



**Call to Action to Improve
Organ Donation and
Transplantation
across the EU**
PHAEUROPE.ORG

Improving organ donation and transplant across the EU: A cross-condition campaign

European Parliament, Brussels, 18 October

Draft report

Agenda

10.00 -10.20 Welcome and introductions

Chair: Ivan Jakovcic MEP

Video: patient testimonials

Speakers:

- Pisana Ferrari (CEO, Pulmonary Hypertension Association Europe)
- Nikola Zgrablic (President, Donor Network of Croatia)

10.20-11.30 Session 1: The regulatory and logistics side of organ donation and transplant

10.20-10.25 Introduction by the Chair: Hilde Vautmans MEP

10.25-11.00 Speakers:

- Stefaan Van Der Spiegel (Team Leader, Substances of Human Origin, Directorate General Santé, European Commission)
- Rafael Matesanz (Director, National Organ Transplant Society, Spain)

11.00-11.15 Response:

- Hilde De Keyser (Coordinator, Cystic Fibrosis - Europe)
- Angelika Widhalm (Member of the Board, European Liver Patients Association)

11.15-11.35 Audience debate

11.35-13.00 Session 2: The medical and awareness side of organ donation and transplant

11.35-11.40 Introduction by the Chair: Mr. Alojz Peterle MEP

11.40-12.20 Speakers:

- Sally Johnson (Director, Organ Donation and Transplant, NHS, UK)

12.20-12.35 Response:

- John Fisher (Chairman, To Transplant and Beyond, UK)
- Prof Raymond Van Holder (President, European Kidney Health Alliance)

12.35-12.50 Audience debate

12.50-13.00 Conclusions and close

- Catherine Hartmann (Secretary General, COPD Coalition and Vice President, EPHA)

Meeting report

Ivan Jakovcic MEP welcomed participants and underlined his interest in all issues relating to organ donation and transplant. His role as President of the Region of Istria, a position he held for more than ten years, made him aware of the importance of the topic and of the challenges relating to the lack of organs.

This is a major public health challenge which needs more attention and discussion. This is why Mr. Jakovcic took the initiative to launch Written Declaration on organ donation and transplant earlier this year. This underlined that 80.000 people across the EU that are waiting for a transplant (ref: Council of Europe). Sixteen people die every day while waiting – this is not just a sad statistic but a matter of life and death.

His country, Croatia is small, but the Donor Network has made a huge difference; the country is now amongst the leading countries in terms of number of donors per million people (i.e. 54).

Mr. Jakovcic MEP then gave the floor to **Pisana Ferrari (Pulmonary Hypertension Association Europe)**, who welcomed participants and expressed her thanks to the hosting MEPs.

Mrs. Ferrari briefly introduced pulmonary hypertension is a rare, progressive and life-limiting lung heart condition. With new treatment, survival has improved by a few years but lung transplant is the only option for end-stage disease – and the difference between life and death. Patients affected by a number of other conditions involving the lung, heart, liver, kidneys, small bowels and other organs are in a similar situation. They face the same problems, i.e. shortage of organs, long waiting lists, high mortality, lack of awareness and understanding in the general population and, in some countries, lack of surgery facilities. This is why PHA Europe decided to develop a **Call to Action** to address these issues. This is intended as part of a cross-condition, transversal campaign where organisations with the same problems could advocate for change together. The Call to Action was launched on European Organ Donation Day 2015 in Lisbon and is currently being endorsed by over 90 national, EU and international level organisations.

Mrs. Ferrari then showed a video, which consisted of a series of brief testimonials of patients who have undergone transplant of different organs and who have been able to lead normal, active and fulfilling lives.

The next speaker was **Dr. Nikola Zgrablic (Donor Network of Croatia)**, who presented the Donor Network of Croatia and its activities. Some 20 years ago, Croatian transplantation medicine was at the rear of Europe, with only 2 to 5 donors per million people. This was reflected in long waiting lists and high mortality rates. There was no organisation in charge of the transplantation programme. However, the Ministry of Health did set up the Institute for Transplantations and Biomedicine.

