AMERICAN SOCIETY OF TRANSPLANTATION®

World Health Organization Secretariat
Comments submitted through online form

August 31, 2026

On behalf of the American Society of Transplantation (AST), the largest professional transplant society in North America representing over 5,000 organ transplant health care professionals, I submit the following comments in response to the invitation for public review of the World Health Organization (WHO) draft global strategy on donation and transplantation.

The benefits of transplantation are invaluable and well established. The need for solid organ transplantation has never been greater given the current global burden of advanced organ disease. Yet, marked discrepancies persist internationally in access to transplantation. We appreciate the many contributing factors described by the authors and agree with this complex overview. We support the call for national leadership to invest in health system-wide enhancements to build equitable and effective transplant programs in order to achieve the life-saving potential of transplantation for patients of all ages. We agree with the stated vision of this WHO document, found the objectives appropriate, and believe the aims are well-stated. We would like to call attention to the following points addressed in the introduction, overview and strategic directives with associated modifications for consideration.

Paragraph #4: Introduction
The AST appreciates the succinct description of the evolution of transplantation and national policy over time. Given the aims of this global strategy, we suggest expanding on the importance of continuous improvement in transplant policy, which is needed in resource-rich as well as resource-limited countries. Expanding on this point will promote pertinence of this WHO initiative more broadly and prevent any impression of this document as relevant to only resource-limited countries. For example, delete “may” from line 15 as presence of disparities is undeniable even in established programs. We also suggest adding language to further clarify this point such as “Even in countries that have organ transplant programs spanning over fifty years, significant disparities in access to care persist, contributing to lack of awareness of recipient candidacy and donor opportunities.”

Paragraph #8: Reference to WHO Resolutions
We recognize and appreciate the valuable prior WHO publications pertaining to transplantation. It would be helpful, however, to clarify intention and scope of some key terminology of transplantation policy that are mentioned repeatedly in the global strategy. For example, “equity” is mentioned repeatedly in this paragraph to demonstrate prioritization in prior resolutions. But the term is also used several times throughout the current WHO global strategy. In this current document, does “equity” pertain only to practices of WHO member states per the prior resolutions, or should it be interpreted more broadly as a guiding principle of transplant policy development?

Unique to organ transplant is that organ donation is considered a shared human resource, subject to allocation rules. The principle of equity would indicate that every individual in the world who needs an organ transplant should have an opportunity to be considered. Selection of recipients and allocation of

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organs based on weighted values of age, waitlist mortality, and likelihood of survival after transplant are practical and logistical considerations. Still, they must be grounded in reasonable fairness coupling recognition of additional mitigating circumstances affecting access (e.g., social determinants of health) and the ethical principle that one life is not more important than another. The AST thus supports inclusion of equity as a guiding principle in the development of the WHO's global strategy and suggest including this clarification in the current draft.

Paragraph #32: Strategic Direction 2: Professional capacity

The AST recommends expanding the reference for "specialized laboratories for testing and compatibility assessment" to recognize the range of diagnostic services needed throughout donor and recipient evaluation, organ allocation, and post-transplant care. These services include anatomic pathology, histocompatibility and immunogenetics, infectious disease testing, and other clinically indicated laboratory services. National systems should ensure timely access to quality-assured diagnostic services, either locally or through regional referral networks.

Paragraph #44: Objectives

The AST agrees and appreciates the strong emphasis placed on the need for national transplant systems to feature enhanced quality and effectiveness of transplant outcomes. Yet, respectfully, definitions of quality metrics and "good outcomes" of transplantation programs are lacking in this draft. While the WHO guidance on national transplant system development in the current draft is very strong, this global strategy could be improved by seizing the opportunity to re-define quality metrics of transplant system and program performance across the full spectrum of transplant practice, not just post-transplant outcomes. We encourage consideration of adding such language to the current draft.

With respect to quality metrics, in addition to short-term graft and recipient survival, we suggest encouraging countries to monitor the following metrics of efficient donation, graft utilization and patient outcomes:

- Organ utilization rates
- Organ non-utilization rates
- Reasons for non-utilization
- Donor conversion rates
- Waitlist mortality
- Long-term recipient clinical outcomes
- Long-term living donor clinical outcomes

Standardizing quality metrics will also help to determine potential longer-term benefits of transplantation that will help inform patients and providers considering pursuit of transplantation. Furthermore, defining effective/good longer term clinical outcomes could lead to further cost-benefit and cost-effectiveness analysis that could very well provide further justification for continued national investment towards sustaining robust transplant programs.

Paragraph #55: Strategic Direction 1: Transplant Governance

Strategic Direction 1 is a remarkably thorough recommendation on formulating national transplant programs that reflect critical tenets of transplantation policy to promote ethical practice and sustainability: prioritizing meeting needs of patients, demonstrating importance of codifying transplant policy via legislative process, establishing need for continuous public investment, and recognizing opportunities for ongoing program improvement via performance metrics. The AST suggests adding language to paragraph 55 stating the importance of endowing independence of a national transplant agency and authority to preserve function of transplant programs, thus making them exempt to changes in political leadership as appropriate.

