



**14<sup>th</sup>**  
**International Donor Registry Conference  
& WMDA Meetings**  
25 – 29 June, 2024 – Cape Town, South Africa  
*All patients & donors matter*  
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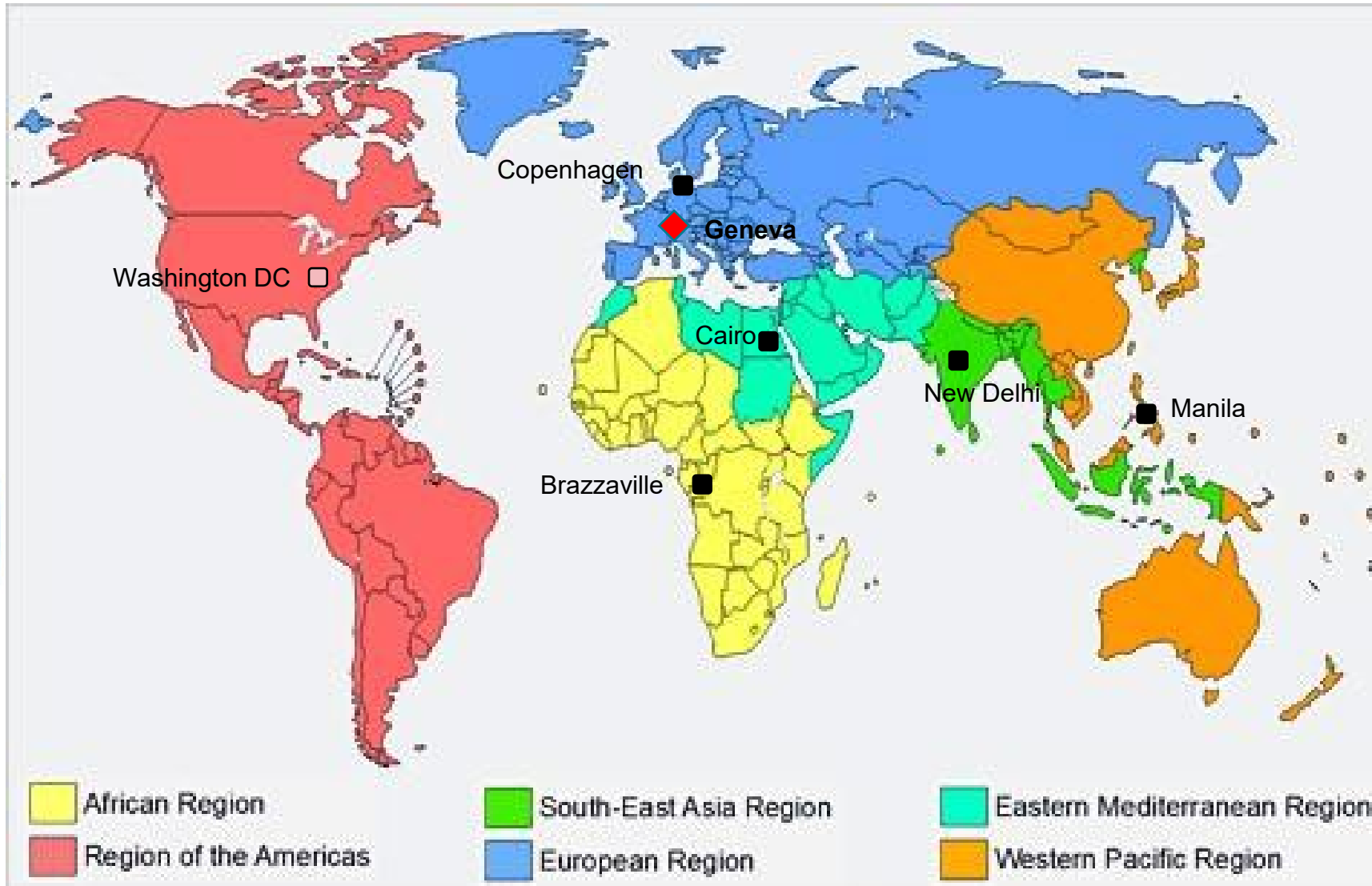


**Efstratios (Stratos)  
Chatzixiros**  
**Head of Transplantation  
Programme**  
**World Health Organization**

**Towards Global Convergence in  
Transplantation: Sufficiency,  
Transparency, and Oversight**



# WHO global presence



**194 Member States  
(WHA)**

**Headquarters  
(Switzerland).**

**6 WHO Regional Offices  
(AFRO, AMRO, EMRO,  
EURO, SEARO & WPRO)**

**WHO field offices in  
150 countries**

# WHO Framework on Transplantation

## 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)**

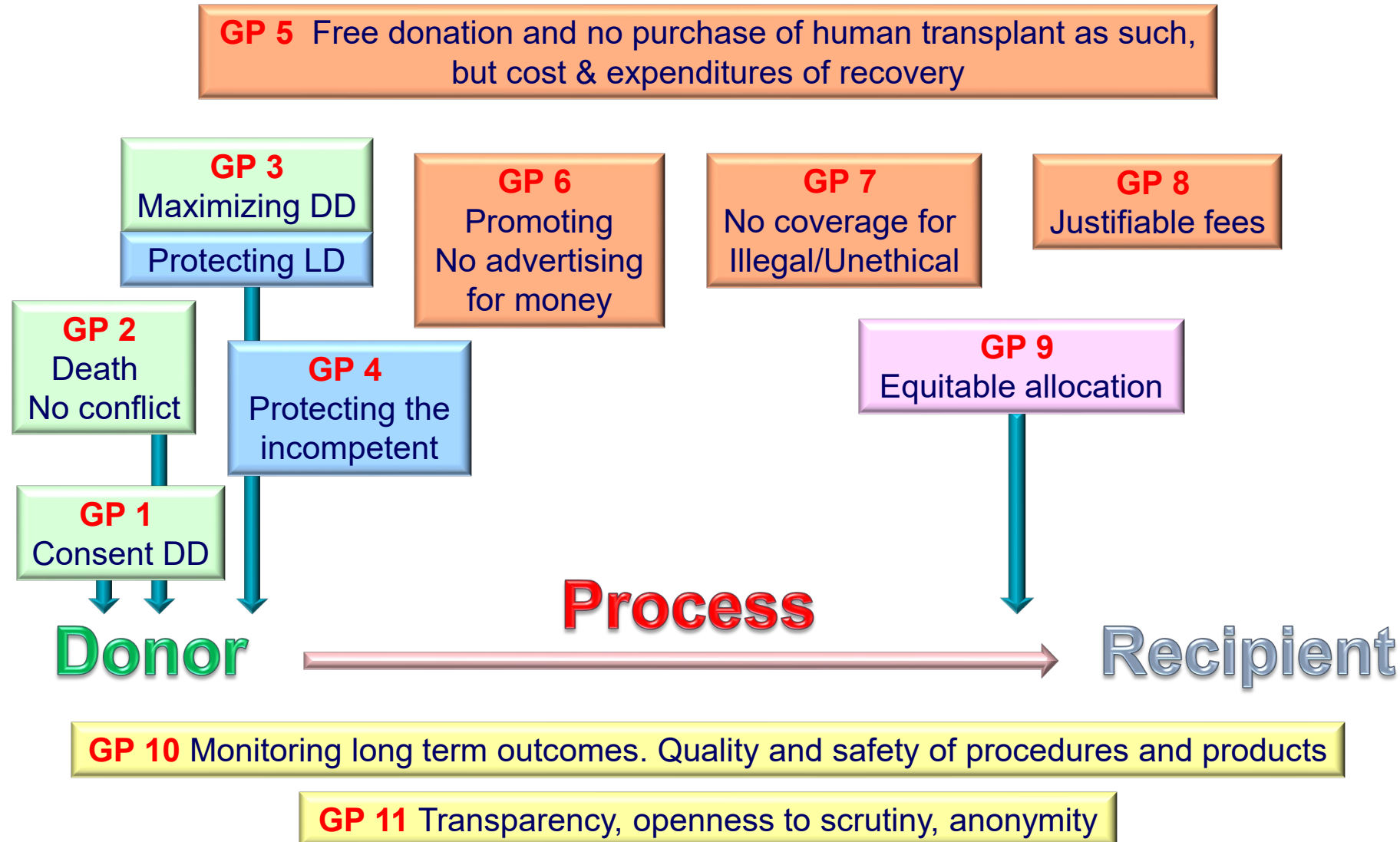
## WHA 63.22 (2010)

