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COMMISSION STAFF WORKING DOCUMENT

**on the mid-term review of the "Action Plan on Organ Donation and Transplantation
(2009-2015): Strengthened Cooperation between Member States"**

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Disclaimer: *This document is a European Commission staff working document for information purposes. It does not represent an official position of the Commission on this issue, nor does it anticipate such a position.*

LIST OF ABBREVIATIONS USED

(for a list EU-funded projects, see also Annex 2)

ACCORD	Achieving Comprehensive Coordination in Organ Donation throughout the European Union (EU funded project)
ACTOR	ACTion Plan on ORgan donation and Transplantation (EU funded study)
AIDS	Acquired immunodeficiency syndrome
Alliance-O	European Group for Coordination of National Research Programmes on Organ Donation and Transplantation (EU project)
BIO-DriM	Personalized minimization of immunosuppression after solid organ transplantation by biomarker-driven stratification of patients (EU project)
BTC	Board of Transplant Coordination (division within UEMS)
CA	Competent authority/ies in charge of organ donation and transplantation, network established by Directive 2010/53/EU
CD-P-TO	European Committee on Organ Transplantation (Partial Agreement) - for the transplantation of organs, tissues and cells, Council of Europe
CETC	Certification of European Transplant Coordinators
CoE	Council of Europe
COPE	Consortium on organ preservation in Europe (EU project)
COORENOR	Coordinating a European Initiative among National Organizations for Organ Transplantation (EU project)
DBD	Donation after brain death
DCD	Donation after circulatory death ('uncontrolled': uDCD or 'controlled': cDCD)
DD	Deceased donation
DOPKI	Improving the knowledge and practice of Organ Donation (EU project)
EACCME	European Accreditation Council for Continuing Medical Education
EC	European Commission
EDD	(Developing Guidelines for the Organisation of) European Donation Days
EDQM	European Directorate for the Quality of Medicines and Health care (CoE)

EDTCO	European Donation & Transplant Coordination Organisation (section of ESOT)
EEA	European Economic Area
EFRETOS	European Framework for the Evaluation of Organ Transplants (EU project)
ELIPSY	European Living Donor Psychological Follow-up (EU project)
ELPAT	Ethical, Legal and Psychosocial Aspects of Transplantation (a section of ESOT) (Conferences organised by this section as EU projects)
ENPi	European Neighbourhood Policy Instrument
EODD	European Organ Donation Day
EOEO	European Organ Exchange Organisation
ESOT	European Society for Organ Transplantation
ET	Eurotransplant
ETC	European Training Course in Transplant Donor Coordination in the European Union (EU project)
ETHICTRANSPLANTATION	Organ transplantation: Ethical Legal and Psychological aspects. Towards a common European Policy 2007 Conference
ETPOD	European Training Program on Organ Donation (EU project)
EU	European Union
EULID	European Living Donation and Public Health (EU-Living Donor) (EU project)
EULOD	Living Organ Donation in Europe (EU project)
EUROSTAM	Europe-wide strategy to enhance transplantation of highly sensitized patients on basis of acceptable HLA mismatches (EU project)
FOEDUS	Facilitating Exchange of Organs Donated in EU Member States (EU project)
FP	EU Research Framework Programme(s): FP6 (2002-2006), FP7 (2007-2013)
HepaMAb	Human monoclonal antibody therapy to prevent Hepatitis C virus reinfection of liver transplants (EU project)
HIV	Human immunodeficiency virus
HLA	Human Leukocyte Antigen
HOTT	Combating trafficking in persons for purpose of organ removal (EU project)

HP	EU Health Programme
ICU	Intensive care unit
IFA	Illegal and Fraudulent Activities
IPA	Instrument for Pre-Accession
LD	Living donation
LIDOBS	International Conference on Living Donation, high quality practices (EU project)
MODE	Mutual Organ Donation and Transplantation Exchanges (EU project)
MS	Member States (of the European Union)
ODEQUS	European Quality System Indicators and methodology on Organ Donation (EU project)
ONE study	A Unified Approach to Evaluating Cellular Immunotherapy in Solid Organ Transplantation (EU project)
ONT	Organización Nacional de Trasplantes (Spanish Competent Authority)
ORGANPROCUREMENT	Policy, law and organ procurement; (EU funded, Marie Curie actions – Intra-European Fellowships)
PA	Priority action (of the Action Plan)
PDSA	Plan, do, study, act methodology
PMP	Per million population
QALY	Quality adjusted life year
QIP	Quality improvement programme
RISET	Reprogramming the immune system for the establishment of tolerance (EU project)
RTD	Directorate General for Research and Innovation of the European Commission
SANCO	Directorate General for Health and Consumers of the European Commission
SAT	South Alliance for Transplantation
SEEHN	South-eastern Europe Health Network (WHO)
SKT	Scandiatransplant

STAR-T REK	Set up and comparison of multiple stem cell approaches for kidney repair (EU project)
STELLAR	Stem cell based therapy for kidney repair, EU-Australia cooperation (EU project)
SWOT	Strengths, weaknesses, opportunities and threats (analysis)
TAIEX	Technical Assistance and Information Exchange, EU instrument for partner countries
TFEU	Treaty on the Functioning of the European Union
TPM	Transplant, Procurement, Management (training course)
TTS	The Transplantation Society
TX	Transplant
UEMS	European Union of Medical Specialists
WHO	World Health Organization
XENOME	Engineering of the porcine genome for xenotransplantation studies in primates: a step towards clinical application (EU project)

EXECUTIVE SUMMARY

More than 60,000 patients are on a waiting list for an organ transplant in the European Union.¹ Of these over 80% are waiting for a kidney, about 10% for a liver, and several thousands for other organs such as a heart or lungs. In 2012 more than 4,000 patients died in the EU while waiting for an organ.

In December 2008, the European Commission adopted the “Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States”. This Action Plan aimed to tackle three main challenges in organ donation and transplantation: 1) increasing organ availability, 2) enhancing the efficiency and accessibility of transplant systems, 3) improving quality and safety. The Action Plan identified 10 key priority actions and 28 specific actions within a common framework. These actions are supported by EU-funded projects under the Health Programme or other Community instruments such as research funding. Some were also taken forward by expert working groups organised by the Commission. The ultimate responsibility for implementation remains of course with the Member States. The Action Plan contributes to, and is complementary to, the legal framework laid down in the Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation adopted on 7 July 2010.

This report on the mid-term review of the Action Plan is a factual progress report taking stock of progress made between 2009 and 2012, both at national and EU level. It also identifies gaps and topics that should be further addressed in the coming years. This exercise is based on a comprehensive external assessment (ACTOR study) focusing on the national level that was concluded in June 2013. It also takes into account the Council Conclusions on organ donation and transplantation of 7 December 2012 agreed upon by EU Member States under the Cypriot Presidency.

The Action Plan (which takes the form of a Commission Communication) foresees that “a mid-term review of the actions will be carried out”. By means of the present report the Commission services aim to comply with this commitment. **This report is therefore not a revision of the Action Plan, but merely seeks to set out, from an EU perspective, where the emphasis of EU activities has lied in the past years and where the emphasis is intended to lie in the remaining period of the Action Plan (2014-15).** It does not repeat the ACTOR study and the Council Conclusions, but takes their key findings and messages into account.

The key findings on the 10 priority actions (PA) are:

Transplant donor coordinators (PA1), when duly appointed and trained in every hospital with a potential for organ donation, are essential to identify and take care of donors and their families, and thus to improve donation rates, while ensuring the quality and safety of organs for transplantation. The importance of this role has been widely recognised in Member States, and many coordinators have been appointed and trained in hospitals all over the EU. This priority action received a lot of attention in the first years of the Action Plan: many training courses were organised, and methodologies and manuals were developed both at EU and national level. Given the essential role of transplant donor coordinators, these efforts need to

¹ Source: Council of Europe Transplant Newsletter 2013

be maintained, but the emphasis will lie on national role-out rather than launching additional EU-funded projects.

Quality improvement programmes (QIPs) (PA2), by providing methodologies and indicators for assessing the different steps in the chain from donor identification to transplantation, can significantly improve donation rates and quality and safety of transplant activities in hospitals. These QIPs are so far only partly taken up in Member States.² In 2013, the EU-funded ODEQUS project delivered new tools to set-up such programmes. The full implementation by Member States in the remaining period of the Action Plan will be key to improving donation quality and rates. The Commission services will study the implementation of QIPs in the 2014 “implementation survey” linked to Directive 2010/53/EU.

Living donation programmes (PA3) are increasingly taken up in Europe, in particular for kidney donation. In the last years, increases in organ donation are largely due to living donation. In order to develop this practice in a trustworthy manner, protection of living donors must be ensured, amongst others through registers capturing their long-term follow-up, as required in Directive 2010/53/EU. Many Member States are developing programmes in this area, and several EU-funded projects (EULID, ELIPSY, ACCORD, LIDOBUS) support(ed) their efforts. It is **proposed to focus** efforts on this PA during the remaining period of the Action Plan.

To improve organ donation, public awareness is key. **Knowledge and communication skills of health professionals and patient support groups (PA4)** can be improved via training programmes, and authorities are encouraged to organise periodic meetings with journalists. This PA was implemented by various measures in the Member States (training courses for staff, workshops for journalists, leaflets etc.), and supported at EU level via the EDD project and Journalist Workshops organised by the European Commission. Following the ACTOR study, these efforts should be further developed, for example via the FOEDUS project and meetings of competent authorities.

Another way to improve organ donation is to facilitate the **identification of organ donors across Europe and cross border donation (PA5)**. The objective was partly addressed in EU-funded projects, such as DOPKI and COORENOR, which compared national organisational systems. The ACTOR study also found that Member States have different consent schemes and tools to identify potential donors. Instruments that are now being developed within the FOEDUS project, and through the implementation of Directive 2012/25/EU, will improve knowledge about national consent systems and thus the identification of potential donors.

As different donation and transplantation models exist across Europe, **enhancing organisational models of organ donation and transplantation (PA6)** allows an exchange of best practices, via twinning and peer reviews. This action was taken up by many Member States with the support of different EU-funded projects (amongst others MODE, COORENOR, TAIEX, ACCORD). Meetings between national competent authorities complemented this exchange. It is proposed to continue efforts in this area, e.g. via the Joint Actions ACCORD and FOEDUS.

² Already before the adoption of the Action Plan, DOPKI made first efforts to assess the performance in the process of donation after death and contained recommendations on methodologies and indicators.

Challenges such as patient mobility or organ trafficking call for the promotion of **EU-wide agreements on aspects of transplantation medicine** (PA7). This PA covers elements which do not directly fall in the mandate of the competent authorities in charge of organ transplantation. It was addressed via EU Research funding and collaboration with key partners such as the Council of Europe, WHO and professional societies. As suggested in the ACTOR study, this PA requires discussion with the competent authorities and professional societies. As initiatives by other partners, as well as several EU research projects are already ongoing, also beyond 2015, this PA is not foreseen as main area of activity at EU level for 2014-15.

The **exchange of organs across borders** (PA8) increases the number of organs available (organs which may otherwise not have been procured and used) and allows better matches to be found between organs and recipients. A lot can be learned from existing European organ exchange organisations and bilateral agreements. An IT-tool for organ exchange has been developed in the COORENOR project. The FOEDUS Joint Action (funded in 2012, for implementation from 2013 until 2016) will expand the use of this tool and develop procedures to offer organs across borders, amongst others for urgent and difficult-to-treat patients. The **high potential of organ exchange** makes this PA a further focus at EU level for 2014-15.

The **evaluation of post-transplant results** (PA9) is important not only for recipients themselves, but also of key importance for the entire sector to share lessons on how best to allocate and transplant the available organs, and to assess the efficacy and safety of the transplant procedures. The EFRETOS project has laid down a common methodology to organise follow-up in a compatible way all over the EU. It also produced recommendations on the setting-up of national systems for the reporting and management of adverse events and reactions, as laid down in Directive 2010/53/EU. In 2014-15, these results should be implemented at national level with the assistance of professional associations. The feasibility of European registers of registries could be explored, possibly for the different types of organs transplanted.

Quality and safety of organ transplantation could be improved via a **common accreditation system for organ donation/procurement and transplantation programmes** (PA10). Training programmes and certification schemes have been developed at different levels, by competent authorities, professional societies and universities. However this PA has proven hard to take-up at EU level, due to the existence of different health professionals involved and national differences in educational and health systems. It is therefore proposed to focus on sharing authorisation schemes of procurement organisations and transplant centres (foreseen within Directive 2010/53/EU), and on mapping recognised training and certification schemes, with the support of competent authorities and professional societies.

In conclusion it can be said that **good progress has been made** by the Member States in the first half of the Action Plan. The most important achievements were made relating to the increase and training of transplant donor coordinators (PA1), the introduction or development of living donation programmes in some Member States (PA3) as well as the improvements of the organisational models (PA6). Concretely, more coordinators were appointed and trained (PA1), thus improving deceased donation rates; living donation programmes were created or developed, seeking also for a better protection of living donors (PA3) and organisational models that proved to be efficient in some Member States were introduced in other EU or non EU countries (PA6).

Many projects on these topics and practices received funding under the **EU Health programme**. Ultimately these very significant efforts contributed to the increase in donation rates in a number of Member States. Other EU-funded projects on quality improvement programmes (PA3), communication aspects (PA4) and the evaluation of post-transplant results (PA9) have also produced concrete results for the availability of organs and their quality and safety.

Taking into account these achievements as well as the on-going projects funded under the EU health programme, it **is envisaged to focus** the efforts at EU level **during the remaining period of the Action Plan (2014-15)** on **(1) living donation** programmes (PA3) and **(2) on the cross-border exchange of organs** (PA8). For these actions, EU-level support has a high potential to help Member States increase and optimise organ transplantation and EU-funded projects are already ongoing.

For many other actions (PA1, PA2, PA4, PA6, PA9), national efforts and EU support have already provided Member States with a good knowledge base and tools. While at some stage further EU funding could be foreseen, the emphasis for 2014-15 will lie on the implementation of these actions. These implementation efforts are primarily the responsibility of Member States. EU efforts - for example on the evaluation of post-transplant results – are expected to be useful, but will realistically not be achieved before 2015 (i.e. within the current time frame of the Action Plan).

Three other Priority Actions (PA5, PA7 and PA10) are not foreseen for major new initiatives at EU level in 2014-15, because efforts are already undertaken by ongoing EU-funded Research projects and by other actors in the field, such as professional societies, the scientific community and other national and international institutions.

Meetings between competent authorities and the Commission, formalised since the adoption of Directive 2010/53/EU, will continue to steer this Action Plan and support its implementation, to **make a greater number of safer organs available for patients in need**.

1. INTRODUCTION

Organ transplantation is a very challenging area of modern medicine. Often the only treatment for end-stage organ failure, transplantation is dependent on recovery of organs from deceased or living donors, and the demand for organs continues to outstrip rates of donation.

At the end of 2012, 64,000 patients were on a waiting list for an organ transplant in the European Union (EU)³: more than 50,000 patients for a kidney, roughly 7,000 for a liver, and several thousands for other organs such as a heart or lungs. Within the same year, 4,000 patients died in the EU while on the waiting list for an organ. This figure does not include patients who died before ever being placed on a waiting list in the first place.

At the end of 2008, the European Commission adopted a Communication: the "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States". The Action Plan sets out ten priority actions in order to help Member States meet three key challenges: (1) increasing organ availability, (2) enhancing efficiency and accessibility of transplant systems and (3) improving safety and quality.

This mid-term review outlines the assessment by Commission services of the progress made during the first half of the Action Plan, from a European perspective. **It does not change the Action Plan**, which takes the form of a Commission Communication, but proposes elements to evaluate the effectiveness of the different priority actions, and identifies areas where additional efforts in terms of implementation are considered useful at EU level for the remainder of the Action Plan's running time: 2014-15. The review follows an external assessment of the uptake of the Action Plan in the Member States, the ACTOR study⁴ published in June 2013. It also considers the political orientation of the December 2012 Council Conclusions on organ donation and transplantation.⁵ While the ACTOR study and the Council Conclusions were primarily centred on the national level, the complementarity of the present report lies in its focus on the European level, in particular in the presentation of the differentiated use of the various tools available (e.g. EU funding mechanisms, working groups with national experts).

Key challenges

Organ transplantation is the transfer of an organ from a donor to the body of a recipient whose own organs are failing. Kidneys are the most commonly transplanted organs, but liver, heart, lung, small bowel and pancreas transplants are also common. A major challenge for organ transplantation is the problem of graft rejection (i.e. rejection of the transplanted organ), due to an immune response in the recipient. This rejection can lead to transplant failure and potentially death. The risk for transplant rejection is reduced through immunological matching of donor and recipient and through the use of immunosuppressive medicines.

³ Source: Council of Europe Transplant Newsletter 2013

⁴ ACTOR study: "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)" http://ec.europa.eu/health/blood_tissues_organs/docs/organs_actor_study_2013_en.pdf

⁵ 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

Organs are usually recovered from deceased donors (mainly after brain death, but also after circulatory death) but can also be donated by living donors (e.g. a kidney or part of a liver). Transplantation raises a number of important ethical and legal questions that should be addressed: What is the definition of death? How is consent for donation obtained? How to prevent illegal activities like transplant tourism, organ trafficking, or trafficking in human beings for the purpose of organ removal?

This report sets out the legal and political context, provides some facts and figures on organ donation and transplantation in the European Union (and neighbouring countries), and describes the priority actions, the achievements in recent years and the remaining challenges.

2. LEGAL AND POLITICAL CONTEXT

Treaty and mandate

Article 168 of the Treaty on the Functioning of the European Union (TFEU) sets out the legal framework for actions on organ donation and transplantation at EU level. In this area, there are two important roles for the EU: 1) facilitating the cooperation between Member States on organ donation and transplantation (Action Plan) and 2) via the EU legislation, ensuring the safety and quality of human organs intended for transplantation, through the creation of minimum standards that facilitate the cross-border exchange of organs in the EU. One important caveat is that EU competence in the health care sector is limited. Healthcare is predominantly an area of national competence and responsibility.

Article 168⁶ of the Treaty on the Functioning of the European Union (TFEU):

"4. [...] the European Parliament and the Council, acting in accordance with the ordinary legislative procedure [...] shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet **common safety concerns**: (a) **measures setting high standards of quality and safety of organs** and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures [...].

In addition, the EU Charter of Fundamental Rights, in its Article 3 (2) c) prohibits making the human body and its parts as such a source of financial gain. In its Article 35, the Charter enshrines the right of access to preventive health.

Following a 2007 Communication⁷, the Commission adopted in 2008: (a) a Proposal for a Directive that provides quality and safety requirements for human organs intended for transplantation⁸, and (b) an Action Plan for improving co-operation between Member States.⁹

Directive 2010/53/EU on standards of quality and safety of human organs

⁶ Consolidated version of the Treaty on the Functioning of the European Union, Official Journal (OJ) of the European Union, (C 115/47)

⁷ COM(2007) 275 final, 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_com_en.pdf

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

⁹ http://ec.europa.eu/health/archive/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf

The Commission's legislative proposal led to the adoption on 7 July 2010 of Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation¹⁰ ("The Organs Directive") by the European Parliament and the Council. This Directive provides for a set of standards of quality and safety for human organs intended for transplantation. These standards include the appointment of competent authorities in every Member State, the authorisation of procurement and transplantation centers and activities, traceability systems, as well as systems to report serious adverse events and reactions. Moreover, the Directive lays down requirements for the safe transportation of organs and for the characterisation (i.e. medical description) of donors and organs. The transposition deadline of the Directive was 27 August 2012 and the Commission is currently analysing these national transpositions.

On 9 October 2012, Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation¹¹ was adopted (to be transposed by 10 April 2014). This Directive is intended to facilitate the exchange of organs between Member States, in particular the communication needed during and after such exchanges.

Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

The 2008 Action Plan¹² identifies three main challenges and ten priority actions in order to support Member States in addressing the challenges in the field of organ donation and transplantation:

- (1) increasing organ availability,
- (2) enhancing efficiency and accessibility of transplant systems and
- (3) improving safety and quality.

The overall aim of the Action Plan is to address these challenges through strengthening the cooperation between Member States and promoting the exchange of best practices and experiences. The Action Plan encourages Member States to develop their own "sets of national priority actions."

As outlined in the Action Plan, a mid-term review is foreseen to evaluate the efficacy of the plan. This review has been conducted on the basis of various inputs:

- exchanges with national authorities and feedback from projects and studies carried out under the EU Health Programme and
- the **ACTOR study**¹³, a study prepared by an external contractor working for the Commission under the EU Health Programme to measure and analyse the uptake of the Action Plan at national and European levels.

¹⁰ Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation (OJ L 207)

¹¹ Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation (L 275/27) http://ec.europa.eu/health/blood_tissues_organs/docs/organs_impl_directive_2012_en.pdf

¹² COM(2008) 819/03

¹³ Request for Specific Services N° EAHC/2011/HEALTH/16 for the implementation of Framework Contract N° EAHC/2010/Health/01 (lot 1: Health reports), "ACTOR study" is the name proposed by

The **Council conclusions** on organ donation and transplantation adopted by Council in December 2012 provided political direction for the mid-term review.

3. EUROPEAN LANDSCAPE

Geographical scope and timeline

The Action Plan is intended for Member States (MS) of the European Union. Certain neighbouring countries have also aligned their work in the field to the Action Plan and are covered by this review: Iceland and Norway (EEA¹⁴), the Former Yugoslav Republic of Macedonia, Moldova, Montenegro, Switzerland and Turkey.

The partner countries implement similar measures to those in EU legislation and some participate in the twice-yearly meetings of the competent authorities for organ donation and transplantation in Brussels.¹⁵ These countries sometimes also participate in EU-funded projects through the Health Programme or benefit from other funding mechanisms such as TAIEX¹⁶ grants (listed in Annex 2). Some also collaborate through other forms of cooperation, like the Council of Europe's Black-Sea-Area project or the WHO South-eastern Europe Health Network (SEEHN).

This document will focus on past, on-going and planned activities under the Action Plan, considered from a European perspective. In this respect, data from the annual Transplant Newsletters (Council of Europe and Spanish Competent authority ONT) have proven very valuable. Data from 2007 and 2012 are used as reference years.

3.1. Facts and figures¹⁷

The number of organ transplants has seen an overall increase by 8% from 2007 to 2012. An increase is also observed across all types of organ transplants (Table 1 above). The increase in transplants is due to a combination of factors:

- A 16% increase in **deceased** organ donors (9,600 vs. 8,300);
- A 32% increase in **living kidney** donors (3,900 vs. 2,900) and a 16% increase in living (partial) liver donors (250 vs. 210);
- An increase of **novel transplants**, such as combined heart-lung and small bowel transplants.

the contractor which won the specific tender and comes for "ACTion Plan on ORgan donation and Transplantation"

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

¹⁴ European Economic Area

¹⁵ These „CA meetings“ are part of the „E01718 - CASOHO - Competent Authorities on Substances of Human Origin Expert Group“

¹⁶ Technical Assistance and Information Exchange

http://ec.europa.eu/enlargement/tenders/taix/index_en.htm

¹⁷ Facts and figures presented here of general, aggregated nature and are not linked to a specific priority action.

