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Organ transplantation and the European Union, 2009–2015 developments

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ABSTRACT

This article provides a high-level picture of the developments in organ transplantation in the European Union (EU) between 2009 and 2015. This was the period during which the European Commission and EU 28 member states developed an EU Action Plan on organ donation and transplantation. This plan was adopted by the European Commission in 2008, following calls for policy action to increase transplant numbers. It set out priority actions for member states and European Commission to address. This article describes the three main approaches used by the European Commission and National Competent Authorities to develop this action plan. We also present a quantitative comparison of 2015 and 2008 transplant data, based on the Newsletter Transplant by the Council of Europe (CoE) and the Spanish National Transplant Agency (ONT). This comparison shows contributions of different EU Member States, as well as of different donation and transplant programs to the overall increase of 4597 transplants per year (+16.4%). While another evaluation study of the action plan reported a strong positive impact of the action plan, it is beyond the remit of this publication to demonstrate a causal relationship between the EU Action Plan and the increase in number of organ transplants.

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Introduction

While the official mandate of the European Union (EU) in the area of human substances for therapeutic use is limited to safety and quality [1], national and EU-level policy makers have called for additional EU-level efforts to increase availability of organs and reduce waiting lists since the beginning of the 21st century.

In 2008, this political support was translated into the EU's "Action Plan on Organ Donation and Transplantation (2009-2015)" [2] (henceforth referred to as "the Action Plan"). With the sub-title, "Strengthened Cooperation between Member States," a clear direction was given on how to achieve an increase in organ donation and transplantation. In this action plan, 10 priority actions were defined to focus and support the voluntary efforts of the transplant services in the EU Member States (Table 1).

An action plan is a policy tool that allows the European Commission to organize voluntary support measures, possibly with EU funding, that go beyond the binding requirements it can lay down in

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Table 1. EU Action Plan – 10 priority actions [2].

Objectives	10 Priority actions
Increase organ availability	PA1. Transplant coordinators
	PA2. Quality improvement programs
	PA3. Living donation programs
	PA4. Communication skills of professionals
	PA5. Information on citizen rights
Enhance efficiency and accessibility of transplantation systems	PA6. Enhance organizational models
	PA7. EU-wide agreements (research, trafficking, ...)
	PA8. Interchange of organs
Quality and safety	PA9. Evaluation of post-transplantation results
	PA10. Common accreditation systems

legislation. The action plan did, however, facilitate the consequent adoption of binding EU legislation, as it provided a way forward on concerns that are difficult to legislate at EU level, knowing that organizational aspects of healthcare fall exclusively in the national mandates of each of the 28 EU Member States. The action plan also addressed possible concerns on a negative, complicating effect of EU legislation on the organization and eventual transplant rates. In 2010, during the Spanish Presidency of the EU, the action plan was complemented by EU Directive 2010/53 that laid down binding standards of quality and safety for human organs intended for transplantation [3].

Consequent EU Presidencies, notably the Polish (2011) and Cypriot (2012) Presidencies, re-confirmed this political support, as did several Members of the European Parliament.

In this article, we present how the actions of this 2009–2015 action plan were implemented by the European Commission and the national competent authorities (NCAs) in the EU 28 member states. Without claiming a causal relationship, we also present a comparison of 2008 and 2015 transplant data in the EU. This comparison shows the contribution of different EU Member States, and of different donation and transplant programs, to the overall increase of 4597 transplants in 2015, compared to 2008.

Development of the action plan

To help the EU Member States make progress on these priority actions, the European Commission coordinated three types of approaches:

EU funded projects

As Table 2 indicates, more than 20 projects were proposed, negotiated, contracted, monitored and disseminated with the EU Member States. Several of these projects were co-organized and co-funded directly with National Competent Authorities (usually national transplant agencies), in the form of so-called joint actions.