At the time, it was thought that one of the major problems of transplantation was a lack of information and awareness amongst the general public. For this reason, a group of physicians founded the Donor Network of Croatia (DNC) in 1998. Its main objective was to change the public attitude toward organ donation in order to increase organ donation rates. From the very beginning, the government was being called upon to help solve the problem.

The DNC's most well-known product is the organ donor card. This is not legally binding but serves as promotional material, a tool to provoke and launch discussions among family members. And, of course, it also shows a person's willingness to donate organs after death. One million copies of the Card have been issued over the last 20 years. Famous politicians, athletes and others have been asked to sign their Cards in public.

It is commonly accepted that a positive public opinion on organ donation is one of the most important issues which can cause an increase in the number of donors. Therefore, many activities have been undertaken to inform the general public; special attention has been given to health professionals (during their training) because of their crucial role in the transplantation process. Hopefully, education in schools will lead to 'generational change'.

Meanwhile, it has become clear that the 'uninformed' public was not the only problem: the lack of educated transplant coordinators emerged as one of the key factors. This is why some coordinators were financed to attend training courses in Spain. These days this kind of training is being provided by the DNC itself, also to other specialists like neurologists. DNC has ensured the involvement of 2-3 specifically trained physicians in transplantation in every Croatian hospital. Cooperation in training has now also extended to neighboring countries.

Clearly, the DNC's engagement has been crucial to the recent successes in organ donation in Croatia. In 2015, Croatia had over 40,2 donors per million people. However, without the strong involvement of the government these successes would not have been possible. In addition, the involvement of non-governmental organisations has helped to raise awareness amongst the general public as well as health professionals.

Session 1: The regulatory and logistics side of organ donation and transplant

Hilde Vautmans MEP took over the chair and stated that organ donation and transplantation is of personal interest to her for two reasons: organ donation and transplantation is one of the greatest medical successes of the 20th century. However, we can only save lives if there are enough organs available for transplantation. In the EU, about 86 000 people were waiting for a transplant in 2014 and every day, 16 die while waiting. IN addition, as the supply of organs is very limited lucrative opportunities emerge for organised criminal groups to track down and remove organs of people in poverty. It is simply unacceptable that poor people and their organs are the target of criminal groups. It is also unacceptable that organs, intended to save people's life, transmit diseases because the quality and safety of the organs are not ensured.

As an MEP, Mrs. Vautmans feels she has the responsibility as well as the opportunity to launch initiatives to ensure organ availability, to ensure the traceability from donor to recipient and to fight organ trafficking.

As for the topic of the session, Mrs. Vautmans underlined the importance of the regulatory and logistics side of organ donation and transplantation as there are many challenges. One of these is time pressure. The process from procurement to transplantation should be completed in only a few hours. Hence, the locations of the donor and recipient become very important. Another challenge is compatibility. Also, in Europe there are different organisation systems and some organisational models seem to be more efficient than others. Regulatory aspects of organ involve the quality and safety of organs, organ procurement, consent and authorisation requirements prior to procurement, donor and recipient protection, protection of data, and many more aspects. This regulatory side can be complex, for example when organ donation and transplantation activity is carried out by professionals in different countries and hence is carried out under different jurisdictions.

Mrs. Vautmans then gave the floor to **Stefaan Van der Spiegel (European Commission, DG Santé)** who emphasised the limited EU level competence in the field of health. The EU's role is to complement national policies, foster cooperation between the Member States and third countries. However, in the field of organ donation, the EU Treaty does call for setting 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives'.

The Commission has therefore indeed come forward with a Directive on safety and quality of organs, which were adopted by the European Parliament and Council in 2010. Consequently the Commission adopted a Directive to support organ exchange between Member States (2012).

The focus if this legal Commission work always relates to safety and quality, covering the entire process from organ donor transfer to recipient, i.e. collecting, testing, processing, storing and distribution. Different levels of quality requirements apply, to medical professionals (e.g. selection, consent), to national competent authorities (e.g. traceability, inspection) and to the European Commission (e.g. support to Member States, rapid alerts, traceability systems).