Paragraph #62: Strategic Direction 1: Financing Policies

This paragraph nicely identifies the importance of removing financial burden on living donors while clarifying the importance of eliminating potential for financial incentive or coercive tactics, though there is

room to build upon these points. The AST endorses policy and practice changes to achieve *at least* financial neutrality in living organ donation and to minimize non-financial donation-related burdens. While recognizing that direct payment for or sale of an organ violates globally accepted ethical principles, we support empirical research—with appropriate ethical safeguards—investigating living organ donation incentives.

The AST recommends that the WHO global strategy should promote establishing financial neutrality for living donors as an explicit standard. We also advise clarifying acceptable reimbursable donor costs across the full continuum of care, including reasonable donor-related costs such as travel, dependent care, lost wages, medical evaluation, complications, and follow-up. The strategy should distinguish reimbursement of legitimate donor-related expenses from payment for donation and recognize that effective access to transplantation requires sustainable financing for long-term follow-up, not simply the transplant procedure. WHO should provide practical examples of sustainable financing and financial-risk protection models adaptable to low-, middle-, and high-resource settings.

To further optimize opportunities for living donation, it is important for national transplant programs to also identify other aspects of donor disincentives such as risk to job security due to time away from work for transplant-related travel, testing and recovery. Donors may also be subject to long-term penalties if their history of donation is incorrectly interpreted as endowing higher medical risk or the equivalent of a pre-existing medical condition, which could result in employment discrimination and insurance barriers. Protections against such discrimination should be included in national transplant program development and considered viable for legislative action if needed. These comments on donor protections could be included in Strategic Direction 1 or Strategic Direction 3.

Paragraph #77: Strategic Direction 3: Organization and infrastructure for donation

The strategy appropriately focuses on increasing donation, and we agree with the suggested guidance including the importance of identifying causes of missed donation to prevent future recurrence. We believe that maximizing utilization of recovered organs is equally important. The current draft appropriately recognizes machine perfusion as an emerging preservation technology, but the role for machine perfusion in increasing graft utilization and expanding access to transplantation could be further emphasized. We suggest adding language recognizing machine perfusion as an important innovation capable of the following positive impacts:

- increases utilization of medically complex donor organs (particularly organs from donation after cardiac death (DCD) donors and livers);
- improves preservation and transportation logistics;
- facilitates objective viability assessment prior to transplantation;
- reduces organ non-utilization while maintaining recipient safety.

Paragraph #85: Strategic Direction 3: Public awareness campaign

The AST heartily agrees with the need for effective public awareness campaigns to improve donor, recipient and referring providers recognition of opportunities for organ donation and transplantation. While providing the benefits of transplantation to the public is a critical component of an effective campaign, it is important to also acknowledge associated risks, which is an important demonstration of maintaining transparency in transplant systems, ethical practice and ultimately allows for better informed patients and providers. We suggest adding some language to this paragraph noting the importance of including awareness of risks to achieve an appropriately informed public.

Paragraph #101/103: Strategic Direction 5: International access to transplantation

The AST strongly supports the myriad positive impacts of international collaboration as described in the current draft to promote donation opportunities and access to transplantation. International collaboration is critical to promote knowledge sharing among nations at different stages of transplant system development, enforcement of ethical transplantation policy and practice, and maintaining critical access to transplant care during public health emergencies. Some countries engage in cross-border organ sharing. The importance of national data collection is directly addressed earlier in the document (paragraph 57), but transnational data collection does not appear to be addressed in this section. Such transnational data

systems should be encouraged to permit international data collection and analysis, and we suggest adding such language to this paragraph.

Paragraph #105: Strategic Direction 6: Investing in technological advancement, research and innovation
We appreciate this important section of the global strategy and its recommended guidance on supporting growth of new areas of research while also being mindful of need for regulatory authority to implement advancements in transplant care (e.g., use of biohybrid devices, xenotransplantation). We also recommend adding language that more explicitly recognizes other areas of active clinical investigation, which have the potential to increase organ availability and improve outcomes (e.g., methods of organ viability assessment and ex vivo organ repair, strategies to mitigate ischemia-reperfusion injury, development in biomarkers and preservation biology).

Sincerely,

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Version 1

26/06/2026

Global strategy on donation and transplantation

Biologicals Norms and Standards and Transplantation (BNT)

Product Standards, Specifications and Nomenclature Unit (PSN)

Medicines and Health Products Policies and Standards Department (HPS)

Health Systems, Access and Data Division (HSD)

World Health Organization, Geneva

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Global strategy for donation and transplantation

Version 1 (26 June 2026)

Introduction

1. The Global strategy on donation and transplantation aims to address the escalating burden of diseases treatable by transplantation and the profound disparities in access to these life-saving and life enhancing therapies, as underscored by the World Health Assembly Resolution 77.4 (2024).[1]

2. Transplantation refers to the medical and surgical procedure in which tissues, cells, or organs are removed from one body and placed into another, or transferred to a different location within the same body. This can be autologous (e.g. skin grafts or haematopoietic cells) or allogeneic (e.g. kidney, liver, cornea, haematopoietic cells), from either a live or deceased individual (a donor).

3. Transplantation evolved over many decades, since the 1960's due to scientific advancements in immunology, becoming a standardized and widely accepted treatment for a wide range of health conditions, with significant benefits in patient survival, reduced morbidity and improvement of the quality of life.

4. However, organ, tissue and cell transplantation are not equally available among the WHO regions, therefore, remaining inaccessible for millions of potential recipients. Demand often exceeds the capacity of national programmes, where they are established, and disparities may exist within given countries, with the poorest populations least likely to have access.

5. Moreover, gaps in access, combined with weaknesses in oversight and legal enforcement, contribute to the persistence of unethical and illegal practices, including trafficking in human organs, tissues and cells, and transplant tourism, where patients travel across borders and long distances to access transplantation.

6. This strategy does not address the use of organs, tissues or cells, for non-clinical research, education and professional training or other applications that do not carry risks to recipients (such as biobanking). In addition, the strategy excludes Advanced Therapy Medicinal Products (ATMPs), noting that ATMPs are specifically addressed by the WHO Expert Committee on Biological Standardization (ECBS).

7. Other substances of human origin such as blood and blood derived products, reproductive tissues and cells or human milk, they are not to be considered as transplantation treatments and therefore, will not be included under the scope of this strategy.

Reference to WHO resolutions on transplantation and other related documents

8. The World Health Assembly has adopted key resolutions [WHA 44.25 (1991); WHA 63.22 (2010)],[2] endorsing the "WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation", which promote voluntary

[1] Resolution WHA 77.4 on increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs, available at https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R4-en.pdf

[2] WHO Guiding Principles on Donation and Transplantation, resolutions WHA44.25 (https://apps.who.int/gb/ebwha/pdf_files/wha63/a63_r22-en.pdf) and WHA63.22 (https://www.who.int/publications/i/item/WHO-HTP-EHT-CPR-2010.01)

unpaid donation, non-commercialization, informed consent, equity, and strong oversight to protect donors and recipients. Resolution WHA57.18 (2004)[3] addressed rising legal, ethical, and safety risks, including shortages of transplant materials and potential use of xenogeneic sources, calling for global guidance. Most recently, resolution WHA 77.4 (2024) highlighted ongoing gaps in access, oversight, and equity, and requested development of a global strategy and updated guiding principles to reflect evolving health systems and innovations.

9. At the regional level, the WHO Regional Committee for the Americas adopted the 2019–2030 Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue and Cell Transplants, setting out measures to address governance, infrastructure and workforce constraints while recognizing that limited availability remains a central barrier.

10. WHO has promoted global alignment in transplantation through expert consultations, technical work, and collaboration with professional and regional partners. A key milestone was the Third WHO Global Consultation on Organ Donation and Transplantation in 2010 (the Madrid Resolution),[4] which provided important guidance on achieving national self-sufficiency in transplant services.

11. To address trafficking in human beings for organ removal and in human organs, the United Nations General Assembly has issued a series of resolutions (most recently 79/189 of 2024)[5] calling on Member States to strengthen regulatory measures and international cooperation. Complementing these efforts, initiatives such as the Declaration of Istanbul[6] and World Medical Association position statements[7] have reinforced the ethical responsibilities of health professionals and the need for robust oversight.

12. In regard to other substances of human origin, WHO has advanced principles for global consensus on ethical practices for medical products of human origin[8] and has developed guidance on the regulation of Advance Therapy Medicinal Products.[9]

[3] Resolution WHA57.18 on Human organ and tissue transplantation, Available https://apps.who.int/gb/ebwha/pdf_files/wha57/a57_r18-en.pdf

[4] WHO 3rd Global Consultation on Organ Donation and Transplantation, Available at https://journals.lww.com/transplantjournal/toc/2011/06151

[5] United Nations General Assembly (UNGA) resolution A/RES/79/189 on strengthening 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, Available at https://docs.un.org/en/A/RES/79/189

[6] The Declaration of Istanbul on Organ Trafficking and Transplant Tourism. Available at https://www.declarationofistanbul.org/the-declaration

[7] WMA Statement on Measures for the Prevention and Fight against Transplant-Related Crimes. Available at https://www.wma.net/policies-post/wma-statement-on-measures-for-the-prevention-and-fight-against-transplant-related-crimes/

[8] WHA A70/19 (2017), Principles on the donation and management of blood, blood components and other medical products of human origin, Available at https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_19-en.pdf

[9] "Considerations in developing a regulatory framework for human cells and tissues and for advanced therapy medicinal products", established by the Expert Committee on Biological Standardization and published in WHO Technical Report Series 1048, Annex 3, (2023). Available at https://www.who.int/publications/m/item/considerations-in-developing-a-regulatory-framework-for-human-cells-and-tissues-and-for-advanced-therapy-medicinal-products

Overview of the global situation

a. Burden of diseases and socioeconomic value of transplantation

13. 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 (i.e. diabetes)/cardiovascular/ fibro-inflammatory diseases, cancer, and trauma – increasingly leads to complex or end-stage clinical scenarios requiring specialized tertiary care interventions.

14. 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 treatment, often closely associated with differences in health system capacity and national income levels.

15. Survival outcomes for patients with end-stage kidney disease differ markedly by treatment modality. Five-year adjusted survival probabilities have been reported at approximately 35% for haemodialysis and 41% for peritoneal dialysis, compared with about 73% for kidney transplant recipients,[10] illustrating the significant survival advantage associated with transplantation. 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. Conservative increases in kidney transplantation global rates, could avert 290,000 chronic kidney disease deaths annually.[11] Liver transplantation significantly improves survival outcomes: over 50% of recipients survive beyond 7 years, compared to about 25% of patients on the waiting list, and median survival increases nearly fourfold (3.1 to 11.1 years).[12] In a defined subset of patients with acute liver failure the survival without an emergency transplantation is very low.[13] Outcomes are even more pronounced in children, where survival often exceeds 25 years,[14] 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%.[15]

16. Tissue transplantation can significantly reduce YLDs (Years lived with disability) by restoring function and patient autonomy in conditions such as corneal blindness, congenital heart disease, trauma, osteoarticular degeneration, and chronic wound care. Since the wider use of donor skin, the mortality rate for patients with burns over 40-50% have plummeted from nearly 100% in the mid-20th century to as low as 10%–20%

[10] United States Renal Data System (USRDS), Annual Data Report. http://www.usrds.org
[11] A Zambeli-Ljepović et al. The potential of kidney transplantation to reduce mortality from chronic kidney disease: a global, cross-sectional, modelling study, 2025 https://doi.org/10.1016/S2214-109X(25)00222-0
[12] Merion RM et al. – "The Survival Benefit of Liver Transplantation" *American Journal of Transplantation*, 2005 https://www.amjtransplant.org/article/S1600-6135%2822%2903550-X/fulltext
[13] Maiwall R, Kulkarni AV, Arab JP, Piano S. Acute liver failure. Lancet. 2024 Aug 24;404(10454):789–802. https://doi:10.1016/S0140-6736(24)00693-7
[14] Analysis of the United Network of Organ Sharing database: Where to go from here. https://doi.org/10.1111/petr.13523
[15] Strategies of Wait-listing for Heart Transplant vs Durable Mechanical Circulatory Support Alone for Patients With Advanced Heart Failure, JAMA Cardiology. https://jamanetwork.com/journals/jamacardiology/fullarticle/2764756

in modern specialized centers.[16,17,18,19] 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).[20]

17. 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, 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 and near-curative outcomes exceeding 90% in some non-malignant conditions. [21,22,23,24] This unique combination of high survival and curative potential makes hematopoietic cell transplantation one of the most powerful interventions in modern medicine.

18. 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. In the United States Medicare system, dialysis costs can exceed US$80,000 per patient per year, whereas kidney transplantation can generate cost savings of up to US$200,000 over the first five years after transplantation, with financial break-even typically reached within 2.3–3.6 years depending on donor type.[25,26,27,28]

19. 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

[16] Strassle et al., *J Burn Care Res* (2017) https://pmc.ncbi.nlm.nih.gov/articles/PMC5393966/
[17] Sharma et al., *Indian J Plast Surg* (2021) https://pmc.ncbi.nlm.nih.gov/articles/PMC8012794/
[18] Alsafy et al., *Modern Plastic Surgery* (2024) https://www.scirp.org/journal/paperinformation?paperid=130430
[19] Yadav et al., systematic review of grafting outcomes (2025) https://www.medicalpaper.net/archives/2025/vol7issue1/PartC/7-1-44-647.pdf
[20] The value-based medicine comparative effectiveness and cost-effectiveness of penetrating keratoplasty for keratoconus. https://pubmed.ncbi.nlm.nih.gov/18812762/
[21] Khamis et al., *Frontiers in Hematology* (2025) https://www.frontiersin.org/journals/hematology/articles/10.3389/frhem.2025.1759405/full
[22] Cibich et al., *Transplantation and Cellular Therapy* (2026) https://www.astctjournal.org/article/S2666-6367%2826%2900057-6/fulltext
[23] Algeri et al., *Hematol Oncol Clin N Am* (2023) https://www.hemonc.theclinics.com/article/S0889-8588%2822%2900150-2/fulltext
[24] Anurathapan et al., *Biol Blood Marrow Transplant* (2020) https://www.astctjournal.org/article/S1083-8791%2820%2930012-4/fulltext
[25] USRDS-based cost estimates https://www.kidneyregistry.com/wp-content/uploads/2025/01/Cost-Savings-Model-White-Paper-Report-January-2025_v4.pdf
[26] Axelrod et al., *Am J Transplant* (economic modeling) https://www.amjtransplant.org/article/S1600-6135%2822%2909535-1/fulltext
[27] National Kidney Registry / cost analyses https://www.kidneyregistry.com/wp-content/uploads/2025/10/NKR-Savings-Analysis-10.20.2025v2.pdf
[28] Transplant cost comparisons and break-even timing https://www.transplants.org/organ-transplant/kidney-transplant/considering/financial-planning

life lost. In the United States and Europe, corneal transplantation is highly cost-effective, with cost-utility estimates generally in the range of approximately $10,000-$12,000 per quality-adjusted life year (QALY) gained.[29,30]

20. 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.

