



# Kidney Donation & Transplantation The gift of life

26 April 2018 | 16:30 - 20:30

Hosted by the MEP Group for Kidney Health

## 2018 European Kidney Forum Summary report



### Welcome and Introduction by MEP Hosts, MEP Group for Kidney Health

By Hilde Vautmans, Belgium, *MEP Group for Kidney Health*

The 2018 European Kidney Forum, attended by members of the kidney community from across Europe, was hosted by the MEP Group for Kidney Health co-chairs Hilde Vautmans (Belgium) and Karin Kadenbach (Austria).

MEP Vautmans opened discussions by highlighting that there is still a high variation of access to kidney transplantation across EU Member States. One of the goals of the MEP Group for Kidney Health, she said, is to improve access to high-quality care for all EU citizens, with particular regard to transplantation.

“I believe that together we can address the barriers and probe incentives to promote the implementation and harmonisation of organ donation and transplantation policies across the EU. And I believe that we, as policy-makers at the very heart of the European Union, have a responsibility to raise awareness of the social burden of kidney disease in Europe and to pave the way for better alignment between Member States.”

MEP Vautmans also gave some personal reflection on the gift of life that is transplantation, with a story of a member of her own family.

Later in the programme, MEP Kadenbach expressed her support for the themes discussed at the Forum and the work of EKHA: “As members in the European Parliament and of the MEP Group for Kidney Health, we can stimulate further actions and provide more

incentives to improve the availability and application of transplantation in our individual Member States. I believe that, according to our mandate to drive EU policies on health, with particular regard to organ donation and transplantation, with the final goal to save the life of patients, together we can promote options to expand donation and improve patient education and information on transplantation. In order to close the gap between Member States, it is essential to provide patients with comprehensive information on all aspects related to chronic kidney disease and their treatments choices.

“Our role is to stimulate the debate and consultations at national level and unleash the potential of the gift of life.”



### **Transplant physician's view point: What is the situation of transplantation in Europe? How are EU countries doing?**

By Prof Rainer Oberbauer, Austria. *European Society for Organ Transplantation*

According to the Global Burden of Disease Network (<http://www.healthdata.org/>), death due to end stage renal disease rose by about 3% over the last one and a half decades. The **epidemiology in the EU 28 countries however is very heterogenous** as indicated by the incidence of renal replacement therapy which ranges from below 100 pmp to more than 200 pmp. **The vast majority of patients are treated by hemodialysis** and only a small fraction receives a kidney transplant.

However, **transplantation restores an almost normal quality of life and is at the same time cost effective. Thus it is clear that renal transplantation is underused in Europe and should be promoted and supported.** Several strategies exist to increase the donor pool. **One of the easiest and most promising is the increase of living kidney donation.** In some countries such as the Netherlands every other transplant is performed with a living donation whereas in other such as Croatia or Slovenia almost no living donor transplants are performed. There is a clear political and medical need for support.

The transplant community has achieved great improvement in outcomes over the last two decades. At the end of the last century roughly 10% of grafts failed within the first year. In recent years this rate could be reduced to below 5%. It is expected that further improvements will occur by increasing the number of preemptively transplanted patients and by further research in innovative immunosuppressive concepts or even progress in immunological transplant tolerance induction.

Kidney transplantation is the key to counterbalance the ESRD epidemic we are seeing in Europe. **Support from health policy makers will be of utmost importance for the medical transplant community to achieve this goal.**



## The EDITH project: What is it and what do the first results show?

Dr. Vianda Stel, Netherlands, *ERA-EDTA Renal Registry*

EDITH stands for “The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes”. EDITH started on 1 January 2017 with funding from the 3<sup>rd</sup> Health Programme of the EU. The EDITH consortium consists of 10 partners from all over Europe together with collaborating stakeholders including the EKHA as well as renal registries, ERA-EDTA, the European Kidney Patients Federation, the French Agence de la Biomédecine and national kidney foundations.