Many other activities needed to organize organ transplantation, fall under (cross-)national mandate in the 28 EU Member States (e.g. consent systems and registers, defining 'death, allowed types of deceased and living donors), patients on waiting lists (inclusion/exclusion on waiting lists), allocation (priorities of available organs), transplantation (funding/availability of organs, medical practice) and health outcomes. The EU-funded Eurotransplant organisation is responsible for the allocation of donor organs in Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia. This international collaborative framework includes all transplant hospitals, tissue-typing laboratories and hospitals where organ donations take place.

To support these national activities, the Commission has launched an EU Organs Action Plan, with the aim to strengthen cooperation between the Member States. The Action Plan consists of ten priorities under three main objectives:

- Increase organ availability: Transplant coordination, Quality improvement programmes, Living donation programmes, Communication skills of professional and Information on citizens' rights
- Enhance efficiency of and access of transplant programmes: enhance organisational model, EU-wide agreements and interchange of organs
- Quality and safety; evaluation of post-transplant results and common accreditation systems.

Mr. Van der Spiegel underlined that the differences between the Member States drive opportunities: while overall donation rates are going up, there is still potential for more organs and the potential to learn from each other.

The Action Programme was been concluded in 2015, and is currently undergoing a final evaluation.

A specific Commission initiative is the FOEDUS Joint Action on organ donation and transplant, targeting the interchange of organs – this connects the organ allocation offices in different countries. This Joint Action has piloted an IT-platform which allowed for 23 additional transplants, which otherwise would not have taken place. The platform, which costs less than 10,000 euros per year to maintain, is expanding now.

Since 2015, the Commission is also managing two pilot projects which were promoted by the European Parliament: on Chronic Kidney Diseases (supported by Karin Kadenbach MEP) and on social awareness on organ donation entitled EUDONORGA (supported by Gabriel Mato MEP).

In conclusion, Mr. Van der Spiegel stated that, despite steady progress, there are still many opportunities to improve and to learn, from other countries as well as from other related fields (blood, tissues, cells ...). The Commission is open to suggestions for improvement and progress.

The next speaker, **Dr. Rafael Matesanz (National Transplant Organization - ONT, Spain)** highlighted the great differences in organ donation rates between the most developed countries. Spain is the country with the highest rates since 1992. As the Spanish population does not have a special predisposition towards organ donation, it is interesting to explore the reasons why Spain is doing so well and has been leading the world in organ donation. The classic approaches to improve organ donation, i.e. changes of Legislation, publicity campaigns, donor registries, donor cards / driving licenses and other ways have not lead to significant improvement anywhere. However, the philosophy of the Spanish model – an integrated management system – has yielded results. Improvement of organ donation and improvement of organization go hand in hand. Several elements are being brought together in this approach, i.e. working inside the hospitals, brain death audits, training professionals, hospital reimbursement, a coordination network, media attention have given the topic a special profile.

Some 190 transplant coordination teams are in place in Spain, with 270 medical doctors (part-time or full-time) and 168 nurses (part-time/full-time); a specific organisation focuses on coordinating the coordinators. Over 17.000 health professionals have received training including ICU and A&E doctors. As the most effective coordinators probably are intensive care specialists, 1000 of these young specialists have been trained in organ donation over the last 9 years.

The increase in organ donation has been steady in Spain, with a current Spanish average of 40,2 donors per million people. The model has been exported to Latin America – via the ‘Master Alianza’ – where 362 professional has received the same training. This has led to a 54 % increase in organ donation since the start of the programme.

Some 8 years ago there was a realisation that potential donors also exist outside the ICU, so training courses now also focus on A&E doctors.

Mr. Matesanz also spoke of his involvement with the EU-funded ACCORD programme, which specifically focused on the pathway of donation after brain death in Europe. In conclusion, he underlined that the only way to improve organ donation and increase donor rates is to integrate organ donation into the medical care provided at the end of life. The key success factors are always the same: trained health professionals and good organisation. Mr. Matesanz emphasised that it does not do to blame the population; ‘if people donate less, it must be something we have done wrong’.