21. 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.

b. Access and coverage of transplantation

22. 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,[31] 173,727 solid 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. These are likely to be much more in the global south.

23. 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,[32] highlighting significant differences in access.

24. Access to tissues is uneven globally: low-income regions face the highest rates of corneal blindness yet lack the specialized infrastructure 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.

25. 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 and financing mechanisms constrain programme development.

c. Transplantation integration within models of care

26. 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

[29] Brown GC et al., *Cornea* (2008) https://journals.lww.com/corneajrnl/Abstract/2008/10000/The_Value_Based_Medicine_Comparative_Effectiveness.7.aspx
[30] Tufts CEA Registry / cost-utility summaries https://cevr.tuftsmedicalcenter.org/databases/cea-registry
[31] Global Observatory on Donation and Transplantation - 2024 report https://www.transplant-observatory.org/
[32] Y Atsuta et al. Haematologica. 2024 Oct 1;109(10):3282-3294. https://doi.org/10.3324/haematol.2024.285002.

specialized services support diagnosis, disease management and referral for advanced therapies, including transplantation.

27. 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.

d. Health system determinants of transplantation

28. Establishing effective 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 must 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.

29. National legislation and regulatory oversight mechanisms should establish quality, safety and efficacy standards in donation, procurement, processing and transplantation activities proportionate to the clinical benefit-risk to recipients. Moreover, compliance to requirements include traceability of donor derived materials, reporting of adverse events and data collection on the donation and transplantation activity, and outcomes.

30. Sustainable financing mechanisms are equally important. Transplantation programmes require dedicated resources to support infrastructure, workforce training, procurement systems, 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.

31. A competent health workforce is essential for all stages, from donor identification and management, procurement, preparation or processing, to transplantation. Programmes rely on multidisciplinary teams including donor coordinators, surgeons, physicians, nurses, technicians, laboratory specialists, and transplant pharmacists, all trained in 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.

32. From a service delivery perspective, transplantation requires specialized infrastructure capable of supporting both donor identification, 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.

33. 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.

34. 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.

e. Social determinants of donation and transplantation

35. 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.

36. 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.

37. 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.

38. 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.

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

39. 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. A lot of direct initiatives are currently being noted, mainly in the private sector, through medical tourism. Such services may worsen inequity in access and are often a cover for commerce. 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 govern cross-border movement of donated organs, tissues and cells and transplant care for non-resident patients.

40. 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.

g. Innovation and future developments

41. 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 and gene editing hold promise for addressing global shortages of transplantable organs.

42. 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 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.

Vision

43. By 2035, Member States should have established a national strategy for donation and transplantation within their health systems. Cell, tissue and organ transplantation will be integrated into national health policies and operational models. All patients who qualify for transplantation would be appropriately identified and have equitable access to referral and treatment, with services delivered in timely fashion at national level or, where necessary, through regulated regional or international cooperation.

Objectives

44. The global strategy is guided by three key objectives: (1) increased availability and improved access to transplantation; (2) strengthening of ethical, legislation and policy, and regulatory frameworks governing donation and transplantation; and (3) enhanced quality, safety and effectiveness of transplantation outcomes.

Strategic directions

Strategic Direction 1: Transplantation governance

45. Strategic direction 1 aims to strengthen transplantation governance and coordination at the national level, responsive to population needs and feasible within the health system context as part of universal health coverage. Effective, ethical and sustainable transplantation requires a coherent national system integrating legislation, policy, service delivery, financing and regulatory oversight across the full donation-to-transplantation continuum.

a. National planning

46. Governments should demonstrate sustained political commitment to ethical, sufficient and sustainable national systems for organ, tissue and cell donation and transplantation. Commitment should be reflected through legislative action, sustained public investment, long-term planning and measurable progress.

47. National planning should include systematic assessment of current and projected population needs in transplantation, of available supply capacity and gaps in access, and should prioritize strengthening nationally coordinated systems within a strong public sector framework to safeguard equity, access, accountability and effective regulation.

48. Where capacity is evolving, phased system development may be appropriate. Targeted investment can build transplant capacity by moving from fragmented, resource-limited services toward coordinated national systems, combining governance and regulation, infrastructure, training and workforce, equitable financing and access.

b. Legislation and policies

49. Legislation should establish a clear framework enabling safe and ethical donation and transplantation practices in accordance with the WHO Guiding principles on human cell, tissue and organ transplantation and the WHO Principles on donation and management of medical products of human origin.

50. Legislative frameworks should ensure informed and voluntary consent; prohibit overt commercialization and financial gain from the human body; define roles and responsibilities across the donation-to-transplantation pathway; safeguard equitable allocation and utilization based on transparent clinical criteria; and criminalize coercion and related illicit practices.

51. Legislation should also define responsibilities for preventing and responding to trafficking in persons for the purpose of organ removal and trafficking in human organs, tissues or cells, including cooperation between designated health and law enforcement authorities, relevant ministries and other stakeholders.

52. Legal recognition of death, based on neurological and circulatory criteria should be harmonized within national law to enable deceased donation, alongside appropriate end-of-life care policies.

