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# Introduction to Resolution WHA77.4 and the Plan for developing a Global Strategy on Donation and Transplantation of Human Cells, Tissues and Organs

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# Introduction

Transplantation is an established form of treatment for end-stage debilitating conditions mostly caused by noncommunicable diseases (NCD).

There are inequities in access to transplantation services across Member States

The WHA has issued a series of resolutions since 1987, including the adoption of the WHO guiding principles on human cell, tissue and organ transplantation. [Resolution WHA 63.22 \(2010\)](#) updated these [principles](#) and provided directions to Member States for their implementation.

Following WHO [report A75/41](#) that highlighted a slow progress, Member States agreed on the need for a new action, and therefore, the 77th WHA (2024), adopted [resolution 77.4](#).

The new resolution calls upon Member States to enhance the availability, ethical access, and oversight of transplantation of human cells, tissues, and organs.

Furthermore, it requests the development of a “Global Strategy on the Donation and Transplantation of Human Cells, Tissues and Organs”.

# WHO Framework on Transplantation

## Ethical and Operational framework

- ❖ Respect for the dignity of donors **and** recipients
  - Voluntary Non-Remunerated Donation (VNRD)
  - autonomous, free, informed decisions
  - protection of vulnerable persons
  - privacy
- ❖ Equitable access to organ transplantation: avoiding discrimination
- ❖ Optimizing risk/benefit: safety, surveillance, reporting systems, data collection, registries

## WHA 40.13 (1987)

- **Development of guiding principles for human organ transplants**

## WHA 42.05 (1989)

- **Preventing the purchase and sale of human organs**

## WHA 44.25 (1991)

- **Human organ transplantation (WHO Guiding Principles)**

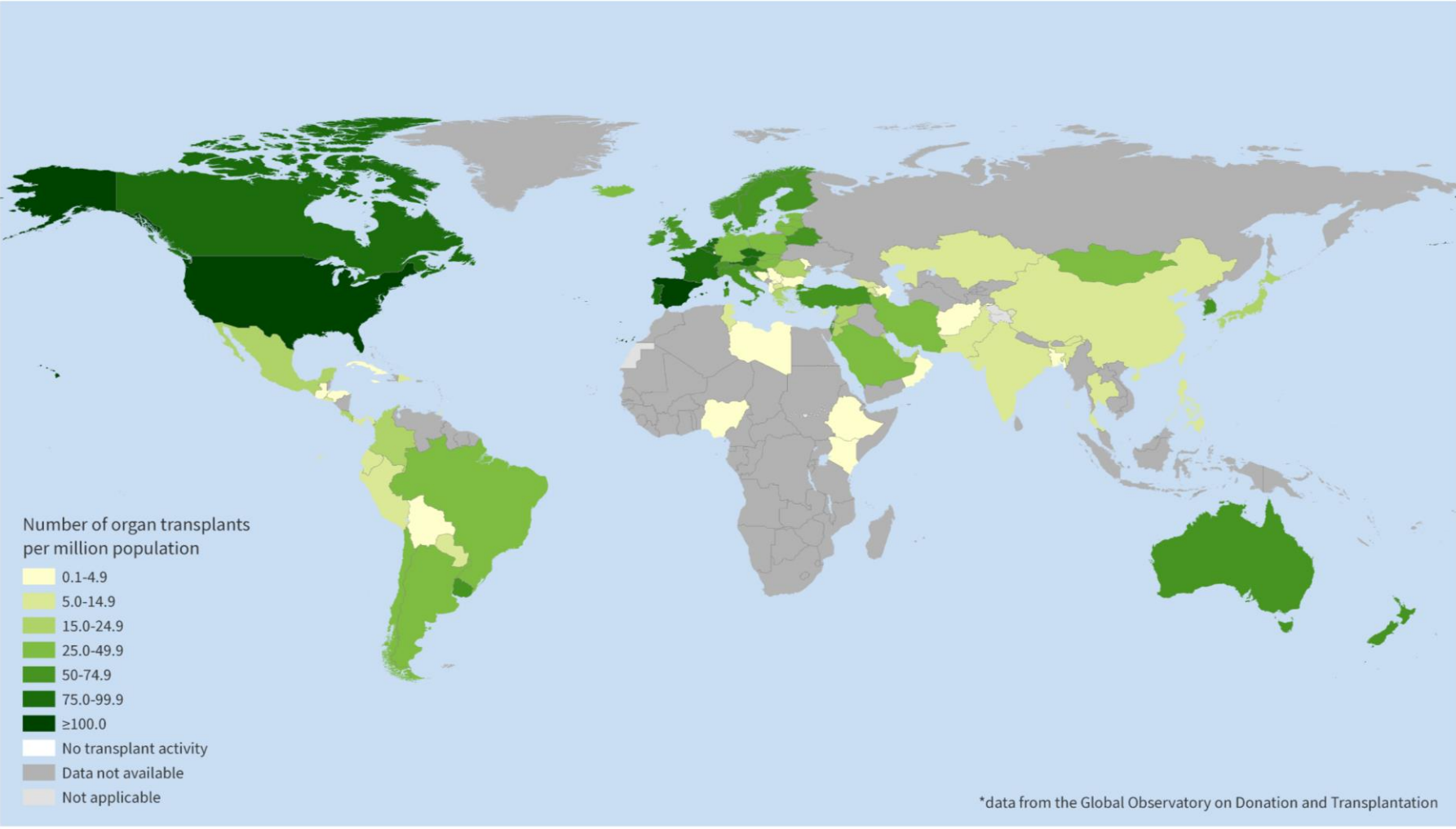
## WHA 57.18 (2004)