Respondents:

Hilde De Keyser (Cystic Fibrosis – Europe) thanked PHA Europe for its initiative (The Call to Action and the event) and briefly introduced her organisation, stating that there are some 40.000 CF patients across Europe. While management of the condition has improved over the last decades, it is difficult to understand the huge differences in life expectancy between the member states. There is a clear lack of awareness of the importance of organ donation; there is also a lack of organs and facilities for transplant. As a single patient advocacy organisation, CF-Europe is not in a position to change the situation. However, the organisation can take strong positions and support political initiatives such as the Call to Action as well as practical actions such a Eurotransplant. The latter is a very useful initiative which should be expanded.

In Belgium, the recent change of legislation ensures that families can no longer stop a person from donating organs when he/she has indicate that he/she wants to donate. This system should be promoted more.

More can be achieved in cooperation with other organisations and across the EU. Awareness and education can be improved in cooperation; organisations have to be more open and ready to move forward together.

Angelika Widhalm (ELPA), a liver recipient herself, underlined the importance of organ donation and transplant as this is – in many cases- the only chance to get a new life. One of the barriers to action is the lack of information

with respect to registration of patients and waiting list. There is a lack of organs – according to the Council of Europe,

there are 80.000 patients waiting. The current waiting period for a liver is between 2 and 5 years across the EU. There is progress but it is not sufficient. The EU should make funds available to improve the situation; awareness campaigns might stimulate progress. There should also be more transparency with respect to surgeons, facilities and choice.

In many cases, the focus of health professionals is on political goals with too little attention for the needs of patients. The Cross-border Regulation should be changed so that patients can have access to organs across the border. ELPA endorses the Call to Action as every patient that needs an organ should obtain it as quickly as possible. Mrs. Widhalm called on the MEPs present to support this view and take practical action.

Session 2: The medical and awareness side of organ donation and transplant

Alojz Peterle MEP took over the chair, stating that awareness of the importance of health-related topics is increasing, judging by the recent huge number of health-related events in the European Parliament. There seems to be a sense of urgency to take action and improve health systems, and organ donation and transplant is an important issue in this respect.

Alojz Peterle MEP remarked that in fact, the more we know, the more questions we have to answer. There are issues in relation to data, in relation to technical and process issues, in relating to dignity of those involved, even after death. Organ donation requires a high level of sensitivity. This is also a cross border issue. The fact that there are many inequalities and differences in this field does not come as a surprise. In terms of health, there is a staggering lack of harmony in the EU and this is a recurrent theme in European Parliament discussions. While the EU remit in the field is limited, MEPs speak in favour of a more favourable interpretation of the Treaty. Despite the limited competence, supportive and complementary measures can be taken.

Mr. Peterle then gave the floor to **Sally Johnson (National Health Service, UK)**, who provided information on some of the promotional activities undertaken by her organisations to increase awareness of the importance and practicalities of organ donation and increase the number of donors.

Between 2008 and 2013, an Organ Donation Taskforce was active, focusing on the reorganisation of donation and retrieval services. During that period, the number of donors increased by 50%; however, the transplant numbers only grew by 31%. The donor rate in the UK was 21.6 per million people, and donation was reliant on donors after Circulatory Death (i.e. 42% of all donors). There was no increase in consent, while donor demographics meant fewer transplantable organs. In other words, there was a need to focus on transplants, not just on donors. Consent was an issue, especially in Black and Asian communities. Donor hospitals had made great progress but were still inconsistent.

This is why the 'Taking Organ Transplantation to 2020' came into being, with the aim to match world class performance in organ donation and transplantation. The aim was to put in place better support systems and processes to enable more donations and transplant operations to happen. An NHS Organ Donor Register was developed which allows people to record a decision about organ donation. Currently 22.5 million people have recorded their consent; 180 thousand have recorded a refusal.

It is important to get the 'right' people to register. Within the White communities, 87% support organ donation in principle. Most people are prepared to support known wishes of a relative but people don't join the Register because of lack of knowledge (50%), inertia (37%) or avoidance/emotional barriers (36%).