Table 1: Aggregated numbers of organ transplants in the EU*, 2007 and 2012

N = 27 countries (492,3 million inhabitants in 2007 and 504,2 million in 2012)

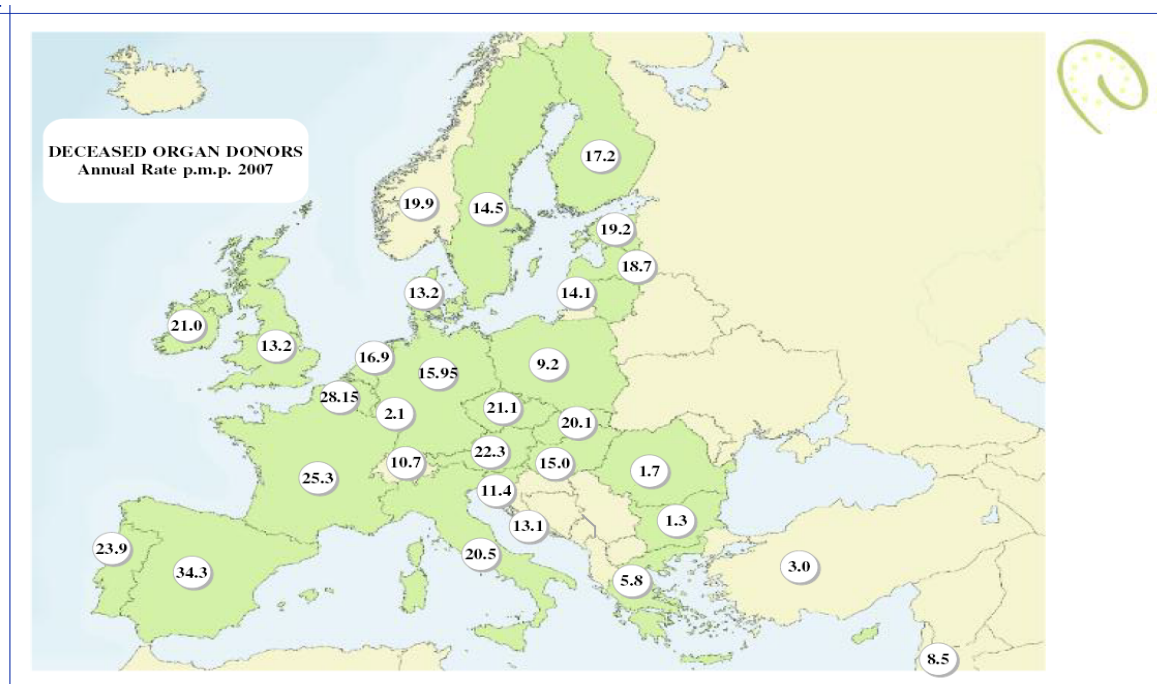
Type of transplant Year	Kidney	Liver	Heart	Lung**	Pancreas	Small bowel	Total
2007	17,306	6,576	2,050	1,347	788	13	28,080
2012	18,854	6,845	1,960	1,756	825	34	30,274
Change	+9%	+4%	-4%	+30%	+5%	+162%	+8%

Source: Council of Europe Transplant Newsletters 2008 and 2013 * Croatia is not included as it joined the EU in July 2013

**Heart-lung counted with lung. Note that the slight reduction for heart-only transplants is covered by the increase in combined transplants of heart-lungs.

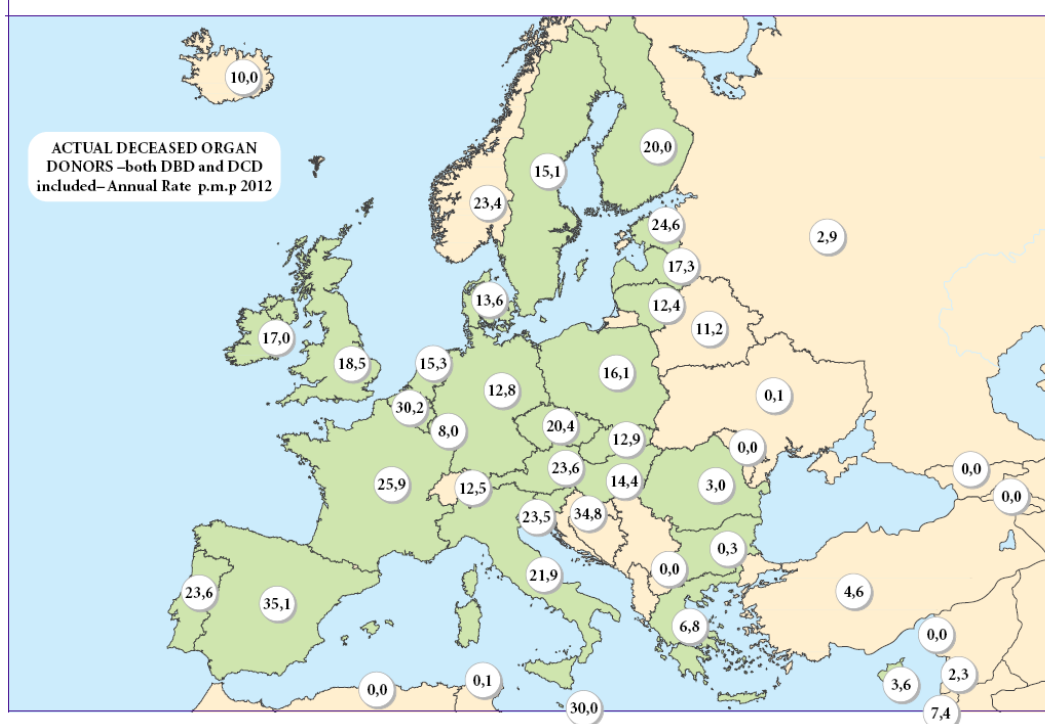
However rates vary significantly between countries. In order to better understand these improvements, it is important to look at European maps, showing the ratios of deceased organ donors by country (per million population, pmp):

Figures 1 and 2: Deceased organ donors per million population in 2007 and 2012



Deceased organ donors, pmp 2007 (Source: Council of Europe Transplant Newsletter 2008)

These maps, which are also summarized in Table 2, show that the evolution of organ donation rates from **deceased donors** varies substantially between Member States. Some countries already had in 2007 high donation rates: Spain (34.3 pmp), Belgium (28.2) and France (25.3), and have kept or even managed to slightly improve these rates. Other countries have seen their **efforts on deceased donation paying off** with increases in donation rates, for example Croatia (from 13.1 to 34.8), Malta (19.5 to 30), Slovenia (11.4 to 23.5) and Poland (9.2 to 16.1). In contrast other countries have seen a stable trend at low level or even a slight decline in deceased donation rates. These countries still have significant potential to increase their donation rates from deceased donors.



Deceased organ donors, pmp 2012 (Source: Council of Europe Transplant Newsletter 2013)

Table 2: Actual deceased organ donor ratios (per million population, pmp), 2007 / 2012

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI
2007	22,3	28,2	1,3	-	21,1	16	13,2	19,2	5,8	34,3	17,2
2012	23,6	30,2	0,3	3,6	20,4	12,8	13,6	24,6	6,8	35,1	20
	FR	HR	HU	IE	IT	LV	LT	LU	MT	NL	PL
2007	25,3	13,1	15	21	20,5	18,7	14,1	2,1	19,5	16,9	9,2
2012	25,9	34,8	14,4	17	21,9	17,3	12,4	8	30	15,3	16,1
	PT	RO	SE	SI	SK	UK	EU*	IS	NO	TR	CH
2007	23,9	1,7	14,5	11,4	20,1	14,5	16,8	0	19,9	3	10,7
2012	23,6	3	15,1	23,5	12,9	18,5	19,1	10	23,4	4,6	12,5

(List of country codes in Annex 1)

*calculated without Croatian data as it joined the European Union in July 2013.

(Countries not shown in this table: In 2012 there was no organ donation in the Former Yugoslav Republic of Macedonia and Moldova in 2012 (data not collected in 2007). For Serbia, data was not collected in 2007 and 2012.)

In contrast, some countries have focused on **living donation**, and have managed to maintain or to increase their already high donation rates, in particular as regards kidney living donation (29 pmp in the Netherlands in 2012, 16.4 in the United Kingdom, 16.3 in Sweden, 16.2 in Norway, 13.8 in Denmark, 20 in Iceland). Some countries with relatively low rates in 2007 have managed to increase their living donation rates, for example Finland, Hungary, Ireland, Italy, Latvia, Poland, Spain (see Table 4 under Priority Action 3 for more details). In the remaining countries, the donation rates of living donors have not significantly evolved, and have a potential for increase.

Differences between national transplant programmes

One should also be aware that obtaining consent for donation does not automatically translate into the transplantation of all organs. Whereas kidneys are widely transplanted, not all countries have the expertise for more complicated transplants like lung or small bowel transplants.

Table 3 outlines the number of countries who have different organ-specific transplant procedures or programmes available. This table shows how many countries have the expertise and have set up programmes for each type of organ transplant (it does not say anything about the quantity and quality of transplants performed).

The table shows that **all EU countries** (including then future EU MS Croatia) **already had kidney transplant programmes in place in 2007**. Yet relatively few countries performed small bowel transplants, and not all countries had their own programmes for liver, heart, lung and pancreas transplants. By 2012, seven additional countries had introduced at national level new transplant programmes for organs previously not covered.

Table 3: Types of transplant procedures existing in 2007 and in 2012 in Europe

(28 EU countries + six others countries listed below***) NB: if a country has at least one kidney transplant programme (or performed at least one kidney transplant procedure), it is counted as 1.

	<i>Kidney</i>		<i>Liver</i>		<i>Lung*</i>		<i>Heart</i>		<i>Pancreas</i>		<i>Small bowel</i>		<i>(Total) Average</i>	
	'07	'12	'07	'12	'07	'12	'07	'12	'07	'12	'07	'12	2007	2012
2007/2012														
27 EU countries**	27	27	22	23	17	17	23	23	15	16	3	5	(107)	(111)
34 countries***	32	32	26	27	20	20	27	27	18	20	3	7	(126)	(133)
													3,71	3,91

Source: Council of Europe/ONT annual Transplant Newsletters 2008 and 2013

* Heart-lung transplants are counted under lung transplants in this table.

** Croatia joined the EU in 2013, therefore its numbers were not captured in the EU data for 2007 and 2012.

*** 28 EU countries (with Croatia from July 2013) + Iceland, Former Yugoslav Republic of Macedonia, Moldova, Norway, Switzerland, Turkey

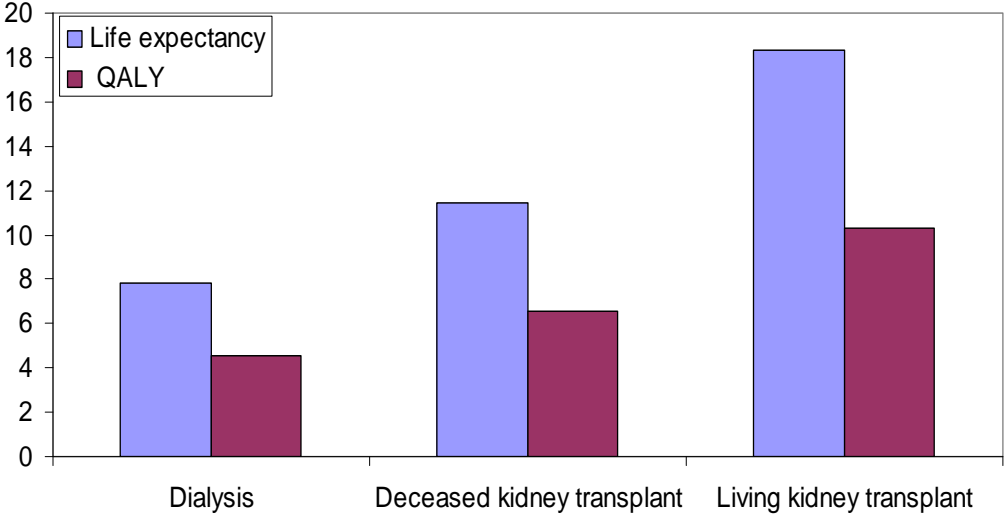
The table shows also that there is still the potential to introduce such transplant programmes. At the same time it should be noted that it might not be beneficial to introduce all programmes in all Member States. In particular smaller Member States may wish to consider concentrating on a sub-set of transplant programmes and instead conclude exchange programmes with neighbouring countries for transplant types not carried out in the Member State, resulting in **cross-border exchanges of organs and patients**. When a country does not have the expertise or resources to organise a more complicated transplant, e.g. a lung transplant, it can offer such transplant therapies to its citizens by concluding an agreement with partner countries. If such agreements exist, patients can access transplant programmes abroad. At the same time, the agreements can also provide for procurement teams from abroad to recover otherwise un-used organs from existing donors. These agreements often bring knowledge-sharing and may eventually lead to the establishment of domestic transplant programmes.

Organ transplantation: saving lives, improving quality of life and maintaining cost-effectiveness

Organ transplantation offers very significant health benefits to recipients. While transplantation is not in itself free of risks, it often proves to be life-saving or at least to significantly improve quality of life. Patients with end-stage renal failure - undergoing dialyses - usually recover well after transplantation and enjoy good health for many years. These patients benefit from increased life expectancy and quality of life (often calculated as QALY¹⁸).

Research shows that compared to dialysis, a kidney transplant from a deceased donor increases life expectancy by 3.6 years of and QALY by 2.0 years, whereas a kidney transplant from a living donor increases life expectancy by 10.5 years and QALY by 5.8 years (better outcomes related to living transplants typically relate to factors such as possibilities for early transplantation, good preparation and selection of donors, minimal organ transport times) (Figure 3).

Figure 3: Life expectancy and QALY gain for type1 diabetic patients with renal failure



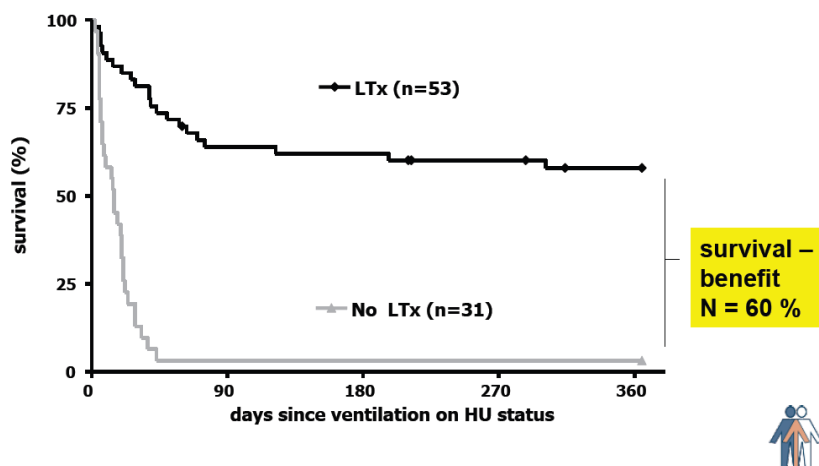
Source: Knoll and Nichol, *Mathematical modelling of 1000 articles, J. AM. Soc. Nephrol* 2003

For lung transplants (Figure 4), the benefits are even more significant, as there are no long-term alternative therapies available. The only treatment is ventilation, which can usually only be administered for a couple of days, during which lungs for transplantation must be urgently found.

While the primary objective of transplantations is to save lives and improve the health of patients, in times of economic and financial crisis it should also be noted that **organ transplantation is cost-effective and brings savings for public health budgets**, in particular for kidney transplants (Figure 5).

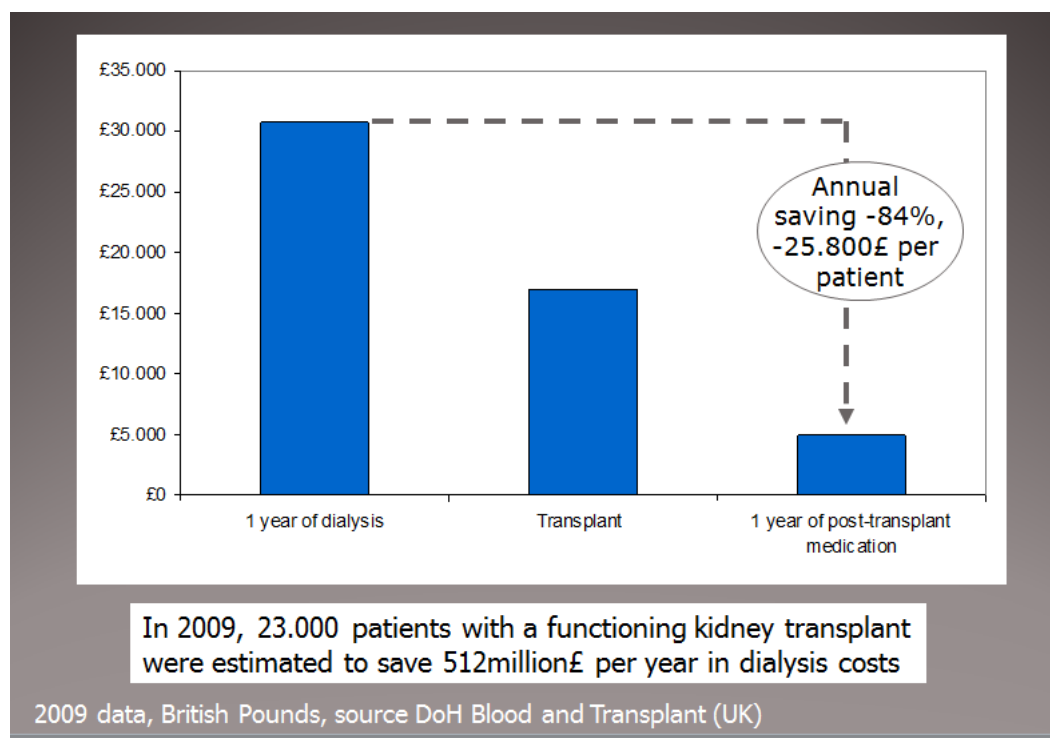
¹⁸ Quality adjusted life year, a year of life adjusted for its quality or its value. A year in perfect health is considered equal to 1.

Figure 4: Survival benefit after lung transplantation in mechanically ventilated patients



Source: MHH, Germany 2005-2008, quoted by Eurotransplant¹⁹ (presented at the 2012 Journalist Workshop on organ donation & transplantation organised by the European Commission); "LTx" means "lung transplants"

Figure 5: kidney transplants offer annual savings²⁰
 Costs per patient of treatment options for end-stage renal failure



In the UK, the Department of Health estimated that a transplant can reduce annual treatment costs of patients with end stage renal disease by over 80% compared with dialysis. In total the Department of Health believes kidney transplants save the government more than half a billion pounds per year. Data from other EU Member States confirm this savings potential for kidney transplants.

¹⁹ http://ec.europa.eu/health/blood_tissues_organ/docs/ev_20121009_co05_en.pdf (slide 54)
²⁰ Data presented in Figures 5 and 3 was also used for the discussions under the Cypriot Presidency of the European Union in 2012: http://www.cy2012.eu/index.php/en/file/8_mdjYoEV0H2nxXo9+AUZw==

3.2. National approaches

While cooperation at EU level is very beneficial, it should not be forgotten that the primary responsibility for an efficient transplant system is the responsibility of Member States. Member States have different traditions and methods for organising their transplant sector. Some of these differences are outlined upon here because they are relevant for the transplant sector, but not covered in more detail under the ten priority actions of the Action Plan and hence in subsequent sections.

Consent systems

In the EU, organs cannot be procured without the consent of donors and/or their relatives. However the establishment of consent differs between Member States. National provisions usually foresee that citizens (donors or relatives) can “opt-in” (explicit consent) or “opt-out” for donation (presumed consent). Mixed solutions also exist, with or without central databases, that register the wishes expressed by citizens. Regardless of the consent system, the opinion of relatives or “next-of-kin” is almost always asked and respected. The ACTOR study found that most European countries have “opt-out”, i.e. presumed consent systems.

Deceased and living donation

It is also Member States’ decision on whether they organise their transplant systems based purely on deceased donation or whether they also encourage living donation. While deceased donation is highly developed in several Southern European countries, some Northern European countries are more advanced in the area of living donation.

Within deceased donation: brain death and circulatory death

A further distinction can also be made between different types of deceased donation that are allowed and organised within a country. **Donation after brain death (DBD)** is the most common type of deceased donation, while **donation after circulatory death (DCD)** is increasingly used as an additional source of organs for transplantation. These two kinds of deceased donation raise different ethical concerns and require different organisational set-ups.

Bilateral and multilateral agreements

Some countries have chosen to take part in **multilateral “European organ exchange organisations”**, such as Eurotransplant (eight countries) or Scandiatransplant (five countries), and manage waiting lists and allocation criteria (at least partially) together. The recently created Southern Alliance for Transplantation (six countries) foresees a similar collaboration. Some countries have entered into **bilateral organ exchange agreements**, e.g. just focusing on the exchange of a specific type of organ with a neighbouring country. Such organ exchanges need, for being fully operational, to be supported by a wide set of organisational and practical agreements, aimed also at ensuring compliance with Article 3 (2) c) of the EU Charter of Fundamental rights and excluding any risk of organs trafficking.

Other general differences

Of course, there are many more differences in the general organisation of **health systems**, in **educational aspects and economic considerations** that impact organ donation and transplantation. Finally, cultural factors such as religion and national views on ethical issues also play a very important role in how transplantation schemes are organised.

4. CHALLENGES AND PRIORITY ACTIONS OF THE ACTION PLAN

This chapter sets out the assessment of the main activities undertaken under the EU Action Plan on Organ Donation and Transplantation (2009-2015) and its conclusions. It is important to note that the Action Plan consists of three main challenges, five objectives and ten priority actions. They can be summarised as follows:

Challenge 1: increasing organ availability

- Objective 1: "Member States should reach the full potential of deceased donations" (priority actions 1 and 2)
- Objective 2: "Member States should promote living donation programmes following best practices" (priority action 3)
- Objective 3: " Member States should increase public awareness of organ donation" (priority actions 4 and 5)

Challenge 2: enhancing the efficiency and accessibility of transplant systems

- Objective 4: " Member States should support and guide transplant systems to be more efficient and accessible" (priority actions 6, 7 and 8)

Challenge 3: improving quality and safety

- Objective 5: " Member States should improve the quality and safety of organ donation and transplantation" (priority actions 9 and 10)

For each of the ten priority actions, the assessment will be presented within the same structure:

- 1) an introduction on the key actions foreseen under the Action Plan for this priority action,
- 2) some facts and figures,
- 3) related activities within the EU since 2009,
- 4) evaluation in the ACTOR study and views of the Council and
- 5) conclusions and next steps proposed.

Challenge 1: INCREASING ORGAN AVAILABILITY

4.1. Priority Action 1: Promote the Role of Transplant Donor Coordinators in Every Hospital with a Potential for Organ Donation

<i>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</i>	<i>(MS²¹ action; EC²² coordinates and monitors)</i>
<i>Action 1.2 Promote the establishment of internationally recognised standards for transplant donor coordinator programmes</i>	<i>(EC Action)</i>
<i>Action 1.3 Promote the implementation of effective training programmes for transplant donor coordinators</i>	<i>(MS + EC Action)</i>
<i>Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators</i>	<i>(MS + EC Action)</i>

1) Introduction

Transplant donor coordinators (also known as key donation personnel in some MS) are key to increasing donation (also known as key donation personnel). Their precise role may differ between Member States, but a common feature is that they are the main contact points for professionals identifying potential deceased organ donors and for families of both donors and recipients. Often they also have an organisational function, for example for coordinating the participation of different procurement teams in organ recovery, and for arranging the appropriate preservation, packaging and transport of the organs recovered. They may be medical doctors or nurses, working full-time or part-time on these tasks. Some develop their activity as part of hospital staff or at dedicated organ procurement organisations.

The first Priority Action aims to promote **the availability of transplant donor coordinators in hospitals where there is a potential for organ donation**, and focuses on hiring and training. Standardisation and accreditation schemes have so far played a less prominent role at EU level.

2) Facts and figures

The exact tasks of the transplant donor coordinators differ from one country to another, depending on the organisational systems. However they often include:

- pro-active identification of possible or potential deceased organ donors,

²¹ Member States, for "Member States of the European Union". The original wording of the Action Plan is kept.

