EUROPE’S ‘DECADE OF THE KIDNEY’

SPECIAL REPORT | JUNE - SEPTEMBER 2021

https://eurac.tv/9TmX
From improving the availability of all treatment options to the development of home therapy and telemedicine, there are many challenges that need to be addressed by the end of the decade to better the lives of chronic kidney disease patients.

The initiative called “decade of the kidney” running from 2020 to 2030 was first launched by the American kidney patient federation (AAKP) and recently adopted by European health stakeholders.

Taking as an example the extraordinary efforts put in place with cancer over the last 30 years, the campaign aims at increasing awareness of kidney disease.

In this special report, EURACTIV explores the next challenges in this decade of the kidney, focusing on research, training of both patients and medical professionals, and availability of treatments in all European countries.
Contents

Patient autonomy, education must be priorities for tackling kidney disease

Kidney disease research pins hopes on new disruptive technologies

Commission: burden of levelling kidney treatment access falls mainly on member states

Promising portable kidney faces innovation, portability bottlenecks

Kidney health and climate change: Shedding light on a long-neglected relationship
Patient autonomy, education must be priorities for tackling kidney disease

By Gerardo Fortuna and Giedre Peseckyte | EURACTIV.com

With incidences of kidney disease predicted to soar in the next decade, health stakeholders are calling for more efforts to ensure patient autonomy and investment in training for both practitioners and patients.

Around 600 million people worldwide have some form of kidney damage. Chronic kidney disease increases the risk of heart attack and stroke, and in some cases can progress to kidney failure, requiring dialysis or transplantation. Its global prevalence is predicted to increase by 17% over the next decade.

In 2016, a total of 64,387 people died from diseases of the kidney and ureter in the European Union, while kidney cancer accounted for 26,439 deaths in 2016. A vast majority of deaths from kidney diseases as well as deaths from kidney cancer concerned people aged 65 or above.

However, if detected early and managed appropriately, deaths can be avoided, moreover, the deterioration in kidney function can be slowed or even stopped.

Education comes into play here as it is the key to ensure early detection, the president of the European Kidney Patients’ Federation (EKPF) Daniel Gallego explains.

“We should promote tools, resources, initiatives and materials that enable real shared decision making,” he told EURACTIV.com.

He added that despite practitioners being aware of the treatment options for kidney diseases, fast changes in the market require an “ongoing process of education for both practitioners and patients”.

TRAINING HEALTH PROFESSIONALS AT ALL LEVEL

In a recent inquiry by the Brussels-based NGO European Kidney Health
Alliance (EKHA), patients on kidney replacement therapy were asked about their satisfaction with the information on peritoneal dialysis they were provided with.

The outcomes of the survey showed that more than a third of respondents were not satisfied with the information received.

According to EKHA President Prof. Raymond Vanholder, the inquiry showed even worse results for satisfaction on information about home haemodialysis and barely better outcomes for transplantation and living donor transplantation.

"The basic training on kidney diseases, in general, is OK. What is lacking is training on how to offer all possible treatment choices to patients with the pros and cons in a way that patient can make an appropriate choice," he told EURACTIV on the sidelines of the annual kidney forum.

Vanholder pointed out that not only nephrologist or practitioners but also nurses and qualified physicians need this kind of training aimed at giving complete information in an objective way so that patients can make the appropriate choice for their health.

"I also think that nurses are better suited for this because of their closer distance to the patient, while doctors often tend to paternalise," he said.

**PATIENTS WANT INDEPENDENCE**

The recent pandemic has impacted many patients, including those suffering from kidney diseases. Most notably, delayed visits to practitioners have had a great burden on many people, which has demonstrated the importance of being able to take care of oneself at home.

For EKPF’s Gallego, this has led patients to prefer the concept of co-responsibility, which includes co-producing guidelines and creating new evidence such as reporting on their experience.

“Chronicity should be managed at home whenever possible. We need to promote the autonomy and independence of the kidney patients, promoting self-caring and self-management,” said Gallego.

He urged healthcare providers to encourage patients to manage their own treatments and promote home therapies, such as home hemodialysis, a treatment that replaces the work of patients’ own kidneys to clear wastes and extra fluid from your blood.

"Usually it is believed that the training for home therapies or for a transplant is too challenging and difficult. Trust me, it’s more difficult to learn to drive than [how to do] home dialysis," he told the European Kidney Forum.

**DIFFERING KIDNEY DISEASE TREATMENTS ACROSS THE EU**

Another key area of focus must be given to training to get everybody up to speed on the latest developments. This is especially important given that kidney treatment differs greatly across the EU.

These differences are seen not only in different levels of access to the kidney replacement therapies, such as dialysis or transplant but also in how training on kidney treatments are being implemented.

In Spain, for instance, the government every year devotes governmental funds to the training of medical professionals.

The training is supported by the Organización Nacional de Trasplantes (ONT) and the Regional Transplant Coordinations, who continuously guarantee their training for the optimal realisation of the pathway.

The director of the Spanish National Transplant Organisation, Beatriz Domínguez-Gil said that medical staff is trained from advanced techniques to how to communicate with patients and their families.

“We train physicians, surgeons and nurses in aspects that extend from the most innovative preservation techniques to the way to approach families to discuss donation opportunities. The ONT allocates every year funds to different non-for-profit institutions to train professionals in alignment with previously specified priorities,” she said.

Domínguez-Gil highlighted the importance of providing patients and their families with all needed information.

“One fundamental aspect in caring for patients with advanced renal disease is to provide them and their relatives with comprehensive information about renal replacement therapies, including kidney transplantation from deceased and living organ donors,” she said.

She added that the primary nephrologist and dialysis unit staff play a key role in initiating discussions about these treatment options.
New technologies for treating chronic kidney disease (CKD) are opening up possibilities for improving patients’ quality of life, with the European Union pledging to ramp up health funding and research initiatives in the wake of the COVID-19 pandemic.

Not many substantial breakthroughs have been experienced in the field of CKD treatment since the mass diffusion of dialysis units in the 1970s, with slow progress in recent decades partly attributed to a lack of funding and research incentives.

However, effective and well-funded research programmes in this field could become an acid test for the EU’s renewed ambition on health which has become a key priority as Europe recovers from the COVID-19 pandemic.

“We are going to be taking ambitious steps in the area of health and, also importantly, when it comes to research on Horizon [the EU’s programme for innovation],” Health Commissioner Stella Kyriakides told the annual European Kidney Forum on 18 June.

She recalled that the European Commission has already funded 40 projects with €64 million addressing chronic kidney diseases, and 24 projects with €47 million related to kidney transplantation.

“And with the new Horizon Europe work programme of 2021-22, there are now more possibilities for research on chronic kidney disease that include dialysis and home care,” Kyriakides added.

A key priority identified by health professionals for kidney disease treatment is the development of simpler, cheaper and more easily transportable dialysis systems.

Other potential innovations may come from blocking kidney fibrosis to arrest the progression of kidney disease, as well as from regenerative medicine with the potential of developing a working transplant kidney out of the host’s own stem cells,

Continued on Page 7
Innovation could also make dialysis more efficient and environmentally friendly, with less water use, plastic waste, and energy consumption, to bring the treatment more in line with the general goals of the EU’s flagship environmental policy, the Green Deal.

According to Kyriakides, the ambitious EU Health Union package presented at the end of 2020 aims to put healthcare and citizens at the centre of the European Union’s policymaking.

“We will continue to support the necessary research and pooling of knowledge to increase the quality of life and life expectancy of chronic disease patients,” she said.

**DISRUPTIVE TECHNOLOGIES**

According to Spanish MEP Manuel Pizarro, who is also co-chair of the European Parliament’s group for kidney health, both the EU health union framework and the Horizon Europe programme mark new momentum in efforts to improve the lives of kidney disease patients.

“I have already seen a positive step forward with this programme, as it recently published a call on medical technology and devices that made specific reference to radically portable dialysis,” he said.

He added that he hopes future calls will follow groundbreaking innovation in this field, especially in preventing the progression of kidney disease.

The Horizon 2020 programme will fund the randomised controlled phase II trial of **TTV GUIDE TX**, which aims to optimise immunosuppressive drugs as a crucial step to minimise the risk of infection and rejection and thereby prolonging patient and graft survival.

The project, coordinated by the University of Vienna, started in May and will last for another five years, with a total budget of €6.1 million.

Another ongoing EU-funded project called **EU-Train** has the ambitious goal of providing medical professionals with innovative and accessible tools for early prediction of individual risk of allograft rejection and transplant loss.

The €6 million **Nephstrom** project conducted by the University of Galway is now in the home stretch and it is focused on the promising stromal cell therapy for diabetic kidney disease. Meanwhile the Italian-led **SCOPE** project on screening and prevention programmes among older people has been recently closed.

Several additional projects have been funded through the SME Instrument. Among them is **Renaparin**, a pharmaceutical compound used to coat the lining of the blood vessels of kidneys prior to transplantation.