Within Black and Asian communities, 44% support organ donation in principle vs 87% in overall population; 28% willing to donate vs. 74% in overall population. Barriers vary by community, but in general there is less trust in medical profession and there are concerns about religious support. Within these communities, the motivation to donate is more motivated by the thought that being an organ donor could benefit family, friends and the community.

A Public Behaviour Strategy was also part of the initiative, with the mission to get families to consent to organ donation on behalf of their loved ones. The objectives were to increase the number of people on the Organ Donor Register (ODR) by 50% by 2020, to stimulate conversations and debate about donation, using the ODR as a marketing tool and to present donation as a benefit to families in end-of-life and grieving process.

As a result, more organs are being used, the retrieval service is improved with all surgeons trained and accredited and service evaluation in new technologies is being supported. Systems and processes are more simple, safe and supportive (e.g. DonorPath: mobile iPad app used by Specialist Nurses to capture all donor characterisation data).

The progress to date is that 22.5 million people currently are on the Organ Donor Register – 75% of people registering this year have had conversation with their family. The potential donors identified and referred are now

96% DBD, 83% DCD. Consent rate is currently 62% (DBD 68%, DCD 59%). Nineteen hearts were transplanted from donors after Circulatory Death (2015/16) and the DonorPath App is in use throughout UK. In other words, the campaign has led to more donors, more transplants and fewer people waiting.

Respondents:

John Fisher (To Transplant and Beyond) talked about his heart transplant, now 16 years ago. His focus was on the donor – in many cases, the donor's family can stop donation. This goes against the wishes of the donor, and therefore, the rights of the donor should be protected and their wishes should be respected. Unfortunately the existing donor card is not legal – however, it clearly indicates the wish and intention of the donor.

In some cases, donation can actually support those who stay behind. In John's case, his donor saved the lives of 5 people and gave a meaning to the loss of the family member. Are there ways to ensure that the donor's wishes are respected?

Professor Raymond Vanholder (Chairman, European Kidney Health Alliance) stated that most kidney patients who progress to the end stage come to a point where there is a choice to be made between dialysis and transplantation. In making the choice between dialysis and transplantation, the reimbursement policy of their country may be an issue; in some countries, there is not sufficient financial incentive to default towards transplantation as the preferred option. In the future, he considered as a potential solution that that reimbursement would be aligned for whatever action is taken, once a patient reaches an advanced stage of chronic kidney disease. Ultimately, health systems should be patient-centered, instead of treatment-centered. There is a lack of awareness of both patients as well as the general public about the full benefits of transplantation both to the individual and to society. However, awareness-raising campaigns must be well prepared. In terms of opting in vs. opting out, legal opting out (presumed consent) very likely will lead to a higher rate of cadaveric donation, and therefore transplantation, than will a policy for opting-in in many countries. In addition, cultural differences between countries need to be taken into account: some countries have relatively high rates of living donation whereas others have high rates of cadaveric donation. Efforts must be made to improve awareness and acceptance of both options. This can be done by means of high-quality and accessible information, donor registries and donor incentives such as health insurance coverage for their medical costs (although discussions on the ethics of this should take place before embarking on this). Scientific programmes can also support progress on organ availability (e.g. stem cell research). EKHA works to raise political awareness at EU level of the full spectrum of issues surrounding kidney disease from prevention through to availability of kidney transplantation. Each year EKHA organizes a European Kidney Forum under the auspices of its MEP Group for Kidney Health. The topic of next year's Forum will be Patient Choice of Treatment.

Discussion

In the audience debate the following issues were raised:

Older patients, older donors: With populations getting older, donors are getting older too. In Spain, since 5 years over half the donors are over the age of 60. There are concerns with respect to the quality of donated organs. Guidelines are being developed in this area.

Impact of 'opting out' in Wales: Wales has recently introduced an 'opting out' system. It will be interesting to see whether this will have an impact on the number of donors/transplants. The number of donors seems to have increased up but whether this is a result of the legislation of better awareness is not clear yet.