In Europe we see significant variation in the management of end stage kidney disease and in access to dialysis and kidney transplantation. Therefore EDITH is examining the effect of this variation on patient outcomes and health expenditure. The EDITH project is composed of several Work Packages (WP). The ERA-EDTA Registry participates in WP 4 entitled: **Treatment modalities choices, outcomes and costs** for ESKD in the EU and associated countries. This work package that will address the epidemiology and costs of different treatment modalities for end-stage kidney disease.

WP5 and WP6 look at setting up a European Living Donor Registry and a European Kidney Transplant Registry for the follow-up of living donors and transplant recipients, respectively. As part of WP6, 24 of 28 countries replied on suggested dataset (donor data, recipient data, transplantation data, follow up data), 4 Member States have indicated the interest in a national registry, and Quality of Life datasets are to be defined.

To understand the reasons for the international differences in the number of patients with a particular form of dialysis or kidney transplant, one of the aims of the EDITH project is **to examine factors that influence the choice of treatment modalities** made by patients and nephrologists. To this end, an EDITH **kidney patient survey on treatment modality choice** is currently being distributed among dialysis and kidney transplant patients in almost all Member States and associated countries. A questionnaire for nephrologists is currently being developed.

The patients questionnaire seeks to gather opinion from dialysis and kidney transplant patients’ on treatment modality choice. More specifically, the questionnaire aims to look at the following aspects:

- Information provision (also on conservative care)
- Involvement in decision making
- Factors influencing choice
- Satisfaction with choice

The EDITH kidney patient survey has been translated in 20 languages (translation ongoing for another 9 languages) and is being distributed as an online questionnaire via patient

associations (email), nephrologists, links on facebook/newsletters/websites, etc. (see link here: <https://www.era-edta-reg.org>)

1535 patients from 13 Member States have replied so far and 30 countries have indicated they are willing to participate in the survey - more responses are thus to come.

Preliminary results indicate strong variations across countries as to if and when patients received information on treatment modalities: while less than 10% UK patients mention having never received information on treatment modalities, more than 30% of patients in Greece condemn the lack information on treatment modalities.

When looking at from whom information was mostly received, it is clear that the main information is nephrologists but in some countries nurses play a big role too (Denmark, Finland, Ireland, UK) while their role is very limited in others (Greece, Romania, Austria).

An interesting preliminary outcome in on home dialysis for which a high number of patients in most Member States admit having received no information. As regards how the decision on treatment was made, it comes out of the survey that it is usually made by doctors and patients together, a process that most patients seem to be satisfied with in all participating Member States.

Quality of life and survival chances are the most important criteria considered by patients. An interesting outcome so far is also that the main reasons for not getting a transplant is not only unavailability of kidneys, but concerning living donation that patients do not want to ask family and friends...

All this and following data gathered in the framework of the patients' survey feeds into the EDITH project which may ultimately help improving access to the most suitable and cost-effective treatment modality.



## **The patient's viewpoint**

By Fiona Loud, *Kidney Care UK*

Kidney Care UK is carrying out a number of initiatives to provide total support to kidney patients and their families, one of them being to raise awareness on kidney disease and transplantation amongst patients, the public and healthcare professionals.

In the UK, in 2017/2018, there were 1,575 deceased donors – a record, but 4,700 have died waiting for a transplant in the last 5 years – that is 3 per day! Likewise, in the UK, 250,000 people a year die, but only 5,000-7,000 will become donors: 4 in 10 families who could approve a donation when their loved one had passed away, say no; this can be as high as 7 in 10 from a black or Asian background.

Patient groups agree that there is a need to improve the way kidney disease is handled in the UK:

- Moderate to severe kidney disease affects about 6% of the UK population, all stages affects 10% percent of the population
- Recent CKD audit in England & Wales of 1,000 practices shows routine checks not done well enough on people at risk
- Early detection, prevention of progression and personalized support programme is essential for a good outcome
- It is estimated that treatment of kidney failure amount to £1.5bn annually
- Of 60,000 kidney patients in the UK, just under half of them are on dialysis, with session at least 3 times a week, lasting 4 hours a time, but resulting in only 10% normal kidney function

Referring to her own experience Fiona Loud argued **in favour of increasing access to kidney transplant because it is “the gold standard treatment”**. In her case, after 5 years on dialysis, she was lucky enough to benefit from a living kidney donation from her husband.

Establishing an “opt-out” system based on presumed consent is being considered in England based on the promising results of Wales where an opt-out system was introduced in 2015. Results are promising, with higher consent at 24.3 donors pmp <https://bit.ly/2qRPyyP>. However, in such opt-out systems, the family retains the right to over-ride that presumed decision of consent if desired.

National conversation is slowly increasing donation numbers BUT for success to increase, there needs to be more education for the public and in schools, adequate resources such as hospital transplant facilities and surgeons, and donors and their families need to be better supported.



## **Organ Donation & Transplantation across the EU: the work of the European Commission**

By Stefaan Van der Spiegel, Belgium. *Team Leader ‘Substances of human origin’, DG Santé, European Commission*

Organ donation and transplantation is considered by the European Commission as falling under the theme “substances of human origin”. As per art 168 of the Treaty of the functioning of the EU, Health is a competence of the Member States (MS), therefore the EC’s role is limited mainly to complementing national policies, foster cooperation between MS and third countries. However, Art 168 4(a) calls to set '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 and introducing more restrictive standards'.

Based on this legal mandate, the EC does develop directives on the matter. Three groups of legislations have so far been adopted addressing the following topics: blood transfer, human tissue transplant and human organ transplant. In 2012, the EC adopted a **Directive to support organ exchange between Member States**.

With these directives, the European Commission is organizing the **framework for the safety and quality of the organ donation process**.

With a view to supporting Member States in the organ procurement and allocation process, the European Commission adopted an **Action Plan on Organ Donation and Transplantation** around 3 objectives with 10 priority actions:

- Improving quality and safety
  - o transplant coordinators
  - o quality improvement programmes
  - o living donation programmes
  - o communication skills of professionals
  - o information on citizens rights
- Making transplantation systems more efficient and accessible
  - o enhance organisational models
  - o EU-wide agreements
  - o **interchange of organs**
- Increasing organ availability
  - o evaluation of post-transplant results
  - o common accreditation system

**Based on an evaluation in 2015 of the EU Action Plan on Organ Donation and Transplantation, it could be demonstrated that the EU Action Plan helped spur a 17% increase in organ transplants between 2008 and 2015** (4600 additional transplants: from 28100 to 32700) with an increase in organ donors from 12000 to 15000 and Spain, France, UK, Poland and the Netherlands being the five main contributors. Bulgaria, Lithuania, Finland, Croatia, Hungary, Czech Republic, Slovenia, Latvia and Denmark demonstrated the sharpest overall increase with some exceptions like Germany where numbers fell with 20%. The Action Plan led to appointment of local coordinators for deceased donation and registries for living donors.

Key Benefits of the Action Plan:

- A **shared agenda**, addressing issues with a common perspective
- Helps obtaining political **support**
- Alignment with other **international** positions (CoE, WHO)
- Facilitates EU-wide collaboration
  - **Exchange** best practices
  - Develop **new ideas/knowledge** and support tools through exchange
  - Overcome problems jointly
  - Build closer **relations** amongst MS
  - Allows to leverage potential of twinning and organ exchange

Key Learnings:

- Bottom-up agenda-setting, **engaging** professionals, administrations, politicians, public opinion
- Fewer **objectives**, with a stronger impact
- Clearly defined objectives, with tangible outcomes
- Bring together **groups** of countries with similar issues and situations.
- Learn from/collaborate with **adjacent areas** of expertise (e.g., tissues&cells, devices)
- More focus on MS with **less developed** transplant systems

- Reflect on **implementation** and sustainability, including IT.

**The European Commission supports a wide variety of actions on these matters with a view to identifying good practices from Member States and sharing these across the EU.** The EC sees the diverse EU landscape as a potential for MS to learn from each other.

One of these actions is **the FOEDUS Joint Action** which aims to facilitate the exchange of organs donated in the EU Member States. A pilot project involving 8 countries was conducted during 9 months.

In addition, the EC holds regular **meetings** of EU-28 National Competent Authorities for organ transplantation, undertakes **funded projects (PHP) on living donation**, has created a dedicated **working group** on living donation which developed a "toolbox for authorities on living kidney donation" –to support this activity.

As for the European Parliament, two pilot projects have been implemented in the last two years: the **EDITH project** (under the patronage of MEP Karin Kadenbach, see above) and the **EUDONORGAN project** (under the patronage of MEP Gabriel Mato) on social awareness on organ donation.

EUDONORGAN is Consortium led by the University of Barcelona in partnership with donation and transplantation institutes from Spain, Republic of Slovenia and Croatia and Italy. It aims not only to train health professionals but also to organize "**awareness raising**" **events** with the support of the trained professionals and to propose and implement **dissemination actions** as well as **monitoring and evaluation** strategies.



## **Challenges in kidney transplantation faced by Europe: what can be done?**

By Prof Raymond Vanholder, Belgium, *EKHA Chairman*

Prof. Vanholder briefly outlined a number of challenges related to living and deceased donations and pointed **measures to boost organ donation rates in Europe.**

There is a number of patients who albeit have a good life expectatios, are not put on the kidney transplantation waiting list one year or more after their ESRD onset e.g : approx. one-third of ESRD patients are not listed for transplantation within one year, with less than 5 years projected life on dialysis). It is thus important, to ensure more of these patients are enlisted in a timely manner.

- To boost donation rates, donors need to be supported as to the cost incurred and their loss in income.
- It is also important to encourage not only spouse living donation but also donation from unrelated people.
- Uniform procedures for donor information and recruitment (guidelines) should be defined and applied.
- Based on evidence, donor and acceptor selection criteria shall be reviewed and relaxed as appropriate

- There should be reimbursement consideration for families of donors (hospital or funeral costs)
- Donor registration should be stimulated and simplified.
- Donation should be formally recognized.

Looking at opting-in vs. opting-out systems, Prof Vanholder clearly outlined, based on results of studies, that presumed consent enhances cadaveric donation and that **opting out systems increases transplantation rates**. The number of deceased donations is growing but this is partly compensated by the reduction in living donations. He invited the EU to move into the direction of cooperation on this matter.

As for expanded-criteria donors (e.g. older kidney donors ( $\geq 60$  yr) or donors aged 50 to 59 yr having two of the following three features: Hypertension, terminal serum creatinine  $>1.5$  mg/dl, or death from cerebrovascular accident), Prof Vanholder outlined that survival chances are worse for expanded donation and mentioned that although these may help, there is room to create evidence base and guidance is needed as regards selection criteria.

A big potential lies in increased patient information and education: a study showed that patient education on transplantation is better than for other modalities (in-center dialysis, home dialysis, self-care haemodialysis, peritoneal dialysis) but results are still not brilliant.

The results of EKHA's treatment choice questionnaire in 9 European countries made to patients, professionals further showed that there is **disharmony in Member States**: while in most countries, information about kidney donation is given, the options between living and deceased donations are often not equally discussed.



## Closing

MEP Karin Kadenbach, Austria – *MEP Group for Kidney Health*

In her capacity as Chair of the MEP Group for Kidney Health, MEP Kadenbach thanked all the speakers and participants who have contributed to the discussion. She deplored that “although kidney donation and transplantation represents the best opportunity for patients with end-stage kidney disease to have a better outcome, it is still under-used”.

MEP Kadenbach stated that “as members in the European Parliament and of the MEP Group for Kidney Health, **we can stimulate further actions and provide more incentives** to improve the availability and application of transplantation in our individual Member States.”.

“I believe that, according to our mandate to drive EU policies on health, with particular regard to organ donation and transplantation, with the final goal to save the life of



patients, together we can promote options to expand donation and improve patient education and information on transplantation”, she said.

MEP Kadenbach further argued that in order to fill the existing gap between Member States, **“it is essential to provide comprehensive information** on all aspects related to chronic kidney disease and treatments choices”.

Lastly, MEP Kadenbach hinted at the fact that “there are different sensitivities to organ donations across Member States”, referring to the fact that some national legislations are in favour of the opt out system, while others support the opt-in organ donation law. “Our role is to stimulate the debate and consultations at national level and unleash the potential of the gift of life” she concluded.