REVIVING EU AMBITION ON ORGAN DONATION AND TRANSPLANTATION

EVENT REPORT
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Transplanting organs is one of the greatest medical achievements but donation remains a challenge for Europe, as 18 patients still die every day waiting for a donor.

Given the current EU legal framework defining the standards for organ transplantation is outdated, there is a new impetus to assess what success there has been so far and the room for improvement.

Stakeholders and lawmakers are also considering how to revisit the issue of an Action Plan on organ donation and transplantation, following a previous successful one that was in force between 2009 and 2015.
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MEP: Revised EU framework, new action plan for organ donation needed

Stronger follow-up on EU organ donation action plan is necessary, health expert says

A Shared Vision for Improving Organ Donation and Transplantation in the EU
The European Commission should consider reshaping the current legislative framework on organ donation and transplantation, according to Hilde Vautmans, a leading MEP politician in the field.

Speaking at the annual European Kidney Forum, organised by the European Kidney Health Alliance (EKHA) on 11 March, which this year brought together patients, policymakers, national competent authorities, medical societies and researchers for a webinar.

The Belgian lawmaker asked the EU executive to consider launching a new EU action plan on organ donation, following a previous one in operation between 2009 and 2015.

Organ shortage is a big challenge for Europe, as it is estimated that, on average, 18 patients die every day waiting for a transplant. “This is unacceptable,” commented the Renew Europe lawmaker, who is also chair of MEP Group for Kidney Health.

“If we want to save more lives through organ transplantation we must take actions to increase organ availability,” she added.

The current EU legal framework defining the standards for organ transplantation, the Organ Directive, laid down the quality and standards for organ.

The directive, which dates back to 2010, covers all the steps in the transplantation process from donation

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to procurement and testing, as well as from handling to distribution.

“Ever since then, the world has changed and technology too. Is our current framework fit enough for the future?,” the MEP said, pointing out that the time has come for an assessment to see if there’s a room for improving the Organ Directive.

“With Ursula von der Leyen, a doctor, at the helm of the Commission, we have an unprecedented window of opportunity for change and really deliver for patients,” she said.

**EU ACTION PLAN**

Vautmans’ advocation for a new EU action plan in the area follows previous measures between 2009 and 2015, which resulted in a steady increase in the transplantation rate by more than 15% in the ten years after its launch, extending the cooperation between member states, despite EU limited competence in health.

The Commission positively assessed the achievements of the Action Plan (2009-2015) in an impact study released in 2017 which found that, during that time, the total number of organ donors at the EU level increased from 12,300 to 14,900. At the same time there was an increase of 4,641 transplants.

**NEW FOCUS ON TRANSPLANTATION**

Prof. Raymond Vanholder, President of the Brussels-based NGO, the European Kidney Health Alliance (EKHA), stressed the importance of developing a new Action Plan that “can stand on the shoulders of the previous one,” but with a focus on organ transplantation.

He added that after transplantation, people live on average twice as long as dialysis patients, improving the quality of life of patients and decreasing healthcare costs too.

“The longer the transplanted organs keep going, the better is the quality of life of the patient,” he said, adding that patients are often concerned about keeping their transplant organ as long as possible.

**TRAINING IS KEY**

According to Mirela Bušić, appointed in 2003 as National Transplant Coordinator at Croatia’s Ministry of Health, training and education play a crucial role in optimising the organ donation rate.

“Training should be provided at all levels, but what we have suggested is focusing at the first stage on providing training to professionals working in the specific field of organ donation and transplantation,” she said in the webinar.

She added that the aim should be developing guidances and harmonising the professional code of practice in the field of organ donation, to facilitate the implementation and integration of the organ donation practice.

Beatriz Dominguez Gil, Director of the Spanish National Transplant Organisation, meanwhile, stressed that training remains critical.

"In Spain, the government has taken responsibility for this matter so every year, we devote governmental funds to the training of these professionals," she said.
Stronger follow-up on EU organ donation action plan is necessary, health expert says

By Gerardo Fortuna | EURACTIV.com

The EU Action plan on organ donation has been encouraging greater co-operation on organ donation and transplants but stronger follow-up on its implementation is necessary, a Croatian health policymaker told EURACTIV in an interview.

