedure.
	+	A register is established at the national level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but Switzerland has not ratified the Council of Europe Convention.
	●	National policy on living donation programs is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. Switzerland deploys programs to improve knowledge and communication skills of all health care (hospital) personnel and patient associations.
	●	Periodic meetings with journalists have not been organised.
	+	Guidelines and deliverables developed by EU supported activities are used to improve knowledge and skills of health professionals.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Switzerland does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Switzerland: residents with a foreign nationality who die in Switzerland, and non-residents who die in Switzerland.
	+	Criteria required to be admitted to the waiting list: residency in Switzerland, local nationality and being signed up with local social security or health care insurance.
	+	99.6% of transplanted patients are local residents, 0.4% are non-residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan. We are working with EUROTRANSPLANT.
	+	EU supported activity Coorenor/FOEDUS project contributed to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Switzerland is not involved in twinning projects.
	+	Transplantation centres or hospitals participate in networks: Working groups for organs with the goal to harmonize national guidelines, policies etc. Donation networks with the same goal as the organ working groups.

	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Switzerland has agreements with other countries for exchanging organs, training/certifying health care professionals (surgeons, coordinators) and other aspects of transplant medicine. Special agreement with France and the SAT-countries. Participating FOEDUS-platform.
	●	Switzerland has no agreements with other countries to prevent and address organ trafficking: the main challenges are: detecting and announcing potential recipients with a transplanted organ from outside of Switzerland.
	+	Future national research programmes should focus on: anonymized register for recipients of an organ which they got abroad.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	Switzerland is part of a fixed collaboration: a multilateral collaboration, namely South Alliance for Transplants (SAT) and a bilateral collaboration with next country France.
	+	Patient groups involved are: all patients and patients with urgent needs for transplantation.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	+	In 2015 27 organs came from abroad, 9 left the country.
	+	Switzerland has offered 38 'non allocated' organs to other countries.
	+	Organs involved are liver, kidney, heart, lung, pancreas, small bowel.
	●	Switzerland does not evaluate the procedures for offering non allocated organs to other countries.
	+	Switzerland has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	Organs involved are liver and children hearts, in total 14 organs.
	+	Switzerland participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	The national policy on the interchange of organs is not influenced by the EU Action Plan.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3 days, 6 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.

	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, HIV, and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the evaluation of post-transplant results
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	●	Switzerland does not yet promote an accreditation system for procurement organisations and transplantation centres, but a national accreditation system is intended for donation (coordinators) and for other staff involved in donation and transplantation.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)
Regarding EU-funded projects, Switzerland participated in the DOPKI[371] project and is a collaborating partner in the Joint Action FOEDUS.

In addition, it is a member of the Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[372]) of the Council of Europe and hosted several times the European Organ Donation Day (recently in 2012 for example).

Conclusions
Switzerland's deceased donation rate increased since 2008, and its living donation rate decreased since 2008. Switzerland may benefit from investing more in quality assurance for transplant coordinators and accreditation schemes for procurement organisations and transplantation centres.

For Switzerland, the most valuable contributions are: to have an overview on what is happening in the donation process in all countries. This helps identifying important factors that can explain the organ shortage which could in collaboration help to minimize the growing disparity between available organs and demand. This includes the implementation of the FOEDUS-platform for organ exchange, the exchange of experiences and also the efforts to harmonize the quality aspects in this field.

Switzerland's goal is to have more donors/organs for transplantation. The National Action Plan (goal 20 pmp until 2018) consisting of the four action fields (formation, processes and quality, structures and resources, public awareness) is established and implemented. The implemented measures are durable. Organ donation is well known and accepted in the population.

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[371] For more information about EU-funded projects, see chapter 3.
[372] For more information about CD-P-TO, see Annex 3.

35. Turkey

Background information[373]
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 PMP under 10 in 2015, Turkey's deceased donation rate is amongst the lowest of the countries included in this study. In 2015, deceased donor transplant procedures were carried out involving kidneys, livers, hearts, lungs, pancreases and small bowels.
With a living kidney donation rate PMP of above 10 in 2015, the Turkey's living kidney donation rate PMP is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver.

Donor organs are allocated at national level.

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

Since May 29th 1979 an opt-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.

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.

[373] Sources: FACTOR 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

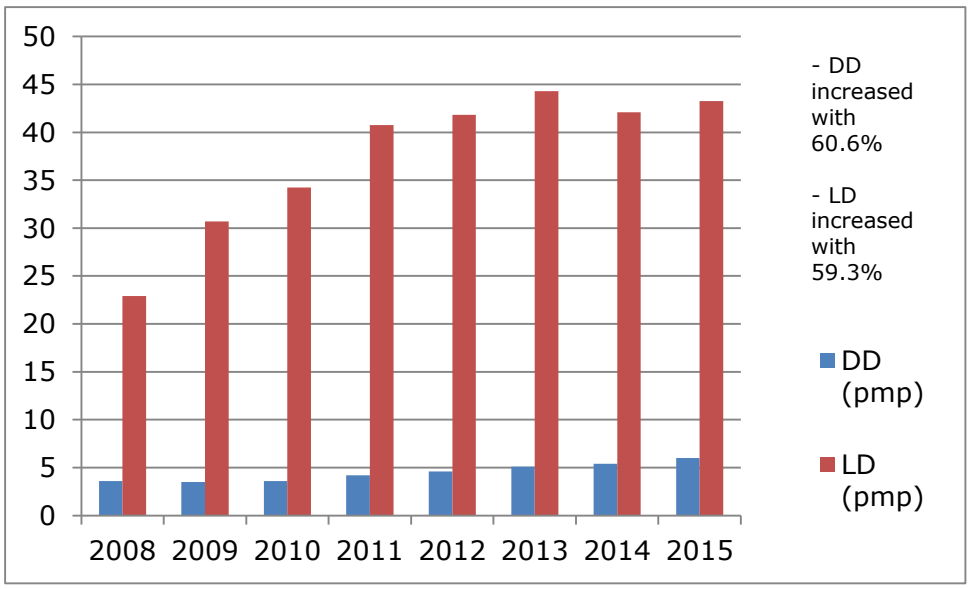
Key figures[374]

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	71.5	74.8	75.7	74.7	74.5	74.9	75.8	78.7
Family refusal rate (refusals/times asked)	458/720	654/952	764/1036	958/1292	1132/1477	1324/1705	1403/1810	1497/1969
Actual deceased donation rate (total/per million population, pmp)	262/3.6	262/3.5	272/3.6	311/4.2	345/4.6	381/5.1	407/5.4	472/6
Multi-organ donation rates (% of total)	96.9	90	-	91.0	-	-	-	69.9
Number of utilised donors (total/per million population)	242/3.4		246/3.3	-	-	-	-	
Number of donors after circulatory death - DCD	3	0	-	-	-	0	-	0
Number of donors older than 60	1		2	-	-	-	129	
Number of transplant centres								
Kidney	44	53	59	62	61	61	65	75
Liver	25	26	34	40	35	35	40	46
Heart	16	14	14	13	9	9	11	16
Lung	1	1	2	3	6	6	6	4
Pancreas	5	5	4	5	4	4	4	9
Bowel	2	2	-	4	4	4	4	6
Number of deceased donor transplant procedures (total/pmp)								
Kidney	414/5.7	431/5.8	395/5.2	521/7.0	524/7.0	585/7.8	634/8.4	670/8.5
Liver	212/3.0	229/3.0	209/2.8	281/3.8	265/3.6	289/3.9	320/4.2	345/4.4
Heart	51/0.7	55/0.7	86/1.1	93/1.2	61/0.8	63/0.8	78/1	89/1.1
Lung	1/0.0	7/0.1	3/0.0	5/0.1	25/0.3	32/0.4	33/0.4	30/0.4
Pancreas	10/0.1	18/0.2	29/0.4	26/0.3	6/0.1	4/0.1	10/0.1	7/0.1
Bowel	3/0.0	1	3/0.0	1/0.0	5/0.1	2/0	5/0.1	6/0.1
Number of living donor transplant procedures (total/pmp)								
Kidney	1248/17.5	1931/25.8	2107/27.8	2421/32.4	2381/32	2359/31.5	2298/30.3	2534/32.2
Liver	390/5.4	364/4.9	486/6.4	623/8.3	736/9.9	959/12.8	892/11.8	871/11.2

- = not known to the research team

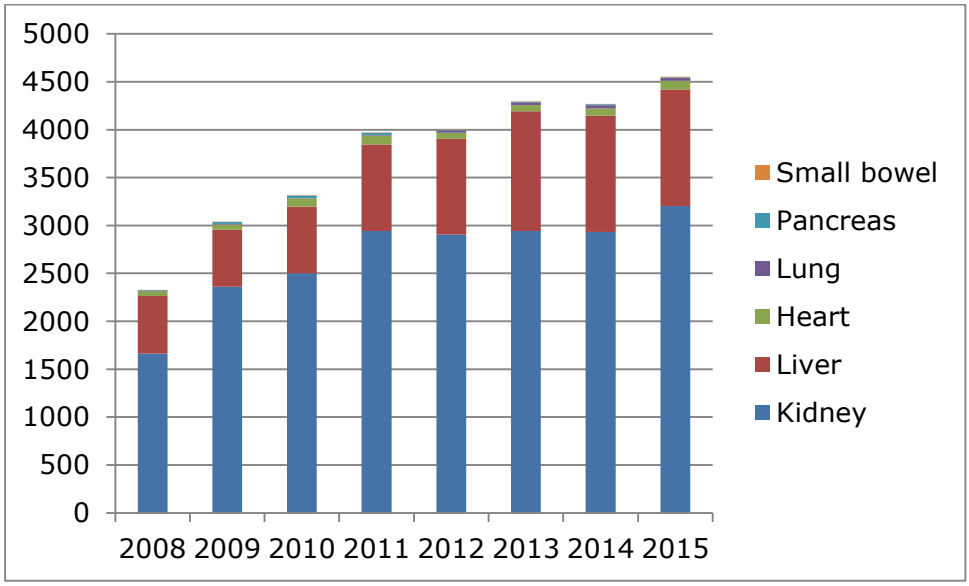
[374] Numbers are based on the Transplant Newsletter of the Council of Europe, and corrected by the Competent Authority.

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in Turkey*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter and corrected by the Competent Authority. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate of the year 2009 and 2010 and for 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplants* per organ per year (2008-2015)



* Deceased and living transplants

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the local/in hospital level 730, at the regional level 56, in total at the national level 786, of which 500 certified.
	+	Transplant coordinators receive regular training.
	+	Summary of the training: 5-day training seminars are provided for the coordinators by the Ministry regarding the donor assessment, determination of brain death, donor care and how to communicate with donor's family. Regular annual symposiums for transplant coordinators are held to share best practices and to make information exchange.
	●	The trainings have not yet been tested for effectiveness. (There is post test after trainings and at least 70 out of 100 is necessary to be certified)
	●	Turkey does not use an accreditation scheme.
	●	The EU Action Plan has not influenced national policy on transplant donor coordinators EU supported activity ETPOD has contributed to the promotion of the role of the transplant donor coordinators.
Priority Action 2: Promote Quality Improvement Programmes	+	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 the follow-up care.
	+	The EU Action Plan has influenced national policy on Quality Improvement Programmes: EU aid project "Technical Assistance for Alignment in Organ Donation" is completed successfully in April 2015. One of the components of this project was "Quality and Auditing". We will consider the suggestions of the Technical Assistance Team in our future works.
	●	EU supported activities have not contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	Turkey has directed[375] living donation programmes. Kidney and liver transplants from the living donor can be performed from the related donors until fourth grade (including affiliated through marriage). These related donors are evaluated by the Council of Organ Transplantation Center in organ transplantation centres. The number of patients awaiting organ transplantation in our country is many times more than the number of

[375] We are aware that the use of the definition 'related and unrelated living donation' is more common in practice. For comparison with 2012, we asked for directed and undirected living donation, which is defined as follows: Undirected living donation (or altruistic living donation) means making a living donation to strangers. Directed living donation means that the donor and recipient have a social relationship (partner, family or friend).

		cadaver organs obtained. Consequently, the number of patients added to the national organ waiting list is increasing and some of those patients lose their lives in consequence of not finding a suitable organ for the transplantation. Due to the inadequate number of cadaver organs, the organs which are provided from live donors are transplanted to those patients. Therefore, special Commissions were established within the Provincial Health Directorates of our Ministry to relieve the grievances of the patients who have voluntary live donors without any expectations of financial benefit and to assess the demands of those patients. Live organ transplantation can be made from the patient's spouse living with him/her virtually for at least 2 years and from relatives within the fourth degree (including the fourth degree) of consanguinity or affinity. The donor and recipient, together with the documents stated in the legislation and with the documents prepared by the head physician's office of the hospital, file an application to the Provincial Health Directorate of the city of transplantation. Living donation can be performed with the donor's consent in the presence of two witnesses.(Bagheri, 2005).
	+	Turkey also has undirected living donation programmes: 4-6% of the living donor transplants are unrelated and they are approved by the Ethical Committee. If ethical committee approve, the transplantation is realized. These committees were established within the Provincial Health Directorates of our Ministry to relieve the grievances of the patients who have voluntary live donors without any expectations of financial benefit and to assess the demands of those patients. The Ethical Committee must approve that the donation between the donor and recipient has been made voluntarily and without any financial gain and within the ethical suitability rules. Undirected living donation is allowed in Turkey but there are not too many numbers of undirected living donations.
	+	At present (January 2016) 121 hospitals (75 Kidney, 46 Liver) have a living donation program.
	+	The Council of Organ Transplantation Center evaluate the living donor before the start of the procedure.
	+	Registers are established at the national, regional and centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, the Council of Europe Convention is ratified by Turkey.
	●	National policy on living donation programs is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the promotion of living donation programs.
Priority Action 4: Improve the knowledge and	+	There are brochures, public spots, posters for informing the public.

communication skills of health professionals and patient support groups	+	Turkey deploys programs to improve knowledge and communication skills for personnel that deal with organ transplantation, for all health care (hospital) personnel and for patient support groups.
	+	Periodic meetings with journalists have been organised.
	+	Guidelines and deliverables developed by EU supported activities are used for informing the public, improving knowledge and skills of health professionals, improving knowledge and skills of patient support groups and organising periodic meetings with journalists.
	●	The national policy on public awareness of organ donation is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	●	Turkey does not provide easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU.
	+	The following people can legally be donors in Turkey: residents with a foreign nationality who die in Turkey and non-residents who die in Turkey.
	+	Criteria required to be admitted to the waiting list in Turkey: Turkish citizen ID number is mandatory for registration so only the Turkish citizens can be registered in the waiting lists for deceased organs.
	+	92% of transplanted patients are local residents, 8 % of transplanted patients are non-residents (only living donation).
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors.
Priority Action 6: Enhancing organisational models	●	Turkey is not involved in twinning projects but is involved with experience sharing and knowledge exchange. 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. These projects led to increasing of public awareness on deceased organ donation.
	+	CA is aware that Turkey has used structural funds or other community instruments for the purpose of the development of transplantation systems. The project "Technical assistance for alignment in Organ Donation" is co-financed by the European Union and the Republic of Turkey.
	●	Transplantation centres or hospitals do not participate international registries.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to enhancing the organisational model of the donation

		and transplantation system.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	Turkey has agreements with other countries for collecting data (ELTR, ERA-EDTA registries…): Some of the transplantation centres are included in the ELTR register system individually.
	+	Turkey has agreements with other countries to prevent and address organ trafficking. There are no main challenges mentioned.
	●	No suggestions for future research programmes.
	●	The development of EU-wide agreements is not influenced by the EU Action Plan EU supported activities did not contribute to this development.
Priority Action 8: Facilitate the interchange of organs between national authorities	●	Turkey is not part of a multi-lateral collaboration.
	●	Turkey has not offered non-allocated organs to other countries, there were no 'non allocated' organs.
	●	There are no evaluation procedures for offering non allocated organs to other countries.
	●	There are no procedures in place for the exchange of organs of urgent and difficult-to-treat patients.
	●	Turkey does not participate in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	●	National policy on the interchange of organs is not influenced by the EU Action Plan.
	●	EU activities did not contribute to the interchange of organs between countries.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level: results are systematically collected in a database/register at national level.
	+	Results are measured 3, 6 and 12 months after transplantation.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	●	EU supported activities have not contributed to the evaluation of post-transplant results.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis. A national accreditation system is used for donation (coordinators), for procurement (surgeons) and for transplantation.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems.
	●	EU supported activities did not contribute to the promotion of accreditation systems.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects Turkey was an associated partner in ELIPSY[376] and also participated in ETPOD. Turkey was an associated partner in ODEQUS (M. Manyalich et al., 2013).

In 2011, the country took part in the annual Indicators' exercise[377]. In addition, it is a member of the Committee (Partial Agreement) on Organ Transplantation (CD-P-TO[378]) of the Council of Europe.

Conclusions

Both Turkey's deceased donation rate and living donation rate increased since 2008. This is a positive sign. The challenge for Turkey is now to maintain these increasing rates. An opportunity to explore further for Turkey might be DCD. Turkey could also consider making agreements with other countries for exchanging organs, and urgent and difficult-to-treat patients.

Turkey could also consider focusing more on issues regarding education, implementation and quality assurance in the field of organ donation.

[376] For more information about EU-funded projects, see chapter 3.
[377] For more information about the working groups, see chapter 3.
[378] For more information about CD-P-TO, see Annex 3.

36. United Kingdom

Background information[379]

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 above 20 in 2015, the United Kingdom belongs to the countries included in this study with a higher deceased donation rate. In 2015, deceased donor transplant procedures were carried out involving kidney, liver, heart, lung, pancreas and bowel.

With a living kidney donation rate per million population higher than 10 in 2015, the United Kingdom's living kidney donation rate per million population is among the higher of the countries included in this study. In 2015 living donor transplant procedures were carried out involving kidney and liver. The UK is specialized in performing pancreas transplants.

Donor organs are allocated at national level.

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

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 had been taken by the deceased. Consent or refusal is registered in the NHS Organ Donor Register. However, since December 2015, Wales adopted a deemed consent system: people who die will be deemed to have given consent to their organs being donated after their death, unless they formally register their wishes not to do so.

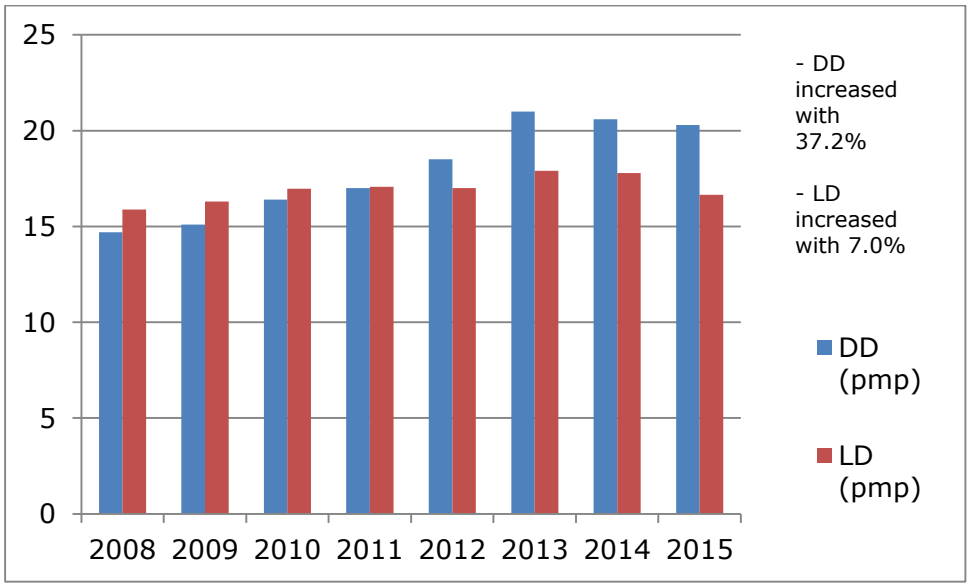
[379] Sources: FACTOR survey filled in by national Competent Authority, Competent Authority United Kingdom. (2011). Presentation National Action Plan United Kingdom, 28 February 2011; Competent Authority United Kingdom. (2011). Third meeting of the Competent Authorities for organ donation and transplantation, 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.

Key figures

Table	2008	2009	2010	2011	2012	2013	2014	2015
Population in millions	60.2	61.8	61.9	62.3	62.8	63.1	63.5	64.7
Family refusal rate (refusals/times asked)	591/ 1551	510/ 1265	1009/ 2348	1104/ 2542	1236/ 2906	1334/ 3225	1401/ 3336	1269/ 3712
Actual deceased donation rate (total/per million population, pmp)	885/ 14.7	931/ 15.1	1015/ 16.4	1056/ 17	1164/ 18.5	1323/ 21	1309/ 20.6	1311/ 20.3
Multi-organ donation rates (% of total)	77.2	74.9	72.3	70.9	70.1	68.0	72.3	72.9
Number of utilised donors (total/per million population)	-		-	-	-	-	-	
Number of donors after circulatory death - DCD	264	318	373	405	504	544	505	548
Number of donors older than 60	-		-	-	-	-	457	
Number of transplant centres								
Kidney	24	27	27	26	27	27	28	25
Liver	8	7	7	7	7	7	7	7
Heart	7	8	7	7	7	7	7	7
Lung	5	6	6	6	6	6	6	6
Pancreas	8	10	10	11	12	11	12	11
Bowel	3	4	4	4	4	3	4	4
Number of deceased donor transplant procedures (total/pmp)								
Kidney	1382/2 3.0	1616/ 26.1	1698/ 27.4	1726/ 27.7	1867/ 29.7	2157/ 34.2	2104/ 33.1	2131/ 32.9
Liver	683/ 11.3	660/ 10.7	688/ 11.1	722/ 11.6	780/ 12.4	874/ 13.9	905/ 14.3	989/ 15.3
Heart	127/ 2.1	138/ 2.2	124/ 2.0	148/ 2.4	142/ 2.3	195/ 2.9	186/ 2.9	194/ 3
Lung	139/ 2.3	149/ 2.4	162/ 2.6	191/ 3.1	182/ 2.9	211/ 3.3	194/ 3.1	202/ 3.1
Pancreas	216/ 3.6	213/ 3.4	195/ 3.2	236/ 3.8	254/ 4	235/ 3.7	239/ 3.8	244/ 3.8
Bowel	9/0.1	22 /0.4	18/0.3	21/0.3	15/0.2	27/0.4	21/0.3	15/0.2
Number of living donor transplant procedures (total/pmp)								
Kidney	920/ 15.3	982/ 15.9	1026/ 16.6	1026/ 16.5	1032/ 16.4	1100/ 17.4	1097/ 17.3	1042/ 16.1
Liver	36/0.6	25 /0.4	24/0.4	37/0.6	36/0.6	30/0.5	32/0.5	35/0.5

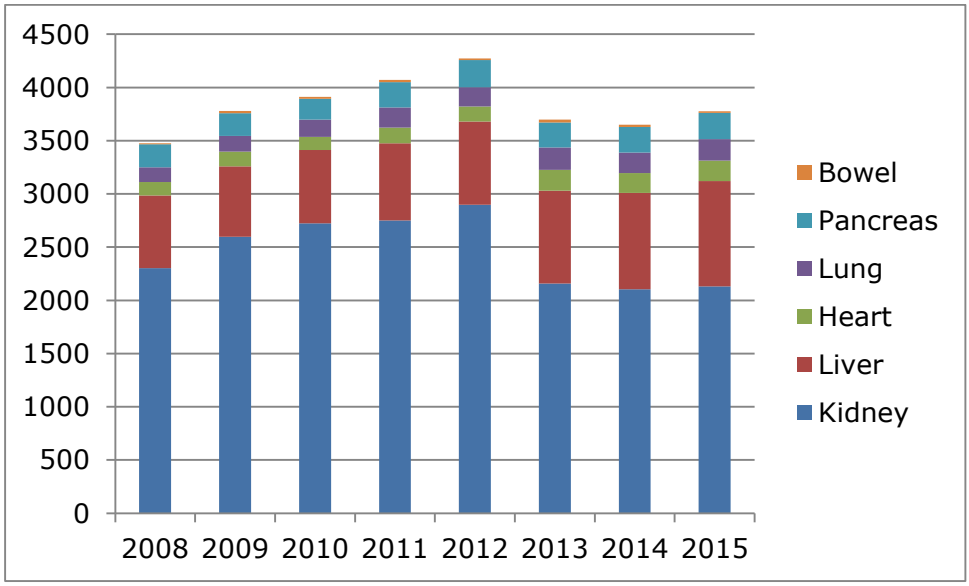
- = unknown to the research team

Figure 1: Deceased Donation (DD) rates per million population (PMP) and Living Donation (LD) rates per million population (PMP) from 2008-2015 in the United Kingdom*



* Deceased Donation rates are based on the numbers as published in the Transplant Newsletter. Living Donation rates are calculated by adding numbers of living liver and living kidney transplant procedures, divided by the population in millions. The percentage decrease or increase is calculated based on the average rate of the years 2008 and 2009 and the average rate of 2014 and 2015. This means that the years in between are not taken into account.

Figure 2: total number of transplantations* per organ per year (2008-2015)



* Deceased and living transplantations

Implementation Action Plan

Priority Action 1: Promote the role of transplant donor coordinators	+	Transplant donor coordinators have been appointed: at the national level 215 WTE Senior Nurse Organ Donation (SNOD) and 29 WTE Team Managers.
	+	Transplant donor coordinators receive both initial and regular training.
	+	Summary of the training: Internal Competency framework and cohort training The trainings have been tested for effectiveness.
	+	The United Kingdom uses an accreditation scheme: National training and Internal accreditation process.
	+	The EU Action Plan has influenced national policy on transplant donor coordinators: the UK took into account policy on the appointment and training in other countries as part of its Transplant Programme and these models are reflected in the Action Plan.
Priority Action 2: Promote Quality Improvement Programmes	+	The government has stimulated initiatives to improve the quality of the identification of potential donors, the donation process, the procurement process, and the transplantation process.
	●	The EU Action Plan has not influenced the national policy on Quality Improvement Programme: EU Directive 2010/53 has influenced Quality Improvement Programmes generally. Several critical steps at which time donors can be lost are earlier in the process than we first realized. As critical care physicians are the gatekeepers at these points, a workshop was developed with the aim of informing them about research findings on breaking bad news, on the roles of the critical care physician and the transplant team about managing end of life care, approaching families about donation and how this can affect donor rates.
	+	EU supported activities have contributed to the promotion of Quality Improvement Programmes.
Priority Action 3: Exchange of best practices on living donation	+	The United Kingdom has directed living donation programmes. The United Kingdom enables Living donation between genetically and emotionally related individuals.
	+	There also are undirected living donation programmes: The UK allows undirected donation through crossover (also called paired or pooled donation) and non-directed altruistic donation where an individual donates anonymously to someone on the waiting list. Every LOD has to be approved by the Human Tissue Authority through an independent assessment process. This is regardless of the relationship between donor and recipient. All donations by non-directed donors are assessed and have to be approved by a panel of the Human Tissue Authority (UK Competent Authority). This a requirement in law.
	+	27 hospitals (24 kidney and 3 liver) have a living donation program.