The majority of projects were funded from the health budget managed by the Directorate-General Health (SANTE – Public Health Programme) and coordinated by a dedicated executive agency (Consumer, Health and Food Executive Agency – CHAFEA). Others were funded through the research budgets (Framework and Horizon Programmes, of the Research and Innovation Directorate-General of the European Commission – DG RTD) or directly from budget allocated by other Directorate-Generals of the European Commission or by the European Parliament (pilot projects). Table 2 gives an overview of the main EU-funded projects in the field of organ transplantation.

The action plan has leveraged the differences in donation and transplant rates between EU Member States. Know-how on donation and transplantation practices that were well developed in some countries was documented. Hence, it became possible to transfer these practices to other countries. On each of the priority actions, some countries were teaching and others were learning.

EU-supported projects covered areas such as the overall organization of deceased donation (COORENOR), collaboration with intensive care units (ACCORD), organization of living donation (LD; ELIPSY, ELPAT, EULID), communication practices (European Donation Day, ACCORD), quality management and audits of donor centers (ODEQUS). Other projects focused on dissemination and training, for example on donor coordination (train the trainers) or on communication (EUDONORGAN).

Some concrete tools were developed in order to support member states to implement some of these good practices, such as registries for living donor follow-up (EULID and EDITH) and a platform for the exchange of surplus organs (FOEDUS).

An overview and more information on the main EU-funded projects can be found on DG SANTE's website [4].

Technical working groups

The European Commission and national transplant agencies also set up technical working groups where

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Table 2. EU supported projects to stimulate transplantation (Table by authors, data source: European Commission – CHAFEA).

Action	Main purpose	Sponsor
Alliance – O	Coordination of national research on transplantation	RTD
DOPKI	Improving the knowledge and practices in organ donation	RTD
ETPOD	European training program on organ donation	SANTE
EULID	European living donation and public health	SANTE
EDD	European donation day	SANTE
ELPAT	Ethical, legal and psychosocial aspects of transplantation	SANTE
EFRETOS	European framework for evaluation of organ transplants	SANTE
ELIPSY	Euro living donor psychosocial follow-up	SANTE
COORENOR	Coordinating a European initiative among national organizations for organ transplantation	SANTE
EULOD	European living organ donation	RTD
ODEQUS	Organ donation European quality system	SANTE
Train the trainers	European training program on organ donation	SANTE
MODE	Exchange best practices in deceased organ donation and transplantation (Joint Action)	SANTE
ACCORD	Achieving Comprehensive Coordination in organ donation throughout the European Union (Joint Action)	SANTE
FOEDUS	Facilitate exchange of organs donated in EU member states (Joint Action)	SANTE
EUDONORGAN	Increase organ donation rate in Europe	EP
EDITH	Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes	EP
Direct Grants – CoE	Multiple topics covering organs, tissues, cells and blood, covered by the European Directorate on Quality of Medicines (EDQM) within the Council of Europe (CoE)	SANTE
HOTT	Combating organ trafficking	JUST
LIDOBS	Living donor observatory – conference	SANTE
ONE study	A Unified Approach to Evaluating Cellular Immunotherapy in Solid Organ Transplantation	RTD
Bio-DrIM	Biomarker-driven personalized immunosuppression	RTD
COPE	Improving preservation and reconditioning strategies for kidney and liver organs procured for transplantation	RTD
STELLAR	Stem cell research in kidney disease	RTD

EP, European Parliament; JUST, Directorate-General for Justice and Consumer affairs; RTD, Directorate-General for Research and Innovation; SANTE, Directorate-General for Health and Food Safety.

experts bring together knowledge and good practices on more horizontal areas of expertise. One working group collected and shared expertise on deceased donation, in particular on how to set up a donor coordinator system, developing a manual with guidelines. A second working group developed a toolbox on how to set up a LD transplant program [5]. A third group collected and shared national transplant indicator data to allow for an annual discussion with National Competent Authorities on current and potential performance. The work of this last group builds to a large degree on the work of the Spanish transplant agency, ONT, for the annual Newsletter by the Council of Europe [6].