**MORE KIDNEY-FOCUSED PROJECTS**

Almost all the projects mentioned are part of the Horizon 2020 Societal Challenge 1 budgetary heading, which is one of the programmes providing funding to this research area.

There are more than 100 projects listed in Cordis, the EU research results database, filed under the keyword “kidney.”

But according to the president of Brussels-based NGO European Kidney Health Alliance (EKHA), Raymond Vanholder, these Horizon projects are not always directly kidney-oriented.

“We need more awareness of the problem [chronic kidney disease] and then this needs to be supported by financial support and research support,” he told the European kidney forum.

Vanholder called for a mechanism which would allow a comparison of the research spending for different diseases and look at what investments have been done.

“It will be very good because we know from the UK and the US that kidney disease is under-supported compared to other chronic diseases,” he said.

Indeed, a recent survey made by CenterWatch showed that investments in research from the US National Institutes of Health (NIH) amounted to $11.1 billion for cancer but only to $680 million for kidney diseases.
Commission: burden of levelling kidney treatment access falls mainly on member states

While inequalities across the EU when it comes to kidney disease treatments are well-known by the European Commission, the ball is ultimately in member states’ courts when it comes to expanding access, according to health stakeholders.

Chronic kidney disease is a major public health issue in Europe, affecting one in ten European citizens. However, quality and access to kidney treatment can greatly differ depending on which part of Europe patients come from.

This issue was highlighted during a recent event by Belgian EU lawmaker Hilde Vautmans, who also chairs the MEP group for kidney health.

“Choosing the most appropriate therapy is not possible for all patients in Europe, which lead to significant disparities in availability and accessibility across countries that have specific social groups,” stressed the liberal MEP.

According to the European Kidney Health Alliance (EKHA), the number of organ donations per million population can differ wildly across the bloc, ranging from almost 60 in Spain to less than 10 in Bulgaria.

The huge disparity between European countries shows there is much room for improvement, EKHA president Raymond Vanholder explained.

“The question is whether all valid candidate patients receive the treatment that is appropriate for them, and which is their preference? And unfortunately, the answer is no,” he said.

Continued on Page 9
Vanholder added there should be a stronger focus on different types of donations, such as living donation, as well as on the uptake of dialysis options, including peritoneal and home dialysis, as these ensure the best possible outcome for the patient, with the lowest economic burden to societies.

However, while Scandinavian countries have an uptake of peritoneal and home dialysis of more than 30%, other EU countries, including Romania, Bulgaria, and Slovakia, do not yet reach 2%.

This could be a consequence of the fact that Scandinavian countries reimburse the real cost of the treatment, but Vanholder said equal reimbursement is not the sole solution.

“We even think it’s not the optimal solution,” he said.

**BALL IN MEMBER STATES’ COURT**

Fighting the existing inequalities in the healthcare system in the EU is among the first specific objectives in the recently approved EU4Health programme.

In its stimulus package launched in May 2020 to help recover from the pandemic, the European Commission proposed this €5.1 billion programme for strengthening the resilience of health systems, increasing coordination on public health and enhancing crisis management.

The programme aims at reducing the burden of communicable and non-communicable diseases by supporting health promotion and disease prevention, but also by promoting access to healthcare and reducing health inequalities.

Health Commissioner Stella Kyriakides said the EU4Health programme will allow the EU to increase the exchange of best practices among EU countries and “support networks for knowledge sharing and mutual learning”.

Stefan Schreck, the adviser for stakeholder relations at the European Commission’s DG SANTE, highlighted that the programme addresses the inequalities in access to healthcare in a unified way.

But he warned that healthcare costs cannot be changed through EU4health unless the member states decide so.

“What we can do is to help exchange best practice, we can help exchange expertise. And we can do things together with several member states, which are easier to be done together than to be done alone,” Schreck highlighted, adding that motivation has to come from member states.

Besides the Next Generation EU fund – the recovery and resilience facility with a total budget of €672.5 billion – other funding options to boost healthcare cooperation are the European regional development fund and the European social fund+.

“Addressing healthcare imbalances in the area of kidney care would be covered by this. It is, however, member states which prepare and submit their recovery and resilient plans, which are the basis for the allocation of the budget,” said Schreck.

National recovery and resilience plans that member states have submitted to the European Commission need to be finally approved by the EU Council.

“It is possible to finance and address those imbalances with the available financial instruments but it has to be included in the national plans which have been forwarded to the Commission,” Schreck summed up.

