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Global strategy on donation and transplantation

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Global strategy for donation and transplantation

Version 1 (26 June 2026) — regional consultation revisions

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, with the potential to reduce long-term treatment costs.**

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). **Products derived from donated human cells and tissues, including** Advanced Therapy Medicinal Products (ATMPs), **may be subject to different regulatory pathways in different jurisdictions. Regardless of their regulatory classification, the principles applicable to their human origin should be preserved, including donor protection, ethical donation, quality and safety, sufficiency, equitable access and sustainability, in line with WHA77.4. Relevant regulatory guidance is provided** by the WHO Expert Committee on Biological Standardization (ECBS). **Member States should consider exemptions from patent protection for life-saving advanced therapy products to improve affordability and equitable access.**

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.

[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

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 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]

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[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)

[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-

[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

20th century to as low as 10%–20% 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 life lost. In the United States and Europe, corneal

[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

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 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

[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.

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, **transplant pharmacists, transplant pathologists, transplant infectious diseases specialists, interventional radiologists, dietitians,** and transplant **social workers or psychologists,** 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 **ethical organ, tissue and cell** donation and transplantation within their health systems. Cell, tissue and organ transplantation will be integrated into national health policies **public health systems-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, **legislative, policy** and regulatory frameworks governing donation and **transplantation, including protection of donors;** and (3) enhanced quality, **safety, efficiency** 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 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. **National policies should provide priority in deceased donor allocation for living kidney or liver donors who subsequently develop end-stage disease of the donated organ, and for first-degree relatives of deceased donors, within transparent allocation frameworks that safeguard clinical urgency and equity.**

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. **Legal frameworks should clearly define the responsibilities of clinicians and other health professionals and provide safeguards for those acting in accordance with applicable law and ethical standards.**

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 **one or more** competent national **authorities with clearly defined responsibilities** for coordinating donation, processing, allocation, transplantation and outcome monitoring. **Implementation arrangements should reflect the constitutional, legislative and administrative structures of Member States, including federal and decentralized systems, with national coordination and clearly defined subnational roles.**

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 **occurrences, including adverse** events and reactions. **National data collection should be complemented by regular and timely international reporting and data sharing through established WHO mechanisms, including the Global Observatory on Donation and Transplantation (GODT), using harmonized definitions.**

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 **(including systematic identification and referral of possible deceased donors, assessment,** maintenance and procurement), allocation and relevant logistics (preservation and transport), processing and storage **of donated tissues and cells** (where applicable), transplant procedure and hospitalization (including the pre-transplant related costs during the waitlisting period), essential **services (including safe blood transfusion and human leukocyte antigen (HLA) laboratory services), 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), **through transparent reimbursement mechanisms** in **accordance with governance frameworks, clearly distinguishing reimbursement from payment for donated organs, tissues or cells or financial inducement to donate. Financing policies should also support transplantation, essential medicines and long-term follow-up for economically vulnerable patients, with private providers sharing responsibility for** a **defined proportion** of

such patients in both living and deceased donor transplantation, in accordance with national policies.

63. Where private sector participation contributes to the financing or delivery of transplantation services, it should operate within transparent governance frameworks that prevent commercialization of human organs, tissues or cells and uphold equity of access. **Donated human organs, tissues and cells must not become objects of financial gain, and donors and recipients must be protected from exploitation. Transparent charges for legitimate services should be distinguished from payment for** donated human **materials. Financing arrangements should support affordable access for economically vulnerable patients, including essential medicines and long-term follow-up, in both** public **and private settings. Measures may include price caps and requirements for private providers to support access for economically vulnerable patients, in accordance with national policies.**

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. **Implementation should address four complementary pillars: (i) organisation and infrastructure; (ii) integrated service delivery; (iii) national capacity and regional networks; and (iv) professional capacity.**

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. **Planning should address the geographical distribution of transplant centres within the country to improve equitable access while maintaining the required expertise and capacity.**

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 **(including donor coordinators, physicians,** surgeons, nurses, **technicians, laboratory specialists, transplant pharmacists, transplant pathologists, transplant infectious diseases specialists, interventional radiologists, dietitians, and transplant social workers or psychologists)** 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 **workup,** coordination and management as **well** 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. **Workforce planning should address health workforce migration and retention, particularly in low- and middle-income settings, with reference to the WHO Global Code of Practice on the International Recruitment of Health Personnel (WHA63.16).**

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 deceased donors should be systematically recognized across relevant health care settings, including hospitals, outpatient services and, where appropriate, community-based care. **Potential living organ, tissue and cell donation should be recognized and regulated through appropriate assessment and counselling pathways, including related and, where permitted by national law, non-directed donation.**

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, **especially** outside intensive care **settings and,** where **feasible, following deaths at home or in care homes.**

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, and systems for organ and tissue retrieval, preservation, packaging and efficient transportation.**