	+	There is an independent body to evaluate the living donor before the start of the procedure: Independent assessors appointed by the Human Tissue Authority.
	+	A register is established at the national level, the regional level and at the centre/hospital level to evaluate and guarantee the health and safety of living donors.
	+	Organ trafficking is prohibited by law, but the United Kingdom has not yet ratified the Council of Europe Convention.
	+	The EU Action Plan reiterates the need for national registers and effective selection, evaluation, consent, and follow up.
	+	The UK is fully supportive of all programmes to support LD programmes and has either participated or been part of the initial development of the projects.
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups	+	There are communication guidelines for informing the public. The United Kingdom deploys programs to improve knowledge and communication skills of personnel that deal with organ transplantation and patient associations (specific stakeholder group to guide operational issues).
	●	Periodic meetings with journalists have not been organised.
	●	Guidelines and deliverables developed by EU supported activities are not used.
	+	The UK fully supports the need and has national policy on raising public awareness on organ donation.
	+	The EU supported activities contributed to the promotion of public awareness.
Priority Action 5: Facilitate the identification of organ donors across Europe	+	The United Kingdom provides easily accessible information to its citizens about their legal position as a possible donor in other countries across the EU: available on NHSBT website.
	+	The following people can legally be donors in The United Kingdom: residents with a foreign nationality who die in The United Kingdom, non-residents who die in The United Kingdom and Illegal persons who die in the United Kingdom.
	+	Criteria required to be admitted to the waiting list: residency in The United Kingdom and EU Citizen and residents of countries with bilateral agreements (with caveats).
	+	For deceased donor organ transplants: 99.4% of transplanted patients were local residents, 0.6% were foreign residents; for all organ transplants: 98.9% of transplanted patients were local residents, 1.1% were foreign residents.
	●	National policy on cross-border donation is not influenced by the EU Action Plan.
	●	EU supported activities did not contribute to the identification of cross-border donors, because UK already had a clear policy.
Priority Action 6: Enhancing organisational	+	The United Kingdom is involved in twinning projects, in both a teaching and a learning role.

models		Topics are: FOEDUS and ACCORD joint action. NHSBT did not take part in the ACCORD twinning but led another joint action.
	+	These projects led to changes: Implementation of Plan Do Study Act (PDSA) improvement system.
	●	CA is not aware of UK using structural funds and/or other community instruments (EU funding) for the purpose of the development of transplantation systems.
	+	Transplantation centres or hospitals participate in networks: Advisory groups for all organ specialities.
	●	The organisational model of the donation and transplantation system is not influenced by the EU Action Plan.
	+	EU supported activities contributed to enhancing the organisational model of the donation and transplantation system: PDSA coming from ACCORD project.
Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine	+	The United Kingdom has agreements with other countries for treating each other's patients, and possibly for exchanging organs and research activities and other aspects of transplant medicine.
	+	The United Kingdom has agreements with other countries to prevent and address organ trafficking: the main challenges are: The UK has robust laws country against trafficking and would work with other countries if trafficking is detected. The UK has signed the CofE Convention on Human and Organ Trafficking and is a member of the Declaration of Istanbul Custodial Group.
	+	Future research programmes should focus on expanding the pool of potential donors and organ utilisation.
	+	The development of EU-wide agreements is and will be influenced by the EU Action Plan: The UK has been actively involved in Action Plans and is a member of the Action Plan steering Group.
	+	EU supported activities contributes to this development: The UK has benefitted from such projects particularly Accord and Foedus.
Priority Action 8: Facilitate the interchange of organs between national authorities	+	The United Kingdom is part of a fixed collaboration: a multilateral collaboration, namely the South Alliance for Transplants (SAT).
	+	In 2015 13 organs came from abroad, 7 organs left the country.
	+	In 2015 the UK has offered 76 'non allocated' organs (and therefore not transplanted) to other countries.
	+	The United Kingdom has procedures for the exchange of organs of urgent and difficult-to-treat patients.
	+	The United Kingdom participates in the use of the FOEDUS IT-tool for the facilitation of cross-border exchange.
	+	The national policy on the interchange of organs will be influenced by the EU Action Plan: UK is looking at introducing the Foedus tool for some

		organs, building on protocols we already have in place.
	+	EU activities contributed to the interchange of organs between countries: the use of unallocated organs in MS thereby optimizing donation.
Priority Action 9: Evaluation of post-transplant results	+	Post-transplant results of organ recipients are evaluated on a national level, results are systematically collected in a database/register at the national level.
	+	Results are measured 3 and 12 months after transplantation and annually thereafter.
	+	The evaluation of post-transplant results is supported by a vigilance system.
	+	Donor organs are accepted from patients with diabetes mellitus, hypertension, renal insufficiency, infectious diseases such as hepatitis, HIV, and from donors aged over 60.
	●	National policy on the evaluation of post-transplant results is not influenced by the EU Action Plan.
	+	EU supported activities contributed to the evaluation of post-transplant results: it builds on procedures etc. in place in the UK.
Priority Action 10: Promote a common accreditation system	+	Procurement organisations and transplantation centres are controlled or audited on a regular basis.
	+	The United Kingdom promotes an accreditation system for procurement organisations and transplantation centres.
	+	The accreditation systems used are for donation (coordinators): national, for procurement (surgeons): national, and for transplantation: national.
	●	The EU Action Plan has not influenced national policy on the promotion of accreditation systems: already in place through implementation of Directive 2010/53.
	+	EU supported activities contributed to the promotion of accreditation systems: UK has such accreditation in place.

Participation in EU-funded projects during the Action Plan period (2009-2015)

Regarding EU-funded projects the United Kingdom was core work package leader in EFRETOS[380] 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[381] 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[382]).

[380] For more information about EU-funded projects, see chapter 3.
[381] For more information about the working groups, see chapter 3.
[382] For more information about CD-P-TO, see Annex 3.

Conclusions

Both United Kingdom's deceased donation rate and living donation rate increased since 2008. This is very positive. It is now the challenge for the UK to maintain these increasing rates. The UK is also encouraged to share its experiences and best practices.

The most valuable contribution of the EU Action Plan and activities of the EU is that countries are brought together and learn from each other. The Joint Actions are very effective. The UK was Work Package leader in the Joint Action ACCORD on the links with Intensive Care Units and a new methodology, PDSA. The feedback of other countries was very helpful and this allows the UK to learn from others and take on board various tools, strategies and manuals developed by other countries in the UK. It also really pushed the identification of donors in the UK. Also the training of donor coordinators developed by EU activities is positive. The UK activities predate the Action Plan, but the UK builds on the success of other countries such as Spain.

The UK has the 2020 strategy, which comprises four main goals for 2020: Increasing the deceased donation rate from 21 to 26, increasing the transplant rate and a better usage of organs, increase consent rates and investigate the cause of the variations in consent rates throughout the UK, and improve the potential donor identification in hospitals.

Possibly a new EU Action Plan is needed according to the UK. Some parts of the Plan were less effective than other parts. It could be more focused on less developed countries. They should be consulted on what their needs are, and more tailored approaches might be more effective. The twinning parts of the Action Plan could be taken up again, this worked very well. The twinnings could even be bigger, for instance some southeastern countries near the black sea are now 'twinning' with eight countries. But the focus should be on the less developed. The developed countries are doing well.

EU efforts should be continued on organ trafficking and reassuring equitable access in all countries to organ transplantation.

ANNEX 2: ANSWERS OF INDIVIDUAL COUNTRIES FOR EACH PRIORITY ACTION

P.A.1 (transplant donor coordinators) N=36	Number of transplant donor coordinators appointed (total)		Transplant donor coordinator receives specific training		Trainings have been tested for effectiveness	
	2012	2016	2012	2016	2012	2016
Austria	25	26	not yet	not yet	?	no
Belgium	96	98	both	both	no	no
Bulgaria	25	58	regular	regular	not yet	not yet
Croatia	34	35	initial	initial	not yet	Yes
Czech Republic	84	84	both	both	not yet	not yet
Cyprus	1	5	other	other	no	no
Denmark	3	104	not yet	yes	N/A	no
Estonia	7	8	other	both	no	no
Finland	yes (?)	yes (?)	?	regular	?	no
France	559	186 MD and 654 nurses	both	both	Yes	Yes
Germany	68	1777	both	both	no	no
Greece	126	108	other	other	Yes	not yet
Hungary	14	34	other	initial	Yes	Yes
Iceland						
Ireland	5	6	initial	both	no	Yes
Italy	315	312	both	both	?	no
Latvia	yes (?)	3	not yet	both	not yet	not yet
Liechtenstein		N/A		N/A		N/A
Lithuania	10	18	both	initial	not yet	Yes
Luxembourg	3	3	initial	initial	no	no
Macedonia	0	6	regular	both		no
Malta	3	3	regular	regular	no	no
Montenegro	1	1?				
Norway	29	27	regular	regular		no
Poland	236	325	both	both	Yes	Yes
Portugal	50	56	initial	initial	no	N/A
Romania	7	48	not yet	both		not yet
Serbia		14		not yet		no
Slovakia		65		both		Yes
Slovenia	12	17	both	both	Yes	Yes
Spain	382	440	both	both	Yes	Yes
Sweden	yes (?)	yes (?)	initial	initial	N/A	N/A
Switzerland	yes (?)	184	?	other	?	not yet
The Netherlands	105	105	both	both		no

P.A.1 (transplant donor coordinators) N=36	Number of transplant donor coordinators appointed (total)		Transplant donor coordinator receives specific training		Trainings have been tested for effectiveness	
	2012	2016	2012	2016	2012	2016
Turkey		786	regular	regular	no	not yet
United Kingdom	266	244	both	both	Yes	Yes

P.A.1 (transplant donor coordinators) N=36 (Table continued)	National or international accreditation scheme used to qualify transplant donor coordinator		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016
Austria	no	no		no		no
Belgium	no	no		no		no
Bulgaria	no	no		yes		yes
Croatia	not yet	Yes		yes		?
Czech Republic	not yet	not yet		?		?
Cyprus	no	no		now and in the future		no
Denmark	N/A	no		yes		no
Estonia	no	no		yes		yes
Finland	no	no		?		no
France	not yet	N/A		N/A		yes
Germany	Yes	Yes		yes		yes
Greece	Yes	Yes		yes		yes
Hungary	no	no		yes		yes
Iceland						
Ireland	no	not yet		yes		yes
Italy	yes	no		no		yes
Latvia	no	not yet		other		yes
Liechtenstein		N/A		N/A		no
Lithuania	not yet	not yet		?		yes
Luxembourg	no	no		yes		?
Macedonia	no	no		no		no
Malta	no	not yet		no		no
Montenegro						
Norway	yes	yes		no		no
Poland		yes		yes		yes
Portugal	yes	yes		yes		yes
Romania	not yet	no		yes		no
Serbia		no		in the future		?
Slovakia		Yes		yes		yes
Slovenia	yes	yes		yes		yes
Spain	Yes	Yes		other		yes
Sweden	no	no		in the future		?
Switzerland	no	yes		no		no
The Netherlands		no		no		no
Turkey	no	no		no		yes
United Kingdom	Yes	Yes		other		?

P.A.2 (Quality Improvement Programmes) N=36	Government stimulated or introduced initiatives to improve the quality of different aspects of the organ donation and transplantation process in individual hospitals (a. Identification of potential donors b. The donation process c. The procurement process d. The transplantation process e. Follow up care)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016
Austria	b,c,d	b,c,d		no		no
Belgium	a,b,c	a,b,c,d,e		yes		no
Bulgaria	a,b,c	a,b,c		?		?
Croatia	b,c	a,b,c,d		in the future		yes
Czech Republic	a,b,c,d,e	a,b,c,d,e		yes		?
Cyprus	a,b,c,d,e	a,b,c,d,e		in the future		no
Denmark	a,b,c,d	a,b,c		yes		no
Estonia	a,b,c	a,b,c,d		yes		?
Finland	?	a,b,c,d,e		?		no
France	a,b,c,d,e	a,b,c,d,e		Other		yes
Germany	a,b,c,d,e	a,b,c,d,e		yes		yes
Greece	a,b,c,d,e	a,b,c		in the future		no
Hungary	a	a,b,c,d		yes		no
Iceland						
Ireland		a,b,c,d		yes		yes
Italy	a,b,c,d,e	a,b,c,d,e		no		yes
Latvia	c,d,e	c,d,e		in the future		no
Liechtenstein				N/A		no
Lithuania		a,b,c,d		no		no
Luxembourg	a	a		yes		?
Macedonia	b,d	a,b,d,e		no		no
Malta		a,b,c,d,e		yes		no
Montenegro	a,b,c,d,e					
Norway	a	a		no		no
Poland	a,b,c,d,e	a,b,c,d,e		yes		yes
Portugal	none	a,b,c,d,e		yes		yes
Romania	none	a,b,c,d,e		yes		no
Serbia		none		N/A		?
Slovakia		a,b,c,d,e		yes		no
Slovenia	a	a,b,c,d,e		yes		yes

P.A.2 (Quality Improvement Programmes) N=36	Government stimulated or introduced initiatives to improve the quality of different aspects of the organ donation and transplantation process in individual hospitals (a. Identification of potential donors b. The donation process c. The procurement process d. The transplantation process e. Follow up care)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016
Spain	a,b,c,d,e	a,b,c,d,e		yes		yes
Sweden	?	none		N/A		?
Switzerland	a,b,c	a,b,c,d		no		no
The Netherlands	a,b,c,d,e	a,b,c,d,e		no		?
Turkey	a,b,c,d,e	a,b,c,d,e		yes		no
United Kingdom	a,b,c,d,e	a,b,c,d		no		yes

P.A.4 (public awareness) N=36	There are communication guidelines for informing the public about organ donation and transplantation		There are programmes to improve knowledge of health professionals		There are programmes to improve knowledge of patient support groups		Periodic meetings with journalists are organised	
	2012	2016	2012	2016	2012	2016	2012	2016
Austria	no	no	e	e	?	no	no	no
Belgium	?	yes	f	e,f	yes	yes	yes	yes
Bulgaria	no	not yet	no	d	no	yes	no	yes
Croatia	Yes	Yes	d	d	yes	yes	yes	yes
Czech Republic	Yes	Yes	d	d	yes	yes	yes	yes
Cyprus	?	no	e	e	yes	yes	not yet	yes
Denmark	?	no	d	d,e	yes	yes	?	no
Estonia	no	no	a	d	no	no	no	no
Finland	Yes	Yes	?	d	?	not yet	no	no
France	Yes	Yes	e	e	Yes	Yes	Yes	Yes
Germany	no	yes	e	e	Yes	Yes	no	no
Greece	Yes	Yes	e	e	Yes	not yet	Yes	Yes
Hungary	Yes	Yes	d	d	yes	yes	yes	yes
Iceland								
Ireland	not yet	not yet	no	d,f	no	yes	no	yes
Italy	?	yes	d	d	yes	no	no	no
Latvia	?	no	?	d	?	not yet	?	not yet
Liechtenstein		no		N/A		N/A		N/A
Lithuania	yes	yes	d	e	yes	yes	yes	not yet
Luxembourg	no	no	e	e	yes	yes	no	no
Macedonia	not yet	yes	b	d	not yet	not yet	not yet	no
Malta	yes	yes	d	d	yes	yes	no	no
Montenegro	not yet		no		no		not yet	
Norway	no	no	d	d	yes	yes	no	no
Poland	yes	yes	d	d	yes	yes	yes	yes
Portugal	no	no	d	d,e	yes	yes	yes	yes
Romania		yes	b	b	no	no/yes		yes
Serbia		no		d		N/A		no
Slovakia		not yet		d		not yet		no
Slovenia	yes	yes	d	d,e,f	no	no, but	no	yes
Spain	yes	yes	e	e	yes	yes	yes	yes
Sweden	?	N/A	d	d	?	no	?	no
Switzerland	yes	yes	e	e	yes	yes	no	no
The Netherlands	yes	yes	e	e	yes	yes	not yet	no
Turkey	not yet	yes	b	d,e	yes	yes	not yet	yes
United Kingdom		yes	d	d	yes	yes		no