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

## 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**

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

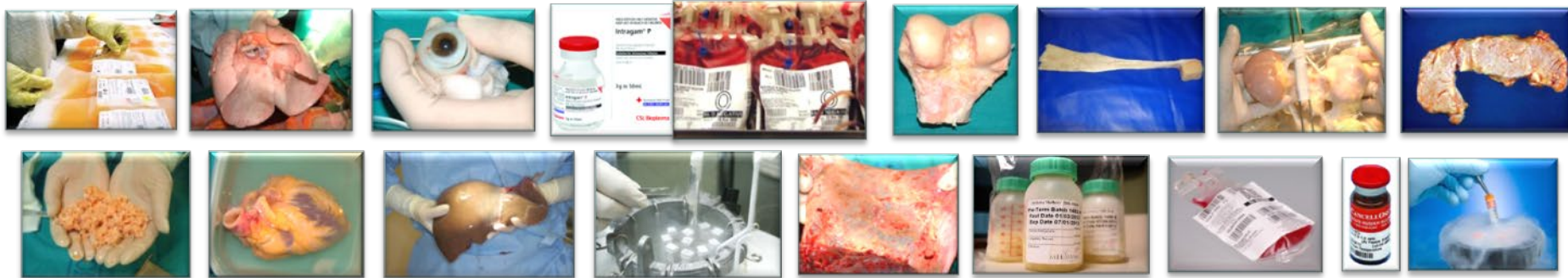


# Medical Products of Human Origin (MPHO)

“Substances

derived wholly or in part  
from the human body and  
intended for **clinical application**”

organs, cells, tissues, blood, gametes,  
secretions (faeces) & excretions (milk)  
irrespective of their fate in the recipient



# Diverse and Challenging...



- ❖ the fragmentation of these products into sub-classes;
- ❖ obtained in different ways;
- ❖ used by different medical specialties;
- ❖ carrying different relative risks, benefits, and alternatives;
- ❖ and regulated by different national authorities.

# MPHO Principles at the 70<sup>th</sup> WHA (2017)

P1: "Government responsibility"

P2: "Equity in donation"

P3: "Clinical utility – Balance risks & benefits"

P4: "Donation should be an informed and voluntary decision"

P5: "Financial neutrality – Protection of the vulnerable"

P6: "Protection against physical and psychosocial risks"

P7: "Provide information about human origin of the product"

P8: "Equity in access - Allocation systems based on clinical & ethical norms"

P9: "Traceability - Quality Management - Vigilance & Surveillance"

P10: "Transparency while ensuring Anonymity and Privacy"

MPHO Common Framework, available at:

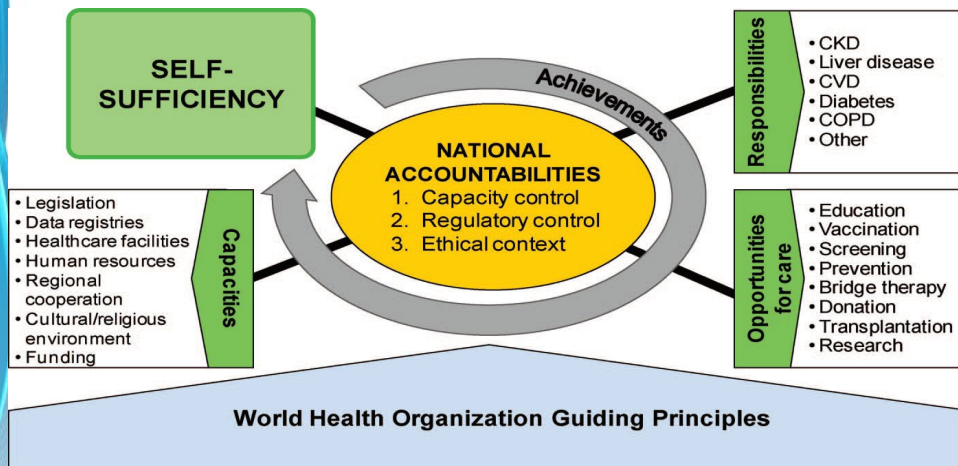
[http://apps.who.int/gb/ebwha/pdf\\_files/WHA70/A70\\_19-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_19-en.pdf)

# Santander Summit Recommendations (Nov. 2023)

1. Improve patient care
2. Make progress towards sufficiency in transplantation
3. Ensure transparency and oversight of practices
4. Strengthen the prevention of human trafficking for the removal of SoHO and trafficking in SoHO
5. Foster responsible innovation for the clinical use of SoHO by
  - mandating the demonstration of quality, safety, and effectiveness of SoHO-based therapies before permitting them to be incorporated into healthcare systems;
  - reinforcing the capacity of donation and transplant systems to oversee ethical conduct and clinical translation of research;
  - ensuring that human organs, tissues and cells do not become marketable products and that necessary fees for services relating to SoHO and benefits from SoHO-derived products are proportionate and consistent with the altruistic nature of donation;
  - ensuring transparency in costs, pricing, and profits from all SoHO-based therapies, and making such therapies affordable to patients;
  - promoting social responsibility in public-private collaboration in the development of SoHO-based therapies.

# National Development and Self-Sufficiency

Every country, in light of its own **level of economic and health system development**, should progress toward the global goal of meeting patients' needs **based on the resources obtained within the country**, for that country's population, and through regulated and ethical **regional or international cooperation** **when needed**.



Schematic representation of the concept of national accountability in meeting the donation and transplantation needs of the population.