Since these working groups completed their tasks and outputs were delivered, ONT has continued to prepare and present annual indicator data to their peer transplant agencies in the EU 28 member states.

Network of national competent authorities

The planning, development and monitoring of the projects and working groups took place within the network of the EU 28 National Competent Authorities. This Network involves national transplant agencies as well as European Organ Exchange Organisations (Eurotransplant, Scandiatransplant and the Southern Alliance on Transplantation). Representatives of all these bodies are brought together on a regular basis by the European Commission, as mandated by Article 19 of the Organs Directive [3]. These meetings offered occasions for peers

to monitor progress, discuss and disseminate findings of the different activities under the action plan.

Progress in the numbers of organ donations and transplants throughout the EU

Overall, organ donation and transplantation rates increased in the EU. Comparing 2008 and 2015 data from the Newsletters by the Council of Europe/ONT [7,8], the 28 EU Member States had jointly increased the annual number of transplants from 28 110 in 2008 to 32 707 in 2015. This made for an increase of 4597 organs, or 16.4%. This growth was driven by an increase of 16.0% in deceased donors (from 9045 to 10 495), the source of multiple organs for transplantation, and by an increase of 75.6% in living donors, (from 2538 to 4458), source for kidneys and (less frequently) part of a livers.

Country performance

As Fig. 1 illustrates, 22 (of 28) EU Member States have increased national transplantation numbers between 2008 and 2015. Growth has been strongest in Bulgaria (+129%) and Lithuania (+119%); both countries had however very low transplant rates per million inhabitants in 2008. Finland (+70%), Croatia (+55%), Hungary (+54%), the Czech Republic (+47%), Slovenia (+46%), Latvia (+44%) and Denmark (+42%) all showed strong growth from a relatively well-established 2008 baseline with rates between 25 and 60 transplants per million population (PMP). Some other countries recorded growth to an already high 2008 transplant rate of more than 70 transplants per million inhabitants. France and Spain belong to this latter group, as do smaller countries like Belgium, Austria and Sweden.

However, six countries had fewer transplants in 2015 compared to 2008. In absolute numbers, the most impactful reduction was recorded in Germany where the number of annual transplants was reduced by 883 (19%). Minor reductions (in absolute numbers) were seen in Luxembourg, which discontinued transplant activities, as well as in Estonia (−15%) and Portugal (−4%, though it needs to be noted that Portugal had already a very high transplant rate of 80 transplants PMP in 2008). Most important drops in activity rates were recorded in Cyprus (−65%) and Greece (−60%).

The five largest contributors in growth between 2008 and 2015 were the UK (+1335 transplants), France (+1170), Spain (+830), Poland (+396) and the Netherlands (+296). Jointly, they represented 70% of the total increase of nearly 4600 transplants.

As Table 3 illustrates, Spain, Belgium, Austria, Croatia and France were the countries with the highest number of transplants per million inhabitants in 2015.

Donation programs

To allow for different types of donations, member states can organize different programs: donations after brain death (DBD), donations after cardiac death (DCD) and LD.

Donations after brain death remain the most important source for transplants in the EU. In 2015, 79.1% of all transplants in the EU resulted from such donations, while 13.6% resulted from LD and 7.3% from DCD (Table 4). The latter two types of donations have, however, been growing most quickly between 2008 and 2015. Living donation allowed in 2015 for up to half of kidney transplants in Denmark and the Netherlands, while DCD allowed for up to a quarter of kidney transplants in Belgium, the Netherlands, Latvia and the UK.

Figure 2 illustrates, based on kidney transplant numbers, how each EU Member State relies to a different degree on each of the three types of donation program (DBD, DCD, LD).