- **Human organ and tissue transplantation (Allogeneic & Xenogeneic transplantation)**

## WHA 63.22 (2010)

- **Human organ and tissue transplantation (updated WHO Guiding Principles)**

# Global transplantation activities of solid organs, 2022\*



**organ transplant operations**

**62% in high-income countries**

**28% in middle-income countries**

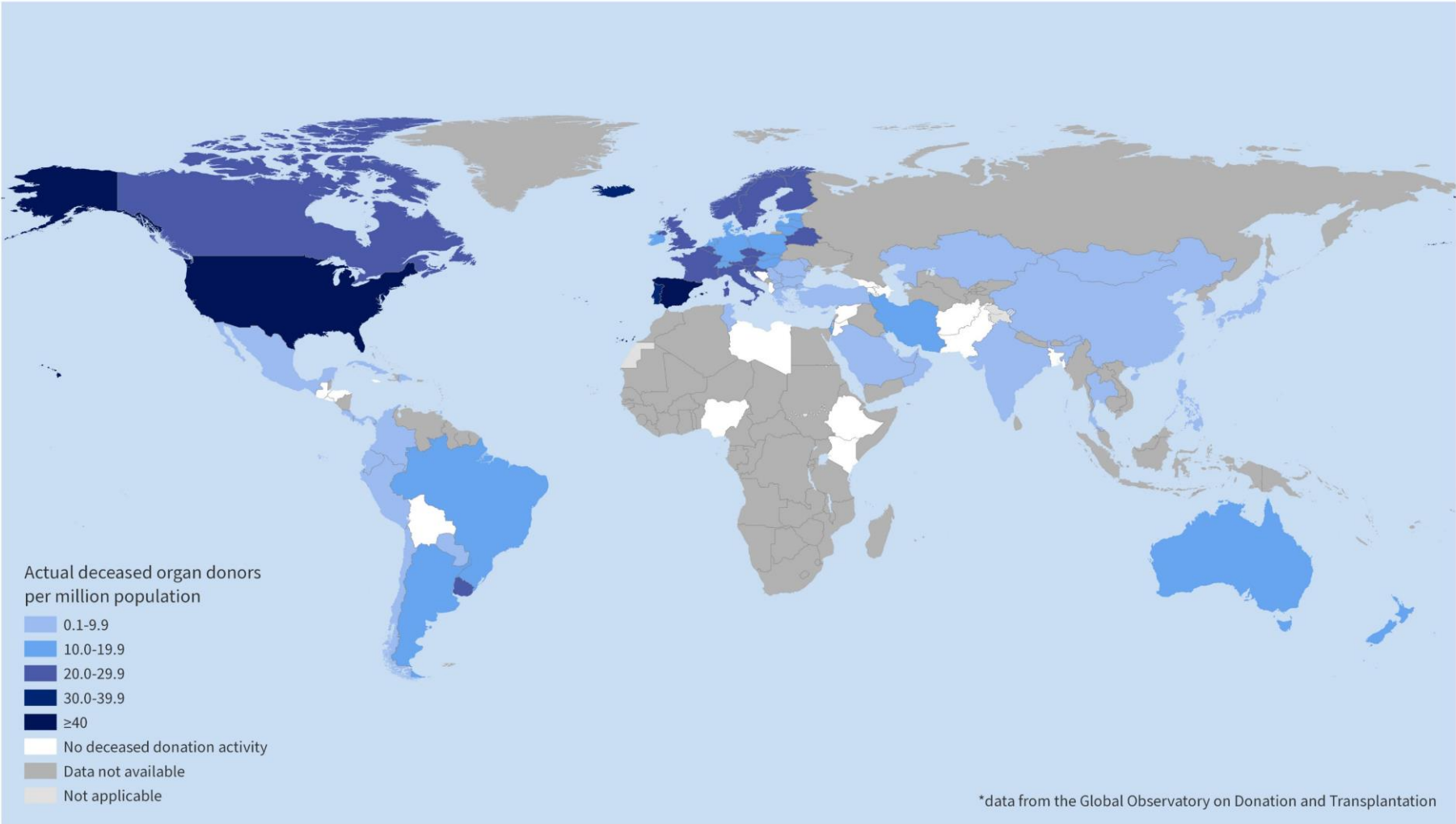
**only 1% in low-income countries**

**(White et al., 2014)**

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Data Source: Global Observatory on Donation and Transplantation  
Map Production: WHO GIS Centre for Health, DNA/DDI  
Map Creation Date: **04 September 2023**

# Actual donors from deceased persons, 2022\*



**Deceased organ donation activity reported only in 74 countries**

**(38% of WHO Member States)**

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# Global activity in organ transplantation

## Estimations 2022

Kidney	Liver	Heart	Lung	Pancreas	S. bowel
102 090	37 436	8 988	6 784	2 026	170

≈ 157 494 solid organ transplants

≈ 9.1% increase vs 2021

≤ 10% of global needs

39 % living kidney transplants

24% living liver transplants

41 792 deceased donors (32 248 DBD and 9 544 DCD donors)\*

# 75th WHA (May 2022)

## Secretariat Report A75/41 on current status of transplantation

Reduced availability (no government support for policies or national strategies).