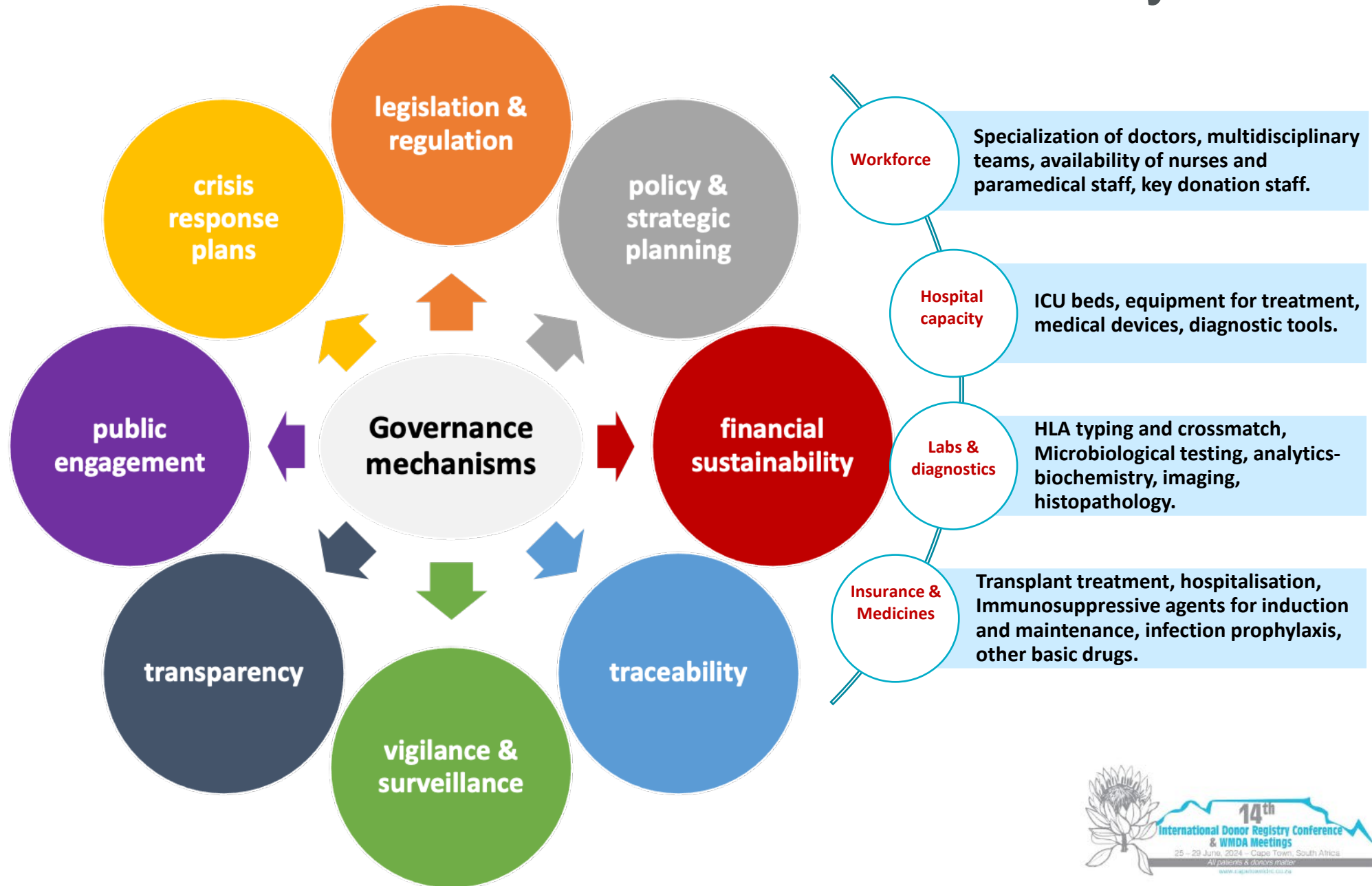
- CKD = chronic kidney disease;
- CVD = cardiovascular disease;
- COPD = chronic obstructive pulmonary disease.

1. Action should begin locally (not precluding international cooperation);
2. Strategies should be targeted to decrease transplantation needs of a population and increasing organ availability;
3. Strategies must be based on solid ethical principles: solidarity, voluntary donation, and non-commercialization;
4. Strategies should be tailored to the local realities.

# Key Considerations for the Establishment of Tx Systems

Each principle should be further elaborated with **strategic approaches** and potential **policy options and interventions** for its attainment.

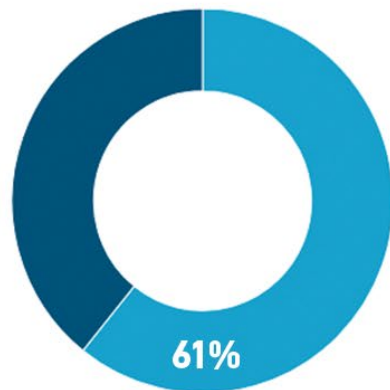
The appropriate mix of policies & interventions to be used at the country level will need to be designed and developed **according to the local context, values and priorities.**



# Deaths from non-communicable diseases since 2000

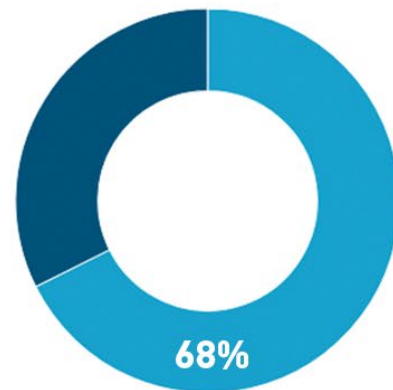
Each year, an average of 36.2 million people die of non-communicable diseases (NCDs), equivalent to 68 percent of global deaths.

■ NCDs-related deaths ■ Other deaths



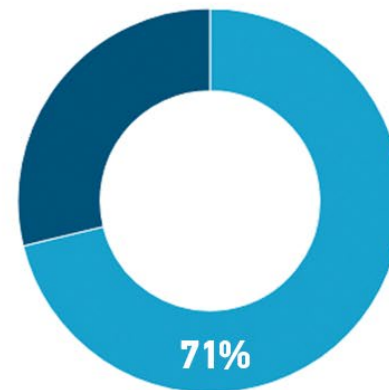
2000

NCDs-related deaths:  
31,170,466



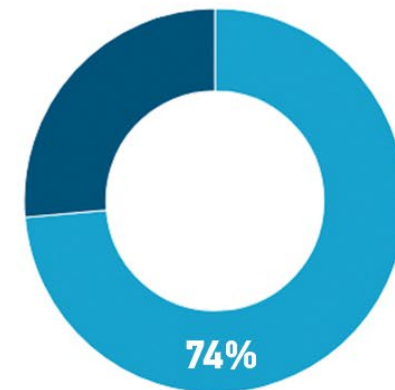
2010

NCDs-related deaths:  
35,190,624



2015

NCDs-related deaths:  
37,945,271



2019

NCDs-related deaths:  
40,804,750

Source: WHO Global Health Estimates

# On the road to 2025: The global NCD deadline

A/Res/73/2 (10 Oct 2018):

Political declaration of the third high-level meeting of the United Nations General Assembly on the prevention and control of non-communicable diseases.