²² European Commission

- checking the wishes of the deceased about organ donation expressed during life time (e.g. through a donor register),
- speaking with the family and documenting the consent decision,
- ensuring the proper evaluation and the characterisation of organ and donor (blood group, medical history...),
- ensuring the physiologic maintenance of the donor to the moment of procurement,
- offering the organs according to national procedures to a central allocation body linked to waiting lists,
- coordinating with recipients' hospitals once allocation has been decided,
- organising procurement/recovery of the organs including the booking of operating theatres and ensuring that necessary staff is available,
- organising appropriate preservation, packaging and transport of organs, and
- during and after donation: caring for and supporting the donor's family and staying at their disposal to answer their questions and address their concerns.
- education and training of hospital staff on issues related to donation and transplantation,
- evaluating performance in the deceased donation process through self-evaluation methods / external audits in coordination with national or supra-national organisations.

Differences between Member States mainly relate to the professional background of coordinators (nurse, doctor, different specialties...), the organisational set-up (attached to a hospital, at regional level or in a centralised organisation etc.), tasks to be accomplished (from the above list), time attributed to the tasks of transplant coordination (e.g. part-time coordinators in small hospitals, full-time in bigger hospitals), training (initial training when appointed, regular training, sometimes both or none), number of coordinators per hospital, per region and per country/inhabitant.

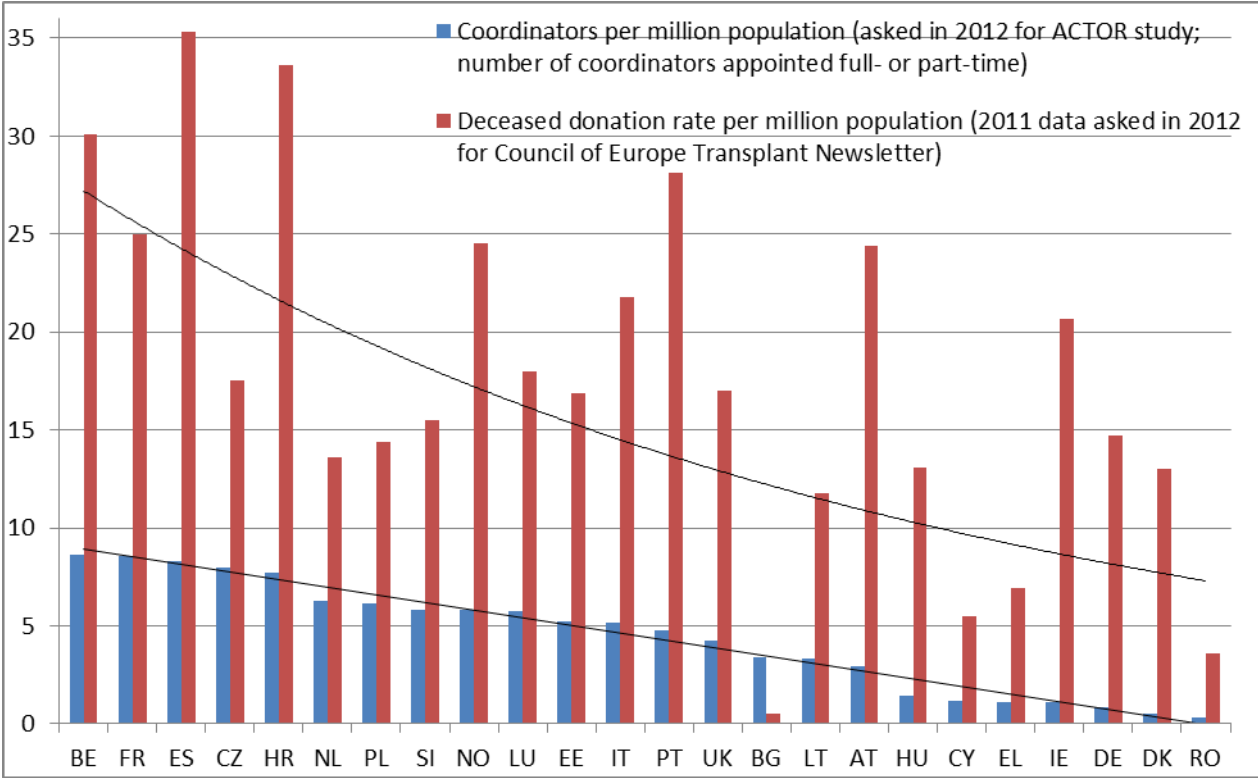
Asked in 2009 by the European Commission, 23 out of 27 EU Member States reported having transplant coordinators. In a survey implemented in 2012 for the ACTOR study, this increased to 26 out of 27, and Croatia, Montenegro, Turkey and Switzerland also reported having transplant donor coordinators in place (therefore totally 30 countries). From these 30 countries, 24 countries shared their numbers of coordinators appointed at the different levels: there had appointed totally 2464 coordinators (full-time or not), the large majority (2220) at hospital or local level, some at national and regional level (equally served with 116 and 112 respectively) and few coordinators at interregional or other levels.

Figure 6 shows on the same graph, for each Member State, the proportion of transplant coordinators appointed per million inhabitants (asked in 2012) and the deceased donation rate, also per million population (2012 Transplant Newsletter). This figure 6 seems to suggest that countries with high numbers of coordinators per million population have higher deceased

donation rates - this seems particularly true for Spain, Croatia, Belgium and France (but of course other factors might also influence deceased donation rates).

Other sources such as the ACTOR study and national competent authorities themselves reveal that the following other factors also play a role: amongst others, the size of the country, organisational set-ups in the country, longevity of the national efforts, training and overall commitment of these coordinators. Despite the important number of factors, a well-established transplant donor coordination seems to be a key condition for high deceased donation rates, as formulated in the Spanish model.

Figure 6: Coordinators appointed and deceased donation rates per million population, 2011-2012



NB: The table shows only countries for which both types of data were available (24 countries). It does not show the number of coordinators in terms of full-time equivalent (data not available) but in terms of coordinators appointed, as Priority Action 1 asks for gradually appointing transplant donor coordinators "in every hospital with a potential for organ donation", e.g. even staff appointed as coordinators part-time (in small hospitals) are thought to be useful to increase donation rates.

Source: ACTOR study (for coordinators), 2012 Transplant Newsletter (for deceased donation rates), EUROSTAT (for population)

3) Activities within the EU since 2009

This priority action should primarily be implemented by Member States (in hospitals), but numerous efforts have been made also at EU level. The main activities are assisting in the establishment of transplant coordination systems, training (trainers in transplant coordination) and the creation of links between coordinators and intensive care units.

To support Member States wanting to set up (or consolidate) their coordination system, the Working Group on Deceased Donation, set-up with national experts from ten Member States and Eurotransplant and chaired by the European Commission, drafted a manual on "setting-up a system of donor coordination: the role of transplant donor co-ordinators and key donation personnel". Based on the experiences of seven Member States (BE, ES, FR, IT, PT, SE and UK), it was finalised in 2011 and shared with other Member States. Eight countries requested a translation, allowing for a use by local professionals. The manual was also shared with non EU countries, for example through by the Council of Europe or by France in North-African partner countries.

Regarding training activities, the Commission funded two training projects via the EU Health Programme (HP): "European Training Program on Organ Donation" (ETPOD, 2007-2009)²³ and the "European Training Course in Transplant Donor Coordination" ("Train the trainers", 2010-2011). The projects brought together respectively 125 (ETPOD) and 85 (Train the trainers) healthcare professionals from all EU Member States. The training programmes were well received and were disseminated further within and outside the EU. ETPOD for example had follow-up activities in South America, within the "European Transplant Network Training" (11 EU Member States) and the "Mediterranean Transplant Network Training" (three EU MS, Turkey, Algeria, Egypt, Israel, Lebanon, Libya, Palestine, Tunisia), as well as a Master Programme and Symposia.

In addition, one work package of the Joint Action ACCORD (2012-2015, HP) focuses on the cooperation between transplant donor coordinators and intensive care units (ICU). The project analyses end-of-life practices relevant to organ donation across Europe and is expected to develop recommendations and tools for the hospitals and Member States involved to facilitate the cooperation between transplant donor coordinators and critical care professionals. It is now concretely assisting participating hospitals across Europe in identifying areas for improvement locally and implementing changes through the Plan, Do, Study, Act (PDSA) methodology. Ultimately, this work package will also lead to good practice recommendations for all EU Member States.

Limited progress has been made in terms of creating an accreditation system for transplant donor coordination. Indeed, although EU-funded projects like ETPOD or "Train the trainers" can offer a common framework and standards for Member States establishing coordination systems, at EU level the focus has been on capacity building (training and increased donation) and on adopting the legislation for standards of quality and safety of organs (July 2010). The development of authorisation systems and accreditation schemes is left respectively to national competent authorities (established by the Directive) and to professional societies such as the European Donation and Transplant Coordinators Organisation (EDTCO, a section of the European Society for Organ Transplantation (ESOT)), which has developed a dedicated project for the Certification of European Transplant Coordinators (CETC) under the auspices of the European Union of Medical Specialists (UEMS) (See also Priority Action 10).

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study found that the priority action relating to transplant donor coordination was well and widely implemented by Member States and supported at EU level. Although all coordinators receive training, the training is not often (or systematically) evaluated and this

²³ <http://etpod.il3.ub.edu/etpod.html>

<http://www.etpod-dissemination.eu>

can be improved. Furthermore, the ACTOR study considered that it may be valuable to develop common accreditation schemes - without specifying if this should be implemented by competent authorities, by professional societies, or by complementary initiatives accrediting/authorising procurement organisations and transplantation centres on one hand, and certifying individual skills on the other hand. As the success of these activities relying on coordinators is essentially based on efforts made by human capital, efforts are required on a continuous basis, to appoint, train and keep coordination teams in place. Those Member States that have not yet taken up efforts in this field should also be encouraged to do so.

This recommendation is in line with the Council Conclusions of December 2012, which invited Member States "to provide for continuous training of professionals involved in deceased organ donation and transplantation, including both donor transplant coordinators and staff from intensive and emergency care units."

5) Conclusion and next steps proposed

Transplant donor coordinators are essential to identify donors and take care of all steps in the donation process. Their role has been **widely recognised and promoted** in Member States: these coordinators have been appointed and trained in many hospitals all over the EU, with often a national and regional or local coordination. Manuals have been developed and trainings have been organised, both at EU and national levels.

In the first half of the Action Plan, many Member States have made progress in this first priority action, with the support of the European Commission via EU-funded projects, in particular ETPOD, European Training Course in transplant donor coordination ("Train the trainers"), the manual on setting up donor coordination, and more recently the Joint Action ACCORD (link with intensive care units). These activities have resulted in strengthened capacities of donor coordination and ultimately in increased deceased donation rates.

There is consensus on the important role of transplant donor coordinators for a successful organ donation system. At the same time, not all Member States have made full use of this tool. It therefore seems important to continue the efforts, primarily at national level. Some Member States still need to improve the availability of coordinators, while for Member States that have a well-functioning system, the challenge will be to sustain and even improve it. Given the essential role of transplant donor coordinators, it is recommended to **maintain these efforts during and after the remaining period of the Action Plan**.

While not a focus for the remaining part of the Action Plan, national efforts could be supported at EU level through the Health Programme 2014-2020, in particular in the form of an EU-funded project similar to the successful "Train the Trainers" course.

Dissemination remains an important priority, and continuous collaboration with institutions such as the Council of Europe will facilitate these efforts.

For the establishment of standards of accreditation, reference is made to Priority Action 10.

4.2. Priority Action 2: Promote Quality Improvement Programmes in Every Hospital Where There is a Potential for Organ Donation

<i>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</i>	<i>(MS action, EC coordinates and monitors)</i>
<i>Action 2.2 Promote accessibility to and training on a specific methodology on Quality Improvement Programmes</i>	<i>(MS action, EC coordinates and monitors)</i>

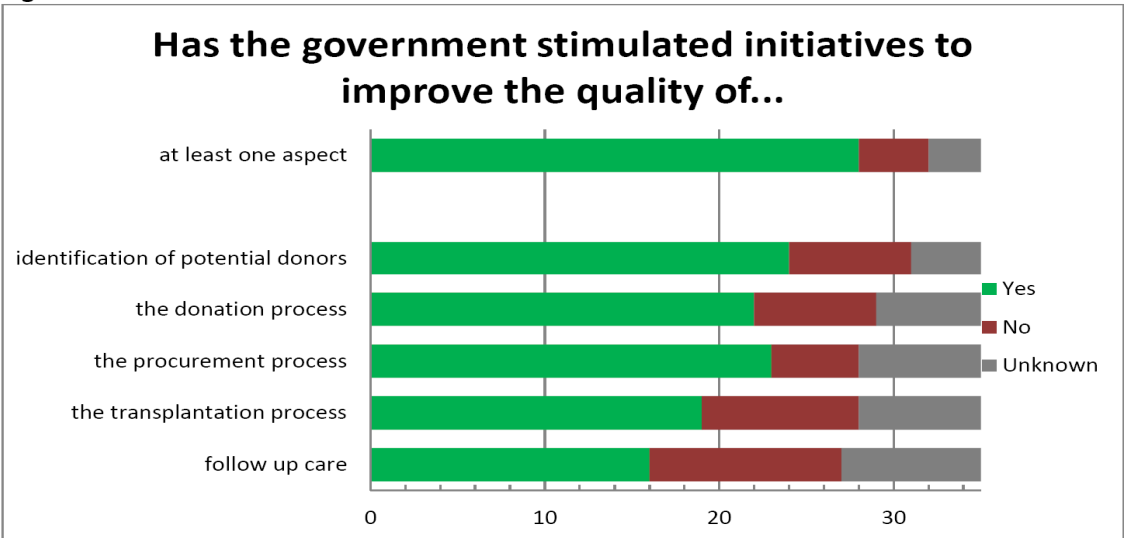
1) Introduction

The success of an organ transplant depends on a number of consecutive steps. A good final outcome, a healthy recipient, depends on the quality of each of these steps. Given the limited availability of organs, it is of key utmost importance that each is regularly evaluated to achieve the optimal outcome, in particular in the hospitals involved in procurement and transplantation.

2) Facts and figures

In 2009, eight Member States reported using quality improvement programmes (QIPs) and eight reported planning to implement such programmes. Nine out of 16 had (or were planning to implement) voluntary QIPs, whereas seven had (or were planning to implement) mandatory QIPs. Two Member States had QIPs in all donor hospitals and four had QIPs in more than 50% of hospitals. In 11 Member States, the QIPs covered the donation process, in eight the procurement process and in three the transplantation process (one MS can have three or two types of programmes). As part of the ACTOR study, a new survey was conducted in 2012 on this topic. Covering 35 countries, the study found that 28 had initiatives aimed at improving the quality of a least one of five areas listed in Figure 7 (below).

Figure 7: Initiatives stimulated by the authorities to improve quality in identification/donation/procurement/transplantation/follow-up *Source: ACTOR study, page 139*



3) Activities within the EU since 2009

Directive 2010/53/EU, adopted in July 2010, focusing on standards of quality and safety of organs, is an important driver of these initiatives. Article 4 in particular requires Member States ensure that a framework for quality and safety is established to cover all stages of the donation/transplantation process including disposal. This includes measures on traceability, reporting and management of serious adverse events and reactions, and training of relevant health care personnel. Each of these aspects can be optimised via QIPs.

Prior to the adoption of EU legislation, several activities contributed to this priority action at EU level. The Working Group on Deceased Donation (see PA1), in its manual, identified "monitoring quality and effectiveness of the process" as a "key requirement in a donation system."

Other EU funded projects and activities also provide a direct contribution to this priority action. DOPKI was one of the first EU funded projects dealing with QIPs in the deceased donation process, having produced piloted recommendations for the implementation of such programmes at a national level, detailing the methodology and producing indicators of performance. The Joint Action ACCORD, through work on twinning activities and on links between transplant coordinators and intensive care units (ICUs) (rapid improvement methodologies) is also contributing to the development of QIPs. Another important contribution was made by the EU-funded project "Organ Donation European Quality System" (ODEQUS). This project included hospitals and institutions (a few of them competent authorities) from 15 Member States plus Turkey, and developed and tested quality criteria and quality indicators at hospital level. In order to optimise ODEQUS results, dissemination has already begun, for example during the September 2013 ESOT Conference in Vienna and CA meeting in Brussels, with further dissemination and implementation work requiring the active involvement of CAs.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study compared the situation in 2009 with 2012 and concluded that:

- "There seems to be an increase in the uptake of this action. [...] In most countries some actions are undertaken to improve quality of the different steps around organ donation and transplantation.
- However, not all aspects are taken up, so this could be improved. It seems that extra efforts are needed especially in the follow-up care."

EU Health Ministers invited Member States in their Council Conclusions in December 2012 "to continue sharing expertise on all key aspects of organ donation and transplantation programmes in order to allow for mutual learning and an increase in the number of available organs." This general recommendation is linked to Priority Action 2 and can read as an invitation to aim for further quality improvement.

5) Conclusion and next steps proposed

Quality improvement programmes (QIPs), by providing methodologies and indicators for assessing and improving the different steps in the chain from donor identification to transplantation (PA2), can significantly improve donation and transplant activities in hospitals where they are taken up. In the first half of the Action Plan, efforts have been made at national level to introduce QIPs in hospitals. The EU-funded projects DOPKI, and more recently in 2013 ODEQUS, also delivered new tools - such as quality criteria and quality indicators - to set-up such programmes. Currently, the ACCORD Joint Action is developing auditing and rapid improvement tools for the process of donation after death, applicable to hospitals, but also valuable for competent authorities. The recent EU legislation offers a new framework for implementation: national transpositions of Directive 2010/53/EU provides for a consolidated set-up to introduce and implement such QIPs. National competent authorities are now required to establish a framework and issue guidance to ensure quality and safety of the whole donation - transplantation process.

Following the ACTOR study, these QIPs are so far **taken up only partly in most Member States**. Therefore more can and needs to be done, building upon results already obtained and methodologies developed. **Member States are invited to make best use of available tools**, in particular the results of the DOPKI and ODEQUS projects, as well as ACCORD activities on ICUs and twinning. The further implementation of QIPs will be an important success factor for Member States in the remaining period of the Action Plan. The results of the transposition check of Directive 2010/53/EU (launched in 2013, analysis ongoing in 2014) will provide more insight into QIPs in the different country and hospital settings. These results will be shared by the Commission with competent authorities. In addition of looking at the national legal frameworks, via the **upcoming “implementation survey” linked to Directive 2010/53/EU**, it could be verified how the implementation of QIPs is progressing and whether additional or new activity areas require the development of new QIPs, based on needs expressed by competent authorities.

QIPs offer the potential to make more organs available for transplantation within existing donation and transplantation programmes, in better quality and safety conditions. The implementation of QIPs is therefore an important topic for the national level during the remaining period of the Action Plan.

Continuing collaboration with the WHO and Council of Europe is important for improving the programmes and making them available to hospitals in as many countries as possible, both within and outside the EU.

4.3. Priority Action 3: Exchange of Best Practices on Living Donation Programmes among EU Member States: Support of Registers for Living Donors

<i>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</i>	<i>(MS action, EC coordinates and monitors)</i>
<i>Action 3.2 Promote the development of registers for living donors to evaluate and guarantee their health and safety</i>	<i>(MS + EC Action)</i>

1) Introduction

In Europe, an increasing number of kidney patients receive an organ from living donors, usually family members (related donation). To a lesser degree, there are also living donations of (partial) livers for transplantation. These living donations offer an additional source of scarce organs for transplantation, with good health outcomes for transplanted recipients.

Nevertheless, living donation carries some risks for the donor. It is therefore of key importance that the physical, social and psychological health of the living donor is well evaluated before, during and after donation.

2) Facts and figures

Many EU Member States have seen a significant increase in living kidney donation, adding up to an overall increase of more than 35% in the EU-28 between 2007 and 2012, as summarised in Table 4 (with numbers per country) and Figure 8 (EU aggregated picture). The importance of living donation has gradually increased: overall more than one fifth (21%) of kidneys transplanted in 2012 came from living donations (compared to 16,9% in 2007).

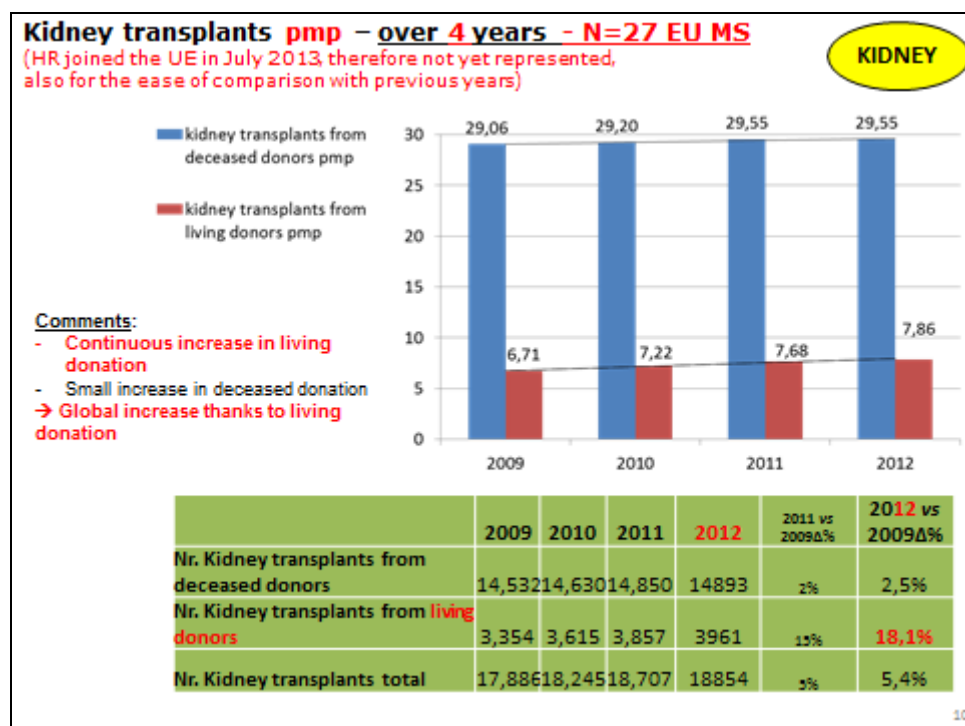
Table 4: Number of kidney transplants from living donors in Europe, 2007 and 2012

	AT	BE	BG	CY	CZ	DK	EE	FI	FR	DE	EL	HR
2007	62	42	16	36	34	56	5	5	235	567	87	0
2012	63	57	9	24	71	77	2	11	357	766	41	9
Growth	2%	36%	-44%	-33%	109%	38%	-60%	120%	52%	35%	-53%	-
	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SK
2007	17	5	99	1	9	0	0	360	22	37	152	14
2012	53	32	193	5	12	-	1	485	51	47	53	3
Growth	212%	540%	95%	400%	33%	-	-	35%	132%	27%	-65%	-79%
	SI	ES	SE	UK	EU-28	IC	NO	MK	MO	CH	TR	
2007	1	137	123	804	2926	7	86			99	911	
2012	0	361	155	1032	3960	6	81	28	4	96	2381	
Growth	-	164%	26%	28%	35%	-14%	-6%			-3%	161%	

Source: Council of Europe/ONT annual Transplant Newsletters 2008 and 2013

Figure 8 shows that the increase over time (2009 to 2012) in the number of kidney transplants over the EU is largely due to increases in kidney living donation.