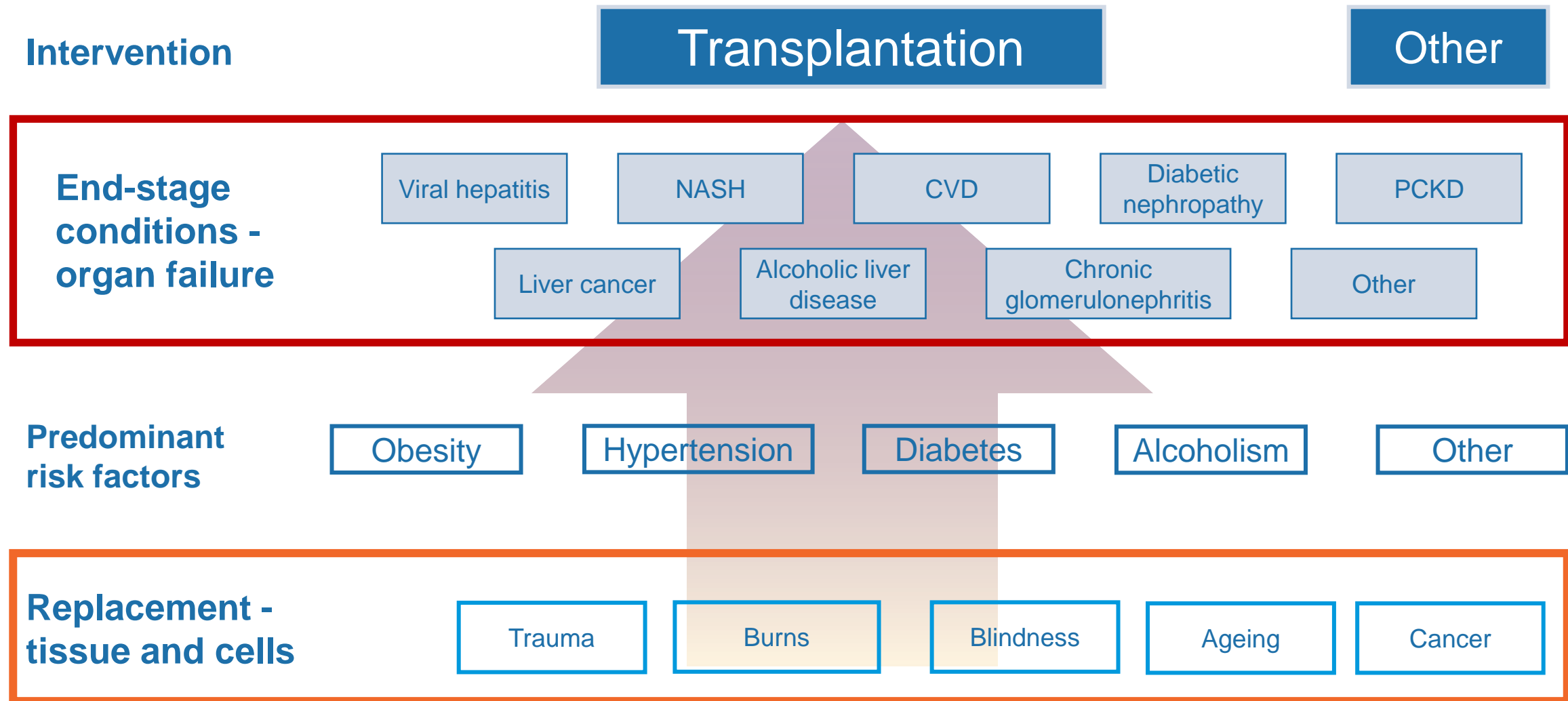
Limited resources (funding, specialised workforce, infrastructure).

Decreased donation systems established only in 40% of MS, differences in rates and capacities.

Dependency only on live donors is not a sustainable option for some types of organs (i.e. heart) or for tissues.