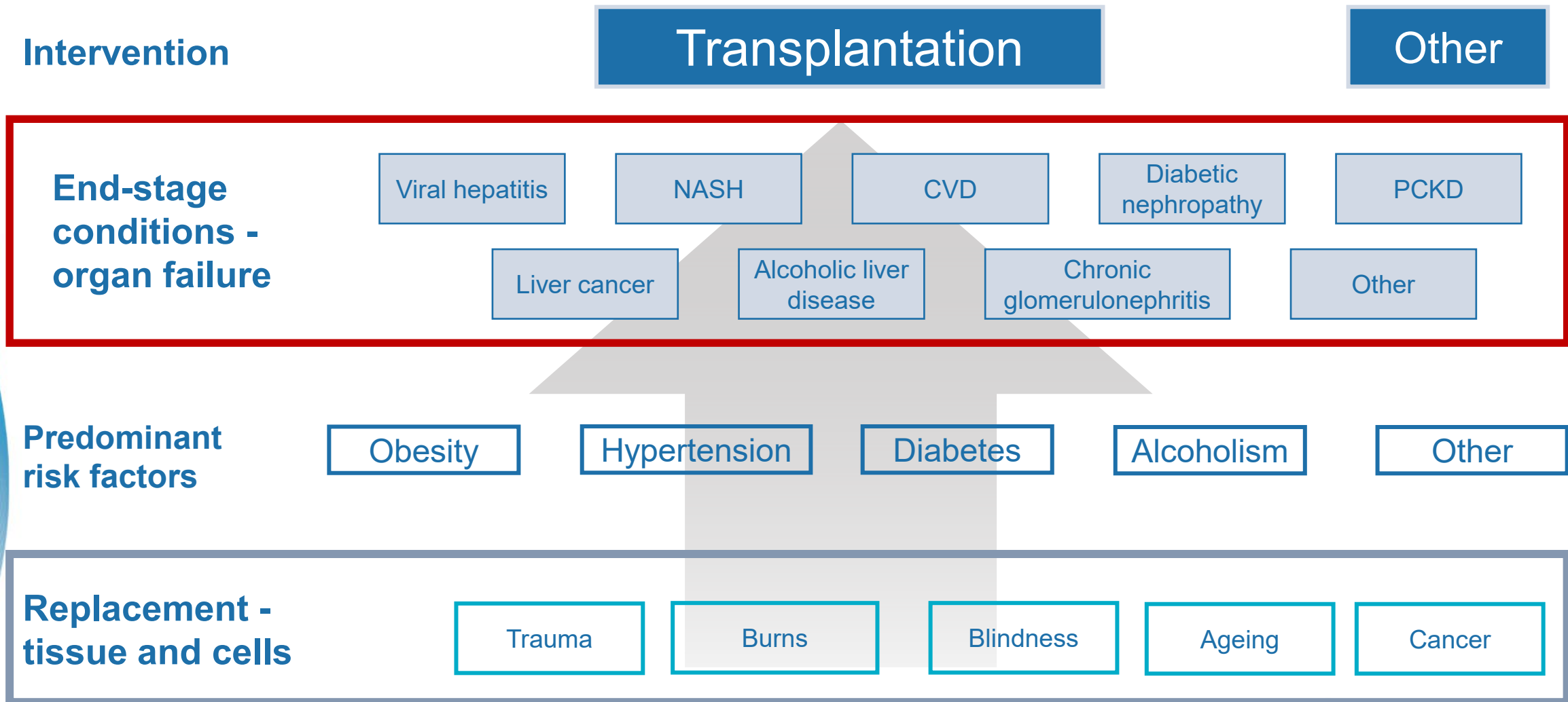


Time to deliver: accelerating our response to address non-communicable diseases for the health and well-being of present and future generations.

## What is at stake?

- **Every minute, 28 lives between the ages of 30 and 70 are cut short because countries have not taken policy, legislative and regulatory measures** to respond to the needs of people living with or at risk of cardiovascular diseases, cancers, diabetes, chronic respiratory diseases, or mental health conditions, **including preventive, curative, palliative, and specialized care.**
- **Twenty-five (25) out of 28 lives lost each minute occur in low- and middle-income countries** where the social, economic, and physical environments afford populations **much lower levels of protection** from the risks and consequences of NCDs than in high-income countries, including protection from tobacco use, the harmful use of alcohol, unhealthy diets, physical activity, and air pollution.

# Increasing Conditions Relevant to Transplantation

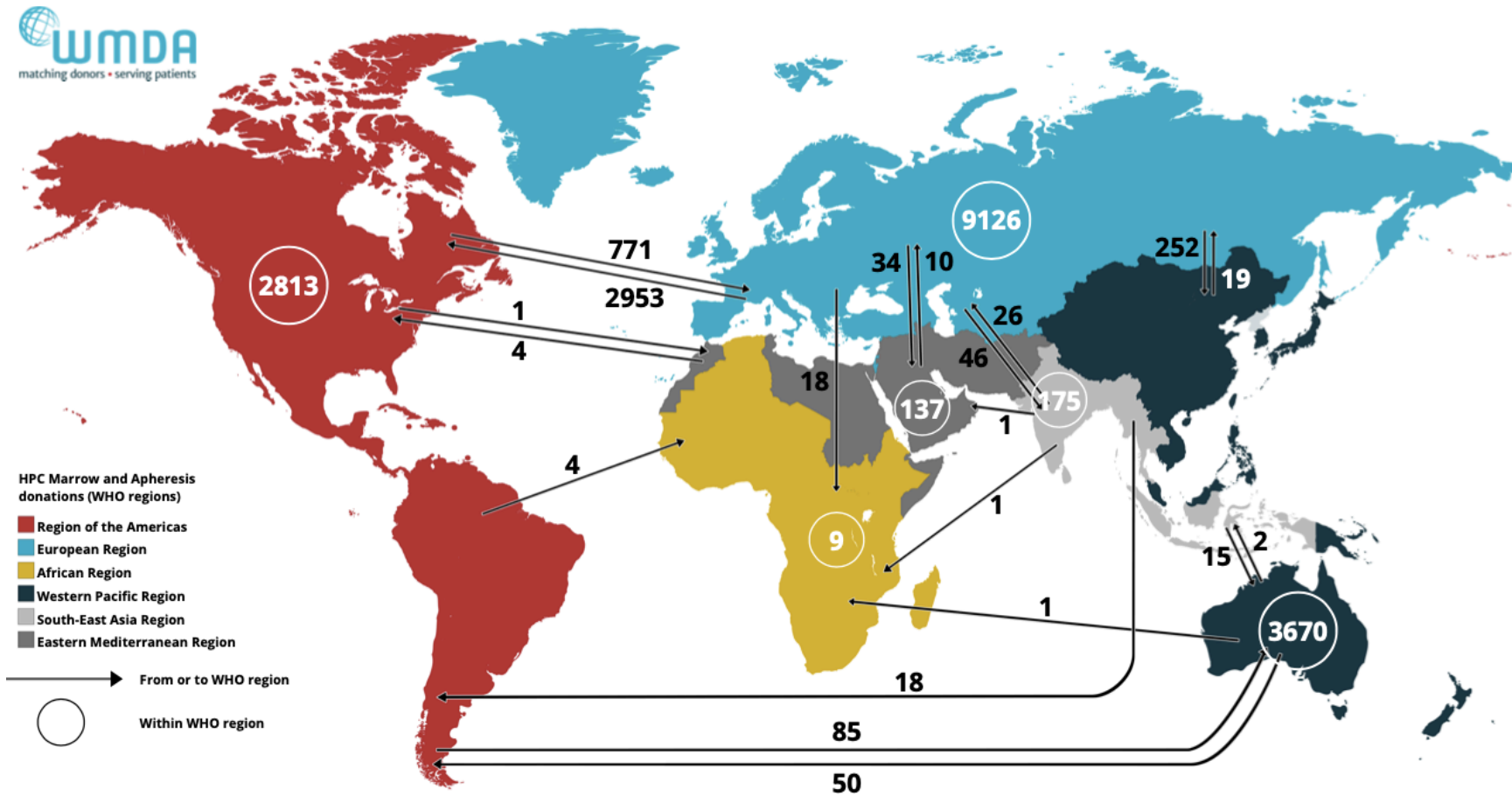


# HSCT: A routine treatment without equivalent

- ❖ Stem cell transplantation can cure more than 90% of patients with haematological malignancies and non-malignant disorders in the early stage of the disease if an optimal donor recipient combination is available.
- ❖ Worldwide, approximately 90.000 first HSCTs (53% autologous and 47% allogeneic) are performed every year, according to the WBMT, with more than 42.000.000 volunteer donors (including CBU) that are registered at global level (WMDA data).
- ❖ HSCT has nowadays surpassed a total of 1.500.000 patients treated, both autologous and allogeneic [WBMT Report. *Blood* 2019; 134 (Supplement\_1): 2035]
- ❖ Although haematological cancers remain the main indication, HSCTs are increasingly considered in the treatment of non-malignant disorders and genetic diseases such as haemoglobinopathies (sickle cell anaemia, thalassaemia) that can benefit greatly from this type of transplant.
- ❖ The medical conditions amenable to HSCT are changing and this has implications for how relevant transplants are available and accessible in all parts of the world, including for low-income countries.

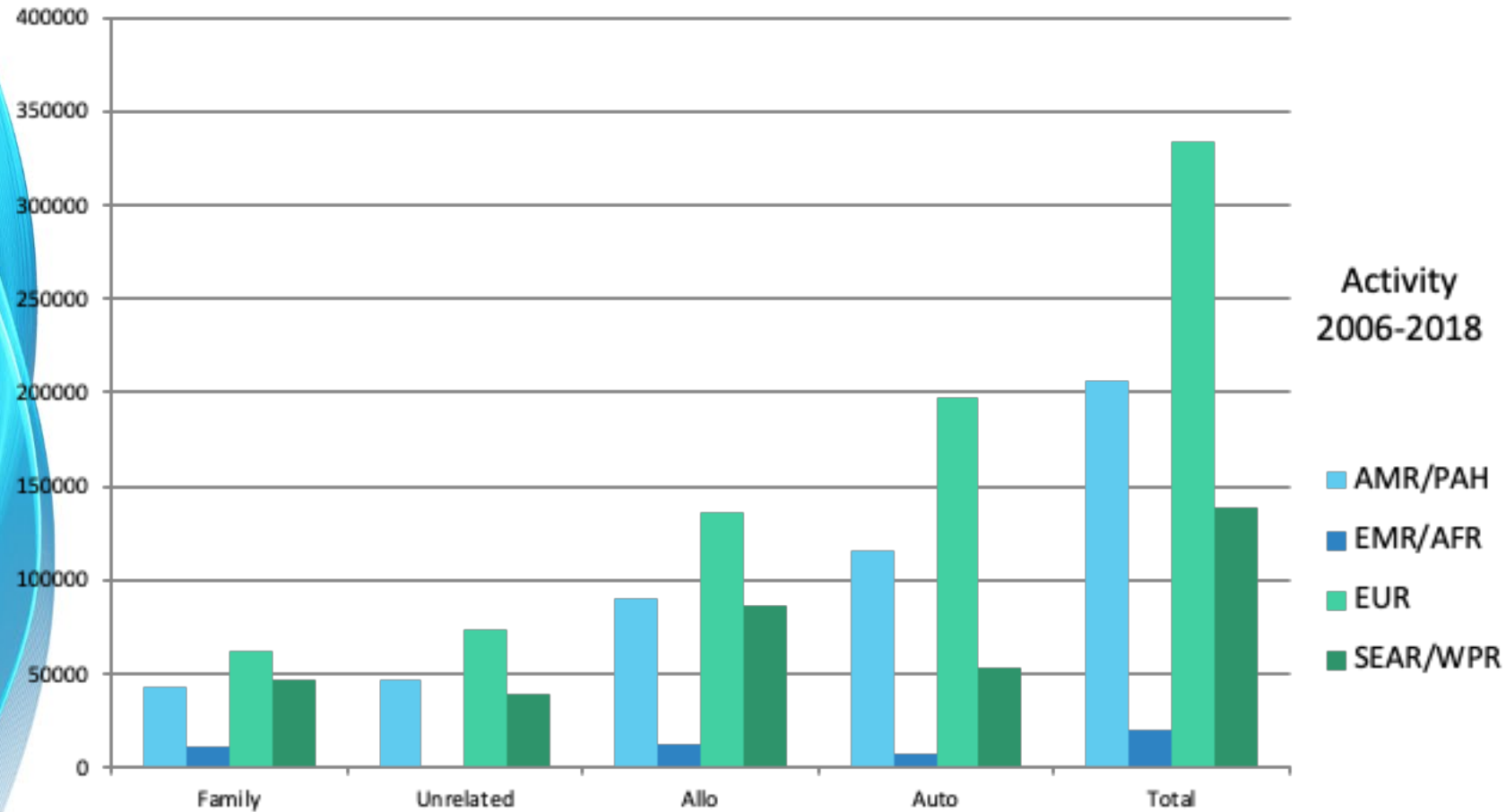
# A shared humanity...

More than 24,000 tx from foreign donors (Marrow, Apheresis and CBU) are performed annually



International Circulation of Haematopoietic Stem Cells among the six WHO Regions (Source: WMDA 2019).

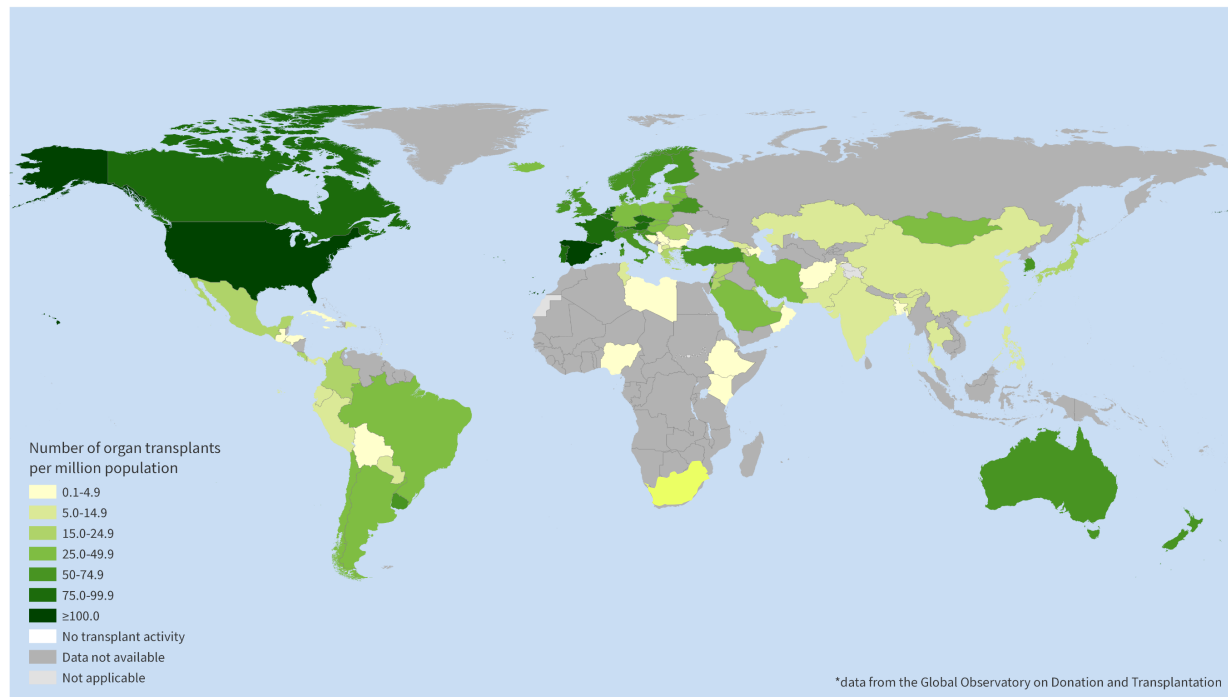
# HSCT Global Activity per WHO Region



WHO Region	N. Teams
AMR/PAH	302
EMR/AFR	30
EUR	656
SEAR/WPR	674
<b>Total</b>	<b>1662</b>

# Organ transplantation activity

## Global transplantation activities of solid organs, 2022\*



The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

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



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)\*

Information of 91 Member States on organ transplantation activities (75% of the global population)