Figure 8: Kidney transplants per million population 2009 to 2012



Source: CoE Transplant Newsletters, Slide prepared in February 2014 within the EU Working group on Organs' indicators under the Action Plan on Organ Donation and Transplantation

Living donation has some specific advantages over deceased donation. In particular living donation allows for optimal planning of transplantations, sometimes without the previous need of dialysis (called "pre-emptive" transplantation), a short transfer time of the organ from donor to recipient (ischemia time) and frequently good immunological matches between donor and recipient. These advantages translate into increased life expectancy and QALY (quality-adjusted life year) for recipients (see Figure 3 above (introduction), on life expectancy and QALY gain for type1 diabetic patients with renal failure, presented in the introduction).

Despite the benefit for the recipient, the safety of the (living) donor is a key concern. To maintain trust in this growing field, registers that record information on the outcomes of living donors in the short, mid and long-term are a key tool for assessing the safety of the living donation procedure. In 2009, 16 EU Member States reported having national registers for living donors. In practice, however, it is difficult to systematically follow-up all living donors.

3) Activities within the EU since 2009

Directive 2010/53/EU requires Member States to ensure the quality and safety of living donation. Article 15 of the Directive requires that measures are in place to ensure the appropriate selection of living donors, the creation of registers or records for these donors, follow-up and vigilance systems for events and reactions related to both donor and recipient. The EU-funded projects "European Living Donor Psychosocial follow-up" (ELIPSY) and the ACCORD Joint Action have complemented the legal requirements by developing standards and registries for follow-up of living donors. In particular, ACCORD is providing detailed recommendations for building up national living donor registries (data set, data dictionary, technical and organisational issues and governance), based on already existing living donor registries and expert opinion. Furthermore, by using the EULID platform, it has provided tools for competent authorities to set down their own national registry. It has finally set down the basis for a supra-national European registry of living donor registries, now being piloted.

Other EU-funded projects have significantly contributed to the development and organisation of living donor programmes in the EU Member States. EULID ("Euro Living Donor") analysed existing legal, ethical and safety practices, and produced further recommendations. EULOD ("Living Organ Donation in Europe", FP7) allowed Member States to exchange good practices and organisational models. The 2010 and 2013 ELPAT conferences ("Ethical, Legal and Psychosocial Aspects of Organ Transplantation in a European context", HP) contributed further to the dissemination of scientific information on ethical, legal and psychological aspects of transplantation.

At EU level, several Member States appointed experts to participate in a Working Group on Living Donation coordinated by the European Commission: Belgium, France, Germany, Italy, the Netherlands, Poland, Spain, Sweden, United Kingdom, as well as representatives of Scandiatransplant. This group is bringing together all these key insights into a toolbox, which will serve as a reference manual for authorities who wish to further develop their living donation activities. In addition, the EU Administrative Commission for the coordination of social security systems made a recommendation concerning financial aspects of cross-border living organ donations (Recommendation No S1 of 15 March 2012), providing common principles for national security schemes to protect living donors.

Many of these elements form the basis for the work of the Council of Europe's Transplant Committee (CoE/CD-P-TO), which aims to further strengthen the set-up of safe living donor programmes in Europe, not only in the European Union.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study found that:

- All Member States, except BG and LV, have living donation programmes, mostly limited to related donors. For some countries, this form of donation is as important as deceased donation (e.g. NL);
- 19 Member States have independent bodies to evaluate living donors;
- About half of the countries have registers to evaluate and follow-up the donor's health. This number should increase when Directive 2010/53/EU is fully implemented. EU-funded projects like EULID, ELIPSY and ACCORD support the development of these

registers, which are an important instrument to gather evidence on the consequences of organ donation during an individual's lifetime.

- EU-funded projects and conferences (EULID, ELIPSY, but also COORENOR, EULOD and ELPAT) have helped prepare the ground for living donation programmes, the different aspects of which are brought together by the Working Group on Living Donation.

The 2012 Council Conclusions:

- welcome (1) the development of a European manual and (2) the efforts undertaken by the Member States in developing living donation programmes while ensuring the protection of the living donor;
- recall (1) the requirement on the Member States to protect living donors and to ensure voluntary and unpaid donation as laid down in Directive 2010/53/EU, (2) the importance of transparent and comprehensive communication to strengthen public trust and (3) the need to scrutinize carefully the removal of organs from a living person taking account that the human body should not be used for financial gain;
- invite the Member States (1) to set up comprehensive mechanisms to protect living donors, including follow-up registers or records, (2) to create transparent and official mechanisms for reimbursing living donors and (3) to improve awareness amongst patients and their families on the different options, including living donation.

5) Conclusion and next steps proposed

Living donation programmes (PA3) are taken up increasingly in Europe, in particular for kidney donation. In order to develop this practice, protection of living donors is to be ensured, amongst others through registers for the long-term follow-up of living donors, as required in Directive 2010/53/EU. Many Member States are developing their capacities in this area, and several EU funded projects (EULID, ELIPSY, ACCORD) support their efforts. This is an area of significant EU added value and it is appropriate to **focus EU attention on this area in 2014-15**.

Living donation programmes, in particular for kidney donation, are complementary to deceased donation. In most European countries, living donation becomes an important alternative to deceased donation for patients with end-stage renal diseases (and more rarely for a liver disease). There were 4200 living donors in the EU in 2012, of which 3950 were kidney donors (almost 1000 kidney donors more than in 2007).

Living donation programmes however require trust of the general public in safety and quality for living donors. Several EU projects have been funded in order to provide tools for Member States to properly evaluate and select living donors, to follow-up their health after donation and to ensure adequate living donor care: EULID, ELIPSY, EULOD, COORENOR, currently ACCORD Joint Action and LIDOBS conference. With the adoption of Directive 2010/53/EU, article 15 requires Member States to take all necessary measures to ensure the highest possible protection of the health of living donors and to keep a register capturing the long-term follow-up of these donors.

For the remaining time period of the Action Plan it is **envisaged to focus on this priority action at EU level**, and more concretely on the common obligation to introduce/maintain registers for long-term follow-up. Concretely, it is envisaged:

- At national level: to implement good practices for living donor evaluation and selection prior to donation and follow-up after donation, including the development of registers recording information on the outcome of living donors. Ultimately, this follow-up at national level needs to capture information about all living donors and if it is conducted in compatible manner across the EU Member States - for example following ACCORD (future) recommendations - it would bring some learning for all Member States.
- At EU level: to verify national transposition, and appropriate implementation of the requirements laid down in Article 15 of Directive 2010/53/EU. This can be supported through Commission funded projects.

While the many ethical aspects of living donation fall within the competence of the Member States, the Commission continues to promote the principle of voluntary unpaid donation as enshrined in Article 13 of Directive 2010/53/EU, in close collaboration with institutions like the Council of Europe and WHO.

4.4. Priority Action 4: Improve Knowledge and Communication Skills of Health Professionals and Patient Support Groups on Organ Transplantation

<i>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</i>	<i>(MS action, EC coordinates and monitors)</i>
<i>Action 4.2 Promote training programmes geared towards health professionals and patient support groups on organ transplantation communication skills</i>	<i>(MS + EC Action)</i>
<i>Action 4.3 Organise periodic meetings at national level (competent authorities) with journalists and opinion leaders and manage adverse publicity</i>	<i>(MS action, EC coordinates and monitors)</i>

1) Introduction

Public awareness, in particular media coverage, plays an important role in the willingness to donate, both positively and negatively.

Organs are gifts from donors to patients with serious health needs, donated either anonymously by deceased donors or by living donors to relatives or friends (or to non-related patients in some specific countries through dedicated programmes). In both cases public awareness on organ donation is very important. From the point of view of deceased donation, it generates discussions within families so that relatives know about each other's views on donation. For living donation, it offers new treatment options that need to be discussed and agreed between the relatives of the patient in need. Therefore public awareness of organ donation can be a facilitating factor in increasing awareness, reflections within families, and ultimately organ availability.

The Action Plan therefore includes actions that focus on the role of media and the need to improve public awareness; to train health professionals and patient support groups on communication and to regularly meet journalists and manage adverse publicity.

2) Facts and figures

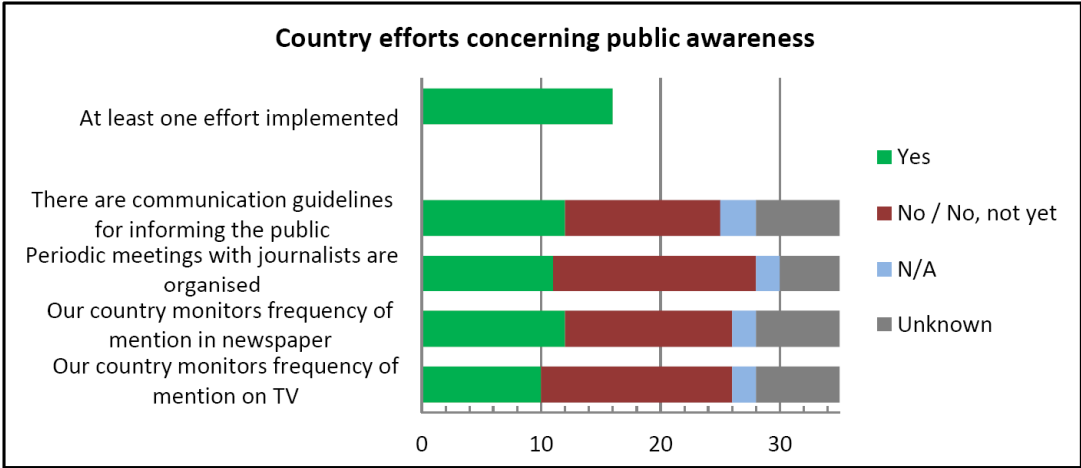
In 2009, 11 of 27 MS reported having programmes to improve hospital relations with the media. 19 had similar programmes for patient support groups. The exact nature of these programmes varies considerably and may include leaflets/brochures in hospitals (19 MS), public awareness campaigns in the media (17 MS) or investing in contacts with patients groups (15 MS). 16 Member States reported organising regular meetings with journalists (and one reported planning to do so).

In 2012, a similar survey was conducted for the ACTOR study covering 35 countries. This survey looked at both general efforts regarding public awareness (Figure 9) and specific programmes for health professionals and patient support groups (Figure 10).

The ACTOR study found that two-thirds of the 35 countries asked had programmes on communication for health professionals and patient support groups. These results suggest

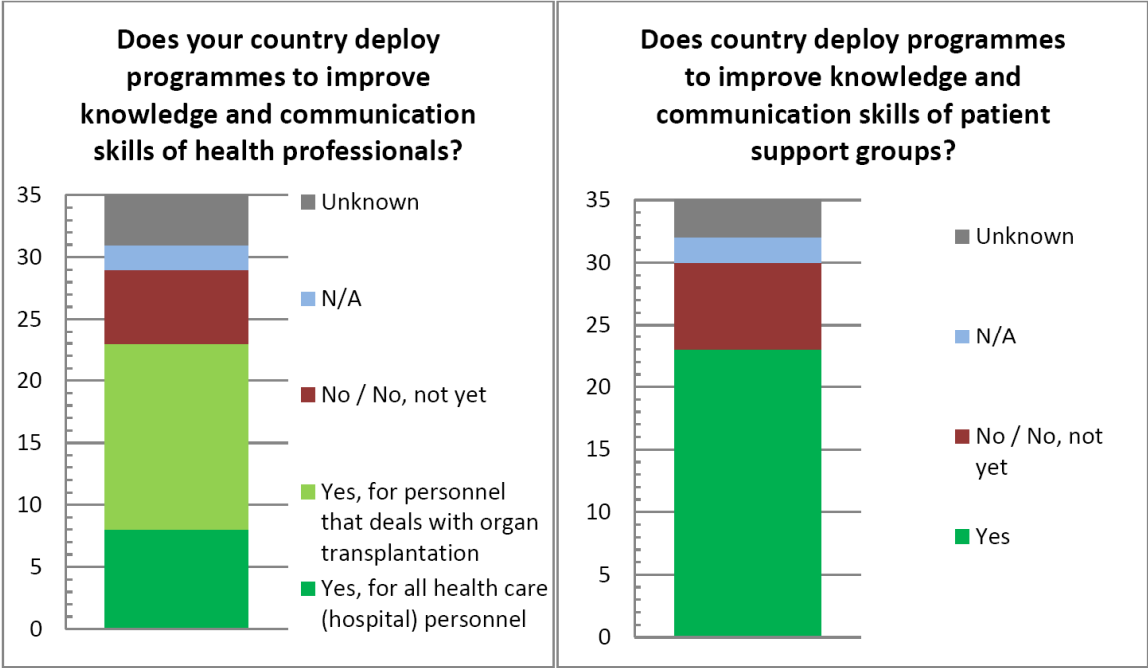
there has been little change since 2009. The programmes mainly cover training of health professionals (transplant coordinators) and, to a lesser extent, use of media officers in hospitals, as well as awareness campaigns in media, investing in contacts with patients groups and leaflets/brochures in hospitals. Other examples were a 24-hour telephone line available for consultation in Spain.

Figure 9: Country efforts concerning public awareness *Source: ACTOR study*



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

Figure 10: Programmes deployed to improve knowledge and communication skills of health professionals and patients support groups *Source: ACTOR study*



For the aspects concerning health professionals and patient support groups, not much has changed since 2009. The training of health professionals involved in organ donation (i.e. family approach), as well as cooperation with patients support groups, remain the main two areas of work. Figures 9 and 10 show indeed that 23 countries deploy such programmes in 2012, compared to only 10 countries implementing TV monitoring, to 11 countries organising period meetings with journalists and to 12 countries having communication guidelines or implementing the monitoring of mention in newspapers. The ACTOR study found in 2012 that 16 countries were engaged in "at least one effort" concerning public awareness.

3) Activities within the EU since 2009

From the data presented above, it is clear that the first type of actions implemented in most of the countries are - already in 2009 - focused on health professionals (mainly training courses) and patient support groups (leaflets/brochures). The same conclusion holds true at the EU level. Indeed, the EU-funded projects ETPOD and "Train the trainers" (described under Priority Action 1) included tools to improve knowledge and communication skills of these two groups; these aspects were assets for the success of these projects, in particular simulation of family interviews and communication with the media. The Manual on how to set-up a transplant coordination system developed under the EU Working group for deceased donation (see PA1) also included this dimension: the summary of the skills and competencies mentions "fully trained in discussing donation with families", as well as "knowledge of family and legal procedures; good verbal and non-verbal communication skills; ability to educate health professionals and the community; ability to professionally represent the organization to key stakeholders, the community and the media." It is known also that many countries implement these elements in their national/regional training courses for transplant donor coordinators, or send their coordinators to "TPM courses²⁴" where it is also included. These efforts focus mainly, within the health care sector, on transplant coordinators, and they contribute to communication to the public but are only an element of it.

To increase public awareness, the Commission also co-funded the 2010 European Organ Donation Day (EODD) in Slovenia, as well as knowledge sharing based on this experience. Guidelines were developed to be used by any countries and institutions organising awareness days or events on organ donation (EU-funded EDD project). Results are available since 2011, formulating different recommendations regarding the planning of such awareness-raising events, activities which can be implemented, promotion of the events etc. For the EODD itself, one recommendation of the EDD project is to always organise it the second Saturday in October to allow for a better identification by a larger public. Founded in 1998, EODD is an initiative of the Council of Europe. It is hosted every year by a different Council of Europe member country. The most recent editions took place in Germany (2009), Slovenia (2010), Switzerland (2011), Hungary (2012) and Belgium (2013). The European Commission supports the work of the Council of Europe on EODD and organ transplantation in general, through close cooperation - and direct funding.

²⁴ TPM stands for "Transplant, Procurement, Management": Professional training course in organ donation, organised by the same Spanish coordinator than the ETPOD project, with similar structure and which was developed also in other national versions, for France for example.

Communication to the general public must be tackled at EU level, and aligned between Member States. The FOEDUS Joint Action (2013-2016 "Facilitating exchange of organs donated in EU Member States") therefore also focuses on these communication aspects.

Since 2012, the meetings of the national competent authorities have also discussed communication issues. This enables authorities to exchange information about their communication strategies (for example for social media), and allows for the discussion of the management of adverse publicity, since media attention often covers several MS.

Most importantly, since 2010, the European Commission has organised "Journalists' workshops on organ donation and transplantation" in order to familiarise journalists from different EU Member States (mainly health correspondents in national/regional newspapers, printed or online) with the different aspects of organ donation and transplantation. The workshop covers EU legislation, Action Plan and activities, the latest developments in the field, the role of the media and different aspects important for transplantation (technical, ethical, organisational, scientific...). The workshop includes patients' testimonies and presentations by professionals. The 4th edition took place on 7 October 2013, a couple of days before the EODD. In total, about 110 journalists participated in past workshops. Articles by past participants are published on the workshop's webpage.²⁵ While not directly targeting public awareness for organ donation, an additional event was organised at EU level (by the EU Executive Agency for Health & Consumers) for journalists in June 2013 in Madrid, covering the different EU projects funded by the Commission on blood transfusion and transplantation of organs, tissues and cells.²⁶

The European Commission also cooperates with European patient support groups, such as the European Kidney Health Association (EKHA) which organises an event for the World Kidney Day every year in March (awareness-raising at the European Parliament). Many contacts also exist at national level - more "naturally" as patients are usually organised at national/regional/local level and in their own language.

4) Evaluation in the ACTOR study and views of the Council

From the ACTOR figures presented above, it is clear that:

- For all types of actions foreseen, there is still "ample room for improvement", in particular regarding public awareness and on efforts implemented only by few countries (communication guidelines, periodic meetings with journalists, monitoring frequency and nature the mention of organ transplantation in media).
- Even if more advanced, the actions regarding knowledge and communication of health care professionals and patient support groups, for example via training courses, still deserve to be better implemented.

The 2012 Council Conclusions on organ donation and transplantation invited Member States, regarding awareness-raising:

²⁵ http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm
²⁶ http://ec.europa.eu/eahc/health/EAHC_conference_2013_-_Transplantation_Blood_Transfusion.html

- 1) "to improve awareness amongst patients and their families on the different transplant options, including deceased and living donor transplantation as well as other alternative replacement therapies";
- 2) "to improve information on donation and transplantation in general" and
- 3) "to engage healthcare professionals in providing appropriate information on organ donation."

In addition to this general information for the public, Member States were invited:

- 4) "to exchange information on their communication strategies",
- 5) "to pro-actively communicate to the general public, including [via] social media"
- 6) as well as "to share information on their national donor consent systems."

5) Conclusion and next steps proposed

To improve organ donation, public awareness is a key element. **Knowledge and communication skills of health professionals and patient support groups** can be improved via training programmes, and authorities are also encouraged to recognise the important role of the mass media and the need to improve the level of information to the public on these topics as well as to organise periodic meetings with journalists.

As concluded within the ACTOR study, this priority action was implemented by **various types of measures in the different Member States** (training programmes, leaflets, meetings...). It was also supported at EU level via the EDD project or via the module on Communication within the "Train the Trainers" course. In addition, some awareness building initiatives have been taken forward like the European Organ Donation Day (EODD, with CoE) or the annual journalist workshops on organ donation and transplantation set-up by the European Commission in 2010.

Following the ACTOR study, these initiatives and efforts **needs to be continued at EU level and further developed and organised at national level**, for example via the FOEDUS Joint Action (2013-2016) and during meetings of competent authorities. It is indeed considered of increasing importance to deal proactively and in a coordinated way with negative events in the media. Awareness building initiatives that have proven valuable should be continued.

More recently, the sector has also seen new initiatives relating to social media. It is clear that best use and dealing with potential risks of these new media will also need to be addressed in the coming years. The FOEDUS Joint Action also addresses this area.

4.5. Priority Action 5: Facilitate the Identification of Organ Donors across Europe and Cross-border Donation in Europe

<i>Action 5.1 Collect and disseminate information about citizen's rights concerning organ donation across the EU</i>	<i>(MS + EC Action)</i>
<i>Action 5.2 Develop mechanisms to facilitate the identification of cross-border donors</i>	<i>(MS + EC Action)</i>

1) Introduction

This priority action concerns citizens in general, and donors in particular, that cross national borders. It is different but nonetheless complementary to Priority Action 8, dealing with organs that cross borders.

Every year a large number of citizens travel around Europe, and an increasing number are settling for professional or personal reasons in a Member State other than the one of their nationality. There may be situations where an individual is a candidate for deceased donation in a Member State other than the one where they have expressed their wishes or consent regarding donation. In this case, it is important that national authorities have rapid access to family members and consent schemes or registries in other EU Member States (amongst others when national registers are in place for expressing "yes" or "no" to donation).

Some individuals may also decide to make a living donation in an EU Member State other than their country of residence. This raises specific questions regarding the rights of these living donors, at home or abroad, in particular for access to medical care to ensure their short and long term health.

2) Facts and figures

Donor consent systems fall under national competence, and different Member States have taken different approaches to establish consent. Only four EU Member States (DE, NL, RO and UK) have an opt-in system, whereby donors have to give explicit consent during their lifetime. Other Member States have an opt-out system, where citizens are presumed to be willing to donate unless they have explicitly expressed the contrary during their lifetime. Even in those Member States with opt-out systems, citizens can sometimes often also explicitly register as a donor.

The general public awareness on the potential and value of donation is known to be important when it comes to approach donor families to ask for the position regarding donation. Often the wishes of the donor are not known at moment of death, and the consent of the next-of-kin (usually close family) is requested and respected. Following numbers available (Transplant Newsletters), family refusal rates range in European countries from less than 10% to close to 50%.

The majority of countries allow donation by non-residents and residents with a foreign nationality. Only 11 EU Member States provide easily accessible information to citizens about their legal position.

3) Activities within the EU since 2009

The COORENOR project ("COORDinating a European initiative among National Organizations for ORgan Transplantation") has allowed the building of an overview of the different national legislations, programmes and practices in the field of organ donation and transplantation. This project identified the major differences and established a common knowledge basis that allows for further cooperation between Member States, while recognising and understanding national differences. Parts of this work are elaborated further in more recent, on-going initiatives like the FOEDUS Joint Action ("Facilitating Exchange of Organs Donated in EU Member States") which will support aligned national communications, amongst others on cross-border donation.

This work is also shared and aligned with several efforts of the Council of Europe's Expert Group on Organ Transplantation (CD-P-TO) which actively looks amongst others at issues like recipients who are listed on multiple waiting lists or the protection of living donors.

Complementary to EU-funded projects, some recent initiatives add new legal elements relevant for this Priority Action. On 9 March 2011, the European Parliament and Council adopted Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (transposition into national laws for October 2013). This Directive introduces amongst others some important rules relevant for living donors abroad: medical follow-up, access to medical records, liability and complaint procedures, national contact/information points, prior authorization and cooperation between Member States, in particular neighbour countries.

In addition, the EU Administrative Commission for the coordination of social security systems made a recommendation concerning financial aspects of cross-border living donation (Recommendation No S1 of 15 March 2012), in particular access to health care for problems related to the donation, for the living donor in the country where the donation took place and reimbursement of expenses and compensation of incapacity of the living donor.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study had following main conclusions regarding this priority action:

- Differences exist between countries regarding who can be a donor. A majority of Member States (22 in 2009) allows non-residents and residents with a foreign nationality to donate, but fewer countries (seven in 2009) permit organ donation from irregular immigrants.
- Because of the potential impact of donor consent decisions and because of national differences in the role of the next-of-kin, investing more in the provision of clear information on this topic is advisable.

The Council Conclusions on organ donation and transplantation:

- welcome the planned development of a comprehensive overview of national donor consent systems.

- recall (1) the importance of encouraging people to commit to becoming organ donors after death and (2) that although this is a matter of national competence, there is a need for each Member State to clearly define and organise donor consent systems and to manage waiting lists in a transparent way at national level.
- invite Member States to share information with each other on their national donor consent systems.

5) Conclusion and next steps proposed

The topic of this priority action, facilitating the identification of organ **donors across Europe and cross border donation**, has partly been addressed in the EU-funded projects DOKPI, COORENOR and the ACTOR study. These projects confirmed that Member States have not only different organisational systems for donation and transplantation, but also different consent schemes (opt-in vs. opt-out) and tools (existence or not of registers) to identify potential donors.

While organ allocation and waiting lists management are Member States competence, the Commission continues to support Member States to build mutual understanding of national practices, e.g. via EU-funded projects (FOEDUS) and the meetings of the national competent authorities. These meetings also allow the clarification of future questions regarding the impact of EU legislation, such as the Cross Border Healthcare Directive and transplantation activities linked to Directive 2010/53/EU.

In order to ensure efficient access to national consent registers (where applicable), it will be evaluated whether a list of national contact points could and should be established for each Member State and made available to the 24/7 desks already dealing with organ allocation. Practically, this could be achieved through the IT solutions already developed (but for other purposes): with the FOEDUS Joint Action for cross-border exchange of organs, or via the “contact detail website” to be set-up with the support of Eurotransplant services to implement Article 8 of Directive 2012/25/EU (see Priority Action 8). If assessed as useful by Member States, these options could be explored and used to facilitate mutual knowledge about national consent systems and thus the identification of potential donors. Their further development will be evaluated with the assistance of the competent authorities and partners involved in these above-mentioned projects.

On related aspects like multiple listing on waiting lists or trafficking in human beings for the purpose of organ removal, it is foreseen to continue close collaboration with other institutions like the Council of Europe and WHO, with the objective to ensure consistency between countries and policies regarding cross-border donation.

Challenge 2: ENHANCING THE EFFICIENCY AND ACCESSIBILITY OF TRANSPLANT SYSTEMS

The second challenge of the Action Plan has as main objective “enhancing the efficiency and accessibility of transplant systems” by “support[ing] and guid[ing] transplant systems” (objective 4). This challenge is linked to three priority actions: enhancing the organisational models of organ donation and transplantation in the EU Member States (Priority Action 6), promoting EU-wide agreements on aspects of transplantation medicine (Priority Action 7) and facilitating the interchange of organs between national authorities (Priority Action 8).

4.6. Priority Action 6: Enhancing Organisational Models of Organ Donation and Transplantation

<i>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</i>	<i>(MS + EC Action)</i>
<i>Action 6.2 Promote twinning projects and peer reviews</i>	<i>(EC Action)</i>
<i>Action 6.3 Assess the use of structural funds and other Community instruments for the development of transplantation systems</i>	<i>(EC Action)</i>
<i>Action 6.4 Promote networks of centres of reference</i>	<i>(EC Action)</i>

1) Introduction

Much of the expertise needed to organise efficient organ donation and transplantation is available within the European Union. Many countries have looked to Spain on how to increase deceased donation rates. Lessons can also be learnt from Croatia, the newest EU Member State, which has a high rate of deceased donation. The Netherlands and the U.K. are very knowledgeable in organising living donations. Many countries have a lot of knowledge and experience on organ exchange through their participation in bilateral cooperations or in European organ exchange organisations like Eurotransplant and Scandiatransplant.

These differences between EU Member States in experience and activity levels show a true potential for sharing and leveraging this expertise amongst them, to enhance organisational models best adapted to their needs.

2) Facts and figures

In 2009, 12 Member States reported already having participated in twinning projects, either as experts or as beneficiaries. Ten reported having used peer reviews to strengthen their organisational models. Of the remaining Member States, almost all expressed an interest in these two forms of knowledge sharing.

In 2012, deceased donation rates in the EU varied significantly between Member States, from more than 30 donors per million population (pmp) to below 10 pmp. Kidney transplant rates from living donors varied from over 25 pmp to below 2 pmp. Table 5 shows that different countries are specialised in different sorts of donation and transplant programmes.

Table 5: Highest rates in Europe for deceased/living donation and for transplants of kidneys, lungs and pancreas, per million population (2012 data, CoE) (Country codes in Annex 1)

<u>Deceased organ donors</u>		<u>Kidney transplants from living donors</u>		<u>Kidney transplants (from deceased + living donors)</u>		<u>Lung* transplant</u>		<u>Pancreas* transplant</u>	
ES	35,1	TR	32	NO	59,8	AT	14,8	NO	5,6
HR	34,8	NL	29	NL	57,5	BE	11,9	UK	4
BE	30,2	IC	20	ES	54,5	CH	6,8	CH	3,8
FR	25,9	UK	16,4	HR	52,5	SE	6,3	SE	2,9
EE	24,6	SE	16,3	AT	50,4	NO	5,6	CZ	2,5

* As also highlighted earlier through Table 3, some countries have agreements in place to transplant patients from neighbouring countries, thus supporting the access for patients to transplant procedures not (yet) available in their country of origin, therefore rates presented might be partly biased by representing transplant activities of national sources as well as due to international agreements in place.

3) Activities within the EU since 2009

“Joint Actions” funded under the EU Health Programme are specifically adapted for building capacities among national authorities for the largest possible number of EU Member States (they are better adapted to this purpose than projects funded after general “call for proposals”). Several of these tools have been co-funded between Member States and Commission to bring together authorities of different EU Member States in order to strengthen the set-up of national transplant systems. The **twinning model** is often used in these settings, bringing together countries with different levels of expertise in order to maximise transfer of knowledge.

- The MODE Joint Action ("Mutual Organ Donation and Transplantation Exchanges", 2011-2012) brought together 11 countries to focus on different areas of interest (traceability, donor screening etc.) addressed through site visits, national analyses of strengths, weaknesses, opportunities and threats (SWOT) and dedicated courses.
- The ACCORD Joint Action (“Achieving Comprehensive Coordination in Organ Donation throughout the European Union”, 2012-2015) brings together 33 partners from 25 European countries. It develops dedicated twinning projects between FR and BG on the organisation of donation and procurement activities, data reporting and paediatric transplantation, between NL and HU on the development of a national curriculum for procurement surgeons and between IT and CZ, CY, LT and MT on the authorisation and auditing of transplant centres. This project will provide results transferable to other Member States.

- The FOEDUS Joint Action (“Facilitating Exchange of Organs Donated in EU Member States”, 2013-2016), bringing together 18 partners, will also contribute to enhancing organisational models, but is merely focused on cross-border organ exchange.

In addition, the COORENOR project allowed for an overview and comparison of organisational aspects and responsibilities in the different countries, and also mapped out differences in specific aspects like diagnosis of brain and cardiac death, consent and public awareness.

At the meetings of the national competent authorities, 14 Member States, as well as Turkey and representatives of the Scandiatransplant area, have presented activities under their National Action Plans to the entire group of EU Member States and associated partners. This is invaluable for exchange of best practices, questions and answers, clarifications and feedback, to the benefit of the presenting and attending Member States.

The role of European organ exchange organisations and cooperations should also be mentioned in this context. Organisations like Eurotransplant and Scandiatransplant exchange not only organs but also medical and organisational expertise amongst their members. The set-up of the South Alliance for Transplantation (SAT) between Italy, France and Spain in autumn 2012 (additional countries joined in 2013) will further add to such exchange of know-how.

In addition, the Commission and several Member States are collaborating closely with the Council of Europe in its Black Sea Area project and with WHO in the South-Eastern Europe Health Network. Both networks aim to strengthen organisational aspects and promote transplantation on a country-per-country basis in Southern and Eastern Europe. The majority of the countries involved are EU Candidate countries or are involved in EU regional partnership policies and as such are eligible for various funding mechanisms such as the Instrument for Pre-Accession funding (IPA), European Neighbourhood Policy Instrument (ENPi) or TAIEX²⁷ funding (See Annex 2).

Other Community instruments such as the EU Research Framework Programmes (FP6 and FP7) have been largely used for the development of transplantation systems (Alliance-O and DOKPI under FP6) and of transplantation techniques and programmes (RISET and Xenome under FP6; BIO-DrIM, COPE, EUROSTAM, HepaMAB, STELLAR, The ONE study under FP7, as well as EULOD for an inventory of living donation practices in Europe; See Annex 2 for the list of main EU projects funded on organ transplantation during the first half of the Action Plan).

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study had the following conclusions regarding this priority action:

²⁷ TAIEX is the Technical Assistance and Information Exchange instrument managed by the Directorate-General Enlargement of the European Commission. TAIEX supports partner countries with regard to the approximation, application and enforcement of EU legislation. It is largely demand driven and facilitates the delivery of appropriate tailor-made expertise to address issues at short notice.

- 16 EU Member States and Turkey have been involved in twinning projects, peer reviews or similar projects. The majority report a positive impact on their organ transplant activities.
- The EU provides financial support for these twinning projects and peer reviews.
- Furthermore, a small number of competent authorities reported that their country has used structural funds (for example Czech Republic, to train coordinators) and/or other Community instruments.
- A knowledge gap seems to exist among CAs on the possible use of structural funds or other community instruments such as the EU Research Framework Programmes.

The Council Conclusions on organ donation and transplantation:

- welcome (1) the setting up of cooperation agreements between national transplant organisations such as the South Transplant Alliance, (2) the sharing of expertise on transplant systems between Member States' competent authorities and with European organ exchange organisations, in particular Eurotransplant and Scandiatransplant.
- recall the need for sufficient administrative capacity within the set-up of national authorities in accordance with Directive 2010/53/EU.
- invite Member States (1) to engage actively in twinning agreements whenever they have fewer than ten deceased donors per million inhabitants or when there is a lack of specific transplantation programmes within their borders, (2) to use community instruments to build up national transplant capacities, where appropriate and (3) to continue sharing information on the set-up and funding of transplant activities and their oversight.

5) Conclusion and next steps proposed

As different donation and transplantation models exist across Europe, **enhancing organisational models of organ donation and transplantation** allows to exchanging best practices, via twinning and peer reviews.

Because it is the essence of the Action Plan and of EU-funded projects to exchange best practices, the enhancement of organisational models of organ donation and transplantation was, not surprisingly, taken up by many Member States, within (but not only) the context of numerous European projects. Several projects have been instrumental for this priority action, for example on donor coordination with ETPOD and “Train the trainers” or on living donation with EULID and ELIPSY. Some projects specifically used twinning activities, for example MODE, COORENOR on transplant organisational models and ACCORD for specific topics (organisational models in organ procurement/data reporting, developing of capacities for paediatric transplantation, auditing and authorisation of transplant centres, procurement surgery). Also EU Research and TAEIX funding was largely used (see Annex 2, respectively parts B and C) to support capacity building in the field of organ donation and transplantation in non EU countries, with the support of national experts from EU Member States. The possibility to use structural funds to develop donation and transplant activities will be further explored with the Member States, but the final decisions about funds allocation, between sectors but also within the healthcare sector, remain at national level.

Mainly twinning activities and Joint Actions (such as MODE, ACCORD and FOEDUS) have allowed for the exchange of know-how across Member States. The meetings between national competent authorities complement this exchange. In addition, the on-going transposition check and planned implementation survey for Directive 2010/53/EU will provide a good view on gaps not yet fully addressed and on practical issues to focus on within future twinning projects.

The idea of a European list of highly specialised transplant centres (“centres of reference” in the field of transplantation) was discussed with competent authorities and still requires further reflection within the context of the implementation of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare. The Commission has adopted in March 2014 the legal framework for the establishment of European Reference Networks as provided in article 12 of the Directive to boost cooperation between healthcare providers across the EU and give patients access to the highest quality of care in any given field. Consequently, this framework could potentially create opportunities for additional action in the field of organ transplantation.

Regarding capacity-building on the side of public health systems, Commission services intend to continue their good collaboration with CoE and WHO to strengthen organisational models in EU Member States as well as in Southern and Eastern European countries.

4.7. Priority Action 7: Promotion of EU-wide Agreements on Aspects of Transplantation Medicine

<i>Action 7.1 EU-wide agreement on basic rules for internal EU patient mobility and transplantation, in compliance with Community law</i>	<i>(MS + EC Action)</i>
<i>Action 7.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patients</i>	<i>(MS + EC Action)</i>
<i>Action 7.3 EU-wide agreement on monitoring organ trafficking</i>	<i>(MS + EC Action)</i>
<i>Action 7.4 EU-wide agreement on common priorities and strategies for future research programmes</i>	<i>(MS + EC Action)</i>

1) Introduction

While the term "EU-wide agreements" on aspects of transplantation medicine is not always clear, it has the merit of allowing addressing some areas which for a number of reasons (political, ethical, technical...) cannot easily be captured within legislation itself or through projects. In 2009, four such themes were identified:

- **Patient mobility:** The shortage of organs and long national waiting lists might give some EU citizens an incentive to actively look at transplant possibilities in other EU Member States. This leads to specific questions like double listing and the access of non-resident citizens to local waiting lists. It should also be remarked here that "given their specificity, access to and the allocation of organs for the purpose of organ transplants" fall outside the scope of the Cross-border Healthcare Directive.
- **Extra-Community patients:** EU transplant systems may also attract non-EU citizens in need of a transplant which cannot be organised within their own country. This issue raises similar questions to the above.
- **Organ trafficking:** Shortages might also give EU citizens an incentive to look for possibilities outside of legal schemes. This brings about issues such as trafficking of human beings for the purpose of organ removal and trafficking in human organs under what is named "transplant tourism."
- **Research** is key in transplant medicine and is happening at the international level, and also within EU Framework Research Programmes. It enables the improvement of existing activities like organ preservation, transport or surgery as well as the development of new alternatives e.g. managing immune reaction through adjuvant bone marrow transplants, regenerating organs with stem cells or artificial hearts as well as promoting good practices in living donation and developing tools that improve the quality and safety of living organ donations in Europe.

Linked to the issue of patient mobility, international agreements between countries aim at facilitating access to transplantation, for example when countries lack a specific transplant

programme (as highlighted above in Table 3). Indeed, the lack of specific programmes - such as lung transplant programmes or paediatric transplants - in a given country can lead to patient mobility within (and from outside) the EU. As bi- or multilateral agreements between countries often firstly cover the exchange of organs across border, this subject is captured under Priority Action 8. However, these agreements between countries also contribute to officially regulate patient mobility and prevent from organ trafficking.

2) Facts and figures

No data is available on the number of patients who go to other EU Member States to get a transplant. However in 2009, 19 EU Member States reported that they allow access to national waiting lists only for residents, 12 had a nationality requirement and 14 asked for membership in the national social security system. At that same time, 16 Member States reported that they require a prior authorisation for patients who wish to go abroad to obtain a transplant, however 24 said that the follow-up of these recipients would be covered by the national healthcare insurance system.

While Eurostat has begun collecting and publishing data from Member States on victims of and prosecutions related to trafficking of human beings including for the purposes of organ removal, the data available on trafficking for the purposes of organ removal is still limited and does not yet provide an accurate picture of the extent of this crime.

The Commission's Research Framework Programmes (FP) managed by the Directorate General for Research and Innovation (RTD) have been instrumental in the transplant sector. As far back as 2004, the 6th FP funded transplant-related projects, before the Public Health Programme managed by the Directorate General for Health & Consumers (SANCO) came into existence. For example ALLIANCE-O ("European Group for Coordination of National Research Programmes on Organ Donation and Transplantation") brought together some national authorities to identify relevant research priorities and programmes on organ transplantation. DOPKI ("Improving the knowledge and practice of Organ Donation") focused for the first time on donation potential and protocols/practices.

In 2009, a majority of (future) competent authorities confirmed their interest in developing reflections, and where possible agreements, in these areas.

3) Activities within the EU since 2009

While no overarching agreements have been reached, several legal and project-based initiatives have been taken on the issues mentioned.

On 9 March 2011, the European Parliament and the Council adopted Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. While this Directive ensures access to transplant programmes in other EU Member States, it also clarifies that access to waiting lists and allocation of organs remain subject to national rules. It also introduces some important facilitating rules on medical follow-up, access to medical records, liability and complaint procedures, national contact/information points, prior authorisation and cooperation between Member States, in particular between neighbouring countries.

To enhance international cooperation at EU level regarding patient mobility in the field of transplantation, the FOEDUS Joint Action funded under the Health Programme will support the exchange of organs, but will also, for countries willing to improve access to transplant procedures that they might not yet have available, enable to map obstacles to and conditions for establishing agreements between countries. Examples of such agreements already exist: Portugal and Spain engaged in a bilateral agreement by which Portuguese patients were admitted into the Spanish lung transplant waiting lists, while organs (such as lungs) procured in Portugal but without finding an appropriate recipient (or transplant centre) in Portugal were offered to Spain, and Portuguese liver urgencies were addressed by livers procured in Spain, under specific medical conditions. Practicalities and possibilities offered by such agreements will be explored within FOEDUS.

Trafficking in human beings for the purpose of organ removal is explicitly included within the scope of Directive 2011/36/EU on preventing and combating trafficking in human beings and protecting its victims and, as such, is also a focus of the EU Strategy against Trafficking in Human Beings for the period 2012-16.

Within the project SoHO V&S ("Vigilance and Surveillance of Substances of Human Origin", HP), a group of national transplant authorities has developed guidance on how to identify illegal and fraudulent activities in the transplant field. This knowledge has been the basis for a seminar in April 2013, co-funded by the Commission, that brought together representatives of transplant authorities with law enforcement officers and customs services with the objective of raising awareness of the activities involved and fostering inter-agency cooperation in order to prevent, detect and investigate instances of illegal and fraudulent activity. Recently, the European Commission has provided funding for the HOTT project (Combating trafficking in persons for the purpose of organ removal) through its Prevention of and Fight against Organised Crime Programme. This project aims to establish a list of indicators which will help to identify trafficking activities more clearly.

Many of these issues are also discussed within the expert groups of the Council of Europe (CD-P-TO) and of WHO. The first group in particular helps to address the concerns of double listing and to define and facilitate data collection related to illicit activities, while WHO is instrumental to bring these concerns onto the global agenda, e.g. through the adoption of the 2010 Madrid Resolution calling on countries to take responsibility for the development of national transplant programmes and become self-sufficient. Regarding extra-Community patients, it is also important to support efforts of non-EU countries in developing their domestic systems. The EU is assisting in this area via funding mechanisms such as the direct grant to the Council of Europe or IPA, ENPi and TAEIX grants which provide financial support towards the establishment of legitimate transplantation systems in partner countries. These systems discourage citizens from turning towards organ trafficking as a means of obtaining a much-needed treatment.

Regarding Research, the European Commission, via its EU Research Framework Programmes, has funded some projects dealing with immune reactions (The ONE study, RISE) and with xenotransplantation (XENOME). In 2013, four new research projects were launched on innovative approaches for organ transplantation, with a total value of more than 20 million euros. In addition, five projects with a value of over 25 million Euros were launched, also in 2013, on medical technologies and artificial organs (See Annex 2 for the list of projects). These research projects were presented to the European network of national

competent authorities in September 2012 and September 2013, to enhance awareness and consistency. Furthermore the Living Donation research project (EULOD)²⁸ established an inventory of living donation practices in Europe, explored and promoted living donation as a way to increase organ availability, and developed tools that improve the quality and safety of living organ donations in Europe.

In addition, activities on-going within professional societies such as the European Society for Organ Transplantation (ESOT) largely contribute to the promotion of EU-wide agreements on aspects of transplantation medicine and to the agenda-setting of transplantation research in Europe and worldwide, with international conferences and relevant publications. An excellent example of these activities is the International Conference on organ donation after circulatory death (DCD), organised in February 2013 by ESOT, for the first time with the support of four competent authorities (FR, ES, NL, UK) able to enhance such programmes - and to encourage²⁹ other public health authorities to do engage in similar DCD programmes. European organ exchange organisations such as Eurotransplant, Scandiatransplant and SAT, have dedicated scientific committees in place that also participate in the definition of and agreement upon common research priorities.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study had the following main conclusions regarding this priority action:

- It remains unclear what exactly is meant by 'EU-wide' agreements. The scope and wording of this action should be reconsidered. In its current state, the priority action is too broad to concretely provide a direction.
- A limited number of countries have agreements in place regarding the four issues.

The Council Conclusions on organ donation and transplantation, dated 7 December 2012:

- welcome the establishment and implementation of bilateral or multilateral agreements between Member States to exchange organs and patients that respect the principle of self-sufficiency in transplantation, as specified in the Madrid Resolution.
- recall that (1) organ trafficking violates fundamental human rights such as those of human dignity and integrity, and has a negative impact on public trust and potential donors' willingness to donate organs and (2) that limited knowledge and research of some scientific and organisational aspects of organ transplantation and the lack of the necessary expertise in some areas limit the further development of transplant activities within the EU.

²⁸ Living Organ Donation in Europe (EULOD) was funded under the EU Seventh Framework Programme for Research and Technological Development (FP7). For more information: http://ec.europa.eu/research/health/public-health/health-systems/projects/living-donation_en.html

²⁹ This type of donation is largely increasing and constitute another source of organs alternative to donation after brain death, but it also implies the implementation of a different organisation (and possibly national legal framework).

- invite the Member States to support national and international collaboration, as appropriate, between transplantation authorities and police and customs services in order to detect and prevent organ trafficking.
- invite the European Commission (1) to include organ transplantation within the scope of EU initiatives against trafficking of human beings, in line with recommendations of the World Health Organisation and the Council of Europe and (2) to address research on technical and organisational aspects of transplantation within the European Research Programme Horizon 2020.

5) Conclusion and next steps proposed

Challenges such as patient mobility, research or organ trafficking call for **the promotion of EU-wide agreements on aspects of transplantation medicine**. Four work areas were identified within this priority action, all to be supported by EU-wide agreements: internal EU patient mobility for transplant purposes, transplant medicine for extra-Community patients, monitoring organ trafficking and common priorities and strategies for future research programmes. The ACTOR study suggests that this priority action has not received very significant or visible attention, at least by the authorities identified as "competent authorities in charge of organ transplantation" in EU Member States. An important reason relates to the fact that these national authorities for transplantation (Public Health actors) are **not directly in the lead to formulate the policies in these areas**, even if they are associated to them. While these topics have an important impact on the current and future transplant landscape, their main directions are set out by other departments: social insurances, justice, law enforcement and custom services, research and policy makers. It may therefore be valuable to **strengthen links with these others actors and authorities**, mainly in the field of research and justice. A common approach from the transplant authorities towards such areas, could be considered as valuable inputs to policies and initiatives of other counterparts at national level.

At EU level, such approach was already successfully taken up within the European Commission for the 6th and 7th Research Framework Programmes (see Annex 2 for a non-exhaustive list of EU-funded research projects on transplantation: at least 70 million euros for 15 projects from 2005 to 2017). The Commission ensured, during the preparation of the future EU Research Programme "Horizon 2020", that **research projects on transplantation** will again have the possibility to compete with other health topics for research funding during the period 2014-2020. Professional societies also play a key role to agree on common research priorities linked to transplantation (such as donation after circulatory death) for the near future.

Regarding **patient mobility** and EU-wide agreements, it is considered necessary and appropriate, for the remaining time period of the Action Plan, to take into account the transposition into national laws of the Cross-Border Healthcare Directive (2011/24/EU) and the EU-funded project FOEDUS (Facilitating Exchange of Organs Donated in the EU). Both will provide new instruments, in the form of a general legal framework and a specific tool, for developing agreements regarding EU patient mobility and transplantation, in compliance with Union law.

Many **trafficking** issues are related to the EU borders, and a good collaboration with actors in the field of justice, police and customs needs to be established. For the last area, consistency

is already sought and should be strengthened with counterparts within the Council of Europe and WHO.

This priority action covers elements which do not directly fall in the mandate of the competent authorities in charge of organ transplantation. It has been addressed via EU Research funding and collaboration with key partners such as the Council of Europe and WHO, but it has also proven to be difficult to implement in a coherent manner and to ensure adequate follow-up. As suggested in the ACTOR study, this priority action requires discussion with the competent authorities and professional societies. As it is however largely based on cooperation with other sectors, primarily at national level, and is bound by national decisions within the healthcare systems (patient mobility and extra-Community patients), it is proposed to encourage Member States to **reinforce consistency between activities and policies at national level and among partners in and outside the EU**. The area would thus not be a major focus at EU level for the remaining duration of the Action Plan.