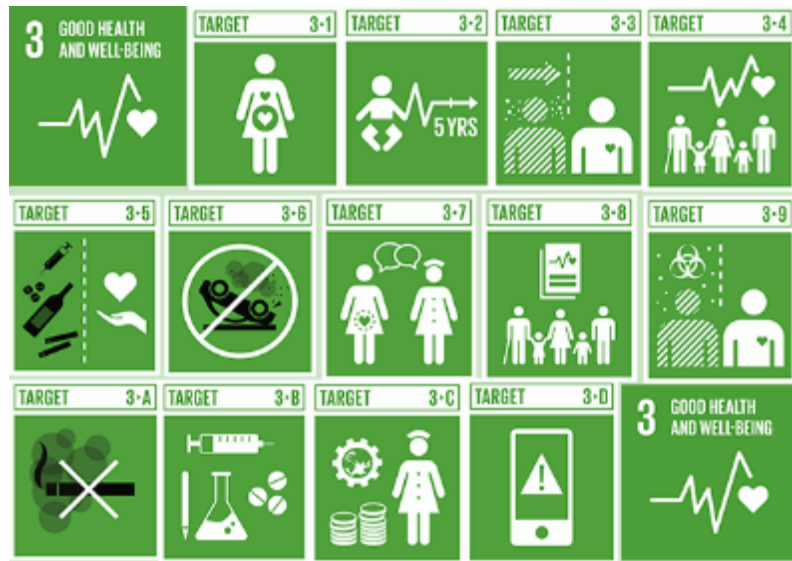
Ethical breaches (organ trafficking, transplant tourism, tissue and cell commercialisation) as a result of no access/availability.

# Increasing Conditions Relevant to Transplantation





# Trends in Premature Mortality: Impact of Transplantation



Target 3.4. ↓ One-third from NCDs  
Target 3.8. Achieve UHC

*Means of implementation:* access to  
medicines, health financing and workforce

# Adoption of a new WHA Resolution 77.4 (2024)

Increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs.

Urges Member States to:

Implement / strengthen preventive strategies to reduce burden of diseases treatable with transplantation

Integrate transplantation into Universal Healthcare policies for non-communicable and other conditions

Protect living donors (consent, medical-psychosocial evaluation, follow-up care)

Increase the availability of cells-tissues-organs by maximizing deceased donation where appropriate

Establish official agreements for exchange of cells-tissue-organs or access to transplant services

Develop, implement and enforce legislative frameworks in line with WHO Guiding Principles

Designate authorities and improve governance of donation/transplantation activities

Authorize and control transplantation centres by data reporting, monitoring and periodic inspections

Ensure safety and efficacy of transplantation by collecting outcome data, biovigilance and surveillance

Include donation/transplantation in National or Regional preparedness plans in the event of crisis

Take measures to prevent/combat trafficking and protect victims

Promote research-innovation for alternative treatments based on cells-tissues-organs

Implement regulatory frameworks for innovative-advanced products based on cells-tissues-organs

### Progress reports: WHA79

- Implementation of resolution WHA77.4 (2024)
- Implementation of resolution WHA63.22 (2010)

### Data collection:

- Analyse and make available global data on legislation, regulations, practices, safety, quality, effectiveness, epidemiology and ethics

### Capacity building & Guidance:

- Strengthen regulatory capacity to effectively oversee donation and transplantation practices
- Monitoring and evaluating transplantation program performance and donor and recipient outcomes

### Global Strategy:

- For consideration by the 79th WHA, through EB158 (2026)
- Explore the feasibility and potential impact of establishing a World Donor Day to enhance public awareness
- Establish an expert committee to assist in developing and implementing the global strategy

# WHO Activities Under the New Resolution

### Technical assistance to MS:

- Developing national legislation/regulations
- Assessing transplantation needs
- Establishing or strengthening national authorities
- Improving capacities to increase the availability of CTO
- Implementing ethical, effective and safe transplant programs

### Reference guidance on death diagnosis

- Death by neurological criteria
- Death by circulatory criteria

### Combat Trafficking

- Improve country, regional and global capacity to respond to identified cases of trafficking in persons for the purpose of organ removal and of trafficking in human organs
- Strengthen Interagency cooperation

### Revise WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

- Novel products and treatments that are developed from human cells, tissues and organs

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# Considerations for the Global Strategy on Transplantation

The Resolution foresees that the Global Strategy is:

- Outcome-driven, equitable, and capacity-building focused
- Leveraging existing resources, where feasible
- Aligned with WHO Guiding Principles on Transplantation
- Establishing an expert committee to assist in developing and implementing the global strategy
- Consultation with Member States and relevant stakeholders during the development