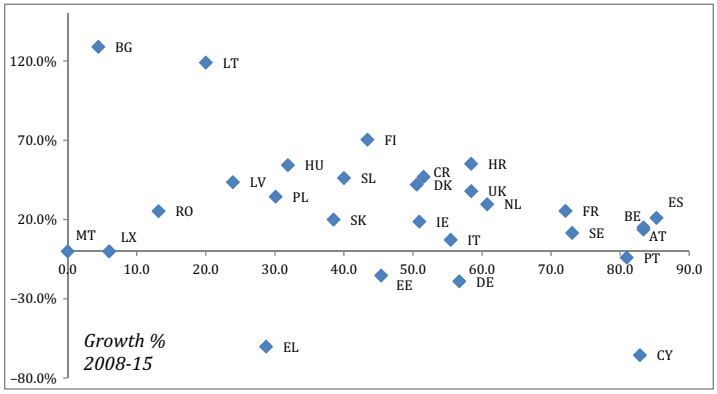

Figure 1 Growth 2008–2015 compared to 2008 baseline (Data from CoE/ONT Newsletters; own figure [7,8]).

Table 3. 2008 and 2015 transplants, absolute values (Abs.) and per million population (PMP), ranked by transplant rates PMP in 2015 (Data from CoE/ONT Newsletters [7,8]; own analyses).

	2008		2015		Growth	
	Abs	PMP	Abs	PMP	Abs	PMP (%)
Spain	3.939	85.3	4.769	103.2	830	21.1
Belgium	892	83.4	1.027	96.0	135	15.1
Austria	692	83.4	787	94.8	95	13.7
Croatia	257	58.4	399	90.7	142	55.3
France	4.584	72.1	5.754	90.5	1.170	25.5
Sweden	672	73.0	750	81.5	78	11.6
The UK	3.517	58.4	4.852	80.6	1.335	38.0
The Netherlands	996	60.7	1.292	78.8	296	29.7
Portugal	858	80.9	824	77.7	−34	−4.0
The Czech Republic	536	51.5	788	75.8	252	47.0
Finland	230	43.4	392	74.0	162	70.4
Denmark	278	50.5	395	71.8	117	42.1
EU-28	28.110	56.6	32.707	65.9	4.597	16.4
Ireland	224	50.9	266	60.5	42	18.8
Italy	3.155	55.4	3.383	59.5	228	7.2
Slovenia	80	40.0	117	58.5	37	46.3
Hungary	322	31.9	497	49.2	175	54.3
Slovakia	204	38.5	245	46.2	41	20.1
Germany	4.661	56.7	3.778	46.0	−883	−18.9
Lithuania	68	20.0	149	43.8	81	119.1
Poland	1.147	30.1	1.543	40.5	396	34.5
Estonia	59	45.4	50	38.5	−9	−15.3
Latvia	55	23.9	79	34.3	24	43.6
Cyprus	58	82.9	20	28.6	−38	−65.5
Romania	276	13.1	346	16.5	70	25.4
Greece	316	28.7	126	11.5	−190	−60.1
Bulgaria	31	4.4	71	10.1	40	129.0

Table 4. 2008 and 2015 transplant numbers in the EU, per program (Data from CoE/ONT Newsletter 2009 and 2016 [7,8], own analyses).

	2008		2015		Growth		
	Number	% Of transplants	Number	% Of transplants	Number	% Of growth	2015 vs. 2008 (%)
DBD	23 783	84.6	25 866	79.1	2083	45.3	8.8
Kidney	13 421	47.7	14 002	42.8	581	12.6	4.3
Liver	6257	22.3	7063	21.6	806	17.5	12.9
Heart	2031	7.2	2235	6.8	204	4.4	10.0
Lung	1260	4.5	1708	5.2	448	9.7	35.6
Pancreas	770	2.7	821	2.5	51	1.1	6.6
Sm Bowel	44	0.2	37	0.1	−7	−0.2	−15.9
DCD	1017	3.6	2383	7.3	1366	29.7	134.3
Kidney	837	3.0	1870	5.7	1033	22.5	123.4
Liver	147	0.5	403	1.2	256	5.6	174.1
Lung	33	0.1	110	0.3	77	1.7	233.3
LD	3310	11.8	4458	13.6	1148	25.0	34.7
Kidney	3098	11.0	4230	12.9	1132	24.6	36.5
Liver	212	0.8	228	0.7	16	0.3	7.5
Total	28 110	100.0	32 707	100.0	4597	100.0	16.4