“The ongoing political focus on this sensitive field of public health is essential to ensure its further sustained advancement,” said Mirela Bušić, who was appointed in 2003 as the national transplant coordinator at Croatia’s health ministry.

The EU action plan was put forward by the European Commission in 2008 as a non-binding tool to strengthen cooperation among member states on organ donation and transplantation.

It helped improve national policy and the activities of organ donations, according to a Commission impact study in 2017 which found that there had been an increase of 4,641 transplants within the EU.

According to Bušić, member states now need to further strengthen capacities and enhance governing and clinical leadership in deceased organ donation.

“A broader collaboration at the national and EU level should be

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strongly promoted, as it is a shared responsibility of the national competent authorities and relevant professional societies such as critical care, neurology, emergency,” she said.

ROOM FOR IMPROVEMENT

In particular, deceased organ donation pathway should be systematically integrated within hospitals’ end-of-life policies to ensure that an opportunity for organ donation in hospital settings is never missed.

In her view, it is crucial to ensure that the end-of-life decision-making process, when medically appropriate, respectfully addresses organ donation in the context of the patient’s best interest and preferences.

Among the recommendations made by the Commission in its 2017 assessment, the EU executive stressed the need to understand and overcome obstacles that critical care professionals face to incorporate donation in end-of-life care plans.

“For such a highly sensitive and optimized approach, critical care professionals should be trained properly and systematically,” she said.

She added that funding for the development of training programs, educational platforms, methodology and tools for more effective monitoring on quality indicators and hospital performance in deceased organ donation should be ensured at both national and common EU levels.

“Additionally, transplantation registries are essential to measure outcomes, improve quality and safety standards and ensure transparency, which in turn promotes equity and benchmark transplantation practice,” she stressed.

CROATIA’S DONATION CULTURE

Croatia’s Ministry of Health carried out a 10-year stepwise approach from 2001 to 2011 to boost organ donation. It resulted in a 5-fold increase in deceased organ donation rate, from 7 to 35 per million people.

In 2015, the donor rate reached 40 per million population, putting Croatia among the countries with the highest capacity in terms of provision of deceased organ donation and transplantation services.

“The altruistic act of donation, as a highly appreciated gesture of loving care for others, has been nourished in Croatia for decades,” Bušić said.

Integration of the topic of organ donation in school curricula, along with public campaigns focusing on “real stories”, has created a positive public perception of organ donation.

Therefore, the “culture” of altruistic deceased organ donation is widely embraced – as well as tissue, cells and blood donation, by Croatian society.

“The Croatian transplantation program is comprehensively grounded on the highest professional standards and ethical principles of altruistic donation, solidarity and equity that all successfully mirror the WHO guiding principles,” Bušić concluded.
More than 30% of European adults suffer from chronic disease (heart failure, cardiovascular disease, liver cirrhosis, chronic kidney disease, diabetes mellitus, among others) and more than 85% die from it.

Professor Raymond Vanholder is the President of the European Kidney Health Alliance (EKHA).

The general perception is that chronic diseases are a problem of the older population, but 45% of patients who die from chronic diseases are actually below 60 years of age. Once these disorders reach their final stage, loss of life can, in most cases, only be avoided by offering transplantation of a well-functioning organ from a living or deceased donor.

In the EU, up to 16 patients die every day waiting for a transplant, and while some countries (such as Spain and Croatia) have seen encouraging increases in organ donation, in others transplantation rates have been stagnating or even decreasing. By the end of 2018, more than 110,000 EU citizens were on organ waiting lists, and this figure is a 7% increase vis-à-vis 2014. Today on World Kidney Day, the European Kidney Health Alliance calls on policymakers to put organ donation and transplantation high on their agenda. Much more needs to be done if we are to alleviate the human, social and economic burden of end-stage kidney disease as well as other chronic diseases for which the only hope of survival is organ transplantation.

**TRANSPLANTATION SAVES LIVES AND MONEY**

The most frequently transplanted organs in Europe are (in rank order) kidney, liver, heart and lung. The only two alternative options at an advanced stage of the disease are conservative treatment, which only assures (limited) comfort or artificial organ treatment. However, the latter option is only available on a large scale for kidney failure (dialysis).