4.8. Priority Action 8: Facilitation of the Interchange of Organs between National Authorities

<i>Action 8.1 Evaluate procedures for offering surplus organs to other countries</i>	<i>(EC + MS action)</i>
<i>Action 8.2 Put procedures in place for the exchange of organs for urgent and difficult-to-treat patients</i>	<i>(EC + MS action)</i>
<i>Action 8.3 Design IT tools in support of the previous actions</i>	<i>(MS + EC Action)</i>

1) Introduction

When it is not possible to allocate an organ in the country of procurement, exchanging organs across borders is one of the most efficient ways of reducing organ shortages. It allows for the optimal use of all organs (possibly) procured (the organs not procured and therefore not transplanted if no cooperation is in place were often called “surplus organs”, but this wording should be avoided in times of organs shortages). In addition, exchange of organs can contribute to the overall health outcome, by optimising the match between recipient and transplanted organ.

Agreements between countries to exchange organs sometimes can also cover the mobility of patients going abroad for treatment. These agreements allow smaller Member States to avoid discarding organs that they cannot transplant, and to see their patients transplanted, without the need to invest in all types of transplant programmes. This offers more cost-efficient health solutions.

Exchanging organs, however, requires good coordination. Many aspects need to be agreed upon like communication in case of emergencies, transport, funding, import/export legislation, allocation rules, and management of waiting lists. Often offering "surplus organs" (organs for which no local recipient is found) is a good first step that can help build the relationship between health authorities in different Member States.

2) Facts and figures

The large majority of EU Member States indicated already in 2009 that they are part of an organ exchange agreement. Countries also indicated that they rely on organ exchanges for specific situations like urgent transplant needs (10/22), paediatric patients (6/22) and rare HLA patterns (4/22). This high participation rate was confirmed in a 2012 survey, asking for the main organ types that were exchanged (Table 6).

These agreements can be either bilateral, involving just two countries, or multilateral as within areas of European organ exchange organisations (EOEOs) such as Eurotransplant (AT, BE, DE, HR, HU, LU, NL, SI), Scandiatransplant (DK, FI, IC, NO, SE) and the South Alliance for Transplantation (ES, FR, IT, CZ, PT, CH). These organisations are fully part of the European landscape and are recognised under Directive 2010/53/EU (Article 21). They actively participate in meetings of competent authorities in Brussels as well as in EU-funded projects.

Table 6: Number of Member States with agreements to exchange organs or patients (2012 survey)

(Sources: ACTOR study (2012), Indicators' Working group)

Kidney		Liver		Heart		Lung	
yes	No	Yes	No	yes	no	Yes	No
17	8	20	5	17	8	19	6
Pancreas		Small bowel		Combined organs		One or more	
yes	No	Yes	No	yes	no	Yes	No
12	13	13	12	11	14	21	4

To highlight the added-value of cross-border exchanges of organs in particular for countries with less than 15 million inhabitants who do not have the capacities to develop the whole range of transplant programmes, Eurotransplant (ET) proposed a comparison between ET countries and other countries of a similar size not part of an EOEO (Table 7).

Table 7: Estimating the increase in organs with better use of available donor organs

Transplanted organs per donor in countries with less than 15 Million inhabitants				
Eurotransplant (ET) countries versus countries without multinational collaboration				
Donors and Transplants (Tx) per donor (p.d.)	ET countries < 15 Mill. population		EU countries < 15 Mill. population - not multinational	
Deceased donors	813 (19,3 pmp)		1061 (15,6 pmp)	
Multi-organ donors	78,7%		57,3%	
Tx kidney p.d.	1,74		1,67	
Tx liver p.d.	0,76		0,51	
Tx heart p.d.	0,27		0,20	
Tx lung p.d.	0,28		0,07	
Tx pancreas p.d.	0,13		0,07	
<ul style="list-style-type: none"> If the use of donor organs in EU countries with a population of < 15 Million (currently without established international collaboration) would be similar to that of the small Eurotransplant countries, the number of available donor organs would increase by: 				
88 kidneys	265 livers	89 hearts	222 lungs	68 pancreas
<ul style="list-style-type: none"> This is a total increase of 732 organs or 2 organs per day over a year without any increase in the number of utilised donors / donation rates pmp 				
Sources: Transplant Newsletter 2010 and Eurotransplant Medical Director A. Rahmel, Kick-off meeting of the EU-funded FOEDUS Joint Action, 7 May 2013				

NB: this extrapolation made for Eurotransplant countries is only an example. Similar calculations could be implemented for other European Organ Exchange Organisations.

Countries that are not part of a collaboration have a lower rate of multi-organ donors. Eurotransplant highlighted that whereas kidneys transplanted per donor are similar for both areas, **other organs such as livers, hearts, lungs and pancreas could be more efficiently “used”** in ET countries, and with the same numbers of deceased donors, it would be possible to have for the countries considered 732 more organs available, i.e. two organs per day. These calculations emphasize the added value, in particular for countries with less than 15 million inhabitants, of being members in EOEOs such as Eurotransplant, Scandiatransplant or the South Alliance for Transplantation.

3) Activities within the EU since 2009

Within the COORENOR project, an IT-platform was developed enabling participating countries to offer amongst themselves organs that cannot be allocated in the country of origin. Some first offers and exchanges of organs have taken place during the pilot phase in 2012. The FOEDUS Joint Action is continuing the development of this platform, with other EU Member States joining it. This Joint Action also allows for the development of the necessary agreements between Member States.

In addition, in October 2012 the Commission adopted Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation. This Directive, to be transposed into national laws by 10 April 2014, will facilitate the potential exchange of organs between Member States, by streamlining communication on organ and donor characterisation, traceability and vigilance (reporting of serious adverse events and reactions). The implementation of this recent piece of legislation and recommendations might vary between Member States (to be confirmed via a “transposition check” after transposition) and has triggered some first questions for national competent authorities. The twice-yearly meetings of national competent authorities offer the forum to allow Member States to exchange views and explain national practices and find common answers. To operationally support the implementation of Article 8 regarding the “interconnection between Member States”, a “contact detail website” is being established with all contact details of the competent authorities and delegated bodies in charge, duly shared - and later on, if necessary, updated - by Member States.

While the Commission can only offer support that facilitates the exchange of organs, the Member States have also moved forward. In 2012 the South Alliance for Transplantation (SAT) was founded by IT, FR and ES (joined in 2013 by CZ, PT, CH), amongst others to work on cross-border organ exchange programs, in particular for urgent, paediatrics (0-5 years) and difficult-to-treat patients. Furthermore SAT is developing a cross-border exchange of paired kidney donation, joint audits for quality assurance, common education programs on public awareness and communication and other exchanges of knowledge and experience. In parallel, the Eurotransplant group has expanded to include Hungary in 2013, with a “phase-in” in 2012. The principal activity of organisations like Eurotransplant and Scandiatransplant is the exchange of organs for their best use and for better health outcomes, but they also include educational programmes and exchange of best practices among peers. As already highlighted under Priority Action 7, several countries are involved in bilateral agreements to address specific patients' needs like access to lung transplant programmes, transplants of combined organs or paediatric liver transplants. In addition, some Member States have ad-hoc exchanges of organs to address specific situations like urgent needs or paediatric organs.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study had the following conclusions regarding this priority action:

- A large majority of the CAs report that they are part of at least one established collaboration with other countries. The respective exchange programmes cover urgent needs, paediatric needs, patients with rare HLA patterns, difficult-to-treat patients or organs otherwise not transplanted. A limited number of countries report that their country evaluates procedures for offering non allocated organs to other countries.
- Less than one third of the CAs report participation in at least one IT-tool for the facilitation of cross-border organ exchanges. Further development of this approach through FOEDUS should be stimulated.
- With the adoption of Directive 2012/25/EU in October 2012 harmonised rules are being established to exchange information about organs that are transplanted in another Member State than the State where the organ was procured. This Directive will not help to have more organs exchanged, but should facilitate and streamline the exchange of information when organs are exchanged.

The Council Conclusions on organ donation and transplantation, dated 7 December 2012:

- welcome (1) the establishment and implementation of bilateral or multilateral agreements between Member States to exchange organs and patients that respect the principle of self-sufficiency in transplantation, as specified in the Madrid Resolution³⁰ and (2) the setting up of cooperation agreements between national transplant organisations such as the South Transplant Alliance.
- recall the significant opportunity that exists to treat more patients and to use an increasing number of available organs effectively within the Member States through the conclusion and implementation of bilateral or multilateral agreements between Member States.
- invite Member States to engage in operational cross-border exchange of organs, including through the participation in a Joint Action dedicated to cross-border exchange agreements starting in 2013 (FOEDUS).

The possibilities and value of cross-border exchange of organs were also explicitly addressed and supported by EU Health Ministers during their Informal Meeting³¹ on 10-11 July 2012.

5) Conclusion and next steps proposed

Increased **exchange of organs across borders** allows making significantly more organs available (organs which may otherwise not have been procured from existing donors) and in addition to find a better match between organ and recipient. Much here can be learned from existing European organ exchange organisations like Eurotransplant, Scandiatransplant and SAT, but also from bilateral agreements between authorities.

³⁰ The Madrid Resolution on organ donation and transplantation: national responsibility in meeting the needs of patients, guided by the WHO principles (Third global consultation organized by the WHO)

³¹ Cross-border collaboration in the field of organ donation and transplantation, examples and potentialities. <http://www.cy2012.eu/index.php/en/file/4eNC84phxCn2nxXo9+AUZw==>

An **IT-tool** to exchange these organs otherwise not allocated has been developed and piloted in the COORENOR project, which was finalised in 2012. The **FOEDUS Joint Action**, which started in mid-2013, will further expand this platform in Europe, inviting national authorities that were not part in COORENOR to join within FOEDUS, and ultimately all EU Member States and associated countries to participate. It will also develop **procedures to offer these organs across borders, in particular for urgent and difficult-to-treat patients**. Within the same project, templates for agreements covering the many practical aspects (funding, transport, language...) will be prepared and presented during the regular meetings of competent authorities.

The high potential of organ exchange, and the added-value of EU cooperation in this field, already experienced, make this priority action an **important focus for 2014-15 at EU level**. The transposition into national law of Commission Implementing Directive 2012/25/EU is due by April 2014. At that moment, a central website will be made available including all contact details for communication between national competent authorities of the necessary information regarding the organs exchanged (organ and donor characterisation, traceability, reporting of serious adverse events and reactions).

Challenge 3: IMPROVING QUALITY AND SAFETY

The third challenge of the Action Plan has as main objective “improving the quality and safety of organ donation and transplantation” (objective 5) and is linked to the last two priority actions of the Action Plan. These priority actions are complementary to Directive 2010/53/EU, which is also focused on quality and safety, and cover two aspects: follow-up of post-transplant results (Priority Action 9) and accreditation schemes (Priority Action 10).

4.9. Priority Action 9: Evaluation of Post-Transplant Results

<i>Action 9.1 Develop common definitions of terms and methodology to evaluate the results of transplantation</i>	<i>(EC Action)</i>
<i>Action 9.2 Develop a register or network of registers to follow up organ recipients</i>	<i>(MS + EC Action)</i>
<i>Action 9.3 Promote common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors</i>	<i>(EC Action)</i>
<i>Action 9.4 Develop and promote good medical practices on organ donation and transplantation on the basis of results, including the use of expanded donors</i>	<i>(EC Action)</i>

1) Introduction

Organ transplantation does not end with the surgery itself: Transplanted patients must take immunosuppressive drugs to avoid organ rejection and their health situation needs to be monitored. Post-transplant follow-up is therefore crucial.

By centralising and assessing these follow-up data important lessons can be learned for future transplantation practices. This data, systematically collected and analysed can, for example, demonstrate if, and which organs, can be successfully transplanted from older donors. Given the scarcity of available organs and the risks inherent to organ transplantation, it is essential that the medical community is able to continuously improve transplant practices.

While not making it mandatory, Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation underlines the need for and importance of evaluating follow-up results in its Recital 24.

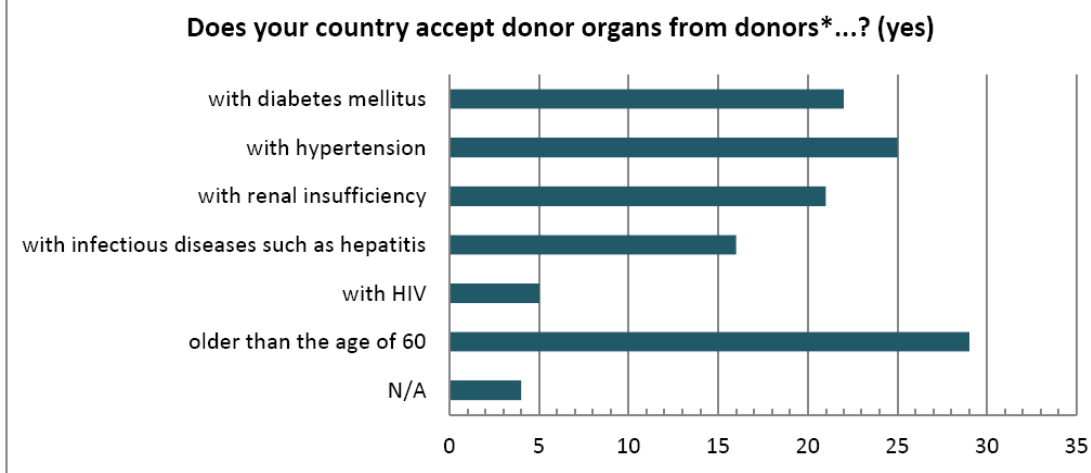
In addition, EU data protection requirements and in particular those laid down in Directive 95/46/EC and in Regulation 45/2001/EC need to be complied with. Article 8 of the Directive and Article 10 of the Regulation have special provisions regarding the process of personal data concerning health.

2) Facts and figures

In a 2009 survey, 17 out of 27 Member States reported that they systematically collect follow-up data, while 6 mentioned that they do this in a non-systematic way. 16 out of these 23 Member States mentioned that they carry out post-transplant follow-up at national level and 15 per transplant centre. In 2012, the ACTOR study found that 23 out of 35 countries try to systematically collect follow-up data in a database/register, with one more in a non-systematic way. Follow-up data are most often collected annually or at quarterly intervals.

Having good follow-up data is essential if the medical community wants to assess the outcomes of transplants in general terms and with expanded criteria donors in particular, e.g. older than 60 or with a specific disease. Such transplants allow for new sources of scarce organs for more patients. The 2012 ACTOR survey found that an important number of countries are already transplanting organs from expanded criteria donors (Figure 11):

Figure 11: Acceptation of donor organs from expanded donors *Source: ACTOR study*



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

These results of the ACTOR study might need to be re-visited as they are just a snapshot at a certain moment (in 2012) of options envisaged (and not necessarily put in practice) in the different countries regarding expanded donors. These results have the value to show that different policies, or practices, are in place in the different Member States regarding the acceptance of expanded donors.

3) Activities within the EU since 2009

There are many medical questions (long-term survival of transplanted patients, donor and recipient factors influencing transplant outcomes...) that cannot be addressed in a satisfactory manner to date, because insufficient follow-up data are available. Donors with special conditions also represent a complementary challenge regarding the follow-up of transplanted patients. For example in an ageing population, donors are also increasingly older, and thus risks of diseases transmissions are often higher. Results from transplants from these older donors and 'expanded criteria donors' such as with HIV/AIDS, hepatitis or other infectious diseases must be carefully monitored and documented. The follow-up of the transplanted patients who have received organs from these donors must be ensured all along their life and results shared within the scientific community, in particular to know how the 'expanded

criteria' in accepting these donors satisfy safety conditions in term of risk of developing infectious diseases at short and medium term.

Collecting these data in a systematic way and bringing them together at European level would improve the situation significantly. DOPKI was the first EU-funded project dealing with the safety limits with the transplantation of organs of expanded criteria donor. A dedicated European registry was developed to share information on the outcomes of recipients transplanted with donors with a past or present history of malignancy, specific infectious diseases and other conditions. The EU-funded project called "European Framework for Evaluation of Organ transplants" (EFRETOS), run by a consortium led by Eurotransplant, also addressed the topic of post-transplant outcomes. In this project, 21 Member States designed a blueprint for the future establishment of a European Registry of registries on pre- and post-transplant outcomes. It also addressed the development of national systems for the reporting and management of adverse events and reactions. While more funding would be needed to effectively build the register of registries, the European Commission has encouraged Member States to start systematically collecting and analysing post-transplant results taking account of the EFRETOS outcomes.

However a number of obstacles still need to be overcome. In the Working Group on Indicators, run by the Commission, the health outcome data collected still seem to be fragmented. The EFRETOS project reached the same conclusion.

Table 8: Registers available for the follow-up of transplanted patients, 2011 and 2012

NB: Answers per country. Please read: in 2011, 18 countries (of 34 countries) reported having registers available to follow-up kidney transplanted patients, 6 countries reported not having registers. In 2012, 18 countries reported to have registers and 11 countries not to have registers. In 2012, totally, 32 of these 34 countries had kidney transplant programmes in place.

Registers available for:	Post-transplant follow-up		Assumption for 2012**	Countries with such transplant programmes running in 2012 (see also Table 3)
	2011*	2012 *		
Kidney yes/no	18 / 6	15 / 11	18 / 11	32
Liver yes/no	16 / 8	14 / 12	16 / 12	27
Lung yes/no	12 / 12	13 / 13	13 / 13	20
Heart yes/no	14 / 10	13 / 13	14 / 13	27
Pancreas yes/no	10 / 14	10 / 16	10 / 16	20
Small bowel yes/no	6 / 18	5 / 21	6 / 21	7

Source: aggregation of national answers to the voluntary Indicators' exercises 2011 and 2012 under the Action Plan

* Not all countries have answered for both 2011 and 2012 exercises.

** Assuming that all countries which answered "yes" in 2011 still have a register in 2012.

Sometimes registers or databases exist (see Table 8), but without comprehensive information collected in a consistent way. In other cases, sometimes follow-up data is collected at the level of transplant centres, but are not fed into a register/database. As an example, within an

exercise in 2011, 18 countries mentioned that they have registers on kidney transplanted patients, but only nine countries provided (partial) data for the 1-year follow-up of 2009 transplants. From these countries, only countries with fewer than 500 kidney transplants per year showed good data completeness. This therefore does not allow for solid interpretations or comparisons at this moment. On an aggregated level, first data however seem to indicate high survival rates of grafts (transplanted organs) and patients, who otherwise would have died.

Table 8 shows that there are still countries without follow-up registers for specific types of organ transplants, even when they actually transplant this type of organ. The information collected on a regular basis to feed these registers (e.g. 1 month / 3 months / 1 year / several years... after transplantation) capture different follow-up aspects and two important indicators are the patients' survival and the grafts' survival.

Finally, it is worth mentioning that the Council of Europe's "Guide to the quality and safety of organs for transplantation" also covers post-transplant aspects and encourage a comprehensive data collection. This guide is directed towards professionals in the field and covers in particular specific risk factors like transmission of infectious diseases or neoplasia transmission. The European Commission supports the Council of Europe's work via a direct grant and contributes to this Guide, amongst others with contributions on EU legislation and EU-funded projects.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study had the following conclusions regarding this Priority Action:

- While collecting and analysing data is seen as relevant by nearly all countries, it is unclear whether results from different countries can be compared at European level.
- A majority of countries try to systematically collect post-transplant results in a database/register.
- Data should be explored to verify the results of the use of organs procured from expanded donors, such as donors older than 60, with diabetes mellitus, hypertension, renal insufficiency, hepatitis or HIV.
- The currently available data for Member States is not fully comparable e.g. as not all countries use the same timeframe for the measurement of post-transplant results. For mutual learning it is essential to agree upon shared definitions and procedures for collecting and reporting such data.
- EU-funded projects have contributed to the progress achieved. This priority action is now set for the final phase: Implementation of post-transplant follow-up by as many countries as possible. Some complex ethical issues and the question of ownership of data will need to be addressed.

The Council Conclusions on organ donation and transplantation, dated 7 December 2012:

- recall the need to improve knowledge on health outcomes in transplanted patients in order to further optimise transplant activities taking into account the scarcity of organs.

- invite the Member States to (1) share expertise on the transplantation of organs from expanded criteria donors (for example older donors) in order to increase the number of available organs, while setting the quality and safety limits of such practice and (2) to engage in collecting and sharing knowledge about quality and safety and in setting up standardised patient follow-up registers or records, based on models commonly developed and agreed upon.

5) Conclusion and next steps proposed

The **evaluation of post-transplant results** is not only important for recipients themselves, but also of key interest for health professionals to share learnings on how best to allocate and transplant the limited supply of available organs. The EU-funded EFRETOS project has laid out a common methodology to organise such follow-up in a harmonised way all over the EU, in line with EU data protection requirements. It also produced recommendations for the reporting and management of adverse events and reactions at a national level, but consistently throughout the EU. The **effective set-up of such an EU-wide register of registers and the model for organ vigilance**, as proposed in DOPKI and EFRETOS results, would require better implementation at local/hospital level, national level and EU level. The need for a major project, with active involvement of Member States and professional associations, will therefore be assessed, including sensitive factors like data sharing and hosting. The financial support of the Commission within the next Health Programme 2014-2020 and guidance developed by the Council of Europe can facilitate these developments, but **Member States' willingness and resources are the first pre-requisites**. Such a large-scale EU project could not be started before 2015, as the objective goes beyond the actual time period of the Action Plan 2009-2015. Member States can however start implementing the EFRETOS methodology at national level. They can also strengthen their links with professional societies which have such registers in place for the different types of transplant procedures. Indeed common registries (depending on the kinds of organs transplanted) building upon DOKPI and EFRETOS results, and well interlinked, on a cooperative basis, with already existing European registries (managed by professional societies and to which many competent authorities already provide data) would be of significant value for the professional community. It would allow e.g. for the assessment of the risks and benefits of transplanting organs of new, "expanded criteria" donor types. With an ageing European population, it is useful to explore the field for increased and optimal use of expanded donor organs.

The feasibility to support (a) European register(s) of registries may be verified. For 2014-15, the follow-up of organ recipients, and possible registers, are for primary implementation at the national level, and for cooperation with professional societies.

4.10. Priority Action 10: Promotion of a Common Accreditation System for Organ Donation/Procurement and Transplantation Programmes

(no specific actions were defined)

(no specific assignments were made)

1) Introduction

The last priority action deals with accreditation of donation and procurement activities as well as of transplant programmes. The wording is general and does not specify concrete actions nor assigns roles to Member States or the European Commission as it was done for other priority actions. An "accreditation scheme" may refer or be related to different activities: certification, authorisation or training, which can be organised or recognised, in this field, by different actors: competent authorities, professional societies, educational systems. For example, the delivery of an authorisation for a procurement or transplant programme by a competent authority might be conditional on the fulfilment of a range of criteria such as a specific diploma or regular training courses. Several of the tasks identified for the competent authorities in Directive 2010/53/EU (which was not in place at the moment of the adoption of this Action Plan) are directly related to this priority action. As stated in Article 17 (2), the competent authority shall in particular "take the following measures: [...]"

(b) ensure that procurement organisations and transplantation centres are controlled or audited on a regular basis [...],

(c) grant, suspend or withdraw, as appropriate, the authorisation of procurement organisations or transplantation centres from carrying out their activities where control measures demonstrate that such organisations or centres are not complying with [...] this Directive;

(e) issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal [...]"