In the 11 plans the Commission has already evaluated, the focus falls more on resilience, digitalisation, telemedicine and strengthening the healthcare infrastructure, rather than on non-communicable diseases.
Portable artificial kidney is perceived as the next big thing in the field of home treatment that could stop dialysis being a full-time job for patients, but barriers to its rollout persist.

In a recent study, more than 1,500 health specialists surveyed about their perceptions of the future of kidney replacement therapies considered portable/wearable kidney as one of the best viable technology together with implantable solutions.

The main concept behind portable/wearable kidneys is to promote autonomy and self-caring, meaning the possibility for patients to adapt their kidney disease treatment to their lives.

But according to Jasper Boomker from the Dutch Kidney Foundation, there is a deadlock preventing the rollout of these devices since established dialysis providers have no incentive to change the business model.

“Home dialysis is not yet actively promoted by doctors as the current clinic-based business model is still profitable,” Boomker told EURACTIV.

Only patients who are relatively fit and independent, he added, do home hemodialysis, although many of the hospital dialysis patients would be able to dialyse at home with some sort of professional support.

On top of that, several national reimbursement systems do not yet seem ready to accommodate the broad rollout of home treatment, though policymakers often stress the necessity to make home healthcare more feasible.

In 2016, over 80% of households in ten member states reported difficulty in covering the costs of professional home care services, in particular in Slovakia (95%), Lithuania (94%) and Greece (93%), according to the EU’s statistical service EUROSTAT.

On the other hand, the highest shares of households that could pay for these services with ease were found in Finland (75%), Sweden (73%) and Denmark (69%).

Continued on Page 11
For Fokko Wieringa, a Dutch engineer associate professor of medical technology at Utrecht University, the development of medical devices is laborious and expensive as it is costly to invest in multiple candidate products, each quite pricey.

“So, manufacturers may be reluctant to invest in innovative products. Moreover, why would they if present technologies are still good ‘cash-cows’ that generate good profits, and growth markets are still emerging?” he wondered.

He referred to what he called the ‘innovation paradox, where the more disruptive a new product is, the higher is the risk for its timely development, particularly in a market where existing technologies are still very profitable.

Wieringa provided an overview of the main pioneers in this field, like Victor Gura, who he considered the “Charles Lindbergh of wearable dialysis”, having already realized three clinical trials with a wearable hemodialysis device, each time with stepwise improvements.

“But lack of funding hampers progress,” he explained, adding that other breakthrough works for an implantable artificial kidney show systematic progression but also lack significant funding.

The US Food and Drug Administration (FDA) recently estimated the overall cost of development for a complex medical device at $526.4 million after accounting for the cost of failures and the opportunity cost of capital.

Many patients are already aware of the option of home hemodialysis but do not have a real understanding of what it would mean to dialyse at home. At the same time, current options for portable devices are not that enticing.

Existing home machines are intrusive and take up a lot of space at home, often requiring house refurbishment because they need a water purification system and high power supply.

Furthermore, the state-of-the-art machines are not that flexible, meaning that patients are still bound to their homes and cannot travel for more than two days.

“I have the most ‘portable’ machine on the market and it weighs 45 kilograms when packed to travel by air. That is not really portable,” kidney patient Henning Søndergaard told EURACTIV.

According to him, more portable devices would be not only a good alternative to going to the hospital but also a great advantage over the different home dialysis modalities currently in use.

“Simply put, nobody wants to go to the hospital 3-4 times a week and spend at least four hours in treatment. Dialysis is close to being a ‘full-time job’,” he continued.

The Dutch Kidney Foundation started 10 years ago a project aimed at giving patients a device that would help them to fit their dialysis treatment in their lives.

The Neokidney project consists of a plug-and-play and user-friendly home hemodialysis machine weighing less than 10 kilograms and fitting into a hand-carried suitcase, also using only between 4 and 6 litres of dialysis fluids.

Once developed, the device will be three times smaller and lighter than the smallest home dialysis machine in the market, also operating on any 110/230V power grid.

“This device is the next step beyond home hemodialysis and we will be able to bring dialysis to the patient. Dialyze wherever, whenever,” said John Stooker, CEO of Neokidney, adding that it could be used not only at home but also in small dialysis hubs such as in retirement homes or holiday resorts.
Kidney health and climate change: Shedding light on a long-neglected relationship

By Marine Faure and Raymond Vanholder | European Kidney Health Alliance (EKHA)

Chronic Kidney Disease (CKD) is often described as the invisible killer, mostly because patients have few or no symptoms until it is too late. On the practical level, this means that the disease, although devastating for both the individual and society, receives little political and public attention when compared with other chronic diseases.

