



MINISTRY OF INTERIOR

# **Concept Paper**

on Organ Donation and Transplantation

Hungarian EU Presidency

## **Ministerial Foreword**

As we stand at the cusp of a transformative health landscape, it is with profound awareness of our shared responsibilities and opportunities that we present this Concept Paper on Organ Donation and Transplantation.

Hungary, with a rich history of pioneering achievements in transplantation, embodies the spirit of innovation and dedication that is essential for advancing this vital area of medicine. Since the first kidney transplant in 1962, Hungary has developed a comprehensive and efficient transplantation system, underscored by an opt-out legislation framework and the support of the Hungarian National Health Insurance Fund.

The 2009-2015 EU Action Plan on Organ Donation and Transplantation led to significant impacts, such as 21% increase in the number of donations. After the expiry of the plan, with the European Union at a crossroads, the imperative for a renewed and vigorous approach to organ donation and transplantation has never been clearer. The statistics speak volumes: thousands of lives saved, improved quality of life for patients, and the undeniable economic benefits that transplantation offers to our health systems.

As we articulate a vision for the future, this paper outlines a comprehensive strategy that encompasses increased organ availability, enhanced efficiency and accessibility of transplant systems, and the improvement of quality and safety standards. It is a call to action for the European Union to embrace innovative practices, improve legal and ethical frameworks, and foster education and public awareness. Through collaboration, we can overcome the barriers that currently hinder the full realization of transplantation potential in the EU.

The Hungarian Presidency envisions a future where every European citizen in need has timely access to life-saving transplants, where the generosity of donors is honoured and maximized, and where our health systems are strengthened by the efficiency and cost-effectiveness of transplantation.

In conclusion, this Concept Paper is not merely a policy document; it is a manifesto for hope, solidarity, and life. As we navigate the complexities of health in the 21st century, let us be guided by the principles of equity, innovation, and compassion. Together, we can achieve a milestone in medical science and public health, reaffirming our commitment to improving the lives of citizens across the European Union. The time for action is now.

**Dr Péter Takács**  
**Minister of State for Health**

# Improving organ donation and transplantation in the European Union

Paving the way towards a renewed EU action plan

Concept Paper of the 2024 Hungarian EU presidency

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## Introduction

### Organ donation and transplantation in Hungary

In Hungary the first human kidney transplantation was performed in 1962, but the programme started in 1973. Hungary currently has 7 transplant centres in 4 cities, where 4 kidney, 1 liver, 2 heart, 1 lung and 2 pancreas transplant programmes are available.

The opt-out system for deceased donation was firstly introduced in 1972, then the current, same type of legislation became available in 1997 by the Act on Health. Authorisation of procurement and transplant centres are defined in a Ministerial Decree.

Financing of organ donation in donor hospitals, organ procurement by centres, transplant procedures and transport costs are reimbursed by the Hungarian National Health Insurance Fund and by the Government by law.

The Hungarian National Blood Transfusion Service (HNBTS, in Hungarian: Országos Vérellátó Szolgálat, OVSz) is entitled by the Ministerial Decree as National Competent Authority (NCA) in the field of organ donation and transplantation. HNBTS operates the National Organ Donation and Transplant Follow-up Registry and the EFI (European Federation for Immunogenetics) accredited Transplant Immunology Laboratory with full national responsibility. HNBTS participated in several EU co-funded projects in the field of organ donation and transplantation: DOPKI, MODE, COORENOR, ACCORD, FOEDUS, EDITH, BRAVEST. HNBTS is the Hungarian contracting partner of the Eurotransplant International Foundation since the full membership introduced in 2013.

The Transplantation Directorate of the HNBTS builds up from 4 departments:

- Organ Coordination Office is the National Organ Procurement Organization (OPO) and responsible for the central coordination of the organ donation process, in accordance with Governmental Decree by operating three levels of the transplant donor coordination network,
- Central Waiting List Office, as the HNBTS is responsible for the national waiting list management with the involvement of 9 Organ Transplant Waiting List Committees,
- Hungarian Bone Marrow Registry,
- Hungarian National Organ and Tissue Donation Opting-out Registry.

A National Action Plan was presented at a Competent Authority meeting on the 28<sup>th</sup> of February 2011.

### Current overview of organ donation and transplantation in Europe

Organ transplantation improves patient survival and quality of life and has a major beneficial impact on public health and the socio-economic burden of organ failure. In the European Union (EU), a relatively coherent and structured approach exists to transplantation with well- developed national programmes, international schemes to facilitate organ sharing and well-defined exchange policies, making Europe a leader in

the field. The added value in this field of EU collaboration has been widely demonstrated by the success of the EU legislative framework on organ donation and transplantation<sup>1</sup> and the 2009-2015 EU Action Plan in particular, which contributed significantly to the strengthening of the European organ donation and transplantation landscape. Since the Action Plan's adoption, as the European Commission's FACTOR Study on the Action Plan's uptake and impact notes, the total number of organ donors at the EU level has considerably increased, i.e. from 12.3 thousand in 2008 to 14.9 thousand in 2015. This accounts to a 21% increase over the period. This overall increase includes an increase in living organ donors of 29.5% and increase in deceased organ donors of 12%. An encouraging trend was observed in the number of transplants over the period of the Action Plan. Overall, there was an increase with 4.641 transplants, from 28.066 transplants in 2008 to 32.707 in 2015. This accounts to a 17% increase over the period. The number of transplants was increasing for all types of organs over the period of the Action Plan, except for small bowel transplants. There was a 16% increase in kidney transplants (the most transplanted organ), and liver transplants increased by 16%, heart transplants by 10%, pancreas transplants by 7% and lung transplants even by 41%.

Since the Action Plan's conclusion, the need of organ donation and transplantation has not waned.

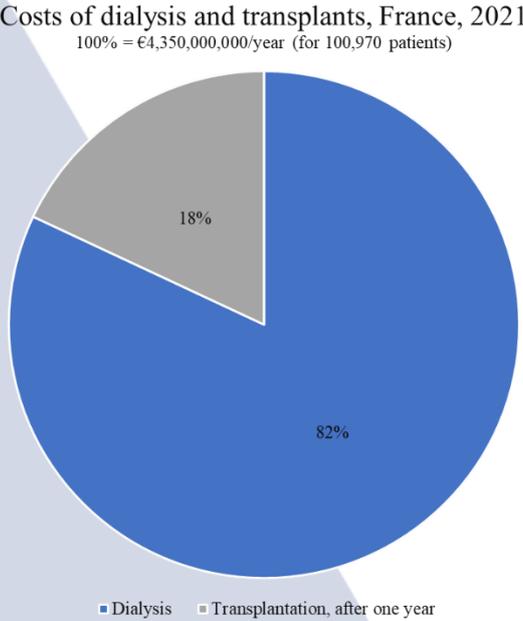
Non-communicable (chronic) diseases (NCDs) impose a substantial burden on healthcare systems, economies, quality of life, employment status and social activities. In Europe, NCDs are responsible for 77% of the disease burden and 86% of deaths<sup>2</sup>, many of which are in young individuals<sup>3</sup>. Changes in population demographics and the growing prevalence of risk factors have contributed to an increase in the demand for organ replacement therapies. Artificial organ support is an option in some instances but is only available on a large scale for kidney failure in the form of dialysis. Hence, transplantation is for many patients the only solution to restoring organ function and preventing premature death. The WHO has urged countries to progress towards self-sufficiency in transplantation, first by preventing NCDs and their progression to end-stage organ failure, but also through the provision of sufficient numbers of life-saving transplants to match their need<sup>4,5</sup>. The WHO further emphasizes that deceased donation should be developed to its maximum therapeutic potential.

Advanced NCDs continue to present a substantial burden for individual patients and overall healthcare systems alike. As of late 2022, 52,000 persons awaited a transplant in the EU<sup>6</sup> and for some of these patients the availability of donor organs can be a life-or-death matter. For most vital organs (liver, heart, lungs), transplantation is the only life-saving therapy. In the case of advanced kidney disease (kidney failure), where alternative treatment by the means of dialysis is available and used on a large-scale, kidney transplantation remains by far the preferred option, both in terms of quality of life and cost-effectiveness.

Although some studies demonstrate the cost-effectiveness of heart and liver transplantation<sup>7,8</sup>, it remains overall difficult to fathom the health economic impact of these procedures as no large-scale alternative long-term therapy is currently available

(the alternative is the patient’s death). The reduction of costs is particularly striking when it comes to the comparison between kidney transplantation and dialysis.

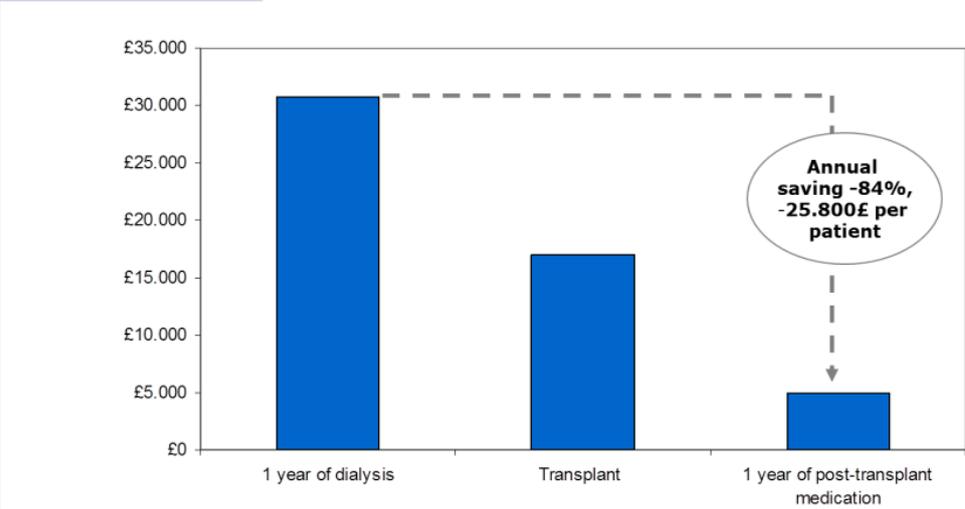
(Figure 1) In France, recent data from 2021 show that dialysis represents 82% of all costs related to the treatment of kidney failure, versus 18% for transplantation one year after surgery.



**Figure 1: Annual spending on different treatments for kidney failure, France, 2021<sup>9</sup>**

*Source: Graph produced by EKHA based on the 2023 economical assessment of the French National Social Security Authority (Caisse Nationale d’Assurance Maladie).*

(Figure 2) In the UK, the comparison of costs between patients after one year on dialysis and patients one year after transplantation including post-transplant medication estimated that transplantation led to a striking saving of £25.800 per patient. If we extend this figure to the number of patients (23.000), we can estimate that kidney transplantation helped save £512 million in dialysis costs.



**Figure 2: Costs per patient of treatment option for end-stage kidney failure, UK, 2009<sup>10</sup>**

*Source:* Graph produced by the European Commission based on the [cost-effectiveness analysis](#) undertaken by the 2009 NHS Blood and Transplant.

(Figure 3) In the EU, dialysis represents 1% of all healthcare expenditure (For only 0.1-0.2% of the population) versus 0.10% for transplantation.

|                       |   | HD + PD          | HD+PD costs<br>% health expenditure |   | DKD + LKD      | DKD + LKD costs<br>% health expenditure |
|-----------------------|---|------------------|-------------------------------------|---|----------------|---|
| <b>Belgium</b>        | € | 385.150.004,00   | 0,83                                | € | 14.205.025,00  | 0,03                                    |
| <b>Croatia</b>        | € | 42.204.478,00    | 0,97                                | € | 2.502.276,21   | 0,06                                    |
| <b>Czech Republic</b> | € | 145.191.150,00   | 0,95                                | € | 4.516.472,00   | 0,03                                    |
| <b>Estonia</b>        | € | 12.602.242,88    | 0,85                                | € | 940.370,00     | 0,06                                    |
| <b>France</b>         | € | 1.993.902.870,99 | 0,87                                | € | 120.785.954,00 | 0,05                                    |
| <b>Germany</b>        | € | 2.223.275.112,68 | 0,73                                | € | 79.183.670,00  | 0,03                                    |
| <b>Hungary</b>        | € | 76.829.598,40    | 0,95                                | € | 4.442.580,00   | 0,06                                    |
| <b>Ireland</b>        | € | 94.786.778,58    | 0,51                                | € | 4.944.864,00   | 0,03                                    |
| <b>Italy</b>          | € | 379.845.073,54   | 0,25                                | € | 75.219.746,00  | 0,05                                    |
| <b>Latvia</b>         | € | 9.154.231,80     | 0,57                                | € | 835.814,00     | 0,05                                    |
| <b>Portugal*</b>      | € | 279.797.930,10   | 1,55                                | € | -              | -                                       |
| <b>Romania</b>        | € | 288.235.319,98   | 2,21                                | € | 4.779.500,00   | 0,04                                    |
| <b>Slovakia</b>       | € | 83.098.159,00    | 1,17                                | € | 2.356.772,00   | 0,03                                    |
| <b>Slovenia</b>       | € | 44.787.500,00    | 1,25                                | € | 3.358.000,00   | 0,09                                    |
| <b>Min</b>            | € | 9.154.231,80     | 0,25                                | € | 835.814,00     | 0,03                                    |
| <b>Max</b>            | € | 2.213.703.109,92 | 2,21                                | € | 102.485.469,00 | 0,09                                    |

**Figure 3: Estimation of the impact of kidney replacement therapy expenditure in Europe, 2016**

*(The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditures and Patient Outcomes (EDITH project))<sup>11</sup>*

*HD: Haemodialysis*

*PD: Peritoneal dialysis*

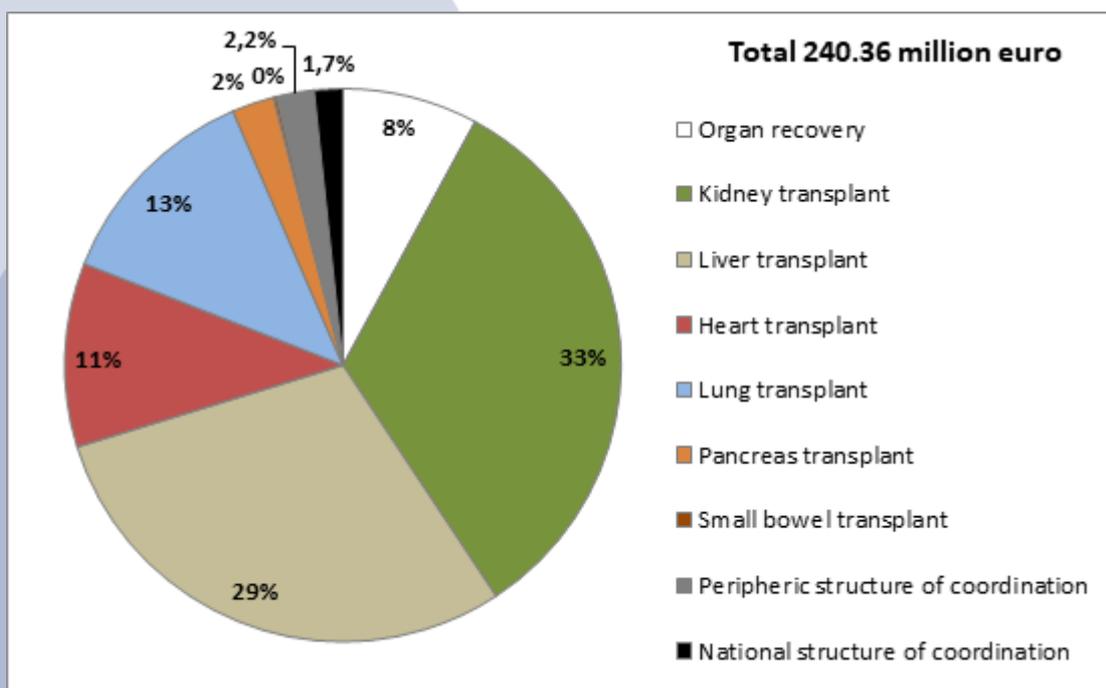
*DKD: Kidney transplantation from a deceased donor*

*LKD: Kidney transplantation from a living donor*

Source: Graph included in the [final report](#) of the EDITH project.

(Figure 4) According to the Spanish Transplant Organisation ‘*Organización Nacional de Trasplantes*’ (ONT), the savings created by transplantation (estimated at EUR 400 million per year)<sup>12</sup>, amply cover the annual costs of transplant programmes for all solid organs (EUR 240.36 million per year). More recent data from the ONT (table below Figure 4), estimate that kidney transplantation helped save more than EUR 700 million within the last ten years<sup>13</sup>.

As population continues to age, so does the strain on our economy, it is pivotal to consider transplantation not only as a life-saving or preferred option for patients, but also as a preferred option for the health systems and a crucial investment for the resilience of healthcare systems in the EU. Beyond financial costs, an uptake in transplantation would also be beneficial for the planet. For example, in the case of kidney failure, the environmental impact of transplantation can be as much as 90% lower compared to that of dialysis.<sup>14</sup>



**Figure 4: Annual cost of solid organ transplant, Spain, National Transplant Organisation (ONT)<sup>12</sup>**

*Source: Graph produced by the European Commission based on data from the Spanish National Transplant Authority*

**Estimated savings per year per kidney transplant patient: 30,000€**

**Estimated savings during the last 10 years: 800 million €**

|   |                      |
|---|----------------------|
| Number of kidney transplants in 2021  | 3,000                |
| Cost of dialysis <i>per patient per year</i>  | 41,120 €             |
| Cost of kidney transplant <i>per patient</i> (first year)   | 26,729 €             |
| Cost of kidney transplant <i>per patient</i> (subsequent years)   | 10,516 €             |
| Savings <i>per patient per year</i> from 2 <sup>nd</sup> year of kidney transplant  | 30,604 €             |
| Number of kidney transplants in the last 10 years   | 30,000               |
| Excluding the transplants performed in the last year, 27,000 patients with a kidney transplant. Considering a graft survival of 90%, savings are estimated on a number of <b>24,000</b> transplanted patients |                      |
| Spanish cost savings in the last 10 years   | <b>734,496,000 €</b> |

*\*2021 data*

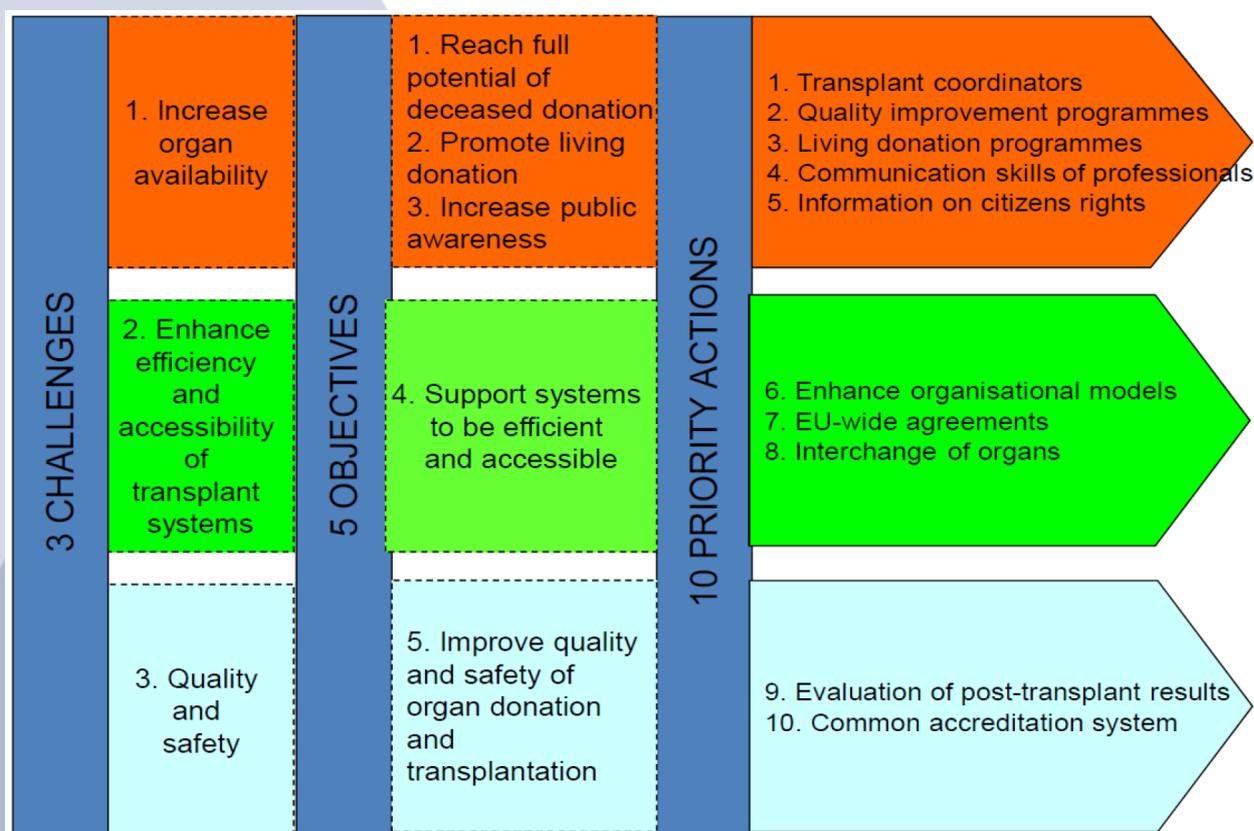
**Table 1: Savings by kidney transplantation in Spain\***

Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States and Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member States – FACTOR Study

The first EU Action Plan aimed to address three main challenges:

- 1) Increase organ availability
- 2) Enhance efficiency and accessibility of transplant systems
- 3) Improve quality and safety

Across these three challenges, the EU Action Plan defined 5 objectives and 10 priority actions:



*Source: Study on the update and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member States, Factor Study<sup>15</sup>*

As the FACTOR study presents, progress was achieved in Member States on five of these ten priority actions (all included in this paper as important priorities that should continue to be leveraged):

- The appointment of transplant coordinators
- The development of quality improvement programmes
- The set-up and/or development of living donation programmes
- The building of public awareness
- The facilitation of organ exchange between countries

While progress was made, the Action Plan's five remaining priority actions were not addressed as intensively enough during the 2009-2015 timeframe:

- **The identification of organ donors across Europe and cross-border donation in Europe**, for which this concept paper provides clear objectives and recommendations such as the activation and expansion of cross-border kidney exchange programmes (KEP) and mismatch programmes, the facilitation of best practices' exchange between countries and the organisation of meetings between national competent authorities under the umbrella of the European Commission.
- **The involvement in twinning of projects and peer review programmes**, for which this concept paper recommends further peer-to-peer exchange between countries/hospitals performing well and countries/hospitals lagging behind which could be facilitated by the European Commission via, for example, the ERASMUS + programme, the EU Structural Reform Support Service, the EU Best Practices Portal and EU-funded programmes. For the latter, the development of solutions to sustain outcomes and infrastructures after the end of the project will be crucial.
- **EU-wide agreements and initiatives**, which this concept paper suggest leveraging via, for example, the development of EU transplant centres of excellence (modelled on the EU network of comprehensive cancer centres) and the continuation of the European Reference Networks, in particular the ERN Transplant Child.
- **The collection of data regarding post-transplant outcomes, and the reporting of that data to relevant European agents**, for which we suggest facilitating the implementation of current initiatives of the European Society of Organ Transplantation (ESOT) for EU-wide registries and to support the collection and sharing of data between Member States.
- **Regular auditing efforts for procurement organisations and transplantation centres**, for which this concept paper suggests the development of EU-wide guidelines.

Moreover, donation and transplantation rates have now stalled or even declined in many EU Member States since the Action Plan ended in 2015. The COVID pandemic drew attention to the different levels of resilience and vulnerability of the Member States, in addition to the 17% decrease in deceased organ donation activity from 2019 to 2020, as pandemic hit. Against this backdrop, this concept paper presents possible interventions that could be part of a second EU action plan. A renewed focus on organ donation and transplantation is imperative to ensure that the progress made since 2009 is maintained and that remaining challenges are addressed. These possible measures divided into specific categories, take account of references listed at the end.

#### FACTOR-study key considerations for a new Action Plan:

1. Invest more in defining clear objectives of the new Action Plan by using a bottom-up approach. Ensure that the representatives of different levels are

involved: professional, administrative, political and the public. There should be fewer objectives but aiming for a stronger impact.

2. Build further upon the power of mutual learning and knowledge exchange. Individual countries that face similar issues can be given support jointly. The Competent Authority meetings could also be organised on this basis, and other relevant stakeholders could be invited more regularly to contribute.
3. Seek opportunities to share with and learn from adjacent areas of expertise, like tissues and cells, to increase the participatory and absorptive capacity of each country.
4. Support countries with less developed donation systems to bring their topics forward and have a more explicit role in the agenda.
5. Reflect more on implementation and sustainability, including the maintenance of IT components in projects, for more of a long-term impact, by commitment of involved parties (government, professional organisations, etc.).

## The following actions could be considered by the EU Member States

At present, the EU's organ donation and transplantation landscape faces multiple challenges, and the further increase in donation and transplantation activity continues to be hampered by a diverse array of barriers.

To increase the uptake of organ donation and transplantation in the EU Member States, an improvement of both the EU's and Member States' institutional and policy frameworks, with the removal of legal and institutional obstacles are crucial.<sup>16</sup>

### EU Member States should:

- a) Develop institutional, legal and ethical frameworks that facilitate the uptake of organ donation and transplantation, in line with EU guidance. Here, the focus should be on:

- a. Reducing financial and infrastructural barriers*

- b. Legislation*

- i. The implementation of opt-out versus opt-in policies (The latter is still applied in several EU countries), keeping in mind that opting-out policies are not the only solution and should only be seen as a fundament on which other measures in this document can be further developed.
  - ii. Address existing loopholes in organ trafficking legislation by:
    1. Sign and ratify the Council of Europe Convention against trafficking in human organs, which remains unratified by several EU countries.
    2. Endorse and implement the recommendations of the Declaration of Istanbul Custodian Group.

3. Establish a general reporting system of all out-of-country organ transplantations and non-resident donor and/or recipient donations/transplantations to a centralised registry.
- iii. Develop incentives to favour transplantation over dialysis for end-stage-kidney-failure patients.

c. *Deceased organ donation*

- i. Establishment and maintenance of national organ donation organization
  1. Create and strengthen donor coordinator networks, for which the 2009-2015 EU Action Plan provided a strong foundation, at the national, regional, and hospital levels, and incorporate key stakeholders in the identification and reporting of potential organ donors, both deceased and living. Here, specific attention should be devoted to:
    - a. The collection of a defined set of reliable and granular data on organ donation and transplantation and their transparent communication.
    - b. The central role of specially trained and committed ICU healthcare professionals as donor coordinators.
    - c. The integration of organ donation into the end-of-life-care practices.
  2. Analyse and target regional differences in organ donation rates including identifying the reasons why specific hospitals have significantly higher or lower retrieval rates.
  3. Ensure the strength of overall health systems to make donation and transplantation processes resilient to health crises, as they were heavily impacted during the COVID-19 pandemic.
- ii. Maximizing the role of donor coordinators in all hospitals with potential for organ donation.
- iii. Optimizing the role of intensive care professionals by the development of intensive care unit (ICU) programmes in collaboration with donor coordination organisations to enable an increase in the number of potential donors identified and the numbers of actual and utilised deceased donors.
- iv. Minimizing and/or optimizing the duration of the donation process.
- v. Promote expanded criteria donation (*donors that are not considered ideal or standard but are still of sufficient quality for transplantation and as such, can significantly shorten the waiting-time to receive a transplantation*), which is currently under-developed or even non-existent in most EU Member States. This should be supported by novel perfusion and preservation technologies.

- vi. Consider the development of DCD (Donation after Circulatory Death) programmes by the development of consensus-based negotiations on the implementation.
- vii. Development of special health care services if required, e.g. infant ABOi heart transplant programmes.
- viii. Implementation of national machine perfusion programmes.

*d. Activation and expansion of living-donation programmes*

- i. Activation and expansion of living kidney donation programmes in kidney transplant centers.  
Create and maintain frameworks to ensure that donation does not result in financial loss for the living donor, that foster greater spouse/emotionally related donation, and that allow for uniformity in the procedures for the recruitment and provision of information regarding donors and recipients. Specific attention should be paid on ensuring that donation remains an altruistic act based on genuine consent.
- ii. Use the EU 'Toolbox Living Kidney Donation' when setting up ethical frameworks for unrelated living donation.
- iii. *National patient and family information programmes about possible treatment options for patients with ESRD*
- iv. Implementation of national kidney paired exchange and ABOi programmes
- v. Open discussion on the altruistic living kidney and liver donation option
- vi. Implementation of living donor liver transplantation programmes

*e. International organ exchange:*

Increase official cross-border cooperation agreements on organ donation and transplantation within the EU (found to be important for the optimisation of the use of the limited number of available organs in the FACTOR study). Here the potential of organ perfusion systems, which can allow for longer transport time, and which are currently underused, should be fully unlocked.

*f. Education and training*

- i. Training of healthcare professionals:
  - 1. Organ donation
    - a. Actively encourage healthcare professionals (from primary to specialist care) to receive specific education in donation and transplantation activities, for example by:
      - i. Including basic information on donation and transplantation in the undergraduate curriculum for physicians and nurses, whilst continued education should be provided.

- ii. Offering reimbursement of fees and/or support schemes for participation in accredited professional training programmes on organ donation.
    - iii. Supporting the implementation of educational quality-assurance programmes.
    - iv. Clustering educational programmes targeted to different healthcare professional specialties.
    - v. Mandating periodic renewal of training in clinical areas where patients with devastating brain damage are treated.
    - vi. Appointing a responsible organisation to coordinate nationally these training sessions.
  - 2. Organ procurement: Support the establishment and continuous training of dedicated teams for the retrieval of organs, for example by investing in surgery units and ICU capacity (taking account of the fact that for living donation, two operating rooms are simultaneously needed).
  - 3. Organ transplantation surgery
- ii. Public education and public awareness:
  - 1. Support efforts to facilitate public education, for which the 2009-2015 EU Action Plan proved instrumental, including:
    - a. The provision of education on organ donation and transplantation in schools, with a particular focus on high schools.
    - b. Information about donation and transplantation via public-awareness campaigns, the press and social media, with a particular focus on communication about the quality of life of living donor.
    - c. Showcase the uniqueness of donors (for directed and non-directed organ donation), as an inspiring example of solidarity in society.
  - 2. Increase transparency of living and deceased donation processes to enhance public trust in the system.
- iii. Patient education
  - 1. Improve information on pre-transplant stage and on post-operative care for:
    - a. ESRD patients for better knowledge and acceptance of organ donation,
    - b. transplant patients to prevent organ loss and enhance patient recovery,
    - c. living donors and their families to improve donor recovery.

#### *g. Funding for programmes and research*

- i. Actively make use of opportunities to secure EU funding for transplant-related research, focused on increasing the number and quality of organs available for transplantation.
- ii. Obtain EU technical support, by applying to programmes with, specifically, a focus on the development and continued shaping of infrastructure, education and training, digitalisation, and research in healthcare.
- iii. Implement policies towards dedicated cost reimbursement to hospitals for donor management (ICU work) and organ retrieval.
- iv. Steer funds to increase the number of transplantation units and the number of medical personnel involved in transplantation.
- v. Encourage and support the use of organs that could not be allocated nationally or internationally, for research purposes (currently discarded in most cases).
- vi. Reflect, together with the European Commission, on ways to sustain EU-funded projects, including the maintenance of Pan-European Organ Transplantation Registries, currently developed by the European Society for Organ Transplantation (ESOT), to measure long-term results and identify differences between therapeutic alternatives in order to improve effectiveness, quality and safety.

#### *h. Inequities*

- i. Develop national strategies and actions designed to combat inequities related to organ donation and transplantation, which may focus on supporting efforts to increase registration for patients who are not systematically registered on transplant waiting lists.
- ii. Review the allocation criteria used by the national organ allocation systems to ensure inequities are identified and tackled.
- iii. Develop systems to reduce waiting times for highly sensitized transplant candidates.
- iv. Support the collection of data on non-waitlisted patients in need of a transplant from transplant centres (i.e. numbers of patients on dialysis, waitlisted versus not waitlisted), including baseline characteristics to identify areas of inequities.
- v. Develop kidney exchange programmes as well as mismatch programmes to increase chances to find a compatible donor.
- vi. Develop targeted communication schemes and educational initiatives, together with patient organisations and representatives of target groups that allow the socially deprived, those with lower education attainment, and those from minority communities to receive tailored information about donation and transplantation, considering different cultural, lingual and religious backgrounds.

- vii. Provide guidance on measures to prevent living donors' financial or employment loss due to donation.
- viii. Develop and facilitate implementation of programmes to reintegrate transplanted patients into employment.
- ix. Clustering of countries.

*i. Benchmarking*

- x. Work in concert with national transplantation organisations and European transplant societies to guarantee the proper registration and analysis of all transplant outcomes (including on survival after transplantation) in an actionable manner. Here, it is crucial to engage in a collaborative exercise to ensure a predefined common dataset ([Recommendation CM/Rec\(2023\)7](#)) and validated data collection.
- xi. Support activities aimed at encouraging the sharing of anonymised summary data between hospitals and comparing their performance.
- xii. Use Patient-Reported-Outcome-Measures (PROMs) to assess quality of life and wellbeing of patients and living donors before and after transplantation.

## The following actions could be considered at European level

Adopt EU actions to support organ donation and transplantation, based on the achievements and lessons learned from the 1st EU action plan, and involve relevant stakeholders (healthcare professionals, professional organisations, administrators, national competent authorities (NCAs), researchers and relevant patient organisations) in its preparation and implementation.

Develop recommendations and guidelines to support Member States' activities to enhance their institutional and policy frameworks and support the involvement of the above-mentioned stakeholders in the development of such guidance.