75. **Deceased donation.** National systems should enable both pathways of deceased donation, including donation after **neurologic determination of** death **(DNDD)** and donation after circulatory **determination of** death **(DCDD),** supported by clear clinical, ethical and legal frameworks, and aligned end-of-life care practices. **Where donation after circulatory determination of death is not established, countries should progressively develop the necessary legal, clinical and organisational arrangements, taking account of national contexts.**

76. **Living donation. Systems** should ensure robust and independent evaluation of donor suitability, including: standardized medical and psychosocial **assessments; informed consent;** independent ethical review or donor advocacy mechanisms; safeguards to confirm **donor understanding and** the voluntary and non-coerced nature of donation; and long-term follow-up of living donors, where appropriate, through dedicated registries or monitoring systems. **Assessment and counselling should be gender-sensitive and address gender disparities and pressures in living donation, where these occur.**

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 **suitable** organs and tissues per donor must be procured and utilized in order to avoid wastage.

80. **National programmes** for paired kidney **donation should be established or strengthened for medically suitable living donor–recipient pairs with incompatibilities, supported by clear policies and standard operating procedures for implementation and expansion, including in low- and middle-income countries. Where clinically appropriate and supported by adequate expertise and resources, other strategies, including direct transplantation across immunological incompatibilities, should also be considered. National programmes should adopt a complementary, patient-centred approach that considers available options according to clinical circumstances, expected outcomes, feasibility, affordability and equity of access. Regulated international paired kidney donation programmes may also be developed under the oversight of participating national authorities and agreed standard operating procedures, excluding the global kidney** exchange **model.**

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, assessment** and **management,** referral, death-determination-related processes and consent processes.

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

83. Competent professionals should deliver appropriate psychosocial support to living donors and families of deceased donors **before, during** and after donation. **Non-financial support and recognition for donor families should be promoted without coercion or financial inducement.**

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. **Active donor awareness campaigns should address both living and deceased donation, dispel myths and misconceptions, and address cultural and religious barriers.**

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. **Regulatory oversight should cover cell procurement, processing, storage and banking, distribution and transplantation. Clinical indications for stem-cell and other cell therapies should be based on credible evidence, with safeguards against unindicated use and exploitation of patients.**

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 incentives **for payment for donated human materials, coercion, exploitation or inequitable access, with prohibited incentives clearly defined** in **national frameworks. Domestic financing and, where appropriate, public–private partnership arrangements should reduce financial burdens on patients and support affordability.**

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 **prohibition of** commercialization of donated tissues or **cells. Cost structures and charges for legitimate processing, storage and distribution services should be transparent and subject to oversight, preventing financial inducement** in sourcing, **exploitation and inequitable access.**

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 **accordance with applicable** national **legal** and **ethical frameworks and policies, including relevant visa requirements, and through regulated bilateral, regional or institutional arrangements under national oversight. Such arrangements should** include the designation of authorized transplant centres, the provision of transplant care to non-resident patients, **clear financing** and **cost-coverage arrangements to protect patients from financial hardship, and continuity of care, including essential medicines and follow-up in** the **home country. Required donor and recipient documentation and responsibilities** for **referral, information exchange and follow-up should be clearly defined. Living donation should be verified as voluntary, informed and non-commercial.** 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. **Regulated exchanges of organs for which no suitable domestic recipient is identified, and exchanges of professionals, should be facilitated through regional networks. Digital tools and, where appropriate, artificial intelligence may support matching, professional collaboration and continuity of care, including access to basic consultations and timely referral. National authorities retain operational oversight of transplantation arrangements.**

102. **Organs for which no suitable domestic recipient is identified within clinically appropriate time limits, including where the required** transplant programme **is unavailable,** or tissues and cells **available beyond domestic requirements** 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 **health technology assessment (HTA) and** careful evaluation to avoid duplication of effort or unsustainable investments. **Regional and international cooperation, including coordinated funding, shared research infrastructure and knowledge and resource sharing, should support efficient investment and avoid unnecessary duplication.**

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, workforce capacity** and **information systems,** and ensuring equitable access in accordance with ethical principles and WHO guidance. **Regional cooperation and networks should support knowledge exchange, research and resource sharing.**

110. Member States should engage relevant national stakeholders – including health authorities, regulatory bodies, **healthcare providers and hospitals,** professional and scientific organizations, educational institutions, civil society groups, donor and recipient associations, and community and religious leaders – to ensure coordinated and contextually appropriate **policy design and** 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 **affordable and** equitable **access across diverse population groups. Private-sector, philanthropic, professional and academic participants should disclose and manage conflicts of interest.**

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. **Health professionals and professional bodies should disclose and manage conflicts of interest and contribute to public outreach on ethical donation and transplantation.**

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. **Research should uphold ethical standards, with disclosure and management of conflicts of interest, and support affordable and equitable access to its benefits.**

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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