53. Legislation should authorize appropriate models of donation, processing and transplantation based on identified need, and require licensing and accreditation of facilities and professionals.

54. Where cross-border movement of organs, tissues or cells occurs, it should be governed by state monitored policy frameworks that assure mutual ethical compliance and regulatory oversight that ensures quality, safety, traceability, while avoiding long-term overdependence on external supply.

c. Oversight

55. Governance arrangements should designate a competent national authority responsible for coordinating donation, processing, allocation, transplantation and outcome monitoring.

56. Regulatory systems underpinned by ethical principles and optimal clinical practices should ensure compliance with quality, safety and efficacy standards that adopt proportionate risk-mitigating principles. These should, include traceability from donor to recipient, biovigilance and safeguards against corruption and illicit practices, supported by mechanisms for inspection audit and enforcement.

57. National systems should support standardized data collection and analysis to capture donation and transplantation activity, systematically monitor outcomes and enable the balance between need and supply, including through national registries and reporting of serious adverse events and reactions.

58. National best clinical practice, and product quality, safety and efficacy adopted standards, should be aligned, where appropriate, with regional or international frameworks to support technical cooperation and responsible cross-border collaboration.

d. Financing policies

59. Dedicated financial resources should be allocated to support the development and sustainability of national transplantation systems, including quality assurance and system modernization, improvement and updates.

60. Sustainable financing mechanisms should support the full donation-to-transplantation continuum and be integrated within national health benefit packages consistent with universal health coverage principles, in a manner that supports equitable and sustainable access.

61. Financing policies should consider costs of donation (assessment, maintenance and procurement), allocation and relevant logistics (preservation and transport), processing and storage (where applicable), transplant procedure and hospitalization (including the pre-transplant related costs during the waitlisting period), essential medications (including immunosuppression) and long-term monitoring (for both recipients and donors).

62. Financing arrangements should ensure that living organ, tissue and cell donors and families of deceased donors do not incur financial disadvantage because of donation, including reimbursement of legitimate expenses and mechanisms to prevent financial hardship due to loss of work (including recovery period), but not in a form of compensation or incentives for donation.

63. Where private sector participation contributes to the financing or delivery of transplantation services, it should operate within transparent governance frameworks that prevent overt commercialization of human

organs, tissues or cells and uphold equity of access. Recognising that donated human substances are public goods, these should not be an instrument of profiteering.

Strategic Direction 2: Access to transplantation

64. Strategic direction 2 aims to strengthen the establishment of transplantation programmes and the capacity to provide related services at national level.

a. Organisation and Infrastructure for transplantation

65. The delivery of transplantation services must run across the continuum of care and should be integrated within broader hospital and referral systems.

66. Infrastructure development should align with national needs for transplantation and in accordance with existing capacities. This includes clinical facilities suitable for transplantation procedures and the managing of perioperative, intensive and long-term care, as well as laboratory and other satellite services.

67. Transplantation and related services may be implemented progressively. Regional collaboration and referral networks may support countries with limited capacity while national programmes are strengthened.

b. Professional capacity in transplantation

68. Trained and qualified professionals (physicians, surgeons, nurses, lab technicians) in transplantation and other relevant specialities must be enrolled and retained in sufficient numbers to support all modalities and aspects of treatment, including pre-transplant coordination and management as wells as post-transplant follow-up. Competency should be achieved and maintained through structured education, certification and continuing professional development. Workforce sustainability should be supported through clear career pathways, appropriate remuneration and professional recognition.

Strategic Direction 3: National donation programmes

69. Strategic direction 3 aims to support the establishment and strengthening of national donation programmes, encompassing both living and deceased donation, in order to ensure availability of organs, tissues and cells, and therefore equitable and timely access to transplantation. This includes a focus on the development of specialised facilities, enhancement of technical capacity and professional expertise, and consideration of the social and ethical dimensions of donation.

a. Organisation and Infrastructure for donation

70. Opportunities for identifying potential living and deceased donors should be systematically recognized across relevant health care settings, including hospitals, outpatient services and, where appropriate, community-based care.

71. Effective systems should use a multi-layered approach combining proactive hospital and community-based donor detection, mandatory referral requirements, external oversight (e.g. national coordination bodies or

organ procurement organizations), and routine audit mechanisms to identify missed donation opportunities. Integrated models are essential to maximize donor identification and minimize missed opportunities, particularly when scaling transplant capacity in both high-income and low-and middle-income settings.

72. At hospital level, minimum operational requirements should include: (1) clearly defined clinical triggers for donor identification in intensive care and emergency settings, (2) the designation of trained donor coordinators in hospitals managing potential donors (3) implementation of routine donor identification audits and feedback mechanisms.

73. Tissue donation programmes should also be strengthened by enabling donation from a wider range of hospital deaths, including outside intensive care settings, where appropriate.

74. Infrastructure requirements should align with the scope of national donation programmes and may be developed progressively. Coordinated systems must be enabled to support potential donor identification, laboratory assessment and management of potential deceased and living donors, including adequate critical care capacity (e.g. ICU availability) where applicable.