Transplantation is life-saving. This is obvious for those organs where no alternative is available (liver, heart, lung) and where transplantation is a question of life or death; but it is also the case for kidney failure, for which dialysis exists as an alternative. Expected average remaining lifetime for a 50-year-old kidney transplant recipient is more than twice as long as that of a patient who remains on dialysis. In addition, quality of life, self-esteem and satisfaction are significantly improved among transplant recipients, while the cost is decreased. One year after transplantation, costs to healthcare systems are 90% lower than for

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dialysis, which is an expensive therapy (up to 80,000 € per patient per year, depending on the country). Finally, transplantation offers the possibility for patients to retain, or indeed return to economic activity, as it removes the medical obstacles for unemployment, thus increasing purchasing power and social integration.

Patients with severe chronic disease take multiple medications, are limited in their activities and social life, suffer from multiple, often debilitating symptoms, and spend much time in hospital and for their treatment. These handicaps are significantly reduced by transplantation.

Stimulating organ donation and transplantation thus has a major impact on physical and mental health, healthcare systems and the economy. Despite its limited competence in health, the European Union (EU) has taken action to optimise organ donation and transplantation through its Action Plan (2009-2015) which contributed to increasing donation and transplantation rates in the EU by more than 15%, reaching close to 35,000 solid organ transplants in 2018.

A CALL FOR CONCERTED ACTION TO ADDRESS SHORTCOMINGS IN ORGAN DONATION AND TRANSPLANTATION IN EUROPE: THE EU THEMATIC NETWORK AND JOINT STATEMENT

The number of donors per year in EU countries ranges from more than 50 per million people for the highest-scoring country to less than 5 per million people for the lowest. These major disparities also exist for almost every other aspect of organ donation and transplantation from a number of people with a functioning graft to living and deceased donation to transplantation after cardiac death.

To better streamline future transplant activity in the EU, the European Commission assigned a group of European stakeholders in the field to develop a Thematic Network and to draft a Joint Statement on how to improve donation and transplantation activity throughout the EU. This Joint Statement was led by the European Kidney Health Alliance, and produced in close collaboration with European Society for Organ Transplantation (ESOT), learned societies of frequently transplanted organs (kidney and liver) and national competent authorities for organ donation and transplantation (Spain, Croatia and the Netherlands). Furthermore, it was endorsed by 54 organizations and 19 individual Members of the European Parliament (MEPs), demonstrating the widely recognised relevance and timeliness of this document.

Together with 8 policy calls and corresponding recommendations to be actioned at national, EU and stakeholder levels, the Joint Statement sets out 14 key measures needed to increase transplantation rates and improve post-transplant outcomes. A central point is the need to optimally organize donor coordination and intensive care procedures for donor selection because this impacts not only the number of donations but also organ quality and thus, the chances that function is maintained in the long term.

Contributing stakeholders also put great emphasis on the importance of education and information, not only for patients but also for medical professionals (directly involved in transplantation or not), students, and the general public, with special attention to minorities and health-illiterate people who may need specific approaches. For greater impact, these efforts should make use of traditional as well as new media.

Additionally, while countries can learn a lot from each other, structured approaches that cluster countries according to their common characteristics may be most effective in finding lasting solutions. Other key takeaways from the Joint Statement include the need to systematically address inequities in access to transplantation (which may be due to race, gender, citizenship status or socioeconomic factors among others); increase the availability and quality of data by appropriate registration and encourage benchmarking of transplant activities; provide appropriate legal and institutional frameworks; ensure sufficient funding of transplant activities, and stimulate transplant research, which involves not only innovative therapeutic approaches but also patients’ quality of life, social aspects and health economics.

It is the sincere hope of all involved stakeholders that the Joint Statement will help generate renewed political momentum and policy action on improving donation and transplantation activities throughout the EU, and prompt a second EU action plan building on the success and experiences of the previous initiative.

The full text of the Joint Statement on Improving Organ Donation and Transplantation in the EU can be accessed here:
