



# **Global strategy on donation and transplantation 2027-2036**

## **APPENDIX (WHO Secretariat Report EB160/XX)**

## APPENDIX A

### INTRODUCTION SECTION: LINKS TO CITATIONS

1. Seventy-seventh World Health Assembly, Agenda item 11.2, 1 June 2024: Increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs. Geneva: World Health Organization; 2024 (WHA77.4; [https://apps.who.int/gb/ebwha/pdf\\_files/WHA77/A77\\_R4-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R4-en.pdf)).
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4. Sixty-third World Health Assembly, Agenda item 11.21, 21 May 2010: Human organ and tissue transplantation. Geneva: World Health Organization; 2010 (WHA63.22; <https://iris.who.int/server/api/core/bitstreams/0c71e777-f93c-4abc-a520-f109a8daefe6/content>).
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8. Seventy-ninth General Assembly, Agenda item 107, 18 December 2024: Strengthening and promoting effective measures and international cooperation on organ donation and transplantation to prevent and combat trafficking in persons for the purpose of organ removal and trafficking in human organs. New York: United Nations; 2024 (A/RES/79/189; <https://docs.un.org/en/A/RES/79/189>).
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10. Declaration of Istanbul Custodian Group (DICG). The declaration of Istanbul on organ trafficking and transplant tourism (2018 edition) [website]. The Declaration of Istanbul Custodian Group; 2018 ([https://www.declarationofistanbul.org/images/documents/doi\\_2018\\_English.pdf](https://www.declarationofistanbul.org/images/documents/doi_2018_English.pdf)).
11. World Medical Association. WMA statement on measures for the prevention and fight against transplant-related crimes [website]. World Medical Association; 2020 (<https://www.wma.net/policies-post/wma-statement-on-measures-for-the-prevention-and-fight-against-transplant-related-crimes/>).
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## APPENDIX B

### OVERVIEW OF THE GLOBAL SITUATION

#### I. Burden of diseases and socioeconomic value of transplantation

1. A wide range of diseases and injuries contribute to conditions that may ultimately require or benefit from the transplantation of organs, tissues or cells. Despite prevention efforts established by several WHO strategies, the growing global burden of noncommunicable diseases – including metabolic disorders (i.e. diabetes), cardiovascular/pulmonary/renal/gastrointestinal diseases, cancer, and trauma – increasingly leads to complex or end-stage clinical scenarios requiring specialized tertiary care interventions.
2. Mortality and disability patterns illustrate the scale of this burden: deaths from chronic kidney disease vary by more than ten-fold across countries, reflecting large variances in disease prevalence and access to renal replacement therapies, often closely associated with differences in health system capacity and national income levels.
3. Across organ types, transplantation is generally associated with a survival advantage compared with other treatment modalities. Survival outcomes for patients with end-stage kidney disease differ markedly by treatment modality. Five-year unadjusted survival was reported at 41.3% for patients starting dialysis, compared with 85.1% for deceased-donor and 94.2% for living-donor first kidney transplants in 35 European countries (2022), illustrating the significant survival advantage associated with transplantation.<sup>1</sup> Studies comparing kidney transplantation with dialysis have shown lower rates of cardiovascular complications, hospitalizations and infections following transplantation, alongside higher patient-reported quality-of-life scores. At a global scale, conservative increases in kidney transplantation rates could avert an estimated 290,000 chronic kidney disease deaths annually.<sup>2</sup> Liver transplantation significantly improves survival outcomes: over 50% of recipients survive 7 years, compared to about 25% of patients on the waiting list, and median survival increases nearly fourfold (3.1 to 11.1 years).<sup>3</sup> In a defined subset of patients with acute liver failure the survival without an emergency transplantation is very low.<sup>4</sup> Outcomes are even more pronounced in children, where survival often exceeds 25 years,<sup>5</sup> resulting overall in substantial population benefit with an estimated 465,000 life-years gained. Evidence from heart transplantation similarly demonstrates a survival advantage, with estimated 5-year survival of 77% among transplant recipients compared with 33% among candidates who did not undergo heart transplantation, corresponding to an absolute survival benefit of 44%.<sup>6</sup>
4. Tissue transplantation can significantly reduce Years Lived with Disability (YLDs) by restoring function and patient autonomy in conditions such as corneal blindness, valvular and congenital heart disease, trauma, spinal conditions, osteoarticular degeneration, and chronic wound care. With the wider use of donor skin, alongside advances in critical care and burn management, a systematic meta-analysis confirms that early excision and grafting reduces mortality risk by 64% in patients without inhalational injury.<sup>7</sup> Evidence from corneal transplantation further illustrates this disability-related benefit. Penetrating keratoplasty in patients with severe keratoconus improves quality of everyday life by approximately 16.5% over the expected lifetime, corresponding to a gain of 5.36 Quality-Adjusted Life Years (QALYs).<sup>8</sup>
5. Hematopoietic cell transplantation—whether autologous or allogeneic, using related or unrelated donors—provides lifesaving and life-enhancing outcomes. Cells that are donated by a living individual, can cure or significantly extend life and improve quality of life for patients with a wide range of malignant conditions (such as leukemias, lymphomas, myelodysplastic syndrome (MDS), and plasma cell disorders) and non-malignant diseases (including bone marrow failure, hemoglobinopathies, autoimmune, and genetic

disorders). Compared with non-transplant therapies, it offers substantial survival benefits, with long-term survival rates of 60–70% in many cancers,<sup>9,10</sup> and near-curative outcomes exceeding 90% in some non-malignant conditions.<sup>11,12</sup> This unique combination of high survival and curative potential makes hematopoietic cell transplantation one of the most powerful interventions in modern medicine.

6. From a health system perspective, transplantation may also lead to reduced long-term health system expenditure. Long-term dialysis requires continuous infrastructure, recurrent treatment and frequent hospital care. Across 14 European Union countries, kidney transplantation has been shown to be more cost-effective than maintenance dialysis, generating mean annual net savings of approximately US\$37,471 per patient and 4.38 incremental QALYs, with financial break-even typically reached within a mean of 3.12 years.<sup>13</sup> Studies in national liver-transplantation programmes may show similar patterns: surviving recipients' labour-market productivity now generates over EUR 100 million annually, exceeding the programme's roughly EUR 75 million annual cost<sup>14</sup>.
7. Corneal infections, ocular trauma, trachoma, vitamin A deficiency, and congenital or degenerative diseases may lead to blindness which is curable by a Corneal transplantation. This condition often affects younger, economically active individuals, contributing to a cycle of poverty that surgical treatment can help break. The burden is further increased by indirect costs, including financial support for caregivers, productivity losses such as absenteeism and reduced employment, and broader economic impacts, alongside years of life lost. In the United States and Europe, corneal transplantation is highly cost-effective<sup>8,15</sup>, with cost-utility estimates of approximately \$11,557 per QALYs gained<sup>15</sup>.
8. While the upfront costs of cell transplantation can be significant, such therapies provide a unique chance for a permanent cure or longer survival and can be considered "cost-effective" when compared to the ongoing costs, for example, of managing chronic blood diseases.
9. Albeit resource-intensive, the combined gains in survival, quality of life and reduced long-term health system expenditure form a strong evidence base for considering transplantation an important component of modern health care systems.

## II. Access and coverage of transplantation

10. The availability and access to organ, tissue and cell transplantation remain highly uneven across and within WHO regions. According to the Global Observatory on Donation and Transplantation, 173,727 organ transplants were performed worldwide in 2024, while 668,160 patients were waitlisted across 75 countries and 31,853 patients died while waiting, illustrating a substantial gap between need and supply<sup>16</sup>. Available data likely understate true need in settings with weak registries or limited waiting-list systems, particularly in low- and middle-income countries.
11. Regarding hematopoietic cell transplantation, the number of procedures reported to the Worldwide Network for Blood and Marrow Transplantation in 2018 was 93,105 (48,680 autologous and 44,425 allogeneic) with wide variations in transplant rates in different regions,<sup>17</sup> highlighting significant differences in access.
12. Access to tissues is uneven globally: low-income regions face the highest rates of corneal blindness yet lack the specialized infrastructure and resources needed for transplants, while a persistent worldwide shortage of banked human skin means that—even in high-income countries with established networks—demand exceeds supply, and availability in many developing regions remains minimal or non-existent.
13. These disparities are closely linked to differences in health system capacity and national income levels. As a result, access to transplantation remains unavailable to many patients, particularly in low- and middle-income countries, where limited infrastructure, workforce capacity, public health priorities, and financing mechanisms constrain programme development.

### III. Transplantation integration within models of care

14. Transplantation should be considered within a broader continuum of care for many chronic and life-threatening conditions rather than as an isolated clinical intervention. Diseases that may ultimately lead to organ failure require coordinated management across different levels of the health system, with primary health care playing a critical role in early detection, initial management and raising patient awareness of transplantation as a potential treatment option, enabling timely referral when appropriate. Secondary and specialized services support diagnosis, disease management and referral for transplantation and other advanced therapeutic interventions.
15. Within this continuum, transplantation provides a life-saving or life-restoring option for patients with advanced or complex stages of disease who no longer respond to other treatments, and requires integration with primary care, specialist services and long-term follow-up systems to ensure appropriate patient identification, continuity of care and sustained outcomes.

### IV. Health system determinants of transplantation

16. Establishing effective donation and transplantation programmes requires coordinated development across multiple components of the health system. Transplantation is not a single clinical intervention but a complex continuum that encompasses donation, procurement, processing, transplantation procedures and long-term follow-up care. As such, national transplantation programmes should be embedded within broader health system structures and supported by appropriate legislation underpinned by ethical principles, with strong governance and regulatory frameworks that secure transparency at all stages and help maintain public trust in donation and transplantation systems, which in turn impacts donation rates especially for deceased donation.
17. National legislation and regulatory oversight mechanisms should establish ethical, quality, safety and efficacy standards in donation, procurement, processing and transplantation activities proportionate to the clinical benefit-risk to recipients. Moreover, compliance with requirements include traceability of donor-derived materials, reporting of adverse occurrences and data collection on the donation and transplantation activity, and outcomes.
18. Sustainable financing mechanisms are equally important. Transplantation programmes require dedicated resources to support infrastructure, workforce training, procurement systems, allocation, medicines and long-term follow-up care. Integration of transplantation within national health financing mechanisms, including universal health coverage policies, helps ensure equitable access and protects patients and donors from financial hardship.
19. A competent health workforce is essential for all stages, from donor identification and management, procurement, preparation or processing, to transplantation, and post-transplant care. Programmes rely on multidisciplinary teams including donor coordinators, surgeons, physicians, nurses, technicians, laboratory specialists, and transplant pharmacists, all trained in donation and transplantation related practices and activities. Workforce development requires structured education, ongoing training and opportunities for international collaboration and knowledge exchange to maintain high standards of clinical care and technical expertise.
20. From a service delivery perspective, transplantation requires specialized infrastructure capable of supporting both deceased and living donor identification, procurement and utilization and recipient care. This includes intensive care units for management of potential deceased donors and post-transplant care of recipients,

adequate facilities for procurement and transplantation procedures, specialized laboratories for testing and compatibility assessment, blood transfusion services and systems for safe transport and preservation of organs, tissues and cells. Effective service delivery also depends on integrated referral pathways that allow patients with advanced or complex stages of disease to be identified, assessed and managed across different levels of care.

21. Transplantation programmes depend on reliable access to essential medical products and technologies, including preservation and transport technologies (e.g. machine perfusion for organs), specialized surgical equipment, safe and sufficient blood products and essential medicines such as immunosuppressive therapies, where needed. These technological and pharmaceutical components are integral to safe transplantation and best long-term outcomes.
22. Robust information systems are required for collecting data to monitor transplantation activity, and establish demand against capacity of supply. Patient registries, donor registries and biovigilance systems allow tracking of outcomes, reporting of adverse events, and evaluation of programme performance. Effective traceability from donor to recipient is essential to ensure safety, quality assurance and continuous improvement of clinical practice.

## **V. Social determinants of donation and transplantation**

23. Donation of organs, tissues and cells is the foundation of transplantation and it is influenced not only by health system capacity but also by broader social, cultural and ethical factors. Public knowledge and understanding of donation processes, perceptions of fairness and transparency in allocation systems, and levels of trust in health institutions all influence willingness to donate. In many settings, limited public awareness, misconceptions about donation procedures and uncertainty regarding the determination of death may reduce participation in donation programmes. Social engagement and sustained public communication are therefore essential to promote informed decision-making and support community confidence in donation systems.
24. Equity considerations are also important. Ethnic minority populations may experience lower rates of donation and transplantation due to historical mistrust of health institutions, disparities in access to care, or limited inclusion in public engagement efforts. Gender dynamics may also influence both donation and access to transplantation, including patterns of living donation within families. Addressing these disparities requires inclusive policies, culturally sensitive communication and equitable access to transplantation services.
25. Cultural and religious beliefs can also shape attitudes toward donation. While many religious traditions support donation as an act of altruism or solidarity, variations in interpretation or lack of accessible guidance from religious authorities may create uncertainty among potential donors and their families. Engagement with community leaders, faith organizations and patient groups can help address concerns and ensure that donation programmes are culturally appropriate and socially acceptable.
26. Social determinants can influence attitudes toward donation, access to transplantation services, and long-term patient outcomes. Inequities in these determinants can create barriers to both donation and transplantation, disproportionately affecting disadvantaged populations. In addition, social and economic vulnerabilities may contribute to the emergence of organ trafficking and transplant tourism, particularly where shortages of organs coexist with poverty and limited social protections. Weak regulatory oversight, inappropriate financial incentives and shortages of donated organs, tissues and cells can create conditions in which vulnerable populations are exploited. Strong governance frameworks, transparent allocation systems and international cooperation are therefore essential to protect donors and recipients while maintaining public trust in donation and transplantation systems.

## VI. International collaboration: insufficiency, public health emergencies, sharing of capability

27. National self-sufficiency may not be technically achievable or economically feasible in some settings or for some transplantation modalities, due to limited population size, resource constraints, absence of essential infrastructure or competing health care priorities. An increasing number of transplantation-related services are being offered through medical tourism, particularly by private-sector providers. Such services may worsen inequity in access and, where appropriate safeguards are absent, may facilitate commercial or other unethical practices. Well-planned bilateral, regional or international collaboration through state involvement can help share technical skills, infrastructure and resources, and support equitable access to transplantation opportunities, while clear policies should regulate/govern cross-border movement of donated organs, tissues and cells and transplant care for non-resident patients.
28. Even where transplantation programmes are established, service provision may be insufficient or disrupted by a range of external factors. Public health emergencies, armed conflict, natural disasters or severe economic crises can disrupt national programmes, result in a dramatic surge in need or severance of established international access for tissues, cells, essential medicines and medical supplies. Health system resilience, contingency planning and international collaboration are therefore important to help maintain continuity of care and protect both patients awaiting transplantation and transplant recipients during periods of system stress.

## VII. Innovation and future developments

29. Advances in transplantation have been driven by major scientific and technological innovations, including improved immunosuppressive therapies that reduce rejection and extend graft survival, as well as developments in organ preservation and machine perfusion that enhance organ viability and expand donor pools. Progress in minimally invasive surgical techniques, and stem cells research is opening new possibilities for tissue repair and bioengineered organs, supporting and/or enhancing transplants. In parallel, digital technologies and improved matching algorithms have strengthened allocation systems, while emerging fields such as xenotransplantation hold promise for addressing global shortages of transplantable organs.
30. At the same time, the introduction of new technologies requires pairing those to careful ethical considerations, the appropriate level and complexity of the regulatory oversight around technological validation standards, and product safety, quality and efficacy, and the critical cost-benefit analysis to ensure that emerging products are developed and implemented in ways that are feasible, deliver against identified need, are effective and can become accessible across diverse health system contexts. Xenotransplantation, for example, raises distinct ethical and public health considerations, including animal use and genetic modification, zoonotic risks, implications for recipients and third parties, and informed consent.

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