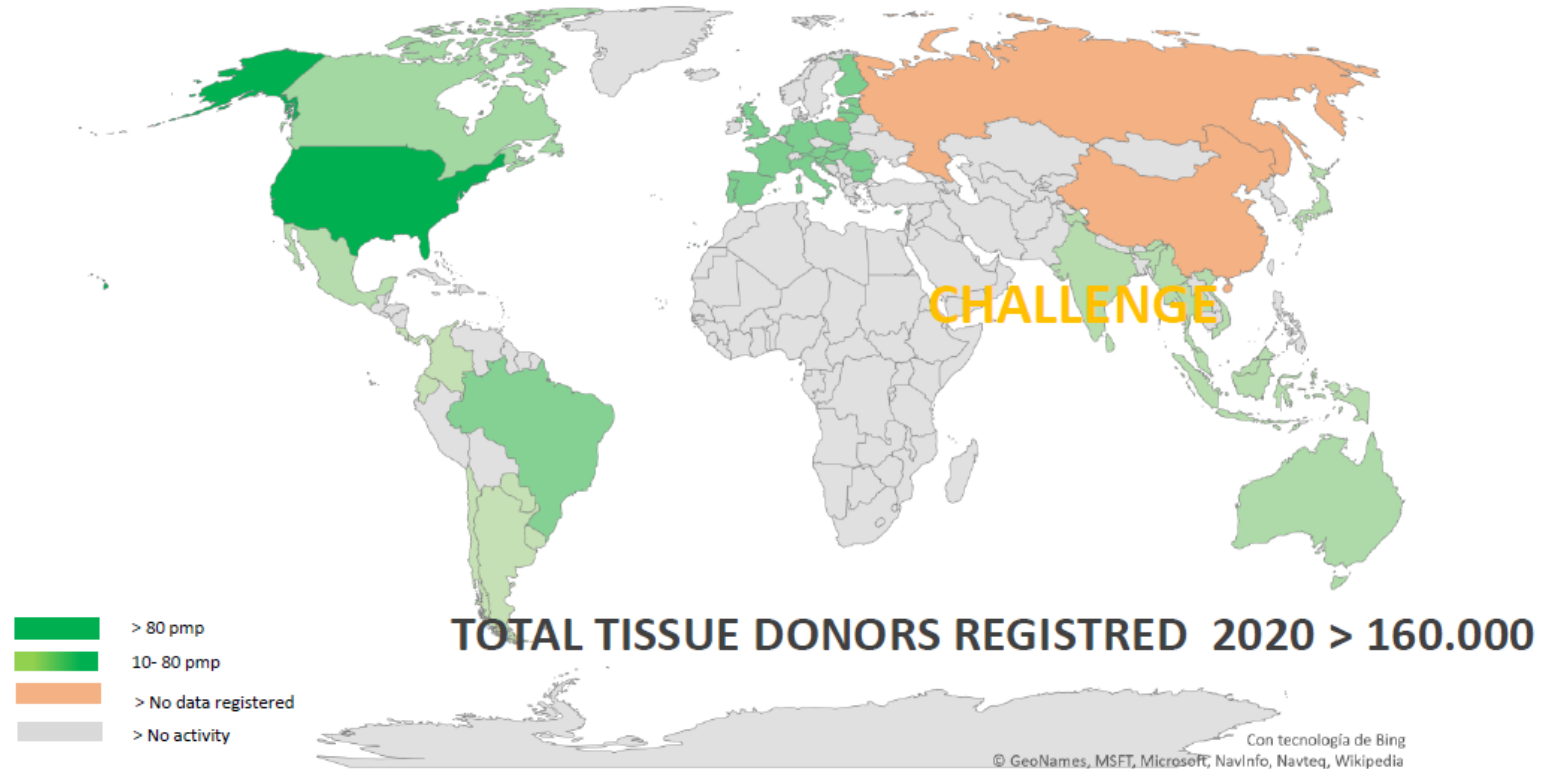
# Distribution of transplant centers among WHO regions

data compiled from GODT reports 2020 and 2022

Transplant centres (millions inhabitants / centre)*	AFR	AMR	EMR	EUR	SEAR	WPR
<b>Kidney</b>	32 (15.0)	885 (1.1)	128 (3.6)	453 (1.9)	624 (2.6)	430 (4.2)
<b>Liver</b>	3 (159.5)	404 (2.4)	35 (13.2)	239 (3.5)	247 (6.7)	231 (7.7)
<b>Heart</b>	0 (0.0)	338 (2.9)	21 (22.1)	174 (4.9)	168 (9.8)	154 (11.6)
<b>Lungs</b>	0 (0.0)	129 (7.6)	8 (58.0)	92 (7.5)	95 (17.3)	81 (29.6)
<b>Pancreas</b>	0 (0.0)	225 (4.4)	5 (94.1)	121 (7.0)	54 (30.3)	68 (26.6)
<b>Small Bowel</b>	0 (0.0)	39 (25.2)	1 (470.3)	46 (18.4)	19 (86.1)	55 (32.8)

\*Million inhabitants per transplant centre are calculated by applying the population of the responding countries.

# Tissue donation worldwide 2020

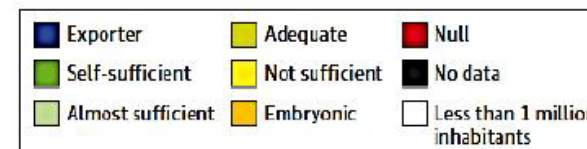
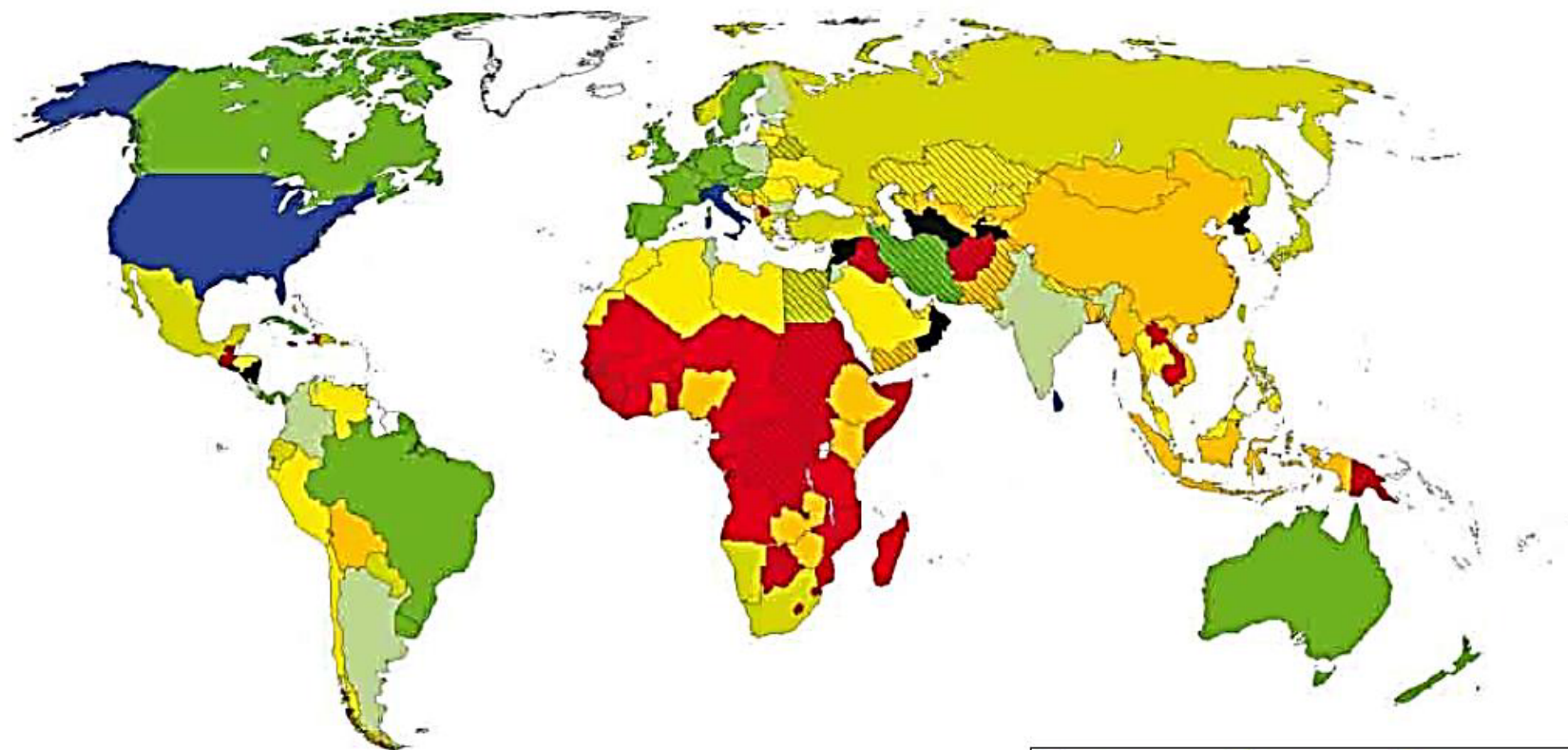