Raymond Vanholder is the President of the European Kidney Health Alliance.

Marine Faure is a Senior Consultant at European Kidney Health Alliance.

The discussions around climate change are no exception. Kidney disease and climate change are rarely addressed together despite being closely linked.

Climate change impacts kidney health by increasing risk factors associated with Acute Kidney Injury (AKI), a life-threatening condition causing an abrupt reduction in kidney function. The frequency and intensity of heatwaves, the spread of infectious & parasitic diseases following floods and the expansion of tropical diseases to other parts of the world are all climate change effects that can give rise to Acute Kidney Injury.

In addition, the growing number of natural disasters pose a major threat to the continuity of care of both acute and chronic kidney patients.

Continued on Page 13
who depend on critical infrastructure for their dialysis treatment (e.g. power and water supplies, transportation and telecommunication services).

More recently, rising temperatures have been identified as a potential cause of epidemics of Chronic Kidney Disease among labourers in Central America. In turn, all kidney disease treatments leave a substantial carbon footprint. This is due to the frequent therapeutic interventions, hospitalisations, use of consumables, intake of a large number of medicines and transports of goods and people.

Dialysis in particular generates large quantities of plastic waste and consumes considerable amounts of water. Annually, this represents >169 billion litres per year worldwide. Yet, solutions to implement sustainable kidney care practices and lessen climate change's effects on kidney health exist. These should be integrated within EU policies and programmes without further delay.

The most cost-effective way to avoid complications with a certain disease is to prevent its onset. The EU4Health programme and Europe's Beating Cancer plan, both of which have a strong focus on prevention, must help bolster education on healthy lifestyles and reduce exposure to Chronic Kidney Disease's risk factors (e.g. tobacco smoking, alcohol consumption, unhealthy diets, lack of physical activity). It is crucial to target in particular the young generation and hard-to-reach groups such as refugees or people with low education and health literacy levels, all more at-risk to develop unhealthy habits.

With regard to dialysis treatments, much needs to be done on putting the concept of green nephrology into clinical practice. EU projects, for example through the EU4Health and LIFE programmes, could support the monitoring of resource usage generated by dialysis facilities, promote practices to reduce waste and disseminate already-existing ways to reuse reverse osmosis reject water.

Furthermore, bold investments into innovative dialysis treatments attentive to patients’ and environmental concerns are woefully lacking. Given that the technology to treat End-Stage Kidney Disease (ESKD) has not substantially evolved since 1945, the European Union could use the Horizon Europe programme to reverse this trend and be a groundbreaker in this field.

Kidney transplantation, which offers a more cost-effective and environment-friendly way to treat End-Stage Kidney Disease, is one more string to the bow of green nephrology. Thanks to the EU action plan on organ donation and transplantation, Europe has achieved remarkable results in increasing transplantation rates and organ availability as well as facilitating EU-wide cooperation in that regard.

However, progress has stalled since the end of the action plan in 2015. Putting forward a new EU action plan, as wished by the EU Member States, or at least relevant EU-funded initiatives, should now be the priority to improve transplant activities from both an environment and health standpoint.

Finally, the European Union should use all the available policy levers to limit climate change's harm to kidney health. The European Green Deal already constitutes a positive step forward but it is now critical that EU policymakers ensure a thorough implementation of the roadmap. Nevertheless, mitigation strategies for climate change will fail to protect Chronic Kidney Disease patients if their condition continues to be neglected.

The lack of awareness of Chronic Kidney Disease and the scarce recognition of its severity are some of the reasons for the rising tide of the disease. An EU action plan on kidney disease, on the same model as Europe's Beating Cancer Plan, would certainly help tackle these challenges and assert EU leadership and commitment to safeguarding the health of its citizens.

The environmental impact of kidney disease and the threat posed by climate change to kidney health can no longer be ignored. EU policymakers have now a moral responsibility to alleviate the future burden resulting from both climate change and kidney disease treatments. The sooner we act, the better for public health and for the planet.
THE DUTCH BID FOR EMA
www.netherlandsforema.eu
From London to...
the Amsterdam Metropolitan Area
Contact us
Gerardo FORTUNA
Agriculture & Health Editor
gerardo.fortuna@euractiv.com
tel. +32 (0) 2 788 36 69
Teresa DOMINGUEZ
EU Affairs Senior Manager
teresa.dominguez@euractiv.com
tel. +32 (0) 47 601 78 26

For information on EURACTIV Special Reports...