Thus not only training programmes, certification schemes, but also administrative procedures to authorise activities in hospitals, as well as the links between these activities and procedures need to be analysed to "promote a common accreditation system". In addition, accreditation and authorisation can directly apply both to professionals and to teams such as transplant donor coordinators (nurses or medical doctors), intensive care professionals, procurement surgeons/teams, transplant teams.

2) Facts and figures

The heterogeneity of topics mentioned and of professionals concerned under the term accreditation in this field makes it difficult to survey and compare the status of this priority action in the Member States. Nevertheless, for the 2012 ACTOR study, 17 Member States responded as having accreditation systems in place. Authorities reported large differences between countries in the type of accreditation systems in place, revealing a mix of guidelines and mandatory procedures to accredit transplant activities and professionals. Some countries combine both approaches (national auditing programmes e.g. in Italy, France and Spain, formal accreditation scheme in Cyprus and the Netherlands, authorisation of transplant in Turkey since 2000...).

The systems are developed by different bodies like for example for procurement teams, defined by professional associations such as the Dutch Association of Surgery or the German Medical Association, in EU-funded projects (ODEQUS guidelines, ACCORD Joint Action in twinning work package). Some authorities mix different approaches: Hungary recognises a joint accreditation by the Division of Transplant of the European Board of Surgery and the European Union of Medical Specialists (UEMS).

3) Activities within the EU since 2009

Several EU-funded projects offer good groundings and frameworks for accreditation efforts.

While the ETPOD project and the European training course ("Train the trainers") (both described under Priority action 1) were not a formal accreditation as such, these training activities were often recognised by the Competent authorities (who had nominated national candidates to participate) and were therefore validated within national accreditation schemes.

Quality criteria and indicators within the chain from organ donation to organ transplantation (and follow-up of transplants), developed in the ODEQUS project (see Priority Action 2) also provide tools for accrediting donation, procurement and transplant activities. An E-learning platform for thoracic organ recovery has been developed within the Joint Action ACCORD, by the Netherlands to train Hungarian surgeons, with the active involvement of the European Society for Organ Transplantation and following testing by 47 UK surgeons. For Hungary, this will deliver an effective training and a certification module officially recognised by the Competent Authority, which uses the opportunity to develop procedures to put in place national schemes for training and authorisation, as required by Directive 2010/53/EU. This tool will be made available to all competent authorities. Within the same twinning work package of ACCORD, the Italian Competent Authority is supporting four countries (Czech Republic, Cyprus, Lithuania, and Malta) to "develop a system for accreditation and audit of organ donation and transplantation activities". Here also, results obtained by 2015 will be transferable and presented to other countries.

Complementary to EU-funded projects and initiatives of Competent Authorities, activities of European professional societies should also be mentioned, in particular the Union of European Medical Specialists and the European Society for Organ Transplantation. The Board of Transplant Coordination (BTC) and EDTCO (European Donation & Transplant Coordination Organisation) - division within the UEMS and a section of ESOT, respectively - have developed the Certification of European Transplant Coordinators (CETC). This certification accredits the knowledge, training and experience of professionals, taking account of job profile, training, experience, participation in research and teaching as well as knowledge measured in an examination offered annually. Additional initiatives exist like the "European Diploma in Transplantation Surgery" (organised by the European Board of Transplant Medicine of the UEMS Division of Transplantation in collaboration with ESOT), the "Examinations in Transplant Immunology" (proposed by the UEMS Board of Transplant Immunology) or training, accreditation and certification schemes offered by organs-specific professional associations, e.g. in the form of a conference recognised with credits by the European Accreditation Council for Continuing Medical Education (EACCME).

The use of accreditation and certification has been strengthened by the adoption of Directive 2010/53/EU. This Directive calls on Member States to ensure safety and quality of procurement (Article 5) and transplantation activities (Article 9) as well as qualifications of

healthcare staff (Articles 4, 6 and 12). Some Member States have therefore already chosen to recognise these international accreditation tools as part of their national authorisation processes.

4) Evaluation in the ACTOR study and views of the Council

The ACTOR study had the following conclusions regarding this priority action:

- More than half of the CAs indicate that additional plans or actions have been undertaken to promote an accreditation system for organ donation/procurement and transplantation programmes.
- There is however a great variety in topics, thoroughness and whether or not accreditation is evaluated. For countries developing an accreditation system, it might be valuable to learn from others. For countries with a more developed accreditation system, it might be worthwhile to share their experiences with others and to invite other countries to participate in the role of auditor.
- If tangible results are expected from this priority action at the end of the Action Plan, a thorough discussion of this priority action is required and a new, more concrete, course of action should be determined.
- With Directive 2010/53/EU, a new tool is also available: EU Member States (and the European Commission) have the possibility to request to each other to "provide information on the national requirements for the authorisation of procurement organisations" and "transplant centres" (Articles 5 and 9). As authorisation and accreditation are often closely linked, this can now be explored.

The 2012 Council Conclusions on organ donation and transplantation invited Member States in December 2012 "to share [their] national procedures for authorisation of procurement organisations and transplantation centres", thus building upon the new possibilities offered by the Organs' Directive.

5) Conclusion and next steps proposed

The Action Plan suggests in its PA10 that quality and safety of organ transplantation can be improved via a **common accreditation system for organ donation/procurement and transplantation programmes**, without defining further possible concrete actions for Member States and Commission to take. The ACTOR study reveals that different training programmes and certification schemes have been developed at different levels, by competent authorities, professional societies and universities. But this PA has proven hard to take-up jointly at EU level, due to the existence of different types of health professionals involved and to national differences in educational and health systems. In addition, the legal framework of organ transplantation has evolved at EU level, with the adoption of Directive 2010/53/EU and its transposition into national laws.

In this light it is **envisaged to focus on two concrete actions**:

1) map **authorisation schemes defined for procurement and transplant activities** at national level by competent authorities as requested under Directive 2010/53/EU (Articles 5,

9 and 17), to be shared among the network of these authorities and the Commission (this mapping will be organised in 2014 within the “implementation survey” foreseen in Directive 2010/53/EU);

2) map **practical tools available and recognised for training, certification, auditing** which will also be discussed between competent authorities. In this second action, health professionals should be associated, with actors like the European Donation and Transplant Coordination Organisation (EDTCO, a section of ESOT) or the Council of Europe, who play a significant role in these areas.

5. OVERALL CONCLUSION

Achievements

The EU Member States have made good progress in the field of organ donation and transplantation in Europe, during the first half period of the “Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States.”

Between 2007 and 2012, the total number of organ transplants in the European Union has increased from 28,080 to 30,274 driven by increases in deceased donation, but mainly thanks to increases in living donation (as highlighted in Figure 8 under Priority Action 3).

The Action Plan has provided Member States with a comprehensive framework to make this progress, each at its own pace and in function of their national situations. While efforts were made for the majority of priority actions during the first half of the Action Plan, some were particularly successful.

Most Member States now acknowledge the **central role for donor transplant coordinators (PA1)** in their transplant systems, and deceased donation rates have been increased thanks to more efficient coordination by more and better trained coordinators. Most Member States have now also set up **living donor transplant programmes (PA3)**. This is an important source of additional organs in the future. Member States with these programmes are actively ensuring that their living donors are adequately protected. Many Member States have also **enhanced their organisational models (PA6)** by exchanging and learning from practices in other Member States with strongly developed transplant systems. EU-funding, like twinning projects and Joint Actions, have significantly facilitated progress in these three priority actions, with EU-funded projects such as ETPOD, “Train the trainers”, EULID, ELIPSY, MODE, COORENOR, ACCORD, LIDOBS.

Other **achievements enhanced by EU-funded projects** are the quality improvement programmes at hospital level (PA2), the focus on communication skills at hospital and national level (PA4) and the improved understanding of donation and consent systems across Europe (PA5). Certain projects have also provided a good set of tools for Member States and health professionals to implement the priority actions, for example DOKPI, ACCORD and ODEQUS on PA2, EDD on PA4.

In addition, Member States recognise the potential of **increasing the exchange of organs across borders (PA8)** and engage more actively in bi- or multilateral exchanges. Via the EFRETOS project, they also built a **common EU-wide understanding of post-transplant results (PA9)**. Exchanges of organs across borders allow optimising the utilisation of available organs, while understanding post-transplant results helps to optimise allocation decisions, and the safety and efficacy of transplantation therapies. The exchange of organs is driven by collaborations – such as Eurotransplant, Scandiatransplant and, more recently, the South Alliance for Transplantation.

The good progress made is the result of some specific **underlying success factors**.

Firstly, the Action Plan leverages the existing strength and know-how in several Member States. Member States have expertise in different aspects of transplant medicine, and the Action Plan allows them to share and further develop this expertise.

Secondly, the Action Plan is complementary to the new legal framework offered at EU level by the Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation, adopted in 2010 and transposed nationally in 2012. This new legal framework provides for a basis to implement the Action Plan further, in the form of a consolidated landscape with established competent authorities. At the same time, several priorities of the Action Plan strengthen the implementation of this new legislation.

Finally, many actions were taken forward thanks to EU funding, mainly from the EU Health Programme and also from other funds like Research Framework Programmes.

Focus at EU level for remaining period 2014-15

While it is up to each Member State to identify and take forward key priority actions, the Commission can support some of these through EU-level coordination and by funding some specific projects or Joint Actions, which are coordinated and implemented by consortia of Member States and partners. As resources are limited, it is considered important to focus on a limited set of activities and priority actions, which add the most value and increase the number of safe and qualitative organ transplants. **The purpose of these proposed conclusions is not to revise the Action Plan but merely to set out where - and to justify why - the emphasis of EU activities is intended to lie in 2014-15.**

Two priority actions are proposed to be the focus of EU level supportive action under the Action Plan in its remaining period 2014-2015 because of their EU added value and strong potential to support Member States in tackling organ shortages. These two priority actions are both already supported by major EU-funded projects.

Living donation programmes (PA3) are increasing in Europe, in particular for kidney donation. In order to help Member States develop this practice, **protection of living donors** should be ensured, amongst others through registers capturing their long-term follow-up, as required in Directive 2010/53/EU. Many Member States are developing their programmes and registers in this area, and several EU-funded projects (EULID, ELIPSY, EULOD, COORENOR, ELPAT and LIDOBS Conferences) have supported and still support their efforts. The Joint Action ACCORD (2012-2015) provides for a concrete model, database and approach to be implemented in 2014-15.

The **exchange of organs across borders** (PA8) helps Member States to **increase organ availability**, by increasing the possibility of using all available donor organs. It also allows a **better match** to be found between organ and recipient. Much can be learned from existing European organ exchange organisations and bilateral agreements. The IT-tool to exchange these (“surplus”) organs developed in the COORENOR project will be provided, via the FOEDUS Joint Action, to other countries. Procedures will be developed to offer these organs across borders, amongst others for urgent and difficult-to-treat patients.

Several other priority actions can be further supported at EU level, but should **mainly be tackled at national level in 2014-15**, building upon national and EU results already achieved.

The **role of transplant donor coordinators** (PA1) has been widely recognised in Member States and many have been appointed and trained in hospitals all over the EU. This priority action received a lot of attention in the first years of the Action Plan: methodologies and manuals have been developed and trainings have been organised, at both EU and national levels (e.g. ETPOD, ACCORD, “Train the trainers”). Given the essential role of transplant donor coordinators and the natural turnover of this human resource, these efforts should be maintained, primarily at national level, and if possible at EU level with another training course such as “Train the Trainers”.

Quality improvement programmes (QIPs) (PA2), by providing methodologies and indicators for assessing and improving the different steps in the chain from donor identification to transplantation, can significantly improve donation and transplant activities in hospitals. This PA was taken up in very different degrees in hospitals and by Member States. While the results of the DOKPI project were already available, there are since 2013 new tools at disposal to implement these actions, amongst others from the EU-funded projects ACCORD and ODEQUS, which can assist national competent authorities to implement QIPs in hospitals, for example via rapid improvement methodologies at hospital level, allowing for improvement of national systems. The Commission services intend to verify the progress through its upcoming implementation survey foreseen in Directive 2010/53/EU. Further implementation by Member States in the remaining period of the Action Plan is seen as an important tool for improving donation activities.

Media attention is an important element in the field of organ donation and transplantation. **Knowledge and communication skills of health professionals and patient support groups** (PA4) can be improved via training programmes, and authorities are encouraged by the Action Plan to organise periodic meetings and workshops with journalists. Even if various efforts were initiated for this PA in the different Member States (trainings, workshops with journalists, leaflets, meetings etc.), and supported at EU level via the EDD project, this action was identified by the ACTOR study as an area for improvement. Many Member States have understood the importance of media and shown interest in developing communication activities. Communication-related aspects should primarily be addressed at national level, in function of the local context, but media attention can also go across borders. The EU-funded FOEDUS project (2013-2016) will support Member States in their national efforts, as well as allowing for cross-border coordination of communication towards media. European activities to build awareness, like the Commission's Journalist Workshop and the European Organ Donation Day, can also be further strengthened, in particular with national initiatives.

As different donation and transplantation models exist across Europe, **enhancing organisational models** of organ donation and transplantation (PA6) allows an exchange of best practices, via twinning and peer reviews. This action was taken up by many Member States, with the support of different EU-funded projects (amongst others MODE, COORENOR, ACCORD, as well as Research and TAIEX funding). The meetings between national competent authorities will further complement this exchange. Efforts will be continued, in particular via the two Joint Actions funded under the Health Programme (ACCORD and FOEDUS).

The **evaluation of post-transplant results** (PA9) is key for recipients themselves, for health professionals to share scientific learnings and for competent authorities to further improve allocation decisions and thus ensure optimal overall health improvement with the limited number of available organs. The EFRETOS project has laid out a common methodology to organise such follow-up in a harmonised way all over the EU, also including aspects related to organ vigilance, i.e. to the reporting and management of adverse events and reactions, as laid down in Directive 2010/53/EU. In 2014-15, these results should be implemented at national level and with professional associations. It is foreseen to verify the feasibility of a unique, or different (per organ-type) European register(s) of registries, making the follow-up of organ recipients a priority beyond 2015. This would require a significant investment of EU resources which cannot be committed at this stage and the commitment of national authorities and professional associations, to find a common way to share, manage and learn from these follow-up data, whilst protecting the confidentiality of personal data. In addition, already established cooperations between some national competent authorities and some European registries could be further explored to check feasibility and to save costs.

Finally, because other actors such as healthcare professionals and scientists are naturally in the lead (the latter largely supported by EU research funding), **three priority actions are not foreseen as main emphasis at EU level** for the remaining period of the Action Plan 2014-15. As stated in the Action Plan, they still remain highly relevant, in particular for national action and for cooperation with other actors already involved.

Priority action 5 “facilitating the identification of organ **donors across Europe and cross border donation**” (PA5), has partly been addressed in the EU-funded projects COORENOR, DOKPI and the ACTOR study. These projects have made clear that Member States have not only different donation and transplantation systems, but also different consent schemes (opt-in vs. opt-out) and tools (existence or not of registers) to identify potential donors. If Member States confirm the need for this, instruments that are now being developed within the FOEDUS project (IT-tool to exchange organs) and for the implementation of Directive 2012/25/EU (contact detail website to exchange information when organs go across borders) could be used to facilitate mutual knowledge about national consent systems and thus the identification of potential donors.

Priority action 7 calls for the promotion of **EU-wide agreements on aspects of transplantation medicine**, covering elements which do not fall in the mandate of the competent authorities in charge of organ transplantation such as research or the fight against organ trafficking. It has been addressed via EU Research funding and collaboration with key partners such as the Council of Europe and WHO. As suggested in the ACTOR study, topics related to this PA will continue to be regularly discussed with competent authorities and professional societies, for the sake of a consistent and coordinated approach. Collaborations with other sectors such as research and social affairs are encouraged also at national level.

The last priority action concerns the “**promotion of a common accreditation system for organ donation/procurement and transplantation programmes**” (PA10). It was drafted in general terms, without definition of specific actions. Differences in national healthcare and educational systems (still) make it difficult to tackle this PA at EU level; however the new EU legislation provides a new instrument. To follow the objective assigned to the priority action, it is suggested, for 2014-15, to aim for two initiatives allowed by the new legal framework:

(1) sharing authorisation schemes for procurement organisations and transplant centres (this will be done by Commission services in 2014, via the upcoming “implementation survey” linked to Directive 2010/53/EU, and reported to national competent authorities), and (2) mapping national and international training and certification schemes, in cooperation with competent authorities and professional societies.

The **Action Plan** is a **flexible tool for Member States to learn from each other and to collaborate**. The European Commission plans to launch in 2014 an “implementation survey” as foreseen in Directive 2010/53/EU and its results will help further understanding the needs at national level and fine-tuning future activities at EU level. National competent authorities will be invited to actively engage in EU-funded projects, to ensure the best use of the results developed within such projects and to share solutions and successful outcomes during meetings of competent authorities.

By building on efforts already invested and results already achieved, a lot can be achieved at EU and national level. Ultimately, the Action Plan will continue to contribute to improved deceased donation rates, increased numbers of living donors donating in safe conditions and with a long term follow-up and strengthened efficiency of donation and transplant programmes. All these actions will lead to **more patients receiving the organ they need, in good quality and safety conditions, and living healthier and longer lives.**

ANNEXES

ANNEX 1: COUNTRY CODES

Country code in alphabetical order	Short name, source language(s) (geographical name)	Short name in English (geographical name)	Official name in English (protocol name)
28 EU countries (From 1 July 2013)			
AT	Österreich	Austria	Republic of Austria
BE	Belgique/België	Belgium	Kingdom of Belgium
BG	България (*)	Bulgaria	Republic of Bulgaria
CY	Κύπρος (*)	Cyprus	Republic of Cyprus
CZ	Česká republika	Czech Republic	Czech Republic
DE	Deutschland	Germany	Federal Republic of Germany
DK	Danmark	Denmark	Kingdom of Denmark
EE	Eesti	Estonia	Republic of Estonia
EL	Ελλάδα (*)	Greece	Hellenic Republic
ES	España	Spain	Kingdom of Spain
FI	Suomi/Finland	Finland	Republic of Finland
FR	France	France	French Republic
HR	Republika Hrvatska	Croatia	Republic of Croatia
HU	Magyarország	Hungary	Hungary
IE	Éire/Ireland	Ireland	Ireland
IT	Italia	Italy	Italian Republic
LV	Latvija	Latvia	Republic of Latvia
LT	Lietuva	Lithuania	Republic of Lithuania
LU	Luxembourg	Luxembourg	Grand Duchy of Luxembourg
MT	Malta	Malta	Republic of Malta
NL	Nederland	Netherlands	Kingdom of the Netherlands
PL	Polska	Poland	Republic of Poland
PT	Portugal	Portugal	Portuguese Republic

RO	România	Romania	Romania
SE	Sverige	Sweden	Kingdom of Sweden
SI	Slovenija	Slovenia	Republic of Slovenia
SK	Slovensko	Slovakia	Slovak Republic
UK	United Kingdom	United Kingdom	United Kingdom of Great Britain and Northern Ireland
Other countries mentioned			
CH	Suisse/Schweiz	Switzerland	Swiss Confederation
fYRoM (MK for short mention)	поранешна југословенска Република Македонија (*)	the former Yugoslav Republic of Macedonia	
IS	Ísland	Iceland	Republic of Iceland
LI	Fürstentum Liechtenstein	Liechtenstein	Principality of Liechtenstein
ME	Crna Gora/Црна Гора	Montenegro	Montenegro
MD	Republica Moldova	Moldova	Republic of Moldova
NO	Kongeriket Norge/Noreg	Norway	Kingdom of Norway
RS	Србија (*)	Serbia	Republic of Serbia
TR	Türkiye	Turkey	Republic of Turkey

(*) Latin transliteration: България = Bulgaria; Ελλάδα = Elláda; Κύπρος = Kýpros; поранешна југословенска Република Македонија= poranešna jugoslovenska Republika Makedonija; Србија = Srbija

Sources: <http://publications.europa.eu/code/en/en-5000600.htm> and [/en-370100.htm](http://publications.europa.eu/code/en/en-370100.htm)

ANNEX 2: MAIN EU-FUNDED PROJECTS DURING THE FIRST HALF OF THE ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION (2009-2015)

Projects presented in alphabetical order, by types of funding (Health Programme, Research Programme...):

A) Funding via the EU Health Programmes or by the Directorate General for Health & Consumers of the European Commission

B) Other EU funding such as Research Framework Programmes (FP 6 and 7)

C) Funding in Partner countries (TAIEX funding, IPA)

A) Projects funded under the EU (Public) Health Programmes (HP): Also accessible on the projects database of the Health Programme on the website of the EU Consumers, Health and Food Executive Agency (Chafea), successor since January 2014 of the Executive Agency for Health and Consumers (EAHC): http://ec.europa.eu/eahc/projects/database.html Leaflet published by the Executive Agency on Transplantation and Transfusion projects: http://ec.europa.eu/eahc/documents/health/leaflet/transplantation-transfusion.pdf						
Acronym of the EU-funded project	Full title of the project	Related Priority Actions (PA) of the Action Plan	Type of project	EC (maximum) contribution ³²	Time frame	Link (also for access to main deliverables of these projects)
ACCORD	Achieving Comprehensive Coordination in Organ Donation throughout the European Union	PA1, PA3, PAs 6, 2, 1 and 10	Joint Action	1 440 000 €	2012-2015 (2011 funding)	http://www.accord-ja.eu/
ACTOR study	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	Action Plan, uptake (all PAs analysed)	Tender	139 359 €	2012-2013 (2011 funding)	http://ec.europa.eu/eahc/health/sc_awarded_under_fw_2011.html http://ec.europa.eu/health/blood_tissues_organs/docs/organs_actor_study_2013_en.pdf

³² Effective contribution when project finalised and amount known, otherwise EC maximum contribution foreseen if project starting or on-going

COORENOR	Coordinating a European Initiative among National Organizations for Organ Transplantation	PA3, 6, 8	Project* ³³	799 145,08 €	2009-2012	
Direct Grants to the Council of Europe	For activities in the field of blood transfusion and transplantation of organs, tissues and cells (to the "European Directorate for the Quality of Medicine", EDQM)	Diverse aspects relating for example to PA1, PA3, PA7, PA10, also PA4 with support to the Guides and European Organ Donation Days	Grant	200 000 € (Two grants of 100 000 € each in 2011 and 2012)	Annual grants for the field "Substances of human origin" (2011) & for organ transplantation (2012)	http://www.edqm.eu/en/organ-transplantation-mission-67.html
EDD	Developing Guidelines for the Organisation of a European/Public Organ Donation Days, and celebration of the 10 th European Organ Donation Day (2010)	PA4	Project	150 586 €	2008-2010	www.europeandonationday.org http://ec.europa.eu/eahc/projects/database.html?prjno=20081109
EFRETOS	European Framework for the Evaluation of Organ Transplants	PA9	Project	750 000 €	2009-2011	http://www.efretos.org/ http://ec.europa.eu/eahc/projects/database.html?prjno=20081101
ELIPSY	European Living Donor Psychological Follow-up	PA3	Project	299 128,25 €	2009-2012/3	http://www.eulivingdonor.eu/elipsy/
ELPAT Conferences	Conferences on Organ Transplantation: Ethical, Legal and Psychosocial Aspects (Expanding the European Platform) - ELPAT is a platform of the European Society for	PA3, PA7	Conference grants	75 000 € in 2009 (for 2010) 100 000 € in 2012 (for 2013)	For 2010 and 2013 ELPAT conferences	http://www.esot.org/ http://www.esot.org/Elpat/Content.aspx?item=22

³³

* after open "calls for proposals" under the Health Programme, <http://ec.europa.eu/eahc/health/projects.html>