P.A.4 (public awareness) N=36 (Table continued)	There are communication guidelines for informing the public about organ donation and transplantation	The guidelines and deliverables developed by EU supported activities are used for (a. Informing the public b. Improving knowledge and skills of health professionals c. Improve knowledge and skills of patient support groups d. Organising periodic meetings with journalists)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
		2012	2016	2012	2016	2012	2016
Austria	no		?		no		?
Belgium	?		a,b,c,d		no		yes
Bulgaria	no		a,b,c,d		yes		yes
Croatia	Yes		a,b,c,d		yes		yes
Czech Republic	Yes		a,b,c,d		yes		?
Cyprus	?		a,b,c,d		?		yes
Denmark	?		?		no		no
Estonia	no		a,b,c		in the future		yes
Finland	Yes		none		yes		no
France	Yes		none		no		no
Germany	no		a,b,c		yes		yes
Greece	Yes		a,b,c,d		yes		yes
Hungary	Yes		a,b		yes		yes
Iceland							
Ireland	not yet		a,b,c,d		in the future		yes
Italy	?		a,b,c		no		yes
Latvia	?		a,b,c,d		in the future		no
Liechtenstein					N/A		no
Lithuania	yes		a,c,d		no		yes
Luxembourg	no		?		?		?
Macedonia	not yet		a,b		no		?
Malta	yes		a,b,c,d		no		no
Montenegro	not yet						
Norway	no		none		no		no
Poland	yes		a,b,c,d		yes		yes
Portugal	no		a,b,c,d		yes		yes
Romania			a,b		no		no
Serbia			none		N/A		no
Slovakia			a,b,c,d		in the future		no
Slovenia	yes		a,b,c,d		yes		yes
Spain	yes		a,b,c,d		yes and other		yes
Sweden	?		?		no		?

P.A.4 (public awareness) N=36 (Table continued)	There are communication guidelines for informing the public about organ donation and transplantation	The guidelines and deliverables developed by EU supported activities are used for (a. Informing the public b. Improving knowledge and skills of health professionals c. Improve knowledge and skills of patient support groups d. Organising periodic meetings with journalists)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
		2012	2016	2012	2016	2012	2016
Switzerland	yes		b		no		?
The Netherlands	yes		a		no		no
Turkey	not yet		a,b,c,d		no		no
United Kingdom			none		other		yes

P.A.5 (identification of donors cross border) N=36	Country provides easily accessible information to your citizens about their legal position as a possible donor in other countries across the EU		The following people can legally be donors in your country (a. Residents with a foreign nationality who die in your country? b. Non-residents who die in your country (e.g. dying on holiday)? c. Illegal persons who die in your country? d. N/A)		The following criteria are required in order to get admitted to the waiting list (a. Residency in the country b. Local nationality c. Signed up with local social security or health care insurance d. Other, namely)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Austria	no	no	a,b,c	a,b,c	?	?		no		no
Belgium	yes	no	a,b,c	a,b	d	a,b,d		no		no
Bulgaria	not yet	yes	a	a	a,bc	a,b,c		yes		yes
Croatia	yes	yes	a,b	a,b	a,bc	a,b,c		?		no
Czech Republic	yes	not yet	none	a,b	b,c	b		?		no
Cyprus	yes	yes	a,b,c	a,b,c	a	a		?		no
Denmark	?	no	?	a,b,c	?	a,c		no		no
Estonia	no	no	a,b	a,b	?	d		yes		yes
Finland	?	no	a,b	a,b	?	a		no		no
France	no	no	a,b,c	a,b,c	?	c		no		yes
Germany	yes	yes	a,b,c	a,b,c	a	none		no		no
Greece	yes	yes	a,b,c	a,b	a,c	a,b,c		in the future		yes
Hungary	yes	yes	none	none	c	c		no		no
Iceland										
Ireland	not yet	no	a,b,c	a,b,c	a,b,c	a,c		in the future		no
Italy	?	no	?	a,b,c	?	a,c,d		no		no
Latvia	?	no	N/A	a,b	a,b,c	a		no		no
Liechtenstein	no	no		N/A		N/A		N/A		no
Lithuania	?	yes	a,b,c	a,b	b,c	a,b,c		no		no
Luxembourg	no	no	a,b	a,b	a,c	a,c		?		?
Macedonia	no	no	d	none	a,b.c	a.b.c		N/A		no
Malta	no	no	a,b	a,b	a,c	a,c		no		no
Montenegro	yes									
Norway	no	no	a,b,c	a,b,c	a,c	a,c		no		no
Poland	not yet	not yet	a,b,c	a,b,c	a,b,c	a,b,c		yes		yes
Portugal	no	not yet	b,c	a,b	a,b	a,b		no		no
Romania		no	a,b	a,b		a		no		no
Serbia		no		a,b		b,c		N/A		no
Slovakia		not yet		a		a,c		in the future		no

P.A.5 (identification of donors cross border) N=36	Country provides easily accessible information to your citizens about their legal position as a possible donor in other countries across the EU		The following people can legally be donors in your country (a. Residents with a foreign nationality who die in your country? b. Non-residents who die in your country (e.g. dying on holiday)? c. Illegal persons who die in your country? d. N/A)		The following criteria are required in order to get admitted to the waiting list (a. Residency in the country b. Local nationality c. Signed up with local social security or health care insurance d. Other, namely)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Slovenia	yes	yes	a,b	a,b	a,c	a,c		?		?
Spain	?	no	a,b,c	a,b.,c	a,b,c	a,b.,c		no		no
Sweden	?	no	?	a,b	?	a,b		no		?
Switzerland	no	no	a,b	a,b	a,b,c	a,b.,c		no		yes
The Netherlands	yes	yes	a,b	a,b,c	a	a,c		no		?
Turkey	not yet	no	a,b	a,b	d	d		no		no
United Kingdom		yes		a,b,c		a,d		no		no

P.A.6 (organisational models) N=36	Country is involved in twinning projects		role in twinning project (a: Learning b: Teaching c: Other, namely)		Twinning project led to changes		Structural funds are used for the purpose of the development of transplantation systems	
	2012	2016	2012	2016	2012	2016	2012	2016
Austria	yes	N/A					not yet	?
Belgium	no	no						
Bulgaria	yes	yes		a	yes	yes	no	yes
Croatia	yes	yes		a,b	not yet	yes	yes	yes
Czech Republic	yes	yes		a,b	yes	yes	yes	yes
Cyprus	yes	yes		a	?	not yet	?	no
Denmark	?	no		?	?	?	?	?
Estonia	yes	no					no	yes
Finland	no	yes		?				no
France	yes	yes		b	yes	yes	no	no
Germany	no	no						
Greece	no	yes		c	N/A	yes	?	no
Hungary	yes	yes		b	not yet	not yet	not yet	not yet
Iceland								
Ireland	yes	yes		a	?	not yet	not yet	no
Italy	?	yes		a,b		yes		not aware
Latvia	?	no					not yet	not yet
Liechtenstein	no	no						
Lithuania	yes	yes		a	?	yes	no	not yet
Luxembourg	no	no					no	?
Macedonia	no	no					no	
Malta	yes	yes		a		yes		no
Montenegro	not yet							
Norway	no	yes		a		yes		not yet
Poland	no	not yet					not yet	
Portugal	no	no					yes	yes
Romania		yes		b		yes		not yet
Serbia		yes		a		N/A		?
Slovakia	yes	yes		a		not yet		no
Slovenia	yes	yes		a,b,c	yes	yes	?	yes
Spain	yes	yes		b	yes	yes	yes	yes
Sweden	?	no					?	?
Switzerland	no	no					no	?
The Netherlands	yes	yes		b	not yet	yes		no
Turkey	yes	yes		c	yes	yes	not yet	yes
United Kingdom		yes		a,b		yes		not aware

P.A.6 (organisational models) N=36 (Table continued)	Country is involved in twinning projects	Transplantation centers or hospitals participate in any networks of centres of reference		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
		2012	2016	2012	2016	2012	2016
Austria	yes	?	N/A		no		?
Belgium	no	yes	?		no		no
Bulgaria	yes	no	no		yes		yes
Croatia	yes	yes	yes		?		no
Czech Republic	yes	no	not yet		?		yes
Cyprus	yes	?	no		?		no
Denmark	?	?	yes		yes		yes
Estonia	yes	no	yes		yes		yes
Finland	no	yes	yes		no		no
France	yes	yes	yes		no		yes
Germany	no	?	no		yes		no
Greece	no	?	yes		in the future		yes
Hungary	yes	yes	yes		yes		yes
Iceland							
Ireland	yes	?	yes		yes		yes
Italy	?		?		no		yes
Latvia	?	?	no		no		no
Liechtenstein	no				N/A		no
Lithuania	yes	no	no		no		yes
Luxembourg	no	no	no		?		?
Macedonia	no	no	no		?		?
Malta	yes	no	no		yes		yes
Montenegro	not yet						
Norway	no	no	no		no		no
Poland	no	not yet	not yet		yes		yes
Portugal	no		no		yes		yes
Romania			not yet		no		no
Serbia			?		N/A		no
Slovakia	yes		no		no		no
Slovenia	yes	no	not yet		yes		?
Spain	yes	yes	yes		no		no
Sweden	?	?	N/A		no		no
Switzerland	no	yes	yes		no		no
The Netherlands	yes		N/A		no		no
Turkey	yes	not yet	no		no		no
United Kingdom			yes		no		yes

P.A. 7 (EU-wide agreements) N=36	Country has agreements with other countries in place for a:exchanging organs b: treating each others patients c: supporting the development of new transplantation programmes d: training/certifying healthcare professionals (surgeons, coordinators) e: collecting data with/for your country (ELTR, ERA-EDTA registries…) f: research activities g: other aspects of transplant medicine		Country has agreements with other countries to prevent and address possible cases of organ trafficking		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016
Austria		a,c,e	?	no		N/A		?
Belgium		a,b,c,d,e,f,g	yes	yes		no		no
Bulgaria		a	yes	not yet		yes		yes
Croatia		a,b,c,d,e		no		?		?
Czech Republic		a,g	yes	yes		?		?
Cyprus		a,b	?	no		?		no
Denmark		a,b,c,d,e,f	?	no		no		?
Estonia		a,b,c,d,e,f	?	no		yes		yes
Finland		a,b,c,d,e,f	?	no		no		no
France		a,d,e,g	no	no		no		yes
Germany		a,e,f	yes	yes		N/A		no
Greece		a,b,c,d	no	no		yes		yes
Hungary		a,b,c,d,e	?	no		no		no
Iceland								
Ireland		a,b	?	no		yes		no
Italy		a,b		yes		yes		yes
Latvia		a	?	no		no		no
Liechtenstein		b	no	no		no		no
Lithuania		a,d,e	yes	yes		no		yes
Luxembourg		a	?	?		?		?
Macedonia		c,d,g	not yet	yes		?		?
Malta		a,b,d	no	no		yes		?
Montenegro			yes					
Norway		a	not yet	not yet		no		no

P.A. 7 (EU-wide agreements) N=36	Country has agreements with other countries in place for a:exchanging organs b: treating each others patients c: supporting the development of new transplantation programmes d: training/certifying healthcare professionals (surgeons, coordinators) e: collecting data with/for your country (ELTR, ERA-EDTA registries…) f: research activities g: other aspects of transplant medicine		Country has agreements with other countries to prevent and address possible cases of organ trafficking		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016
Poland		a,e	no	no		yes		yes
Portugal		a,b,e,f		not yet		no		yes
Romania		a,b,c,d		no		no		no
Serbia								
Slovakia		a,b,e		no		in the future		yes
Slovenia		a,b,d,e,f	?	no		no		?
Spain		a,b,c,d,e,f	yes	yes		yes		yes
Sweden		a,c	?	N/A		?		?
Switzerland		a,d,g	no	no		no		no
The Netherlands		a,d,e,f		no		yes		?
Turkey		e	yes	yes		no		no
United Kingdom		b,f,g		yes		yes and in the future		yes

P.A.8 (cross border exchange) N=36	Country is part of a fixed collaboration with other countries		Patient groups involved: 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		organs involved a. Liver b. Kidney c. Heart d. Lung e. Other, being pancreas, small bowel f. Other, being		Number of organs from abroad		Number of organs that left country	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Austria	multi- and bilateral	multi- and bila-teral	a	a	a,b,c,d, pancreas, small bowel	a,b,c,d, pancreas, small bowel		304		225
Belgium	multi-lateral	multi-lateral	a,b,c,d, e,f	a	a,b,c,d, pancreas, small bowel	a,b,c,d, pancreas, small bowel	?	?	?	?
Bulgaria	not yet	bila-teral	b,c	a	b,f	a,b,d, pancreas, small bowel, f	0	2	1	7
Croatia	multi-lateral	multi-lateral	b,c	b,c	a,b,c,d, pancreas, small bowel	a,b,c,d, pancreas, small bowel	72	119	113	161
Czech Republic	bilateral	multi- and bila-teral	b,c,e	b,c,e	c,d	a,b,c,d	1	13	5	2
Cyprus	?	not yet					?	?	?	2
Denmark	multi-lateral	multi-lateral	a	a	a,b,c,d, pancreas, small bowel	a,b,c,d, pancreas, small bowel	47	36	35	38
Estonia	other	multi- and bila-teral and other	a	a	a,b,c,d, pancreas, small bowel	a,b,c,d, pancreas	1	3	9	21
Finland	multi-lateral	multilate ral	a	a	a,b,c,d, pancreas, small bowel	a,b,c,d, pancreas, small bowel	?	40	?	42
France	bilateral	multi- and bilateral	a,b,c	a,b,c	a,b	a,b,c,d, pancreas, small bowel	14	10	22	30

P.A.8 (cross border exchange) N=36	Country is part of a fixed collaboration with other countries		Patient groups involved: 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		organs involved a. Liver b. Kidney c. Heart d. Lung e. Other, being pancreas, small bowel f. Other, being		Number of organs from abroad		Number of organs that left country	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Germany	multi-lateral	multi-lateral	a	a	a,b,c,d pan-creas, small bowel	a,b,c,d pan-creas, small bowel		N/A		N/A
Greece		multi- and bilateral	b,c	b,c	a,d	a,c,d	1	2	13	9
Hungary	multi- and bilateral	multi- and bilateral	b,c,f	a	a,b,c	a,b,c,d pan-creas, small bowel	11	102	35	185
Iceland										
Ireland	bilateral	bilateral	b,c	b,c	a	a,b,c,d		1		10
Italy		multi- and bilateral		b,c		a,c,d		16		11
Latvia	other	bilateral	a	a	a,b,c	a,b,c,d		3		3
Liechten-stein	bilateral	bilateral	a	a	a,b,c,d pan-creas, small bowel	a,b,c,d pan-creas, small bowel		N/A		N/A
Lithuania	other	other	b	b,c	a,b,c,d	a,b,c,d	1	2	7	6
Luxembourg	multi-lateral	multilateral	a	a	a,b,c,d pan-creas, small bowel	a,b,c,d pan-creas, small bowel	0	0	48	79
Macedonia	no	not yet	?	?	?	?		N/A		N/A
Malta		multi-lateral	a,b,c,d	a,b,c,d	b,c	b,c	0	0	21	3
Montenegro	bilateral									
Norway	multi-lateral	multilateral	a	a	a,b,c,d pan-creas, small bowel	a,b,c,d pan-creas, small bowel	39	47	114	68
Poland	bilateral and other	other	b	b	d	a,c,d	0	0	4	6

P.A.8 (cross border exchange) N=36	Country is part of a fixed collaboration with other countries		Patient groups involved: 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		organs involved a. Liver b. Kidney c. Heart d. Lung e. Other, being pancreas, small bowel f. Other, being		Number of organs from abroad		Number of organs that left country	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Portugal	bilateral	multi- and bilateral	b	b,c,f	a,c,d	a,c,d, small bowel	0	0	25	?
Romania	other	bilateral	b	f	a,d	d		0		0
Serbia		no						N/A		N/A
Slovakia		bilateral		b,c		a,b,c,d		3		19
Slovenia	multi- and bilateral	multi- and bilateral	a,b,c	a,b,c	a,b,c,d pan-creas, small bowel	a,b,c,d		58		96
Spain	bilateral	multilateral	b,f	f	d	f	19	29	7	4
Sweden	multi-lateral	multilateral	?	a	?	a,b,c,d pan-creas, small bowel	?	No data available	?	No data available
Switzer-land	bilateral	multi- and bilateral	b	a,b	a	a,b,c,d pan-creas, small bowel	25	27	12	6
The Nether-lands	multi-lateral	multilateral	a	a	a,b,c,d pan-creas, small bowel	a,b,c,d pan-creas, small bowel	149	151	94	172
Turkey	not yet	no						N/A		N/A
United Kingdom		multilateral						13		7

P.A.8 (cross border exchange) N=36 (Table continued)	Offered 'non allocated' organs to other countries		Country evaluates procedures for offering non allocated organs to other countries		Country has procedures in place for the exchange of organs of urgent and difficult-to-treat patients		Country participates in an IT-tool for the facilitation of cross border exchange		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Austria	no	no	no	no	yes	yes	?	?		no		?
Belgium	no	?	?	?	yes	yes	yes	yes		no		no
Bulgaria	yes	yes,7	no	no	no	no	no	yes		yes		yes
Croatia	yes	yes, ?		no	yes	yes	not yet	no		?		?
Czech Republic	yes	yes, 10	yes	yes	yes	yes	yes	yes		?		yes
Cyprus	?	yes, 2	?	no	?	yes	?	no		no		no
Denmark	?	yes	?	no	yes	yes	?	yes		no		no
Estonia	yes	yes, 19	no	yes	yes	yes	no	yes		yes		yes
Finland	yes	yes, ?	yes	yes	yes	yes	yes	yes		no		no
France	yes	yes	yes	yes	no	?	yes	yes		no		yes

P.A.8 (cross border exchange) N=36 (Table continued)	Offered 'non allocated' organs to other countries		Country evaluates procedures for offering non allocated organs to other countries		Country has procedures in place for the exchange of organs of urgent and difficult-to-treat patients		Country participates in an IT-tool for the facilitation of cross border exchange		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Germany	no	no		N/A		N/A	N/A	N/A		N/A		N/A
Greece	no	yes, 25	no	not yet	yes	yes	N/A	yes		yes		yes
Hungary	?	no	no	no	yes	yes	yes	yes		no		no
Iceland												
Ireland	?	yes, 27	?	no	?	yes	?	no		?		no
Italy		yes, 13		yes		not yet		yes		yes		yes
Latvia		yes, 3	?	yes	?	yes	?	not yet		no		no
Liechten-stein	no	no		N/A		no		N/A		N/A		no
Lithuania	yes, 7	yes, 6	yes	yes	yes	yes	yes	yes		no		yes
Luxem-bourg	no	no	no	no	no	no	no	yes		?		?
Macedonia	no	no	?	not yet	?	no	no	no		?		no
Malta		no	yes	yes	no	no	yes	yes		no		no
Monte-negro												
Norway		no		yes	yes	yes	yes	yes		no		no
Poland	yes	yes, 6	yes	yes	yes	no	yes	yes		yes		yes
Portugal	yes	yes, ?	no	no	yes	yes	no	not yet		in the future		no
Romania		no		no		no		no		no		no

P.A.8 (cross border exchange) N=36 (Table continued)	Offered 'non allocated' organs to other countries		Country evaluates procedures for offering non allocated organs to other countries		Country has procedures in place for the exchange of organs of urgent and difficult-to-treat patients		Country participates in an IT-tool for the facilitation of cross border exchange		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016	2012	2016
Serbia		no		N/A				N/A		N/A		no
Slovakia		yes, 19		yes		not yet		yes		in the future		yes
Slovenia	yes	yes, 1-2	not yet	not yet	yes	yes	not yet	yes		yes		?
Spain	yea	yes	?	yes	yes	no	not yet	yes		yes		yes
Sweden	?	no 'non allocated' organs	?	?	?	?	?	no		no		?
Switzer-land	yes (/)	yes, 38	no	no	no	yes, 14	no	yes		no		?
The Nether-lands	yes	no		yes	yes	yes	yes	yes		no		?
Turkey	no	no	no	no	no	no	no	no		no		no
United Kingdom		yes, 76		yes		yes		yes		yes		yes

P.A.9 (evaluation post-transplant results) N=36	Country evaluate post-transplant results of organ recipients on a national level		Moments post transplant results of organ recipients are measured: (a. 3 months after transplantation b. 6 months after transplantation c. 12 months after transplantation d. Other, namely)		Evaluation of post transplant results is supported by a vigilance system	
	2012	2016	2012	2016	2012	2016
Austria	yes	yes	?	?		N/A
Belgium	yes	yes	?	a,c		yes
Bulgaria	yes	yes	a,c,d	a,b,c,d		no
Croatia	yes	not yet	a,c	a,b,c		yes
Czech Republic	yes	at a regional or local level	a,c	a,c		not yet
Cyprus	?	yes	?	d		no
Denmark	?	yes	?	c,d		?
Estonia	yes	yes	?	?		yes
Finland	yes	yes	a,b,c	a,b,c,d		yes
France	yes	yes	c,d	a,b,c,d		yes
Germany	yes	yes	a,c	a,c,d		yes
Greece	yes	yes	b,c	b,c		not yet
Hungary	not yet	not yet	?	?		?
Iceland						
Ireland	not yet	not systematic		c		no
Italy	yes	yes		c,d		yes
Latvia	?	at a regional or local level	b	a,b,c		yes
Liechtenstein		N/A				N/A
Lithuania	yes	at a regional or local level	a,c,d	a,c,d		not yet
Luxembourg	no	no				
Macedonia	not systematic	not systematic	a,b,c,d	a,b,c		no
Malta		yes	a,b	a,b		not yet
Montenegro	yes					
Norway	yes	yes	a,b,c	a,b,c		not yet
Poland	yes	yes		a,b,c,d		yes
Portugal	yes	at a regional or local level	a,c	a,b,c		yes
Romania	not yet	at a regional or local level		a,b,c		yes
Serbia		no		?		N/A
Slovakia		yes		a,c		not yet

P.A.9 (evaluation post-transplant results) N=36	Country evaluate post-transplant results of organ recipients on a national level		Moments post transplant results of organ recipients are measured: (a. 3 months after transplantation b. 6 months after transplantation c. 12 months after transplantation d. Other, namely)		Evaluation of post transplant results is supported by a vigilance system	
	2012	2016	2012	2016	2012	2016
Slovenia	yes	yes	c,d	c,d		yes
Spain	yes	yes	a,b,c,d	a,b,c,d		yes
Sweden	?	at a regional or local level	?	?		not yet
Switzerland	yes	yes	b,c,d	b,c,d		yes
The Netherlands	yes	yes	a,c,d	a,c,d		not yet
Turkey	yes	yes	d	a,b,c,d		yes
United Kingdom	yes	yes		a,c		yes

P.A.9 (evaluation post-transplant results) N=36 (Table continued)	Country accepts donor organs from: (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)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016
Austria	a,b,c,d,f	a,b,c,d,e,f		no		?
Belgium	a,b,c,d,e,f	a,b,c,d,e,f		yes		?
Bulgaria	f	a,b,d,f		yes		no
Croatia	a,b,c,f	a,b,c,d,f		?		no
Czech Republic	b,d,f	a,b,d,f		?		?
Cyprus	a,b,c,f	a,b,c,f		no		no
Denmark	?	a,b,d,f		no		no
Estonia	a,b,c,d,f	a,b,c,d,f		yes		?
Finland	a,b,c,f	a,b,c,f		no		no
France	a,b,c,d,f	a,b,c,d,f		no		no
Germany	a,b,c,d,f	a,b,c,d,f		no		yes
Greece	a,b,c,d,f	a,b,c,d,f		in the future		yes
Hungary	a,b,c,f	a,b,c,f		no		no
Iceland						
Ireland	a,b,c,d,f	a,b,c,d,f		?		?
Italy	a,b,c,f	a,b,c,d,f		no		no
Latvia		a,b,f		no		no
Liechtenstein	N/A	N/A		N/A		no
Lithuania	b,f	a,b,f		no		no
Luxembourg	f	a,b,c,f		?		?
Macedonia	b,f	b,f		?		no
Malta	a,b,f	a,b,d,e,f		in the future		no
Montenegro						
Norway	a,b,c,d,f	a,b,c,d,f		no		no
Poland	a,b,c,d,f	a,b,c,d,f		in the future		no
Portugal	a,b,c,f	a,b,f		no		no
Romania	g	a,b,c,f		no		no
Serbia		a,b,c,f		N/A		no

P.A.9 (evaluation post-transplant results) N=36 (Table continued)	Country accepts donor organs from: (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)		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016
Slovakia		a,b,c,f		in the future		no
Slovenia	a,b,c,d,f	a,b,c,d,f		in the future		?
Spain	a,b,c,d,f	a,b,c,d,f		yes		yes
Sweden	d,f	d,f		N/A		?
Switzerland	a,b,c,d,e,f	a,b,c,d,e,f		no		no
The Netherlands	a,b,c,f	a,b,c,f		no		?
Turkey	a,b,c,d,e,f	a,b,c,d,f		no		no
United Kingdom	a,b,c	a,b,c,d,e,f		no		yes

PA.10 (accreditation) N=36	Procurement organisations and transplantation centres care ontrolled or audited on a regular basis		Country promotes an accreditation system for procurement organisations and transplantation centres		Action plan influenced national policy in this area		EU supported activities contributed to this Priority Action	
	2012	2016	2012	2016	2012	2016	2012	2016
Austria		yes		no		no		?
Belgium		not yet		yes		yes		no
Bulgaria		yes		no		yes		yes
Croatia		yes		yes		?		yes
Czech Republic		yes		yes		yes		yes
Cyprus		no		no		no		no
Denmark		yes		no		no		no
Estonia		yes		yes		yes		?
Finland		yes		no		no		no
France		?		yes		no		no
Germany		yes		not yet		no		no
Greece		yes		not yet		yes		yes
Hungary		not yet		not yet		no		no
Iceland								
Ireland		yes		yes		yes		yes
Italy		yes		yes		no		?
Latvia		yes		yes		in the future		yes
Liechtenstein		N/A		N/A		N/A		no
Lithuania		yes		?		no		yes
Luxembourg						?		?
Macedonia		no		not yet		?		no
Malta		not yet		not yet		in the future		no
Montenegro								
Norway		yes		yes		no		no
Poland		yes		yes		no		yes
Portugal		not yet		not yet		in the future		no
Romania		yes		yes		no		no
Serbia		no		no		N/A		no
Slovakia		not yet		not yet		in the future		yes
Slovenia		not yet		not yet		no		?
Spain		yes		yes		no		no
Sweden		not yet		no		no		?
Switzerland		yes		not yet		no		no
The Netherlands		yes		yes		yes		no
Turkey		yes		yes		no		no
United Kingdom		yes		yes		N/A		yes