75. National systems should enable both pathways of deceased donation, including donation after brain death (DBD) and donation after circulatory death (DCD), supported by clear clinical, ethical and legal frameworks, and aligned end-of-life care practices.

76. For living donation, systems should ensure robust and independent evaluation of donor suitability, including: standardized medical and psychosocial assessments where appropriate; independent ethical review or donor advocacy mechanisms; safeguards to confirm the voluntary and non-coerced nature of donation; and long-term follow-up of living donors, where appropriate, through dedicated registries or monitoring systems.

77. There must be safe conditions for the procurement of organ, tissues and cells in suitable clinical or mortuary settings as well as appropriate systems for preservation and transport of donated materials.

78. Where appropriate, synergies across systems established for diverse medical products of human origin (e.g. organs and tissues or cells and blood) may be leveraged, including common pathways for donor detection and screening, as well as shared approaches to traceability and biovigilance. These synergies can improve cost-effectiveness and strengthen quality and safety in donation and transplantation.

79. Where deceased donation is established, a maximum number of organs and tissues per donor must be procured and utilized in order to avoid wastage.

80. Systems for paired kidney exchange need to be incorporated into national allocation schemes as a measure of increasing the donor pool, where incompatibilities exist.

b. Professional capacity in donation

81. Key donation professionals should be available through dedicated or designated roles, with training appropriate to their responsibilities in donor identification and assessment, referral, death-determination-related processes and consent processes.

82. Training programmes should include communication skills for approaching potential donors, families, ethical aspects of donation, and clinical donor management.

83. Competent professionals should deliver appropriate psychosocial support to living donors where appropriate, and families of deceased donors before and after donation.

84. Workforce sustainability should be supported through structured training pathways, recognition of donation specialties, and integration into national health workforce planning.

c. Public awareness

85. Public awareness on the benefits of transplantation and processes of living and deceased donation should be promoted through structured and sustained national communication strategies, adapted to cultural and social contexts.

86. Practical approaches may include: engagement with media organizations, including training of journalists to ensure accurate and ethical reporting on donation and transplantation; integration of donation topics into school curricula and health education programmes; inclusion of donation and transplantation topics in training of healthcare professionals.

87. Engagement of deceased donor families, living donors, community leaders and civil society actors may support trust, address misconceptions and overcome sociocultural or religious barriers.

88. Mechanisms should be available to allow individuals to record their donation preferences. Donor registries, where implemented, may serve both as operational tools to document legally recognized consent or refusal and public engagement tools to increase awareness and normalize donation.

89. Family communication should be encouraged to support respect for individual decisions.

Strategic Direction 4: Cell and Tissue processing

90. Strategic objective 4 aims to strengthen national and regional capacity for the processing, storage and distribution of tissues and cells, in support of safe, ethical and equitable access to transplantation. Approaches should be adapted to different levels of health system maturity, with an emphasis on sustainability, quality, self-sufficiency where possible, and progressive development.

a. Organisation and Infrastructure

91. Tissue banking facilities and relevant cell processing services should be established in accordance with the identified demand, and operate within nationally regulated systems.

92. Given variations in resources and capacity, not all Member States may require or be able to sustain full national processing facilities. In such cases, regional or multinational models, including shared facilities and service agreements, may provide efficient and equitable access while maintaining quality and safety standards.

93. Efficiencies can be derived from multi-tissue and cell processing within single facilities as well as from optimizing existing infrastructure and integrating services across different medical products of human origin. Donated tissues and cells should be processed, preserved, stored and distributed in authorized facilities operating under nationally agreed standards of safety and quality, supported by robust quality assurance systems.

94. In the case of hematopoietic cells, as programs are strengthened through the development of autologous and/or related allogeneic transplantation, access to unrelated stem cell donor registries and, where appropriate, cord blood banks should be considered. These systems should ensure secure data management, donor follow-up and international interoperability, including connection with global networks (e.g. World Marrow Donor Association), to facilitate cross-border donor matching.

b. Professional capacity

95. Processing, storage and distribution activities should be performed by a competent and specialized technical workforce with training aligned to defined standards of practice. Competency should be achieved and maintained through structured training programmes, accreditation where applicable and continuing professional development including opportunities for international knowledge exchange. Workforce development strategies should support retention and ensure alignment with evolving technical and regulatory requirements.

c. Financial sustainability

96. Operational models for processing facilities should be sustainable and aligned with identified current and projected demand, taking into account infrastructure, workforce, quality systems and long-term maintenance. Planning should ensure that financing mechanisms support equitable access and do not create financial barriers for patients or lead to inappropriate incentives in the system.

97. Involvement of the private sector may contribute to service delivery and innovation, but must operate under strict governance and regulatory oversight, ensuring full compliance with adopted ethical principles including caveats to commercialization of unprocessed donated tissues or cells; transparency in cost structures that avoid overt profit-driven sourcing, manufacturing choices or selective market distribution of human material.

Strategic Direction 5: International access to transplantation

98. Aims to optimize access to transplantation services in settings of limited availability or in public health emergencies. Countries should strengthen national capacity and progressively attain self-sufficiency, however, where domestic provision cannot fully meet population needs, consideration should be given to establishing bilateral or regional cooperations.

