# Development of a Global Strategy for Donation & Transplantation of human cells, tissues and organs

## Background

Transplantation of human cells, tissues, and organs is a cornerstone of modern medicine, offering life-saving benefits and wellbeing for countless individuals throughout the world. Various reports highlight that transplantation may have a potential impact on reducing premature mortality associated with noncommunicable and other diseases, it improves the patient's quality of life and helps communities to diminish the high costs of alternative treatment modalities. There is, however, a huge disparity in the availability and access to transplantation services across WHO regions and among Member States, with the highest rates in the Americas and Europe, and the lowest in Africa and Southeast Asia. Insufficient access to transplantation services is one of the root causes of trafficking in persons for the purpose of organ removal and trafficking in human organs.

In response to these challenges, the 77th World Health Assembly in 2024, adopted resolution 77.4 on increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs. WHO is requested to develop, in consultation with Member States, nongovernmental organizations and other relevant stakeholders, a global strategy that supports Member States to integrate donation and transplantation into health care systems and promotes the implementation of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Furthermore, upon the request of the resolution, WHO will establish an Expert Advisory Committee that will assist in developing the proposed global strategy and support its implementation. The global strategy should be submitted for consideration by the 79th World Health Assembly (May 2026), through the Executive Board at its 158th session (February 2026).

## Process

A strategy is a plan that guides the development of a programme or intervention via a process that ensures the maintenance and continued viability of continuity plans. Typically, it outlines a rational and systematic process with specific steps such as vision and mission, goal setting and objectives, evaluation and action planning to achieve and sets priorities for the implementation process. The development of WHO strategies involves an extensive consultative process, including global and regional consultations with Member States, and a broad range of partners, in order to discuss objectives and build consensus on the vision and strategic directions.

An outline of the global strategy for donation and transplantation has been developed by WHO, following consultation with key stakeholders. The newly established Expert Advisory Committee on Donation and Transplantation will process the information and views collected through this preliminary phase, in order to develop a zero-draft version of the strategy. A series of regional consultations will be held with Member States, professional societies, patient representatives and development partners, in order to validate the strategic direction of the draft global strategy, identify region-specific priorities and implementation pathways, and assess feasibility in relation to national capacities. Following consolidation of regional feedback, a revised draft will be submitted for Member State consultation through established WHO governance mechanisms. This step will allow countries to propose refinements, highlight expected implementation challenges and clarify alignment with national health strategies, including within the context of universal health coverage.

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# Annotated Outline (version October 2024)

## 1. Introduction

**a) Why we need a global strategy on donation and transplantation**

*Explain the global burden of diseases that are amenable to cell, tissue or organ transplantation. Furthermore, provide information on the current development of transplantation programmes (availability and access).*

**b) Building on solid foundations**

*Brief reference to the previous WHA resolutions, including the guiding principles (scope and impact).*

**c) How does this strategy relate to other WHO strategies**

*References to strategies on NCDs, Universal Health Coverage, etc.*

**d) How the global strategy was developed**

*Brief reference to the process that includes the role of the Expert Committee, consultations with NSAs in official relations and other stakeholders, Regional consultations with Member States.*

## 2. High returns from investing in Transplantation

**a) The business case**

*What is the value of transplantation for the individual, the society and the health system (i.e. cost-effectiveness, quality of life, reintegration, etc.)*

**b) The impact on SDGs**

*Brief reference to SDG Targets:*
*3.4 - Reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.*
*3.8 - Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.*

## 3. A global strategy to lead us to 2035

**a) Vision:**

By 2035, every Member State will be able to address its patients' needs in life-saving or life-enhancing transplantation.

*Cell, tissue and organ transplantation should be integrated in health care policies that address the need for treatment from end stage diseases /debilitating conditions. All patients that qualify for a transplant should be identified and solutions should be made available at home country or through cross border care where possible.*

**b) Objectives:**

- Increase Availability

*(Refer to deceased and living donation, capacity of transplant workforce, reduce wastage of organs)*

- Improve Access

*(Establishment of transplant programmes, referral of patients, health coverage, equity in allocation)*

- Enhance Quality and Safety

*(Biovigilance, outcome monitoring, long term survival)*

**c) Target audience:**

*A successful global strategy requires coordinated efforts between governments, international organizations (i.e. the WHO), healthcare providers, and civil society to address challenges comprehensively.*

- Leaders – political and government and health care leaders
- Donation and Transplantation experts/leaders
- All health and care workers
- Educational institutions and professional/scientific organizations, societies, unions
- General population and the community
- Key stakeholders and donors
- Media and communication professionals and bodies

## 4. Strategic objectives and directions

**a) Organization of National Transplant Systems (policy and governance)**

- Political commitment and policies
- Legislation / Regulation
  (*Principles to be upheld, regulations regarding consent, free unpaid donation, trafficking, penalization, etc.)*
- Oversight
  (*Established authority that coordinates and controls the system*)
- Financing
  (*Development and operational costs for hospital centres as well as for the donation*)
- Health Coverage
  (*Who pays for patient treatment, follow-up, immunosuppression*)

**b) Developing Transplantation Programs for Cells, Tissues and Organs**

- Infrastructure (*transplant centres, hospital services*)
- Professional Capacity (*training, knowledge, retaining workforce*)

**c) Establishing Donation Programs for Cells, Tissues and Organs**

- Infrastructure (*establishment of deceased donation for organs and tissues, banks, HPC donor registries, labs, equipment, etc.*)
- Professional Capacity (*donor coordinators, ICU staff, etc.*)
- Public Awareness *(targeted campaigns, media, communication, donor registration)*

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**d) Implementing processing capacity for cells and tissues**

- Infrastructure *(establishment and operation of tissue banks, cell expansion facilities)*
- Professional Capacity *(training, competence, retaining workforce)*

**e) Establishment of International Collaboration**

- National insufficiency
  *(Should a country be unable to provide a specific transplantation service, then there should be international agreements in place to serve the needs of the patient population, especially in urgent cases or pediatric, provided that there is a capacity for follow-up of patients at home country)*
- Emergency situations
  *(There should be preparedness plans in case of natural or manmade disasters that may disrupt the supply chain or increase the need for certain types of transplants. Furthermore, transplantation may be required in disasters with massive casualties such as burns from wildfires or bone marrow toxicity in nuclear accidents)*
- Combating trafficking
  (*International collaboration in detection, investigation, prosecution*)

**f) Investing in growth and innovation**

*Accelerate research and development for alternative sources to human origin products as solutions for meeting the gap.*

- Biotechnology
- Xenotransplantation

## 5. Implementation (roles and responsibilities) and Monitoring

*Brief reference to what each of the main stakeholders (Member States, Non-State Actors, WHO) must commit to in order to move forward and how to measure the progress that has been made.*