Country	population (in millions)	population (in millions)	Source: report			Source: report		
year	2008/2009	2014/2015	2008/2009	2014/2015		2008/2009	2014/2015	
PMP			DD rate	DD rate	change	LD rate	LD rate	change
Austria	8,3	8,55	24,65	24,85	0,8%	8,37	8,42	0,6%
Belgium	10,75	11,2	25,60	29,25	14,3%	6,04	8,76	44,9%
Bulgaria	7,25	7,15	1,30	5,80	346,2%	2,34	1,75	-25,2%
Croatia	4,4	4,25	18,20	37,65	106,9%	2,95	2,23	-24,6%
Czech Republic	10,45	10,6	19,50	23,90	25,5%	2,68	5,56	107,5%
Cyprus	0,8	0,8	13,15	5,05	-61,6%	33,75	25,65	-24,0%
Denmark	5,5	5,55	12,90	14,80	14,7%	14,95	20,25	35,4%
Estonia	1,3	1,3	24,60	16,95	-31,1%	1,15	2,30	100,0%
Finland	5,3	5,45	16,45	22,75	38,3%	1,40	2,75	96,4%
France	63,75	64,5	24,70	26,70	8,1%	3,66	8,43	130,3%
Germany	82,05	81,7	14,75	10,65	-27,8%	7,80	8,37	7,4%
Greece	11,1	11,05	7,60	4,00	-47,4%	3,85	3,50	-9,1%
Hungary	10,05	9,9	14,35	22,15	54,4%	2,40	4,30	79,2%
Iceland	0,3	0,3	13,15	25,00	90,1%	28,32	25,00	-11,7%
Ireland	4,45	4,7	19,20	15,30	-20,3%	3,15	7,75	146,0%
Italy	58,4	60,45	21,20	22,80	7,5%	2,51	4,91	95,8%
Latvia	2,3	2	13,90	16,50	18,7%	1,50	4,50	200,0%
Liechtenstein								
Lithuania	3,4	2,95	12,20	15,00	23,0%	2,05	3,70	80,5%
Luxembourg	0,5	0,55						
Macedonia	2,1	2,1						
Malta	0,4	0,4	22,50	22,50	0,0%	15,00	6,25	-58,3%
Montenegro	0,7	0,6						
Norway	4,8	5,15	20,85	21,85	4,8%	21,05	13,00	-38,3%
Poland	38,1	38,4	11,10	14,55	31,1%	1,13	2,17	92,7%
Portugal	10,6	10,45	28,85	29,15	1,0%	5,52	5,89	6,7%
Romania	21,15	20,55	2,45	6,10	149,0%	5,08	2,64	-48,0%
Serbia								
Slovakia	5,35	5,45	15,20	14,50	-4,6%	3,75	3,10	-17,3%
Slovenia	2	2,1	17,65	23,35	32,3%	0,25		
Spain	46,45	46,6	34,30	37,95	10,6%	4,82	9,25	91,9%
Sweden	9,25	9,7	15,15	17,25	13,9%	16,64	14,96	-10,1%
Switzerland	7,65	8,25	12,70	15,75	24,0%	16,64	14,96	-10,1%
The Netherlands	16,45	16,85	13,05	16,80	28,7%	25,38	31,28	23,2%
Turkey	73,15	77,25	3,55	5,70	60,6%	26,80	42,67	59,3%
United Kingdom	61	64,1	14,90	20,45	37,2%	16,09	17,21	7,0%

Country	Source: country sheets			Source: country sheets			Source: country sheets			Participated in # projects	Twinning
year PMP	2008/2009 > 60 years	2014/2015 > 60 years	change	2008/2009 rare organs	2014/2015 rare organs	change	2008/2009 DCD	2014/2015 DCD	change		
Austria	6,30	6,90	9,5%	4,16	2,81	-32,5%	0,24	0,70	191,2%	3	
Belgium	1,77	8,30	369,8%		0,18		5,07	8,39	65,5%	4	
Bulgaria		0,14								6	
Croatia		7,29		3,07	1,53	-50,2%				5	
Czech Republic	2,25	7,45	231,4%	2,58	3,40	31,4%	0,05	0,57	1083,0%	8	x
Cyprus		1,25								7	x
Denmark		1,98			0,18					0	
Estonia		0,77			0,77					6	
Finland		4,77		0,09	3,21	3303,7%				1	
France	3,13	6,21	98,4%	1,49	1,26	-15,2%	0,85	0,74	-13,9%	11	x
Germany	5,17	4,03	-22,2%	1,65	1,42	-14,0%				9	
Greece	0,77	0,77	0,5%	0,23						5	
Hungary	0,30	2,12	610,6%	0,70	1,37	97,2%				8	x
Iceland	1,01	0,74	-26,4%	2,36	0,64	-72,9%		0,85		1	
Ireland		1,50								2	
Italy	2,95	6,57	122,3%	1,20	0,78	-35,1%	0,04	0,08	93,2%	11	x
Latvia		2,50		0,22			5,22	5,00	-4,2%	3	
Liechtenstein										0	
Lithuania	0,44	2,88	553,1%	1,18	0,51	-56,8%				6	x
Luxembourg		0,91								0	
Macedonia										1	
Malta		7,50								4	x
Montenegro					0,83					0	
Norway	1,56	5,92	279,0%	2,71	6,02	122,3%		0,78		3	
Poland	1,29	3,32	158,2%	0,52	1,02	93,5%		0,04		8	
Portugal		5,69		1,60	2,58	61,1%				11	
Romania		0,68			0,32		0,02			9	
Serbia										0	
Slovakia	0,47	1,01	116,0%							7	
Slovenia		5,00		0,50	1,19	138,1%				9	
Spain		20,33		1,42	1,14	-20,0%	1,98	5,44	174,7%	11	x
Sweden		3,81		1,62	3,71	128,9%				8	
Switzerland	0,82			1,83	1,15	-37,1%		2,06		2	
The Netherlands	0,73			1,12	2,08	84,7%	5,41	8,55	58,0%	6	x
Turkey	0,01	0,83	12115,3%	0,22	0,18	-17,1%	0,02			3	
United Kingdom		3,56		3,77	4,05	7,4%	4,77	8,21	72,2%	8	

ANNEX 3: ADDITIONAL INFORMATION ON ACTIVITIES ON EU LEVEL

Table A1: Overview of countries involved in EU-funded projects[383,384]

Project **Country**	**Alliance-O**	**DOPKI**	**ETPOD**	**EULID**	**EDD**	**ELPAT**	**EFRETOS**	**ELIPSY**	**COORE** **NOR**	**EULOD**	**ODEQUS**	**Train the trainers**	**MODE**	**ACCORD**	**FOEDUS**	**HOTT-project**	**Total per country**
Year started	**2004**	**2006**	**2007**	**2007**	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**	**2010**	**2011**	**2012**	**2013**	**2012**	
Austria			MUW								MUW	x					3
Belgium										KUL		x		Ghent university hospital cooll. partn	PFS PH		4
Bulgaria			**BEAT**							BCB		x		**BEAT**	**BEAT**	Bulgarian Centre of Bioethics	**6**
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																	0
Estonia			**TUH**							**TUH**		x	**TUH**	**TUH**	**MSA**		6

383 A list of abbreviations and acronyms of EU-funded projects and of the various institutions involved can be found in Table A2

384 **Bold** = Competent Authority (as identified in 2016 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 is ongoing.

Project **Country**	**Alliance-O**	**DOPKI**	**ETPOD**	**EULID**	**EDD**	**ELPAT**	**EFRETOS**	**ELIPSY**	**COORE** **NOR**	**EULOD**	**ODEQUS**	**Train the trainers**	**MODE**	**ACCORD**	**FOEDUS**	**HOTT-project**	**Total per country**
Year started	**2004**	**2006**	**2007**	**2007**	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**	**2010**	**2011**	**2012**	**2013**	**2012**	
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**	**EOM**		**5**
Hungary	HT	HT							**HNBTS**		**OVSZ**	x	**OVSZ**	**HNBTS**	**OVSZ**		8
Iceland															**MOH**		1
Italy	**CNT**	**CNT**	FITOT; **ISS**	**ISS**			**CNT;** Univ Padua		**CNT**		FITOT	x	**ISS**	**CNT**	**ISS-CNT**		**11**
Ireland												x		**HSE**			2
Latvia									PSCUH			x		**PSCUH**			3
Liechtenstein																	0
Lithuania			**NBT**						**NBT**			x	**NBT**	**NBT**	**NBT**		**6**
Luxembourg																	0

Project **Country**	**Alliance-O**	**DOPKI**	**ETPOD**	**EULID**	**EDD**	**ELPAT**	**EFRETOS**	**ELIPSY**	**COORE** **NOR**	**EULOD**	**ODEQUS**	**Train the trainers**	**MODE**	**ACCORD**	**FOEDUS**	**HOTT-project**	**Total per country**
Year started	**2004**	**2006**	**2007**	**2007**	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**	**2010**	**2011**	**2012**	**2013**	**2012**	
Malta											Mater dei Hospital	x		MOH	**MHEC Mater Dei hospital**		4
Macedonia																University St. Cyril and Methodius	1
Montenegro																	0
Netherlands							NTS; UMCG			Erasmus MC		x		**NTS**	**NTS**	Erasmus MC (cord), Dutch Police	6
Norway				Rikshospitalet										**HDIR**	**HDIR**		**3**
Poland			**PT;** MUW	**PT**					**PT**; MUW	**PT**	**PT**	x		**PT**	**PT**		**8**
Portugal	**OPT**	**OPT**	**ASST**	HGSA EPE				HGSA EPE CHP	**ASST**		**ASST**	x	**ASST**	**ASST**	**IPST**		**11**
Romania			UTM	**NAT**					FCI	SACRI	FPT	x		**NAT**	**MOH**	SACRI	**9**
Serbia																	0

Project **Country**	**Alliance-O**	**DOPKI**	**ETPOD**	**EULID**	**EDD**	**ELPAT**	**EFRETOS**	**ELIPSY**	**COORE** **NOR**	**EULOD**	**ODEQUS**	**Train the trainers**	**MODE**	**ACCORD**	**FOEDUS**	**HOTT-project**	**Total per country**
Year started	**2004**	**2006**	**2007**	**2007**	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**	**2010**	**2011**	**2012**	**2013**	**2012**	
Slovak Republic			**UNM**		**UNM**		DUH		**UNM**			x		**NTO**	**NTO**		7
Slovenia		**ST**		**ST**	**ST**		**ST**				**ST**	**x**	**ST**	**ST**	**ST**		**9**
Spain	**ONT**	**ONT**	IL3, IMAS	FBG, HCB			**ONT**	HCB			IL3; DTI; FIB	x, **ONT**; Iavante	**ONT**	**ONT**	**ONT**		**11**
Sweden			MUH	SUH				SUH		Univ. Gothenb.	KI	x		**NBH**		Lund University	**8**
Switzerland		SwT													SwT		2
Turkey			AUTC					MPAHC				MPAHC					3
UK	**NHSBT**	**NHSBT**		**NHSBT**			**NHSBT**				**NHSBT**	x		**NHSBT**	**NHSBT**		**8**
Europe/ International		ET			ET; CoE	ESOT	ET, SKT ESOT,		ET	ESOT				ET, WHO, Scandiatransplant, EDQM, ESCIM, EDTCO, HOPE, ORG. DES ÉTABLISSMENTS DE SOINS	ET, Moldova	ET, ESOT, ELPAT, Moldova, USA, EUROPOL, UNODC, South African Police service, The Hebrew University of Jerusalem,	

Project **Country**	**Allian ce-O**	**DOPKI**	**ETPO D**	**EULID**	**EDD**	**ELPAT**	**EFRETOS**	**ELIPSY**	**COORE** **NOR**	**EULOD**	**ODEQUS**	**Train the trainers**	**MODE**	**ACCORD**	**FOEDUS**	**HOTT-project**	**Total per country**
Year started	**2004**	**2006**	**2007**	**2007**	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**	**2010**	**2011**	**2012**	**2013**	**2012**	
																Special Prosecutio n Office of the Republic of Kosovo	
Total*	6	10	16	11	5	-	11	7	11	8	11	25 **	8	25	24	5	

Other efforts of international organisations (not directly related to Action Plan)

European Commission

Some initiatives that are relevant in organ donation and transplantation which have been developed, undertaken or financed at the EU level, but fall outside the scope of this report:

- European reference network, focusing on specific patient groups: paediatrics, hypersensitised recipients (within DG SANTE);
- Trafficking and donation by non-residents (within DG HOME/JUST);
- Scientific advancement: repairing/growing organs (within DG RTD);
- Financial compensation for living donors (within DG EMPL).

Council of Europe

The Council of Europe Committee (Partial Agreement) on Organ Transplantation (**CD-P-TO**) is working under the European Directorate for the Quality of Medicines & Healthcare (EDQM).[385] CD-P-TO is the steering committee in charge of transplantation activities at the EDQM. Its mandate includes elaborating guidelines and recommendations aimed at improving access to transplantation and high ethical, safety and quality standards in the field. The CD-P-TO is composed of internationally recognised experts from the Council of Europe member states, observer countries, the EU Commission and WHO, together with members of the Council of Europe's Committee on Bioethics (DH-BIO) and representatives of several professional non-profit organisations (EDQM, 2017).

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, 2015). Furthermore, CD-P-TO and EDQM recently published the Guide to the quality and safety of organs for transplantation. The Guide aims to improve the rate of successful and safe organ transplantation. It supports professionals on a practical level. Updated information is collated to provide professionals with the most recent advances in the field as well as technical guidance to ensure the safety and quality of organs of human origin thatare intended for transplantation (EDQM & CD-P-TO, 2016). The Council of Europe is deeply involved in the development of policies concerning organ donation and transplantation in countries of the **Black Sea Area**[386] (Armenia, Azerbaijan, Bulgaria, Georgia, Moldova, Romania, Russian Federation, Turkey and Ukraine – some of them being also EU countries or EU neighbouring/candidate countries).

On 9 July 2014, The Council of Europe Convention against Trafficking in Human Organs was adopted by the Committee of Ministers of the Council of Europe. The adoption of the Convention represents a historical milestone in the fight against organ trafficking. It is the first legal document that provides an internationally agreed upon definition of trafficking in human organs, identifying the activities that ratifying States must criminalize in their national laws. Like other criminal law instruments, the Convention also includes provisions to deter these practices and to protect victims. This instrument complements the existing international legal framework against trafficking in human beings (including for the purpose of the removal of organs), which does not reach some transplant related crimes and many of the actors, such as surgeons, whose involvement lies at the heart of the criminal activity.