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# Global Strategy Draft Outline

## Vision and Objectives

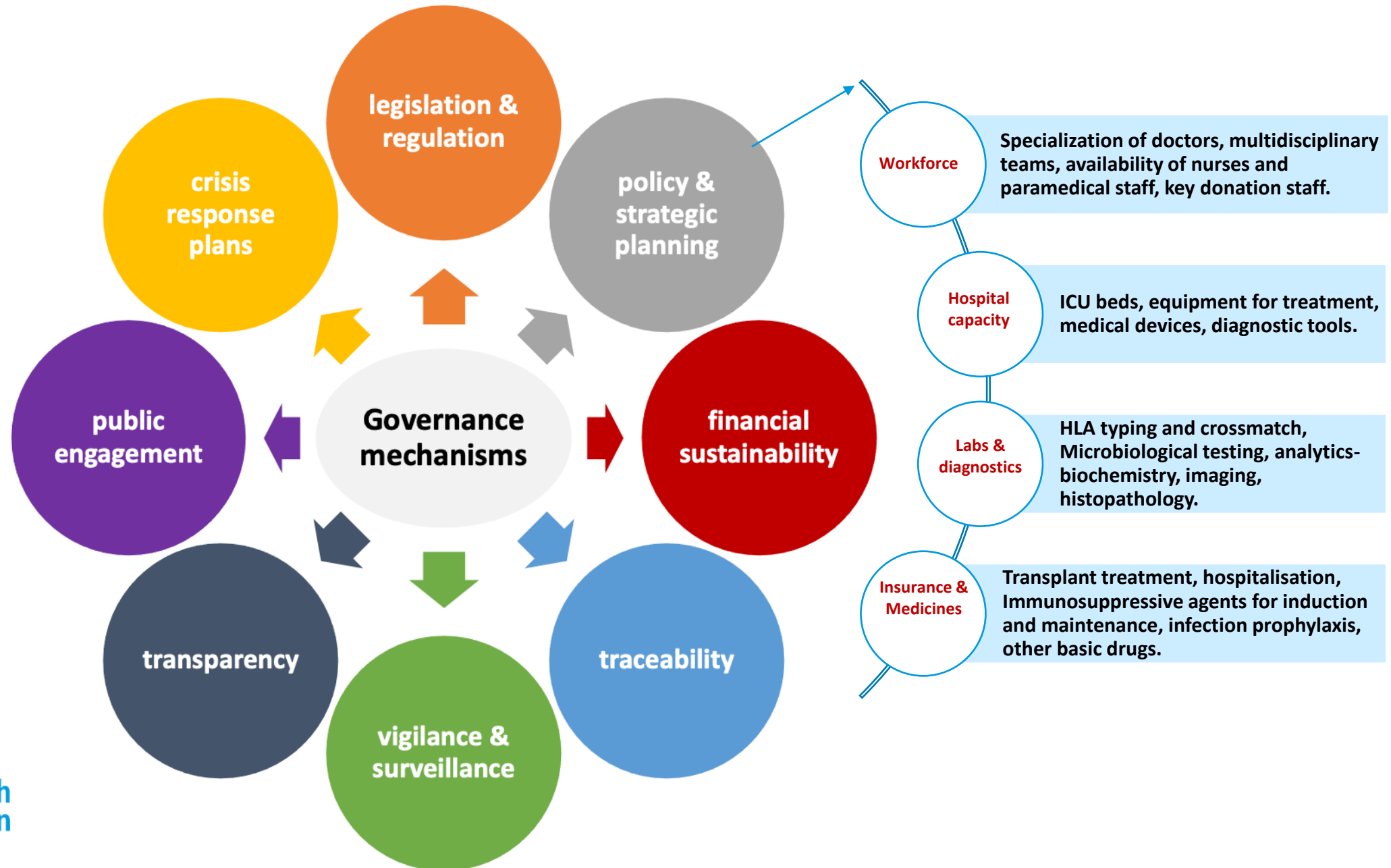
The vision of the Global Strategy is that by 2035, every Member State will be able to address its patients' needs for life-saving transplantation treatments.

The objectives are to increase availability and accessibility, as well as to enhance safety and quality of transplantation of human cells, tissues and organs.

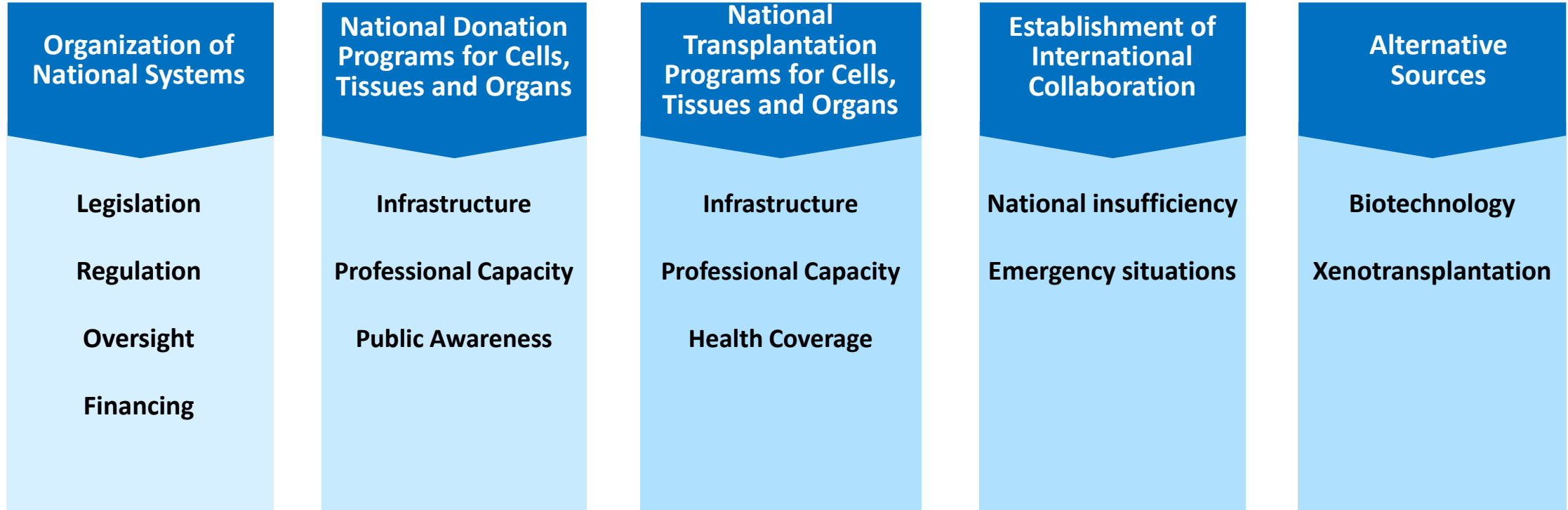
## Key elements of the strategy:

- **Strategic Actions:** Areas of interventions
- **Implementation:** Actors, Partnerships, Funding
- **Evaluation/Progress monitoring:** Measurable indicators / Benchmarking tool

# Key Considerations for the Establishment of Tx Systems



# Areas of Strategic Action (Proposed)



# Global Strategy process/timeline





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# Member State Requests

- All Member States encouraged to provide feedback on the proposed initial outline of the global Strategy (vision, objectives and areas of action).
- All Member States to consider identifying national experts that will assist in defining national priorities and participate in the consultative process.
- All Member States encouraged to join the global and regional consultations.
- All Member States encouraged to engage in relevant discussions during the meetings of the WHO regional committees.
- Member States that are planning new or supporting existing regional or global initiatives on transplantation are invited to collaborate with WHO.

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# Thank you for your attention

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## Contact

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