Encourage and support cross-border cooperation between Member States on organ donation and transplantation, including the activation and kidney exchange programmes (Kidney exchange programmes involve two living donors and two recipients, located in different countries. If the recipient from one pair is compatible with the donor from the other pair, and vice-versa, the programme can arrange for a 'swap' for two simultaneous transplants to take place, in different territories) and mismatch programmes (such as the Acceptable Mismatch programme initiated by Eurotransplant)<sup>17</sup> and the exchange of best practices.

Further develop the system of national focal points (NFPs) and central reporting to provide facts for legal responses and to increase transparency on travel for organ donation and transplantation, including a framework for regular reporting mechanisms.

Collaborate with Member States to improve systems of registration on waiting lists and facilitate the creation of EU-wide waiting lists.

### Options for the European Commission to support Member States:

- a) Encourage and support the clustering of Member States that face comparable process-related issues and facilitate peer-to-peer exchange.
- b) Support studies to understand obstacles that critical care face to incorporate donation in end-of-life care plans and how these could be overcome.
- c) Make use of the expert knowledge and planning capability on organ donation and transplantation contained within the EU Structural Reform Support Service, particularly to provide expert advice and plan for reorganisation and investment.<sup>16</sup>
- d) Facilitate increased investment in national transplant programmes, for example via the European Semester or the InvestEU programme.
- e) Make available funding opportunities, which were shown to be invaluable in the implementation of the 2009-2015 EU Action Plan, for national, regional and local programmes using the European Structural Investment Funds (ESIF), the European Regional Development Fund (ERDF), the European Structural Fund (ESF) and the European Social Fund Plus (ESF+).
- f) Identify and rank, in collaboration with Member States, regions and hospitals with higher or lower organ donation rates, understand their specific strengths

and weaknesses, define target numbers for donation and provide specific, tailored funding to reach these targets.

- g) Ensure that organ donation and transplantation prominently feature among the topics covered by the strategic plan of the future Horizon Europe programme, so as to dedicate appropriate funding to this field of research.
- h) Develop and strengthen a network of centres of excellence on donation and transplantation research, modelled on the EU network of Comprehensive Cancer Centres<sup>18, 19</sup>, so as to foster cross-border research collaboration.
- i) Support the provision of education and training of relevant stakeholders in Member States, including through the facilitation of best-practice exchange (for example via the EU Best Practices Portal), and particularly the continued organisation of meetings of national competent authorities.
- j) Support the establishment of training and education initiatives, including through the Erasmus+ programme (for example, by facilitating the short-term exchange of healthcare professionals in hospitals or countries with low donation and transplantation rates, to hospitals or countries performing best).
- k) Examine and develop different aspects of communication to assess and improve their effectiveness (such as public awareness campaigns, use of the press and social media, education in schools).
- l) Join forces with the European Directorate for the Quality of Medicines & Healthcare of the Council of Europe (EDQM) to support international cooperation in the field of (organ) biovigilance and to promote the European Donation Day on official EU channels.
- m) Support programmes and initiatives to help Member States tackle inequities and increase access for the specific sub-groups.
- n) Facilitate the social reintegration and rehabilitation of transplant patients by supporting employment and education possibilities, for example via the European Pillar of Social Rights.
- o) Further leverage the European Reference Networks, in particular the ERN Transplant-Child (*ERN TRANSPLANT-CHILD brings together experts in post-transplantation care to improve outcomes for children and their families. The network aims to reduce hospitalisation time and the use of complex and long-lasting treatments. It is working to improve psychological support services as children transition to adulthood. TRANSPLANT-CHILD aims to make available the latest techniques and medical, pharmacological and therapeutic advances*), and guarantee sustainable and appropriate funding for these networks.
- p) Encourage and support Member States in registering, analysing, and acting upon all donation and transplantation outcomes (including pre-donation and pre-transplantation data).
- q) Develop EU-wide guidelines for the standardisation of data collection ([Recommendation CM/Rec\(2023\)7](#)), evaluation, auditing, and hospital-performance comparison.
- r) Facilitate the establishment of current ESOT initiatives for EU-wide registries, and actively support the collection and sharing of data between Member States. Here, the sets of key data collected and shared by all Member States, that allow meaningful comparisons, should be defined.

- s) Support for the implementation of international kidney paired exchange programmes.
- t) Develop recommendations and guidance for the development and/or implementation of informed-consent donation procedures in Member States.

## Conclusion

These possible measures deserve further exploration, which should remain flexible and tailored according to individual country needs, could form the basis of further EU action on organ donation and transplantation, including a second EU action plan. The FACTOR study notes that Member States strongly valued the opportunities brought by the first EU action plan, such as having a common set of priorities, a shared-agenda and the possibilities of exchanging know-how<sup>15</sup>. The advantages of transplantation, in particular cost-effectiveness, living quality, safety, environmental sustainability, and survival outcomes are undeniable. The upcoming Hungarian presidency of the Council of the EU in 2024 is the perfect opportunity to have a renewed EU action plan on organ donation and transplantation, in which cross-border collaboration and EU guidance remain essential. Only prolonged and coordinated action will result in sustained efforts to improve conditions for patients and society.

Hungary is ready to support the preparation and implementation of any future EU and national initiatives in the field of organ donation and transplantation.

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