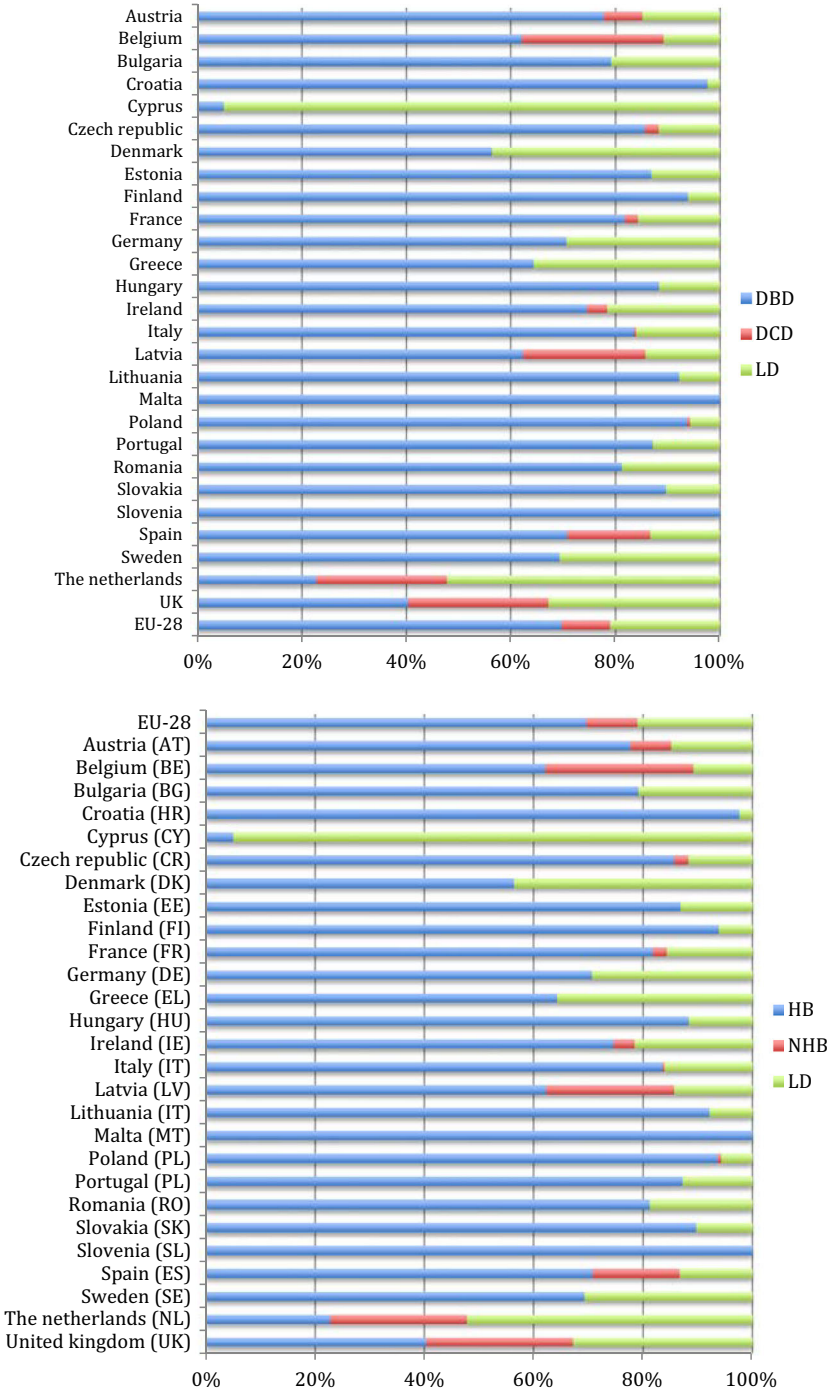

Figure 2 Weight of different donor types, as percentage of 2015 kidney transplants (Data from CoE/ONT 2016 Newsletter [8]; own analyses).

Transplant programs

Following these different donation programs, member states can organize transplantation of different organs in 11 different transplant programs, combining donation program type with solid organ type. DBD leads to transplants of six different organs (kidneys, liver, heart, lung, pancreas, small bowel). DCD allows for transplants of kidneys, livers and lungs, while LD allows for transplants of kidneys and liver. Table 4 provides an overview of absolute numbers and indicates the importance of different transplant programs in the EU, comparing 2008–2015 data from the Newsletter by the Council of Europe/ONT [7,8].

Programs for donation after brain death

Kidney transplants following DBD continued to be the most frequent type of organ transplant in the EU. With

14 000 transplants throughout the EU, this practice counted for 43% of all transplants in 2015. Overall growth between 2008 and 2015 was however limited to 4%. Except for small bowels (−16%), increase of other solid organ transplants following DBD was more important in the same period: liver (+13%), heart (+10%), lung (+36%) and pancreas (+7%).

Donation after brain death has allowed large countries such as the UK, France, Spain and Poland to sharply increase the absolute number of organ transplants, while it has been the main driver for overall growth in many Central and Eastern EU Member States, in particular for kidney transplants (Bulgaria, Lithuania and Romania), and for liver transplants (Buglaria, Romania, Croatia, the Czech Republic, Estonia, Hungary and Poland). The important increase in lung transplants following DBD is driven by strong uptake in some countries (Denmark, Ireland, Czech Republic, Spain) together with continued efforts in other member states (Belgium, Austria and the Netherlands).

Programs for donation after cardiac death

Donation after cardiac death transplant programs have been taken up strongly, and in 2015 the practice was in place in 12 of the 28 EU Member States and enabled 7% of all transplants. DCD has allowed to increase DCD kidney transplants by 123% (which makes up 9% of all kidney transplants in 2015), DCD liver transplants by 174% (which makes up 5% of all liver transplants) and DCD lung transplants by 233% (which makes 6% of all lung transplants). In Belgium, the Netherlands, Latvia and the UK DCD enabled a quarter of kidney transplants in 2015.

Living donation transplant programs

In 2015, 25 EU Member States had LD transplant programs in place. Thirteen percent of all organs transplanted came from living donations. LD is in particular an important source for kidney transplantation. Following an increase of 37%, 21% of 20 102 kidney transplants in 2015 were enabled by a LD. Of the 2746 additional kidney transplants organized in 2015, compared to 2008, 1132 were enabled by living kidney donation. Living kidney donation and transplantation therewith was the main driver for growth (41%) in kidney transplants. For liver transplants, LD contributes a smaller proportion of organs for transplant. In 2015, LD accounts for 228 or 3% of liver transplants, and only a low uptake (+7%) was seen between 2008 and 2015.

Thirteen EU countries have added at least 50% of living kidney transplants to their 2008 totals (Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Italy, Latvia, Lithuania, Poland and Spain), with France, Italy and Spain each increasing living transplant rates by around 150%. These three countries now account for about 29% of kidney transplants from LD.

Discussion

Different countries are served by different donation programs

Progress in different countries, in terms of increase in transplant numbers, is built on the organization of different donation and transplantation programs. The establishment and development of kidney and liver transplant programs from DBD has allowed for strong uptake of organ transplantation in several Eastern European countries, often from a low level of activity in 2008. In countries where organ transplantation is more established, DBD has also facilitated strengthening and/or set up of transplants of less transplanted organs such as lungs. Countries with the highest activity levels have been able to further increase transplant numbers by developing transplantation from all donation programs (DBD, DCD and LD) in parallel.

Positive national performances show opportunities for growth

In the spirit of the EU Action Plan, differences between member states with regard to transplant rates indicate opportunities for improvement. In 2015, LD accounted for more than 50% of kidney transplants in the Netherlands compared to an EU average of 21%. In the same year, DCD allowed for one in four kidney transplants in Belgium, the Netherlands, the UK and Latvia, compared to an EU average of 9%. These levels indicate a high potential for further uptake of transplant programs based on both programs.