[385] http://www.edqm.eu/en/organ-transplantation-work-programme-72.html, Retrieved on 18-07-2012

[386] http://www.edqm.eu/en/organ-transplantation-projects-1452.html, Retrieved on 18-07-2012

The Convention, which was conceived to have a global scope, is open for signature and ratification not only by Council of Europe member or observer countries but by any State in the world, and several have already indicated that they are considering acceding to the Convention, as have additional COE member States.[387] In relation to this, the Resolution CM/Res(2013)5 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system was adopted already.
Furthermore, the Committee of Ministers of the Council of Europe adopted Resolution CM/Res(2015)10 on the role and training of critical care professionals in deceased donation. This Resolution recommends that member states implement measures to ensure that healthcare professionals caring for potential organ donors have clear legal and ethical frameworks to guide their work, specifying which practices facilitating donation after death are permitted within a given jurisdiction. In addition, it encourages hospitals to incorporate organ donation as a routine activity in intensive care units (ICU) and emergency departments and recommends that professionals working in ICU and emergency departments, in co-operation with the relevant professional societies, receive continuous training in deceased donation from the outset of their clinical practice.
Furthermore, various resolutions are adopted by the Committee of Ministers on living donation: Resolution CM/Res(2015)11 on Living Donation Registries and Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes.[388] Furthermore. the latest resolution was adopted this year (Resolution CM/Res(2017)1), on principles for the selection, evaluation, donation and follow-up of non-resident living organ donors. This resolution is aimed at protecting non-resident living donors who, for a number of reasons – economic, emotional, cultural or physical – may be particularly vulnerable, and whose post-donation care and follow-up may be difficult to guarantee.[389]
The collaboration between the Council of Europe and the 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 Commission 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.
In 2012, the work of CD-P-TO could be linked to Priority Action 4 (EODD), 5 (listing of non-residents on waiting lists), 7 (organ trafficking), 9 (Guides, expanded criteria donors) and 10 (CoE reflection about qualification and training). Since 2012,CD-P-TO also paid attention to living kidney donation (Priority Action 3), the identification of potential donors (Priority Action 1), living donation (PA 3), training of care professionals and awareness (especially organisation of European Organ Donation Day (EODD)(Priority Action 4), cross border donation (PA 5), the evaluation of post transplant results (PA 9).[390]

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

[387] http://www.declarationofistanbul.org/resources/recommended-reading/the-council-of-europe-convention-against-trafficking-in-human-organs, retrieved on 5-12-2017
[388] https://www.edqm.eu/en/transplantation-projects#Council%20of%20Europe%20and%20CD%20P%20TO%20framework, Retrieved on 06-12-2017
[389] https://www.edqm.eu/en/transplantation-projects#Council%20of%20Europe%20and%20CD%20P%20TO%20framework, Retrieved on 06-12-2017
[390] https://www.edqm.eu/en/news/transfusion-and-transplantation, retrieved on 1-8-2016.

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.
The WHO continued its work on **transplant tourism** and to address the wider problem of **international trafficking of human organs and tissues** by making efforts to the declaration of Istanbul, the Madrid Resolution, the NOTIFY-project, the **SOHO V&S project** and Song-project.[391] Furthermore, a 2012 international transplantation workshop convened by WHO considered global traceability and recommended close collaboration between national health authorities and agencies and scientific and professional societies.[392] The work of the WHO contributed to Priority Action 7 (EU-wide agreements).

ESOT
ESOT and its 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 and Transplantion Coordination Organisation (EDTCO, fusion of European Donation Commission of ESOT and ETCO)[393] contribute to the Action Plan in many ways. First of all, with their dissemination of research and promotion of organ and tissue donation, they contribute to PA 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 (PA 10). ESOT's donation and procurement section (merged with EDTCO), 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. EDTCO 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. A new ESOT-congress is organized in September 2017.[394]

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 eight European countries: Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia, covering over 135 million inhabitants.[395,396] It was founded in 1967.[397] In 2012, Hungary joined Eurotransplant (R. Langer, 2011; RM Langer, Cohen, & Rahmel, 2012;

[391] http://www.who.int/transplantation/organ/en/, retrieved on 1-8-2016
[392] http://www.who.int/transplantation/organ/en/, retrieved on 27-11-2017
[393] http://www.esot.org/organisation, Retrieved on 02-05-2017
[394] http://www.esot.org/events-education/events/5896/overview
[395] http://www.eurotransplant.org/cms/index.php?page=cooperation_brief, Retrieved on 06-12-2017
[396] http://www.efretos.org/Partners.aspx, Retrieved on 18-07-2012
[397] http://www.eurotransplant.org/cms/index.php?page=about_brief, Retrieved on 05-12-2017

R. M. Langer, 2012). 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 (PA 5), EU-wide agreements of transplantation medicine (PA 7) and the interchange of organs between national authorities (PA 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), PA 10 (accreditation system), PA 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).[398] 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 (PA 5), EU-wide agreements of transplantation medicine (PA 7) and the interchange of organs between national authorities (PA 8). Scandiatransplant also provides authorities and patient support groups with relevant information (PA 4) and educates personnell on transplant medicine (PA 7, 4) (Scandiatransplant, 2013).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 3 (living donation), PA 9 (evaluation of post-transplant results), PA 10 (accreditation system), PA 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). Scandiatransplant keeps on developing and renewing techniques, for instance, notifications via sms in urgent cases are now implemented.[399]

Southern European Transplant Alliance

New cooperation agreements were made; the South Transplant Alliance (SAT). The main objective of SAT is to establish a formal accord of cooperation between the competent bodies for the donation and transplantation of human substances for countries in the South West of Europe. The idea of this cooperation arises from the interest of Italy, France and Spain to find shared solutions to the same problems, the three organizations have common bioethical principles in the field of organ donation and transplantation, all have a similar organisational and regulatory system, and their business is largely based on the transplant from deceased donors. These forms of agreement are relevant in the light of the transposition of the European Directive 53/2010 on the quality and safety in the donation and transplantation of organs from the Member States, which makes it particularly necessary to develop common strategies among national organizations. The promoters of this initiative are the national organizations for transplantation of Italy, France and Spain, namely the Italian National Transplant Centre, the Agence de la biomédecine and Organizacion

[398] http://www.scandiatransplant.org/history.htm, Retrieved on 18-07-2012

[399] http://www.scandiatransplant.org/members/ntcg/minutes_NTCG_may_2016.pdf, retrieved on 02-08-2016.

Nacional de Transplantes (SAT, 2013).[400] At this moment, SAT exists of Spain, France, Italy, Portugal, Switzerland, and Czech Republic.

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 (Roels & Wight, 2001).[401]

European Kidney Health Alliance

The European Kidney Health Alliance (EKHA) is an alliance of not-for-profit organisations that 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.[402] 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.[403] 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, including patients' testimonies (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.

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).[404]

[400] http://trapianti.net/en/sat-south-transplant-alliance/
[401] http://www.donoraction.org, Retrieved on 10-02-2016.
[402] http://www.ekha.eu/index.php, Retrieved on 10-02-2016.
[403] http://www.ekha.eu/htmldocs/ekha/4-16/ekha/kidney_health_disease.html, Retrieved on 10-02-2016
[404] http://www.easl.eu/discover/what-is-easl/why-does-easl-exist, Retrieved on 30-01-2017.

ANNEX 4: ADDITIONAL ANALYSES OF CHANGES IN LIVING AND DECEASED DONATION RATES

The table belowindicates that for deceased donation the majority of countries are found in the categories: high-stable and and low-increased donation rates. For living donation most countries are found in the category of low-increased donation rate.

Deceased donation rate (pmp)*		Participated in 5 or more projects	Twinning
High			
Decreased	EE, IE (2)	1	0
Stable	AT BE FR IT MT NO PRT ES (8)	4	4
Increased	HR CZ FI (3)	2	2
Low			
Decreased	CY DE GR (3)	1	1
Stable	DK, SK SE (3)	2	
Increased	BG HU IS LV LT PO RO SI CH NL TR UK (12)	8	3

Living donation rate (pmp)**		Participated in 5 or more projects	Twinning
High			
Decreased	CY MT NO (3)	1	2
Stable	IS SE CH UK (4)	2	0
Increased	DK NL TR (3)	1	1
Low			
Decreased	BG, HR RO SI (4)	3	0
Stable	AT DE GR PT (4)	3	0
Increased	BE CZ EE FI FR HU IE IT LV LT PO ES (12)	7	5

*low is below 15 pmp, stable is below 15% change, of 5 countries, no numbers are available

** low is below 10 pmp, stable is below 15% change, of 5 countries, no numbers are available

ANNEX 5: LIST OF ABBREVIATIONS AND ACRONYMS

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
AT	Austria
AUTC	Akdeniz University Transplant Center, Turkey

B

BCB	Bulgarian Center for Bioethics, Bulgaria
BEAT	Bulgarian Executive Agency for Transplantation
BEL	Belgium
BG	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
CY	Cyprus
CUB	Charité Universitätsmedizin Berlin, Germany
CZ	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
DE	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
EE	Estonia
EEA	European Economic Area (EU countries + Iceland, Liechtenstein, Norway and Switzerland)
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
ES	Spain
ET	Eurotransplant International Foundation
ETCO	European Transplant Coordinators Organisation (merged with ESOT in 2011)
EDTCO	European Donation and Transplantion Coordination Organisation (fusion of ETCO and EDC (European Donation Commission of ESOT)
ETPOD	European Training Program on Organ Donation (EU-funded project)
EU	European Union
EUDON-ORGAN	Platform for increasing organ donation in the European Union and neighbouring countries (EU-funded project)
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)
EUROSTAM	Europe-wide strategy to enhance transplantation of highly sensitized patients on basis of acceptable HLA mismatches – for kidney transplantation (EU-funded project)

F

FACTOR	A study on the uptake and impact of the Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member States. Final Review.
FBG	Fundacio Bosch I Gimpera, Barcelona, Spain
FCI	Fundeni Clinical Institute, Romania
FIB	Fundación para la Investigación Biomédica del Hospital Gregorio Marañón, Spain
FI	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

GKBT	Global Knowledge Base on Transplantation
GR	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
HR	Croatia
HSE	Health Service Executive, Ireland
HT	Hungaro-transplant
HU	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
IE	Ireland
ISHLT	International Society for Heart and Lung Transplantation
IS	Iceland
ISS	Instituto Superiore di Sanità, Italy
IT	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

LI	Liechtenstein
LT	Lithuania
LU	Luxembourg
LV	Latvia

M

MPAHC	Medical Park Antalya Hospital Complex, Turkey
MKD	Macedonia
MT	Malta
ME	Montenegro
MK	Macedonia
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 present donation and transplantation rates)
PL	Poland
PT	Portugal
PSCUH	Paula Stradina Dliniska Universitates Slimnica, Pauls Stradins Clinical University Hospital (PSCUH), Latvia
PSTC	Paraskevidion Surgical and Transplant Center of Cyprus

R

RO	Romania
RS	Serbia

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
SE	Sweden
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 Organisational Aspects of Cooperation between countries on Organ Transplantation (former Council of Europe Committee)
ST	Slovenija – Transplant
STELLAR	Stem cell based therapy for kidney repair (EU-funded project)
SUH	Sahlgrenska Universitetssjukhuset - Sahlarenske University Hospital, Sweden
SK	Slovakia
SV	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
TR	Turkey

U

UEMS	European Union of Medical Specialists
UK	United Kingdom
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

Annex 6: COM (2008) 819/3 : Communication on Action Plan

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 8 December 2008
COM(2008) 819/3

COMMUNICATION FROM THE COMMISSION

Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

{SEC(2008) 2956}
{SEC(2008) 2957}

EN EN

COMMUNICATION FROM THE COMMISSION

Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

1. INTRODUCTION

On 31 May 2007, the Commission adopted a Communication on organ donation and transplantation[1]. This Communication and the accompanying Impact Assessment[2] made a number of suggestions for actions at Community and Member State levels designed to help increase the supply of organ donors across the EU and ensure the quality and safety of the procedures.

The Communication proposed a dual mechanism of action: an Action Plan enhancing active coordination and cooperation between Member States complemented by a legal instrument containing the basic quality and safety principles.

Following the adoption of this first Communication, the Commission started a process of consultation with national experts and key stakeholders with the focus on the quality and safety requirements of human organ donation and transplantation and key priority areas for the proposed action plan. This consultation process enabled the Commission to identify 10 priority actions, which are grouped under three challenges:

- Increasing organ availability
- Enhancing the efficiency and accessibility of transplantation systems
- Improving quality and safety.

2. STRENGTHENED COOPERATION ON ORGAN DONATION AND TRANSPLANTATION

Article 152(4)(a) of the Treaty provides for the possibility of the EC to adopt harmonising measures to ensure organ safety and quality. The same Article (152(2)) also states that Community action should complement national policies directed towards improving public health. The Community has to encourage cooperation between Member States in the areas referred to in this article and, if necessary, lend support to their actions.

In this respect, Member States have to liaise with the Commission and coordinate their policies and programmes. Working in tandem with the Member States, the Commission may take any initiatives that might be useful or necessary to promote such coordination.

In the field of organ donation and transplantation in particular, there is huge potential for sharing experience and expertise among EU Member States. This Action Plan aims at reinforcing the cooperation between Member States, through the identification and development of common objectives and guidelines, jointly-agreed indicators and benchmarks, regular reporting, and identification and sharing of best practices.

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1 SEC(2007) 704 – SEC(2007) 705.

2 Impact Assessment accompanying the Communication from the Commission to the European Parliament and the Council. Organ donation and transplantation: policy actions at EU level http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

Actions at Community level will complement Member States' efforts to improve the quality and safety of organ donation and transplantation, combat the organ shortage problem and make transplantation systems more efficient. Through the utilization of Community tools, especially the Health Programme 2008-2013, the Commission will provide assistance to the Member States.

3. PRIORITY ACTIONS FOR ORGAN DONATION AND TRANSPLANTATION

In recent years, the Commission has put considerable effort, under different Community programmes, into supporting initiatives in the area of organ transplantation. A large number of projects have been co-funded[3], the results of which have generated a considerable amount of information and knowledge. It is very important that further work under the existing programmes should be continued and where necessary extended, involving not only the Member States but also other relevant stakeholders.

Having gathered the information, knowledge and expertise generated in the field of organ donation and transplantation, the Commission has identified a detailed list of priority actions. These objectives and priority actions are dispatched under the 3 above mentioned challenges. In turn, the Action Plan divides each priority action into various actions enumerated in Annex.