	Organ Transplantation					
ETC / "train the trainers"	European Training Course in Transplant Donor Coordination in the European Union	PA1, PA10	Tender	270 757 €	2011 (2010 funding)	http://ec.europa.eu/eahc/health/tenders_H03_2010.html http://www.etc.iavante.es/
ETPOD	European Training Program on Organ Donation	PA1, PA10	Project	782 633,31 €	2007-2009	http://etpod.il3.ub.edu/ http://ec.europa.eu/eahc/projects/database.html?prjno=2005205
EULID	European Living Donation and Public Health (EU-Living Donor)	PA3	Project	524 893 €	2007-2010 (2006 funding)	http://www.eulivingdonor.eu http://ec.europa.eu/eahc/projects/database.html?prjno=2006211
FOEDUS	Facilitating Exchange of Organs Donated in EU Member States	PAs 8, 7, 6, 4	Joint Action	1 149 959 €	2013-2016 (2012 funding)	http://ec.europa.eu/eahc/news/news232.html
LIDOBS	International Conference on Living Donation - high quality practices	PA3	Conference grant	46 510 €	2013 funding for Conference in 2014	http://www.eulivingdonor.eu/lidobs/
MODE	Mutual Organ Donation and Transplantation Exchanges	PAs 6, 7, 1. DD/LD, transplantation programs, enhance organisational models.	Joint Action	284 591,30 €	2011-2012 (2010 funding)	http://www.mode-ja.org/ http://ec.europa.eu/eahc/projects/database.html?prjno=20102101
ODEQUS	European Quality System Indicators and methodology on Organ Donation	PAs 2, 3, 10. DD and LD, quality improvement	Project	599 965,69 €	2010-2013	http://www.odequs.eu/ http://ec.europa.eu/eahc/projects/database.html?prjno=20091108

SoHO V&S	Vigilance and Surveillance of Substances of Human Origin	PA 7 (for illegal and fraudulent activities)	Project	794 313 €	2009-2012 (2009 funding)	http://www.sohovs.org/ http://ec.europa.eu/eahc/projects/database.html?prjno=20091110
TOTAL				8 406 840,63 €		

Other EU projects or activities funded via the EU Health Programme or by the Directorate General for Health & Consumers of the European Commission directly:						
Journalists Workshops (2010, 2011, 2012, 2013)	... on organ donation & transplantation (for journalists from EU Member States). Organised since October 2011 few days ahead of the European Organ Donation Days.	PA4	Organised by the EC, with the logistical support of an external contractor	37 304 € (2010) 38 812 € (2011) 38 377 € (2012) 37 064 (2013)	November 2010 October 2011 October 2012 October 2013	http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm
Workshop on Illegal and Fraudulent Activities (IFA) in transplantation (organs, tissues & cells)	Workshop organised by French Competent authorities for Tissues&Cells with customs and police services	PA7	Co-funded by the European Commission directly	13 790,16 €	April 2013	
Working groups under the Action Plan - WG directly managed by the Commission, with the active involvement of national experts nominated by Competent authorities:						
Working Group (WG) on deceased donation	Developed with national experts a Manual on how to set up a transplant donor coordination.	PA1, PA6	EC reimburse travel costs of national experts when WG meetings		2009-2011	Shared within EU network of CAs established by Directive 2010/53/EU.
Working Group (GP) on living donation	Developed with national experts a toolbox with best practices, to support countries developing living donation programmes.	PA3, PA6			2012-2013	Shared within EU network of Competent authorities established by Directive 2010/53/EU.
Working Group Indicators on organ donation & transplantation	Develops annual exercises to map donation and transplantation activities in EU countries.	Transversal: 1) donation, 2) waiting lists, 3) allocation, 4) transplantation, 5) health outcomes, 6) health resources.			Annual exercises since 2010	Shared within EU network of Competent authorities established by Directive 2010/53/EU.

B) Other EU funding such as Research Framework Programmes (FP): [list non exhaustive but including main research projects on organ transplantation]						
Alliance-O	European Group for Coordination of National Research Programmes on Organ Donation and Transplantation	PAs 6, 7, 9, 8	FP 6 ("coordination")	1 999 999 €	2004-2007	http://ec.europa.eu/research/fp7/pdf/era-net/publishable_summaries/fp6/alliance-o_publishable_executive_summary_en.pdf
BIO-DrIM	Personalized minimization of immunosuppression after solid organ transplantation by biomarker-driven stratification of patients to improve long-term outcome and health-economic data of transplantation (5 clinical trials)	PAs 7, 9	FP 7	5 989 000 €	2012-2017	http://cordis.europa.eu/projects/rcn/106158_en.html
COPE	Consortium on organ preservation in Europe (four clinical trials)	PA7, Organ (kidney + liver) preservation	FP 7	5 990 843 €	2013-2017	http://www.cope-eu.org/ http://cordis.europa.eu/projects/rcn/106192_en.html
DOPKI	Improving the knowledge and practice of Organ Donation	PAs 7, 9	FP 6 ("policies", coordination action)	5 584 430 €	2006-2009	http://www.ont.es/internacional/Documents/DOPKI.pdf http://cordis.europa.eu/projects/rcn/78476_en.html
ETHICTRANSPLANTATION	Organ transplantation: Ethical Legal and Psychological aspects. Towards a common European Policy 2007 Conference (future "ELPAT conferences")	PAs 7, 3	FP 6 ("society")	107 798 €	2006-2008	http://cordis.europa.eu/projects/rcn/84620_en.html

EULOD	Living Organ Donation in Europe	PAs 3, 6, 7	FP 7	1 099 657 €	2010-2012	http://cordis.europa.eu/projects/rcn/94218_en.html http://www.eulod.org
EUROSTAM	A Europe-wide strategy to enhance transplantation of highly sensitized patients on basis of acceptable HLA mismatches	PAs 7, 9	FP 7	2 623 500 €	2012-2015	http://cordis.europa.eu/projects/rcn/106298_en.html
HepaMAb	Human monoclonal antibody therapy to prevent Hepatitis C virus reinfection of liver transplants: advancing lead monoclonal antibodies into clinical trial	PAs 7, 9 Liver transplants, Hep. C re-infection	FP 7	5 986 903 €	2013-2017	http://cordis.europa.eu/projects/rcn/106378_en.html
HOTT	Combating trafficking in persons for the purpose of organ removal	PAs 7, 3, 6	EC, Directorate General Home Affairs	600 000 €		www.hottproject.com
ORGANPROCUREMENT	Policy, law and organ procurement; can behaviour and mentalities be modified by social engineering (Marie Curie actions – Intra-European Fellowships)	PAs 6, 7, 10	FP 6 (“mobility”)	142 472 €	2007-2009	http://cordis.europa.eu/projects/rcn/84357_en.html
RISSET	Reprogramming the immune system for the establishment of tolerance	PAs 7, 9	FP 6	9 781 150 €	2005-2010	www.risetfp6.org http://cordis.europa.eu/projects/rcn/75691_en.html
STAR-T REK	Set up and comparison of multiple stem cell approaches for kidney repair	PA 7. Kidney repair, alternative to renal transplant		2 999 500 €	2008-2011	http://cordis.europa.eu/projects/rcn/88607_en.html

STELLAR	Stem cell based therapy for kidney repair (EU-Australia cooperation)	PA 7. Kidney repair, alternative to renal transplant	FP 7	5 998 050 €	2012-2017	http://cordis.europa.eu/projects/rcn/105515_en.html
The ONE study	A Unified Approach to Evaluating Cellular Immunotherapy in Solid Organ Transplantation	PAs 7, 9. Research, clinical trial, cell therapy	FP 7	10 836 201 €	2010-2015	http://www.onestudy.org/http://cordis.europa.eu/projects/rcn/96748_en.html
XENOME	Engineering of the porcine genome for xenotransplantation studies in primates: a step towards clinical application	PA 7. Xenotransplantation	FP 6	9876 546 €	2006-2012	http://cordis.europa.eu/projects/rcn/84970_en.html
Total				69 016 049 €		

C) Funding in partner countries (TAIEX funding, IPA): (non exhaustive list but main activities linked to organ donation & transplantation)

Information is available on each event with an event ID on TAIEX library, by typing this link followed by the event ID:

Example: http://ec.europa.eu/enlargement/taieux/dyn/taieux-events/library/detail_en.jsp?EventID=50267 (for event 50267)

Event ID	Event category (participants)	Month/Year (length)	Name (related Priority Actions of the Action Plan)	Beneficiary	Beneficiary Institution	Group (associated partners/countries)	City, country event's place	Keyword
	Contract TR2009/0 328.01	04/2013 to 04/2015	Alignment in Organ Donation (ALOD). Includes legislative work, activities such as Journalists Workshops (first: organised in 11/2013) (PAs 4, 6, 7)	Turkey	Ministry of Health	IPA		Organ Donation
50267	Workshop (121 part.)	07/2013 (2 days)	Multi-Country Workshop on Deceased Donation and Transplantation (PAs 6, 7, 1, 2)	Albania, Bosnia and Herzegovina, Croatia, Iceland, Israel, Kosovo, Moldova, Montenegro, Serbia, Turkey, former Yugoslav Republic of Macedonia	Ministry of Health	IPA, ENPI-EAST, ENPI-SOUTH (SI, BG, RO)	Zagreb Croatia	Transplantation
51962	Workshop (93 part.)	04/2013 (2 days)	Multi-Country Workshop on Funding Models for Deceased Donation and Transplantation (PAs 6, 7, 1, 2)	Albania, Bosnia and Herzegovina, Croatia, Israel, Moldova, Montenegro, Serbia, former Yugoslav Republic of Macedonia	Ministry of Health Transplant Agency	IPA, ENPI-EAST, ENPI-SOUTH	Chisinau Moldova	Donation, transplant
51276	Workshop (19 part.)	02/2013 (1 day)	Workshop on Preparation of Transplant Manuals (PAs 1, 6, 7)	Albania	Ministry of Health	IPA (ES, SI)	Tirana Albania	Transplant

50400	Expert Mission (34 part.)	11/2012 (5 days)	Expert Mission on Reviewing the Standard Operating Procedures and Protocols in the Field of Transplantation (PAs 1, 6, 7)	Moldova	Ministry of Health	ENPI-EAST	Chisinau Moldova	SOP (standard operating procedures); transplantation
49147	Expert Mission	09/2012 (4 days)	Expert Mission on Establishment of a Human Leukocyte Antigen Laboratory	Moldova	Ministry of Health/ Transplant Agency	ENPI-EAST	Chisinau Moldova	Transplantation
48363	Workshop (51 part.)	08/2012 (2 days)	Workshop on Brain Death Diagnostics (PAs 1, 6, 7)	Albania, Bosnia and Herzegovina, Croatia, Israel, Moldova, Montenegro, Serbia, Turkey, former Yugoslav Republic of Macedonia	Ministry of Health, Republic of Croatia	IPA, ENPI-EAST, ENPI-SOUTH (BG, ES, IT, RO, SI)	Ljubljana Slovenia	Brain Death
48718	Workshop (57 part.)	06/2012 (2 days)	Multicountry Workshop: Technical Requirements for Donation and Procurement of Human Tissues and Cells	Albania, Bosnia and Herzegovina, Croatia, Kosovo, Moldova, Montenegro, Serbia, former Yugoslav Republic of Macedonia	Ministry of Health	IPA, ENPI-EAST (DE, ES, IT, UK, TTS, WHO)	Ohrid, former Yugoslav Republic of Macedonia	Organ donation
48625	Expert Mission (13 part.)	05/2012 (3 days)	Expert Mission on Drafting Legislation on Organ Donation and Transplantation (PAs 4, 6, 7)	Montenegro	Ministry of Health	IPA (SI, PL)	Podgorica, Montenegro	Organ donation and transplantation
48390	Workshop (56 part.)	05/2012 (1 day)	Workshop on Guidance on Conducting Inspections in the Tissue Establishments and Transplantation Institutions (PAs 6, 7)	former Yugoslav Republic of Macedonia	Ministry of Health	IPA (FR, PT, RO)	Skopje former Yugoslav Republic of Macedonia	Tissues
47700	Study Visit	05/2012 (5 days)	Study Visit on Tissues and Organ Transplant	Albania	Ministry of Health	IPA	Barcelona Spain	Organ transplant

47370	Expert Mission	02/2012 (5 days)	Expert mission on training of transplant coordinators' trainers	Moldova	Transplant Agency staff, transplant coordinators	ENPI-EAST	Chisinau Moldova	Transplant Coordination
43847	Study Visit (4 part.)	03/2011 (5 days)	Study Visit on the provisions of the Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation	Moldova	Ministry of Health - Transplant Agency	ENPI-EAST	Madrid Spain	Human organs
42609	Workshop (50 part.)	02/2011 (1 day)	Workshop on Organ Donation and Transplantation Medicine Collaboration in South Eastern Europe (PAs 6, 7)	Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Moldova, Romania, Serbia, former Yugoslav Republic of Macedonia	Ministry of Health and Social Welfare Republic of Croatia	IPA, nMS, ENPI-EAST (European Commission, WHO Europe, ETCO)	Zagreb Croatia	Transplantation Medicine
43141	Study Visit (4 part.)	03/2011 (1 day)	Study Visit on Transplant Registry (PAs 6,7)	Croatia	Ministry of Health - Republic of Croatia	IPA (Eurotransplant, NL)	Leiden The Netherlands	Transplant
43123	Workshop (52 part.)	12/2010 (2 days)	Workshop on Training for ICU doctors and hospital transplant coordinators (PAs 1, 6, 7)	Croatia	Ministry of Health and Social Welfare Republic of Croatia	IPA (BE, ES, PL)	Zagreb Croatia	Transplant coordinators
41955	Study Visit	10/2010 (3 days)	Study Visit the field of organ donations and transplant organisation (PAs 6, 7)	Croatia	Ministry of Health and Social Welfare Republic of Croatia	IPA	Madrid Spain	Transplant Organisation ONT
42651	Workshop (92 part.)	09/2010 (2 days)	Workshop on Legislative, organisational and economical aspects of donation and transplantation (PAs 6, 7)	Moldova	Ministry of Health of Republic of Moldova/Transplant Agency (BE, CZ, ES, FR, PL, RO)	ENPI-EAST	Chisinau Moldova	Transplantation

ANNEX 3: ORIGINAL ACTION PLAN AND COMMENTS FROM THE MID-TERM REVIEW

Original wording in the Action Plan adopted in December 2008		Comments from the mid-term review of the Action Plan
<i>Challenge 1: INCREASING ORGAN AVAILABILITY</i>		
Priority Action 1: Promote the Role of Transplant Donor Coordinators in Every Hospital with a Potential for Organ Donation		<i>Key priority action already well taken into account at EU and national levels</i>
<i>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</i>	<i>(MS action; EC coordinates and monitors)</i>	<i>Taken up in most of the Member States, to be further continued and maintained</i>
<i>Action 1.2 Promote the establishment of internationally recognised standards for transplant donor coordinator programmes</i>	<i>(EC Action)</i>	<i>To be enhanced together with Priority Action 10, with two main aspects to be considered: 1) Authorisation aspects under Directive 2010/53/EU and 2) Accreditation and training schemes existing.</i>
<i>Action 1.3 Promote the implementation of effective training programmes for transplant donor coordinators</i>	<i>(MS + EC Action)</i>	<i>Taken up in most of the Member States, supported at EU level by projects (ETPOD, Train the Trainers, ACCORD), to be further continued.</i>
<i>Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators</i>	<i>(MS + EC Action)</i>	<i>To be enhanced together with Priority Action 10, with two main aspects to be considered: 1) Authorisation aspects under Directive 2010/53/EU and 2) Accreditation and training schemes existing.</i>
Priority action 2: Promote Quality Improvement Programmes in Every Hospital Where There is a Potential for Organ Donation		<i>Priority action to be further implemented to increase organ availability</i>
<i>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</i>	<i>(MS action, EC coordinates and monitors)</i>	<i>Increasingly taken into account, with Directive 2010/53/EU can be better implemented by Competent authorities in charge of the whole quality and safety framework. To be monitored via the upcoming "Implementation survey" for Directive</i>

		2010/53/EU
<i>Action 2.2 Promote accessibility to and training on a specific methodology on Quality Improvement Programmes</i>	<i>(MS action, EC coordinates and monitors)</i>	<i>Implemented in some Member States, tools made available at EU level with ODEQUS project and ACCORD Joint Action (twinning Work package), to be further enhanced at national level thanks to Directive 2010/53/EU</i>
Priority action 3: Exchange of Best Practices on Living Donation Programmes among EU Member States: Support of Registers for Living Donors		<i>Constant increase in living donation over the last years</i>
<i>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</i>	<i>(MS action, EC coordinates and monitors)</i>	<i>Increasingly taken into account, becomes with Directive 2010/53/EU mandatory for Competent authorities to protect and follow-up living donors. To be monitored via the upcoming "implementation survey" for Directive 2010/53/EU</i>
<i>Action 3.2 Promote the development of registers for living donors to evaluate and guarantee their health and safety</i>	<i>(MS + EC Action)</i>	<i>Support at EU level via projects EULID, ELIPSY, ODEQUS as well as ELPAT and LIDOBBS conferences, via the "Living donation toolbox" developed by the EU Working group on living donation. A specific Work package of the Joint Action ACCORD is expected to deliver a common tool.</i>
Priority Action 4: Improve Knowledge and Communication Skills of Health Professionals and Patient Support Groups on Organ Transplantation		
<i>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</i>	<i>(MS action, EC coordinates and monitors)</i>	<i>Still to be increasingly addressed at national level, topic introduced in CA meetings, Work package on Communication within FOEDUS Joint Action</i>
<i>Action 4.2 Promote training programmes geared towards health professionals and patient support groups on organ transplantation communication skills</i>	<i>(MS + EC Action)</i>	<i>Often done for transplant coordinators (speaking to families) but to be more widely implemented</i>
<i>Action 4.3 Organise periodic meetings at national level (competent authorities) with journalists and opinion leaders and manage adverse publicity</i>	<i>(MS action, EC coordinates and monitors)</i>	<i>At EU level: annual Journalist Workshops on organ donation & transplantation; at national level some initiatives were taken, but to be more widely implemented</i>

Priority action 5: Facilitate the Identification of Organ Donors across Europe and Cross-border Donation in Europe		
<i>Action 5.1 Collect and disseminate information about citizen's rights concerning organ donation across the EU</i>	<i>(MS + EC Action)</i>	<i>Still be improved, will be facilitated via FOEDUS Joint Action</i>
<i>Action 5.2 Develop mechanisms to facilitate the identification of cross-border donors</i>	<i>(MS + EC Action)</i>	<i>Still be improved, will be facilitated via FOEDUS Joint Action</i>
<u>Challenge 2: ENHANCING THE EFFICIENCY AND ACCESSIBILITY OF TRANSPLANT SYSTEMS</u>		
Priority Action 6: Enhancing Organisational Models of Organ Donation and Transplantation		
<i>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</i>	<i>(MS + EC Action)</i>	<i>Taken up in most of the Member States, to be further continued and maintained</i>
<i>Action 6.2 Promote twinning projects and peer reviews</i>	<i>(EC Action)</i>	<i>Largely supported by EU-funding (MODE, ACCORD, TAEIX grants), to be further continued and maintained (EC + MS action as twinning and peer reviews rely on national experts)</i>
<i>Action 6.3 Assess the use of structural funds and other Community instruments for the development of transplantation systems</i>	<i>(EC Action)</i>	<i>Assessed in ACTOR study and present document, EU Research Framework Programmes largely used (EC + MS action as structural funds are managed at national level and Research funding depends on applications of research consortiums)</i>
<i>Action 6.4 Promote networks of centres of reference</i>	<i>(EC Action)</i>	<i>To be discussed with Member States (CAs), in link with Cross-Border Healthcare Directive; Indicators' Working group could assist (EC + MS action)</i>
Priority Action 7: Promotion of EU-wide Agreements on Aspects of Transplantation Medicine		
<i>Action 7.1 EU-wide agreement on basic rules for internal EU patient mobility and transplantation, in compliance with Community law</i>	<i>(MS + EC Action)</i>	<i>To be discussed with Member States (CAs), in link with Cross-Border Healthcare Directive; FOEDUS Joint Action will supported Member States in their bi- or multilateral agreements</i>

<i>Action 7.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patients</i>	<i>(MS + EC Action)</i>	<i>To be discussed with Member States (CAs), in link with Cross-Border Healthcare Directive (firstly for MS action as healthcare system and social security schemes are national)</i>
<i>Action 7.3 EU-wide agreement on monitoring organ trafficking</i>	<i>(MS + EC Action)</i>	<i>Enhanced via the adoption of Directive 2010/53/EU (consolidation of national competent authorities) and via cooperation with the Council of Europe</i>
<i>Action 7.4 EU-wide agreement on common priorities and strategies for future research programmes</i>	<i>(MS + EC Action)</i>	<i>EU Research funding largely used for transplantation activities (see list of projects in Annex 2), to be continued also with professional societies such as ESOT</i>
Priority Action 8: Facilitation of the Interchange of Organs between National Authorities		
<i>Action 8.1 Evaluate procedures for offering surplus organs to other countries</i>	<i>(EC + MS action)</i>	<i>Explored in COORENOR project (scientific consensus and IT-tool), to be now implemented thanks to FOEDUS Joint Action</i> <i>The expression "surplus organs" is not ethically correct in times of organs' shortages and should be re-worded into "organs otherwise not procured and allocated "</i>
<i>Action 8.2 Put procedures in place for the exchange of organs for urgent and difficult-to-treat patients</i>	<i>(EC + MS action)</i>	<i>Done via European Organ Exchange Organisations and bilateral agreements, will be further enhanced thanks to FOEDUS Joint Action</i>
<i>Action 8.3 Design IT tools in support of the previous actions</i>	<i>(MS + EC Action)</i>	<i>Pilot created within COORENOR project, to be further enhanced via FOEDUS Joint Action, with new Member States joining</i>
<u>Challenge 3: IMPROVING QUALITY AND SAFETY</u>		
Priority Action 9: Evaluation of Post-Transplant Results		
<i>Action 9.1 Develop common definitions of terms and methodology to evaluate the results of transplantation</i>	<i>(EC Action)</i>	<i>Supported via EU funding of EFRETOS project, should not be assigned alone to EC as scientific expertise available at MS level, with health professional (prof. societies)</i>

<i>Action 9.2 Develop a register or network of registers to follow up organ recipients</i>	<i>(MS + EC Action)</i>	<i>Blueprint of a register of registers developed by EFRETOS project, to be implemented at national level, by the CAs and with the support of health professionals, and possibly at EU level if further funding available</i>
<i>Action 9.3 Promote common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors</i>	<i>(EC Action)</i>	<i>CAs (MS), professionals and EOEOs are already working on these activities. It should not be assigned alone to EC as scientific expertise available at MS level, with health professionals (prof. societies)</i>
<i>Action 9.4 Develop and promote good medical practices on organ donation and transplantation on the basis of results, including the use of expanded donors</i>	<i>(EC Action)</i>	<i>CAs (MS), professionals and EOEOs are already working on these activities. It should not be assigned alone to EC as scientific expertise available at MS level, with health professionals (prof. societies)</i>
Priority Action 10: Promotion of a Common Accreditation System for Organ Donation/Procurement and Transplantation Programmes		
<i>(no specific actions defined)</i>	<i>(no specific assignments made)</i>	<p><i>Split into two more concrete actions: map and share among MS (MS + EC Action)</i></p> <p><i>1) Authorisation schemes (for procurement organisations and transplant centres) now foreseen under – for action by MS (implementation) and EC (implementation survey related to Directive in 2014)</i></p> <p><i>2) Accreditation, training, certification: was partially already supported via EU projects ODEQUS, ACCORD, Train the Trainers, ETPOD. Proposal is to explore existing schemes (national, professional societies...). For MS action, EC to coordinate exchange of information.</i></p>