How to make the most of the EU health remit: Questions were asked in relation to the disharmony across the EU in terms of health policy – impacting on organ donation and transplant as well; how could more harmonisation be ensured without the Commission having a clear mandate to do so? The Commission can facilitate the exchange of good practice and share learnings. This can help to find solutions and progress.

In addition, the Cross-border Directive should be promoted. We need to explore what else can be done in the frame of the Lisbon Treaty to ensure less inequality in terms of health and quality of life. However, local health care settings need to be taken into account. It is not possible to change the entire systems; we need to work with the systems that exist. Good practice exchange is useful but it is up to every country to take it back home and see how it can support the local situation.

In some Member States the survival rate is much lower than in others. This difference shows that some countries have knowledge and others don't. We can and should do much more with what we already know and share this knowledge. The political will to cooperate needs to be stimulated and developed. The Cross-border Directive can be helpful in bringing countries together and boost quality services.

Access disparities: The disparities between European countries are enormous: for kidneys, in Norway, 70 % of those in need have transplants, while in Germany this is only 30 %. Dialysis seems to be the preferred treatment in many countries. Different countries have different medical cultures as well.

European Reference Networks: Rare diseases need rare competences. In the field of rare diseases, European Reference Networks are being developed. The Commission published a call for proposals and has received 24 applications received for very complex and rare conditions. These Networks are not aiming to replace what is already happening but want to add to the possibilities. Scientific societies are involved to make sure that there is no duplication of efforts; patients are very much involved with the development of the ERNs as well. They will be launched in March 2017.

Family consent: A recent change of legislation in Belgium means that, once a person has registered as a donor, the family cannot intervene after the person has died. This is just another example of the differences between countries. If this is possible in Belgium it should be possible in the UK as well. However, it needs to be remembered that the moment of the patients' death is critical and very distressing; health care staff needs specific training for addressing families. In the UK, families are approached by trained specialist nurses. Their training is intense and takes 6 months before they are competent. They do not ask families for consent but state that the donor gave his/her consent and ask for the families' support. Decisions not to give consent are often very practical. If the right conversation can be had, these barriers can be overcome.

In many countries 'opting out' is theoretical as the family has the right to say yes or no. In 'persuading' families to give their consent, transplant coordinators have more leverage to talk to the family. The family has the right to refuse consent (in many countries) but transplant coordinators can explain what will be happening and maybe persuade families.

- *The need to raise awareness:* It will be very important to raise awareness on organ donation and transplant and change the organ donation culture in the EU. This is a topic which is close to citizens, and EU citizens wish to benefit from the fact that 28 countries are working together.

Conclusions

Bringing the meeting to a close, **Catherine Hartmann (COPD Coalition)** first briefly introduced COPD as a chronic non-curable lung disease, affecting up to 10% of adult population in the EU. Lung transplant is often the last solution for people suffering from end-stage of the disease.

In the field of organ donation and transplant, one country in need must be able to seek help and organs from another EU country. Here is a perfect example of the added-value of being part of the European Union, where competences and organs can be shared. The EU has a tremendous role to play in facilitating and supporting exchange of knowledge and expertise, donations at EU level (there should not be any border for organs travelling to save a life) and raising awareness on organ donation and transplant.

Eurotransplant and Scandiatransplant are useful initiatives but too few countries are members of these networks. Spain and Croatia provide examples of what works: training, involvement of critical healthcare professionals and good organisation.

Mrs. Hartmann called on the EU to support the three A's in organ donation and transplant: Awareness, Availability and Accessibility – which entails more information at national and pan-European levels on organ donation via communication campaigns, supporting 'opting-out' systems where the family consent is fully taken into account, sharing information on availability of organs across the EU through IT tools and on-line platforms much more developed than what exists presently and enhanced training of healthcare professionals.

It is important that representatives of diseases or specific organs work together to improve the conditions of those suffering from a failing organ, and put forward common solutions to address these issues. It is hoped therefore that more associations join the Call to Action and the campaign.

Mrs. Hartmann closed the meeting by warmly thanking the host MEPs and all participants