Each Member State will decide what action and measures need to be taken in order to achieve the desired objectives; these will be included in their Sets of National Priority Actions, which should serve as a platform for discussion, exchange of expertise, and identification of best practices in the framework of this Action Plan. The Sets of National Priority Actions should be country-specific and tailored to the specific situation of each Member State.

3.1. Priority Actions for increasing organ availability

Currently, the demand for organs exceeds the number of available organs in all Member States and this demand for organs is increasing faster than organ donation rates. There are currently more than 56 000 patients waiting for a suitable donor organ within the European Union[4].

There are large differences in practices and results among Member States. Exchanging information and best practices will help countries with low organ availability to improve their availability rates. Implementation of elements of the Spanish Model in Italy, for example, has been very successful in increasing organ donation rates, which demonstrated that changes in the organisation of organ donation and procurement can substantially increase and sustain organ donation rates.

3.1.1. Increasing deceased donations to their full potential

Improvements in the complex process from donor identification to the transplantation of an organ have been shown to have a large impact on organ donation rates[5]. The success of some Member States in increasing organ availability has been largely down to the organisation of the process, which shows that some ways of organising the organ donation process might be better suited to achieving high availability of organs than others[6]. The combination of an efficient system for organ donor identification, detection and procurement has been identified as one of the keys to increasing deceased donation. In particular, the presence of a key

[3] A description of the projects is available in the Impact assessment attached to this Communication.
[4] Council of Europe (2007).
[5] See, for example, Roels et al. (2002) and Simini (2000).
[6] ALLIANCE-O (2007b).

(1)

(2)

(3)

(4)

(5)

donation person at hospital level (transplant donor coordinator), whose main responsibility is to develop a proactive donor detection programme, is the most important step towards optimising organ donation and improving donor detection rates[7].

Member States should therefore aim to incorporate in their Sets of National Priority Actions the objective of gradually appointing **Transplant Donor Coordinators (Priority Action 1)** in all hospitals where there is potential for organ donation. The Commission could have a coordinating and monitoring role in this respect; for that purpose Member States should be encouraged to report to the Commission the number of hospitals that have appointed a transplant donor coordinator. Building on this principal objective, the Action plan must help establish internationally recognised standards for transplant donor coordinator programmes in the forthcoming years of the Action Plan and promote the implementation of effective training programmes for transplant donor coordinators[8]. At a later stage the Commission and the Member States should aim to establish European or international accreditation schemes for transplant donor coordinators.

Of equal importance is to promote **Quality Improvement Programmes for organ donation (Priority Action 2)** in every hospital where there is potential for organ donation. These programmes are primarily a self evaluation of the whole process of organ donation[9] according to the characteristics of the hospital and the health system. These will make it possible to compare results and thus to pinpoint areas for improvement. Consequently, it will also be beneficial to promote accessibility to and training for a specific methodology in relation to these Quality Improvement Programmes.

3.1.2. Living donations as complementary to deceased donations

Being complementary to deceased donation, living donation is a real alternative to improving the availability of organs for transplantation. Member States should therefore deploy the Action Plan to **promote the exchange of best practices on living donation programmes (Priority Action 3).**

The Action Plan aims to the promotion of altruistic donation programmes and the development of registration practices regarding living donors in order to assess and guarantee their safety.

The Commission will help to develop adequate tools to facilitate the proper collection of information on the medical, psychological, financial and social consequences of a living donation – in the short and the long term. This information, coupled with the exchange of best practices on living donation programmes among the Member States, should help to develop evidence-based guidelines and consensus documents, and address the selection, evaluation and follow-up of the living donor. Registers of living donors should be established to facilitate monitoring and follow-up. All of these measures must be in compliance with the existing European legal framework on the protection of personal data consisting in particular of the Data Protection Directive 95/46/EC.

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7 Council of Europe Recommendation (Rec (2005)11) on the role and training of professionals responsible for organ donation.

8 ETPOD.

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

(6)

3.1.3. *Increasing public awareness*

The success of the Spanish Model has shown that investing heavily in public awareness campaigns does not always yield the expected results. Great attention must be paid to the specific information given to the media: systematic and comprehensive information should be provided about organ donation and transplantation through media outlets. Researchers have argued that the use of the mass media in Spain on the issue of organ donation has greatly influenced the creation of a positive social atmosphere around organ donation and transplantation[10].

It has been proven that there is an important positive correlation between having discussed the issue of donation within the family and the willingness to actually donate organs. Since public awareness and opinion play a very important role in increasing organ donation rates, continuing education should form an essential part of all Member States' communication strategies on the issue. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. Only 41% of European citizens seem to have discussed organ donation within their families[11].

There is therefore a need **to improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation (Priority Action 4).** Awareness campaigns should include information regarding the rights citizens and patients have concerning organ donation and transplantation in different Member States. The Commission can actively contribute by helping Member States to collect this kind of information.

People's mobility also underlines the need to **facilitate the identification of organ donors across Europe and cross-border donation in Europe (Priority Action 5).** The Commission will help Member States to develop identification mechanisms.

3.2. Priority Actions for enhancing the efficiency and accessibility of transplantation systems

Even among EU countries with well-developed health and organ transplant services, there are still considerable differences in organ donation and transplantation activity. It is clear that some organisational systems are performing better than others. Hence, initiatives focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics are promoted by the Action Plan.

3.2.1. *Supporting and guiding transplant systems*

The Action Plan calls on Member States to enhance the efficiency of transplant systems **(Priority Action 6)**. To this end, they will develop their own Sets of National Priority Actions in 2009. These will provide the basis for an overall evaluation of the success Member States have in achieving the aforementioned common objectives.

Member States should then aim to establish, in close collaboration with the Commission, a common set of indicators to monitor organ policy and a methodology to evaluate the potential in each Member State. Common definitions both of terms and methodology need to be adopted in order to evaluate the results of transplant systems. The Commission will help Member States achieve this objective in particular by issuing *ad hoc* recommendations on the basis of regular reporting. The Action Plan further encourages Member States to promote the

[10] Matesanz and Miranda (2002). Also Matesanz and Miranda (1996).
[11] Eurobarometer survey 2006.

twinning of projects and peer review programmes, which should be part of a voluntary, mutual learning process. Peer reviews should encompass scrutiny of existing policies, programmes or institutional arrangements that have been identified as good practice in the various Sets of National Priority Actions. This could prove to be a useful tool for Member States when designing and implementing more efficient and effective policies.

3.2.2. Interchange of organs between Member States

The exchange of organs is already common practice between Member States. There are, however, significant differences between the number of organs exchanged across borders between Member States that have set up bodies and rules for the international exchange of organs, such as Eurotransplant and Scandiatransplant, and the other Member States. Participants in the Eurotransplant area exchange around 20% of all organs transplanted each year (around 3 300 organs) between each other, while only 2% of organs leave or enter the Eurotransplant area. Without such comprehensive exchange agreements Member States exchange far fewer organs, but the rate can potentially increase if there are bilateral agreements in place[12].

These differences in exchange rates indicate that the full potential of exchanging organs has not yet been reached. If there is no exchange of organs between Member States, then recipients that need an infrequent match will have very low prospects of finding an organ, while at the same time donors will not be considered because there are no compatible recipients on the waiting lists. This is of particular relevance to "difficult-to-treat" patients (paediatric, urgent or hypersensitised patients that require very specific matching) and for small Member States in general. The Action Plan thus aims to have a system or a structure for the **exchange of organs for urgent patients and difficult to treat patients (Priority Action 8).** An IT tool to support this action could be designed with guidance from the Commission and Community funding. Moreover, the Commission will support the Member States in the development of a structured system for exchanges of surplus organs between them.

3.2.3. EU-wide agreements on aspects of transplant medicine

The Action Plan strongly supports **EU-wide agreements on various aspects of transplant medicine (Priority Action 7).** A cooperation method is the ideal context to discuss issues of mutual concern and come up with common and shared solutions and monitoring mechanisms. For instance, Member States are advised to establish such EU-wide agreements to deal with all aspects concerning transplant medicine for extra-Community patients.

This cooperation method seems especially pertinent to identifying the main challenges of increasing patient mobility, in particular in border regions and small Member States. The Action Plan recommends that EU-wide agreements be put in place to tackle the basic rules for internal EU patient mobility in respect of transplantation, in compliance with the principle of free movement of recipient of services as provided for in the EC Treaty and in Community legislation. These agreements will facilitate the relevant procedures in practice and solve any problems surrounding the equitability of transplantation systems.

A common understanding of the priorities and strategies of future research programmes on organ donation and transplantation also needs to be fostered. The creation of a European transplant research network could be considered in the context of an EU-wide agreement setting common priorities and objectives.

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

3.2.4. Organ trafficking

One of the potential consequences of organ scarcity is the trafficking of human organs. . Organ trafficking can be linked with trafficking in human beings for the purpose of the removal of organs which constitutes a serious violation of fundamental rights and, in particular, of human dignity and physical integrity. This practice is carried out by organised criminal groups, who track down and remove organs from donors in developing countries and hand them on to recipients within the European Union.

While it is recognised that, ideally, the best way of fighting organ trafficking is to increase the number of available organs, the Action Plan, in the meantime, urges Member States to establish EU-wide agreements on monitoring the extent of organ trafficking in Europe. Given the lack of investigative information on the issue, such agreements will help Member States – through active collaboration and exchange of information – to examine and, at a later stage, find the best ways of monitoring organ trafficking.

At the same time, the Commission will for its part continue to work together with other international organisations such as the Council of Europe and the World Health Organisation in a bid to combat organ trafficking.

3.3. Priority Actions for improving quality and safety

These actions should complement the European legal framework referred to in the Commission Communication on Organ Donation and Transplantation[13]. The future legal instrument will encompass the principles needed to establish a basic quality and safety framework across the EU, including, for example, the creation of national competent authorities and other relevant structures.

3.3.1. Improving follow-up procedures and registers

The Action Plan sets out to complement this legal framework by way of a compilation of information in the form of **registers facilitating the evaluation of post-transplant results (Priority Action 9),** which will in turn help to develop good medical practices in organ donation and transplantation. Evaluating post-transplant results through common definitions of terms and methodology, as suggested in the Action Plan, could help to promote EU-wide registers, if necessary, and in compliance with the existing European legal framework on the protection of personal data consisting in particular of the Data Protection Directive 95/46/EC, or create a methodology to compare the results of existing post-transplant follow-up registers of organ recipients.

In an effort to increase the pool of organs available for transplantation, the use of expanded donors (donors that from a medical point of view can only be considered for specific recipients under specific circumstances) should also be considered. Since, in practice, published experience is not enough to establish safety limits; the Action Plan recommends common definitions of terms and a methodology to help determine acceptable levels of risk in the use of expanded donors. This compilation of information will consequently help to determine acceptable levels of risk in the use of expanded donors.

These actions will ultimately help Member States to develop and promote good medical practices on organ donation and transplantation on the basis of results.

[13] SEC(2007) 704 – SEC(2007) 705.

3.3.2. Common accreditation system

The Action Plan also seeks to develop a methodology that could support the EU legal framework in order for Member States to accredit programmes on organ donation, procurement and transplantation. This could help, in the long run, to build a **common accreditation system for organ donation/procurement and transplantation programmes (Priority Action 10)** at EU level and provide support for centres of excellence.

4. CONCLUSIONS AND FOLLOW UP ACTIONS

This Action Plan identified 10 priority actions in order to aid Member States address the challenges in the field of organ donation and transplantation. It will promote strengthened cooperation between MS and exchange of best practices as a key element in the strategy.

This cooperation process shall be based on the identification and development of common objectives and guidelines, jointly-agreed quantitative and qualitative indicators, benchmarks and identification and sharing of best practices.

On the basis of these actions Member States should develop their own Sets of National Priority Actions. The Action Plan will provide the basis for an overall evaluation of the success Member States have in achieving the aforementioned common objectives. A mid-term review (mid-term review 2012) of the actions will be carried out to evaluate the efficacy of this Action Plan.

ANNEX: SPECIFIC ACTIONS PROPOSED

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.	
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.	MS action EC coordinates and monitor
Action 1.2 Promote the establishment of internationally recognised standards for transplant donor coordinator programmes.	EC Action
Action 1.3 Promote the implementation of effective training programmes for transplant donor coordinators.	MS + EC Action
Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators.	MS + EC Action
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.	MS action EC coordinates and monitor
Action 2.2 Promote accessibility to and training on a specific methodology on Quality Improvement Programmes.	MS action EC coordinates and monitor
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.	MS action EC coordinates and monitor
Action 3.2 Promote the development of registers for living donors to evaluate and guarantee their health and safety.	MS + EC Action
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.	MS action EC coordinates and monitor.
Action 4.2 Promote training programmes geared towards health professionals and patient support groups on organ transplantation communication skills.	MS + EC Action
Action 4.3 Organise periodic meetings at national level (competent authorities) with journalists and opinion leaders and manage adverse publicity.	MS action EC coordinates and monitor.
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.	MS + EC Action
Action 5.2 Develop mechanisms to facilitate the identification of cross-border donors	MS + EC Action

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.	MS + EC Action
Action 6.2 Promote twinning projects and peer reviews.	EC Action
Action 6.3 Assess the use of structural funds and other Community instruments for the development of transplantation systems.	EC Action
Action 6.4 Promote networks of centres of reference.	EC Action
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..	MS + EC Action
Action 7.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patients.	MS + EC Action
Action 7.3 EU-wide agreement on monitoring organ trafficking.	MS + EC Action
Action 7.4 EU-wide agreement on common priorities and strategies for future research programmes.	MS + EC Action
Priority Action 8: Facilitate the interchange of organs between national authorities.	
Action 8.1 Evaluate procedures for offering surplus organs to other countries.	EC + MS action

Action 8.2 Put procedures in place for the exchange of organs for urgent and difficult-to-treat patients.	EC + MS action
Action 8.3 Design IT tools in support of the previous actions.	EC + MS action
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.	EC Action
Action 9.2 Develop a register or network of registers to follow up organ recipients.	MS + EC Action
Action 9.3 Promote common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors.	EC Action
Action 9.3 Develop and promote good medical practices on organ donation and transplantation on the basis of results, including the use of expanded donors.	EC Action
Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.	

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