The relatively fast growth of transplant numbers of liver, heart and in particular lung (in comparison to kidneys) indicate that more organs from deceased donors can be utilized. This offers room for further maximization of transplant rates. Some developments will determine to which degree this opportunity can be realized in the member states, in particular donation by older donors, extended donor criteria and organ preservation and improvement technologies.

Insights from negative national performances

The negative development of transplant rates in some countries also allow to point to the importance of the

two main contextual factors in place for organ transplantation: public willingness to donate and organizational capacity in the health-care systems.

Compared to 2008, German 2015 data show a decrease of 883 transplants or 19%. This decrease followed 2012 media reports on several transplant centers had manipulated medical data to allow certain liver patients to move up waiting lists. This scandal has affected public trust and willingness to donate, and consequently possibilities to approach potential donor families, which resulted in an overall drop of around 30% in the number of deceased donors [7-8,10-14]. By 2015, donation rates had not yet recovered. Given that Germany is the EU Member State with one sixth of EU population, this negative performance has also limited growth of overall EU transplant numbers.

Transplant systems are highly dependent on the overall strength of health-care systems, and require a continuous level of investment in health-care infrastructure and expertise. Countries such as Greece and Cyprus, particularly impacted by the overall economic crisis, have not only seen a reduction in public (healthcare) spending, but also a strong drop (over 60%) in transplant rates between 2008 and 2015. Reducing such investment might, however, be counterproductive from an economic perspective, in particular as transplants of kidneys (the most commonly transplanted organ) are known to offer important savings compared to substantially more expensive dialyses therapies for end-stage renal dysfunction. The National Health Service Blood and Transplant (NHSBT) in the UK estimated in 2009 that kidney transplants resulted in savings of over £500 million in the National Health Service (NHS) budget spent on renal failure (3% of the total NHS budget) [15]. This insight was one of the triggers for the UK national Action Plan setting targets to increase organ donation and transplantation rates. In the course of 2008–2015, the UK added the highest number of transplants to EU growth in organ transplant rates.

Role of the action plan

Transplant systems are complex and their success is influenced by many factors which do not allow for a direct quantitative assessment of the impact of the action plan. However, the 2017 FACTOR study [9] made a qualitative assessment of the impact of the action plan a posteriori, by building on extensive reports on the experiences of the National Competent Authorities in the EU Member States.

The most valuable result reported in the FACTOR study was the establishment of a common strategy and agenda that aims to direct, coordinate and support efforts at national level, while being aligned with EU policies and activities. Up to half of the member states reported that national policy was influenced by the EU Action Plan. This was the case in particular when working on the first three priority actions focusing on (PA1 – see Table 1 on priority actions) transplant coordinators, (PA2) quality improvement programs and (PA3) LD programs.

Besides offering support to take up the three first priority actions, member states also noted that their efforts had been supported by projects focusing on more specific priority actions such as (PA4) communication skills and (PA6) organizational models. Noteworthy also was that 23 (of 28) EU Member States expressed interest in the organ exchange platform that was developed under the FOEDUS Joint Action (PA8).

National Competent Authorities also mentioned the importance of the central and joint coordination of the action plan, and the many EU-funded projects, in particular through networking during project meetings (mainly joint actions) and regular meetings of the EU-28 National Competent Authorities, organized by the European Commission.

Though, the most valuable outcome is probably that these regular contacts allowed for establishing and building trust among a community of peer National Competent Authorities, facilitating exchange of good practices to improve national organization of transplant medicine. This is a solid ground to further increase the number of transplants for patients all over the European Union.

Authorship

SVdS: conceived this study, performed the research and drafted the paper. PSB and HB: contributed substantially to the interpretation of the data and critically revised the text. All authors approved the paper.

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Conflicts of interest

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