99. Regional approaches may enable concentration of highly specialized transplant services (including paediatric transplantation) in centres with sufficient expertise and volume, while ensuring equitable access across participating countries.

100. The cross-border movement (travel) of individuals seeking transplantation should take place in the context of bilateral national agreements and policies that include the designation of authorized transplant centres, the provision of transplant care to non-resident patients, and the coverage of costs for avoiding out-of-pocket expenditure for the patients. Travel for transplant must be recognised as different from routine medical tourism and appropriately monitored and governed to prevent trafficking, commercialization and other illicit practices, supported by international cooperation for information exchange and coordinated action.

101. Cooperation agreements should support the sharing of technical expertise, capacity building, training and knowledge exchange, and may facilitate equitable access to donated organs, tissues and cells.

102. Surplus organs (not matched due to unavailability of a transplant programme or a suitable recipient) or surplus tissues and cells should be shared with other neighboring countries through established regional platforms, respecting mutual ethical principles and the impact on existing programs.

103. Clear policies should govern the cross-border exchange of products, ensuring that such arrangements do not undermine domestic system development or equitable access, and do not negatively affect the health system capacity of exporting countries, while adhering to similar safety and quality standards.

104. Preparedness planning should address potential disruptions to supply chains or sudden increases in demand, including through emergency reserves or regulated cross-border cooperation.

Strategic Direction 6: Investing in technological advancement, research and innovation

105. Aims to promote growth and acknowledge responsible innovation in transplantation systems, focusing on areas of identified need and demonstrated value within national health system contexts. A coordinated global strategy to provide considerate and responsible support towards the development and incorporation of new technologies in transplantation should combine guidance on changes required in governance and regulatory oversight, including sources of sustained investment, and international collaboration. International data sharing, collaborative research and workforce capacity-building may support evidence generation and continuous system improvement.

106. The progressive trend in the development of alternative solutions to the increasing demand for organs, tissues and cell transplants must be considered in the mapping of future development and capabilities through adaptative governance and regulatory pathways (e.g., for xenotransplantation, ATMP-based bioengineered products, and biohybrid devices), alongside robust approval frameworks and long-term safety surveillance systems to manage risks and monitor outcomes. such as immune rejection and zoonotic transmission.

107. Significant public and private funding will be required for translational research, biomanufacturing infrastructure, and enabling technologies, as well as the creation of global registries and biosecurity standards. Such investment decisions should prioritize interventions with demonstrated quality, safety, effectiveness and deliver meaningful population-level impact. Adoption of novel technologies should be guided by careful evaluation to avoid duplication of effort or unsustainable investments.

108. Policies must ensure equitable access, workforce development, and integration of these innovations into healthcare systems, enabling a scalable reliance on technology driven therapies.

Roles and responsibilities

a. Member States

109. Member States retain primary responsibility for implementing this strategy. This includes developing national action plans, enacting and enforcing appropriate legislation and regulatory frameworks, allocating sustainable financing, strengthening infrastructure and workforce capacity, and ensuring equitable access in accordance with ethical principles and WHO guidance.

110. Member States should engage relevant national stakeholders – including health authorities, regulatory bodies, professional and scientific organizations, educational institutions, civil society groups, donor and recipient associations, and community and religious leaders – to ensure coordinated and contextually appropriate implementation.

b. World Health Organization

111. The WHO Secretariat will consider the development of implementation guidance and tools that draw on existing evidence and best practice, while allowing for contextual adaptation to national and regional realities. Furthermore, a monitoring framework may be developed for measuring progress and supporting Member States in reaching their targets.

112. The WHO Secretariat will continue to collaborate with international and regional organizations, professional associations, academic institutions, non-state actors in official relations with WHO, and other relevant partners to facilitate knowledge exchange, capacity-building and appropriate bilateral or multilateral cooperation.

c. Partners, civil society and private sector

113. Transplant professionals, national donation and transplantation authorities, health and care workers, educational institutions, media and communication bodies, private sector partners, philanthropic actors and community representatives each have complementary roles in advancing the objectives of this strategy. Their contributions may include workforce development, research and innovation, public awareness, ethical oversight, advocacy and accountability, and support for equitable access.

114. Health professionals and professional bodies – including clinicians, donation specialists, ethicists and allied health professionals – are central to ensuring ethical practice, high-quality care and evidence-based allocation and utilization of organs, tissues and cells. Professional and scientific organizations contribute to standard-setting, workforce development and knowledge exchange.

115. Educational and research institutions support workforce development through curricula, professional training and continuing education. They also play a critical role in advancing research, innovation and responsible introduction of emerging biotechnologies relevant to donation and transplantation.

116. Communities and civil society, including donor and recipient advocacy groups, community leaders, and religious and theological authorities where culturally relevant, contribute to public engagement, culturally appropriate awareness initiatives and promotion of ethical donation practices. Community participation is essential to building trust and supporting equitable access.

117. International organizations, regional bodies and development partners, can support Member States through technical cooperation, policy dialogue, knowledge sharing and facilitation of regional and cross-border collaboration where appropriate. The private and philanthropic sectors may contribute to research, innovation and system strengthening within appropriate governance frameworks.

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