**Sources:**

- Eurocet Report 2019. Tissue Data 2018. [http://old.iss.it/binary/ecet/cont/tissue\\_report\\_2019.pdf](http://old.iss.it/binary/ecet/cont/tissue_report_2019.pdf) (European countries)
- Newsletter transplant 2018. Tissue Data 2018. <http://www.transplant-observatory.org/download/newsletter-transplant-2019/> (Latinamerican countries)
- Eye Bank Association of America (EBAA). <https://restoresight.org/what-we-do/publications/statistical-report/>
- Eye Bank Association of Australia and New Zeland (EBAANZ). <http://www.ebaanz.org/ebaanz-corneal-donation-and-outcome-data/>
- Canadian Eye and Tissue Banking Statistics. [https://professionaleducation.blood.ca/sites/mtsi/files/2016\\_etdc\\_final\\_updated\\_report\\_july\\_2018.pdf](https://professionaleducation.blood.ca/sites/mtsi/files/2016_etdc_final_updated_report_july_2018.pdf)

Data 2020

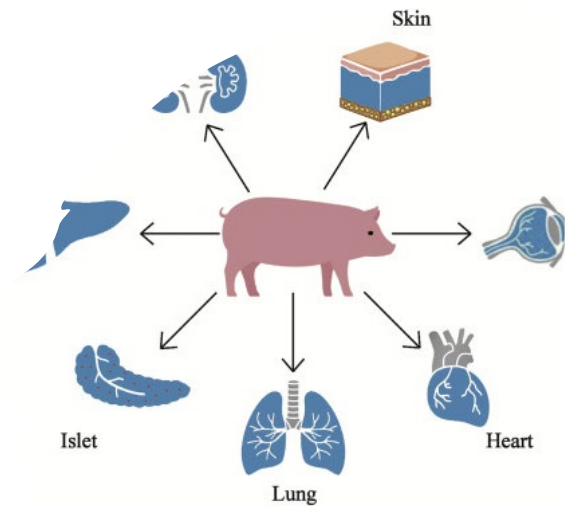
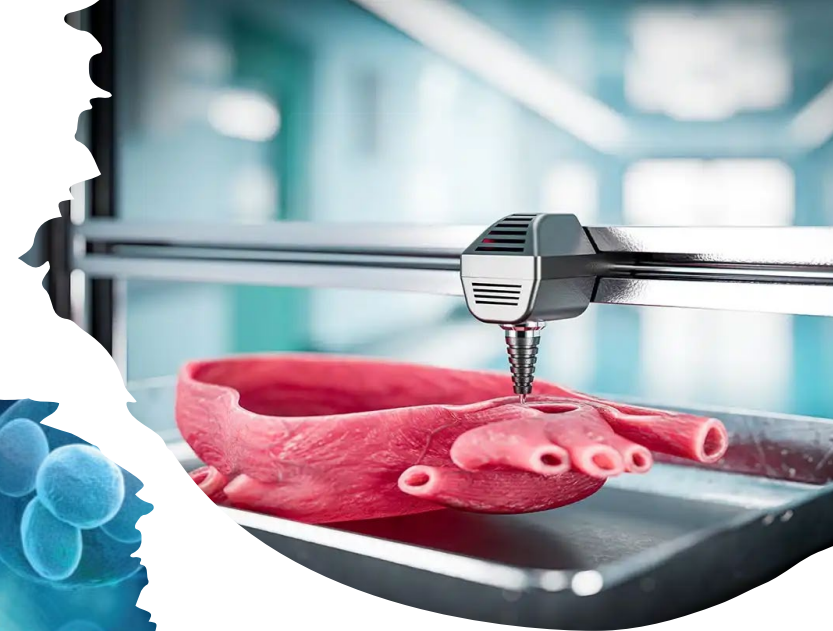
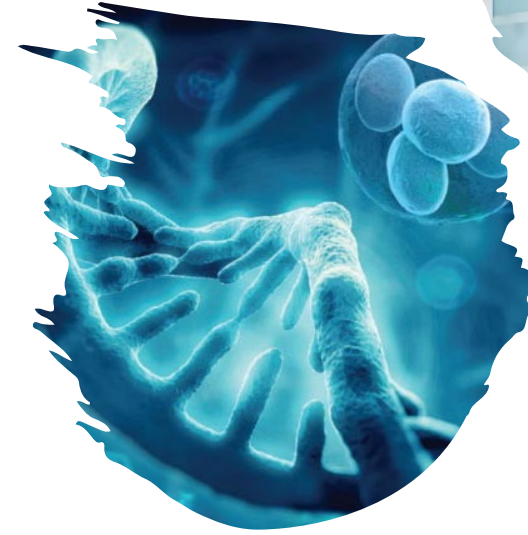
# Supply and Demand of Corneal Transplantation in 148 countries



Gain P, Jullienne R, He Z, et al. Global Survey of Corneal Transplantation and Eye Banking. JAMA Ophthalmol. 2016;134(2):167–173. doi:10.1001/jamaophthalmol.2015.4776


# Key advancements in science and technology (opportunities/challenges)


- **Donor Alternatives**
  - Xenotransplantation
  - Bioprinting
  - Artificial organs
- **Regenerative Medicine**
- **Immunogenetics**
- **Organ Preservation**





# Monitoring trends in emerging technologies and Science


~100 innovations

 **IG1** Innovation group 1: Diagnostic technology

 **IG2** Innovation group 2: Health products and drug delivery technology


  **IG3** Innovation group 3: Tissue engineering and regenerative medicine

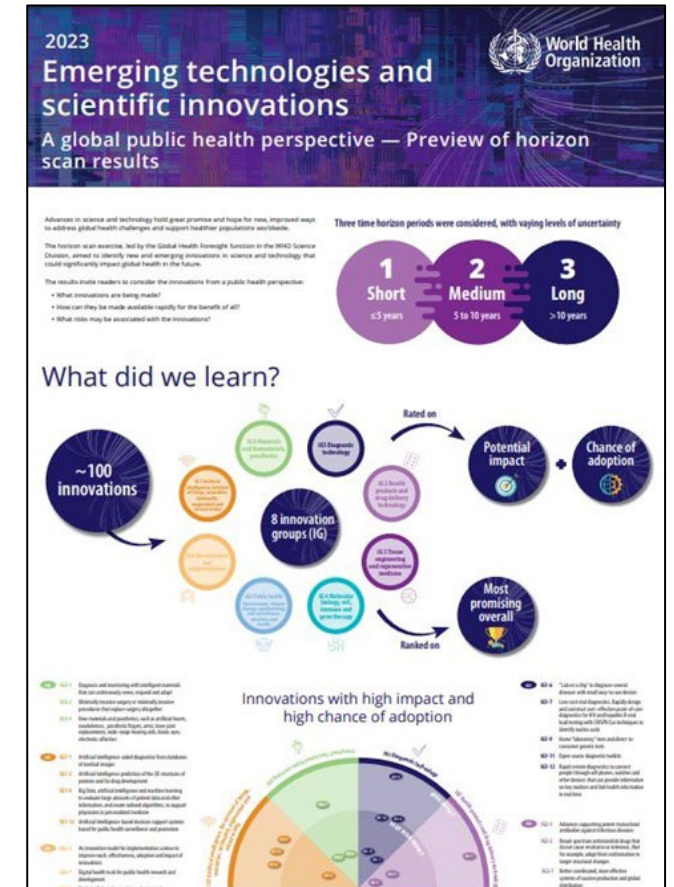
  **IG4** Innovation group 4: Molecular biology, cell, immune and gene therapy

 **IG5** Innovation group 5: Public health: Environment, climate change, epidemiology and surveillance, nutrition and health

 **IG6** Innovation group 6: Dissemination and implementation

 **IG7** Innovation group 7: Artificial intelligence, Internet of things, wearables, telehealth, augmented and virtual reality

 **IG8** Innovation group 8: Materials and biomaterials, prosthetics



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

Limited resources (funding, specialised workforce, infrastructure).

Deceased 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 and transplant tourism, tissue and cell commercialisation) as a result of no access/availability.

# 75th WHA (May 2022)

Secretariat Report A75/41  
on current status of  
transplantation

# Adoption of a new WHA Resolution (2024)

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

## Urges Member States to:

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

Integrate donation (deceased), transplantation, follow-up, into healthcare policies for non-communicable and other diseases

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

Increase the availability of OTCs by maximizing deceased donation (DBD or DCD) where appropriate

Establish official agreements for exchange of OTC or access to transplant services

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

Designate authorities and improve governance of donation/transplantation activities

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

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

Include donation/transplantation in National or Regional preparedness plans in the event of crisis (increase resilience)

Take measures to prevent/combat trafficking and protect victims (reporting of cases by health professionals)

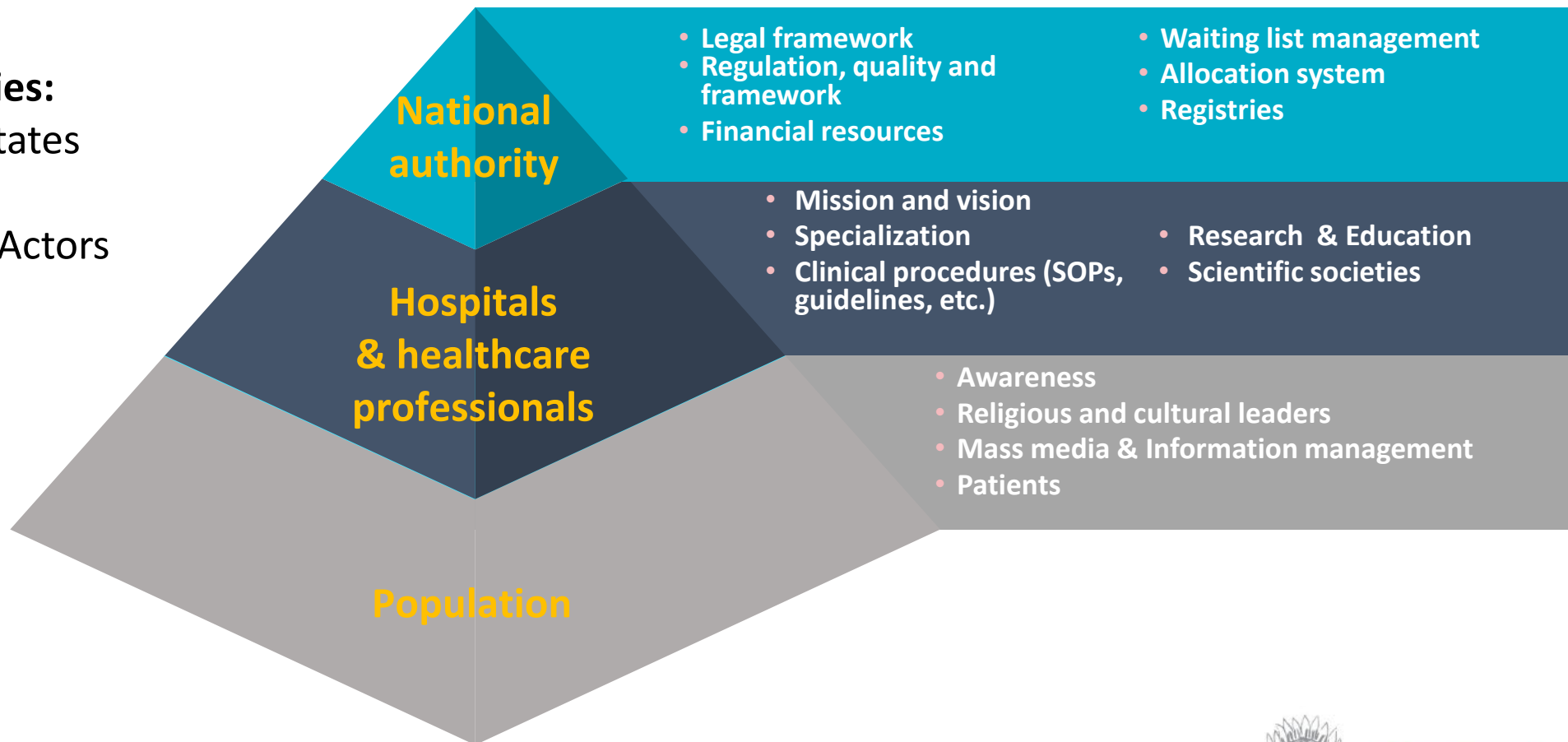
Promote research and innovation for optimizing outcomes and development of alternative treatments based on OTC

Implement regulatory frameworks for innovative-advanced products based on OTC (protection of donors, equitable access)

# Key Elements of a Global Strategy

## Roles and Responsibilities:

- Member States
- WHO
- Non-State Actors



# Conclusion



- The burden of non-communicable diseases is increasing worldwide, and prevention strategies are not always successful, therefore, premature mortality is a major issue.
- Transplantation is the best and most cost-effective treatment option for replacement of organs, tissues or cells.
- Improving access to transplantation is contingent on a multitude of financial, governmental, and societal factors.
- Many countries lack the pre-requisite of transplant facilities, waitlists, workforce, political will, and publicly funded health-care systems (universal health coverage) to facilitate increased access to transplantation, especially from deceased donors (organs and tissues). In addition, there is low public awareness and education.
- National self-sufficiency in transplantation may be achievable only through international collaboration, regional exchange and support.
- Dependency on human donation may not be a sustainable solution – need to invest in alternative sources
- Through a new global strategy, WHO seeks to support its Member States, especially LMICs, in increasing availability and access to transplantation.

**Thank you.**



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