

# WHO activities for advancing the access to transplantation of human organs, tissues and cells (WHA Resolution 63.22)

## Member States Information Session

14 April 2022, WHO headquarters, Geneva

# The life value of transplantation

The transplantation of human tissues, organs or cells is an established form of treatment that has been acknowledged as the best and very often only life-saving therapy for several serious and life-threatening congenital, inherited and acquired diseases and injuries.



- **Vital organs (kidneys, liver, lungs, hearts)** can be replaced after chronic or acute failure due to NCDs, infections or behavioral factors (i.e. alcoholism, obesity).
- **Tissues (skin, bone and tendons, birth tissue, cardiac valves, eye tissue)** provide better survival rates following severe burn trauma, recovery of movement, closure of chronic wounds, rehabilitation of heart function and restoration of sight. Corneal disease (scarring or perforation) can be successfully addressed through transplantation in 80% of affected individuals.
- **Haematopoietic Progenitor Cells (stem cells, bone marrow)** are used in treatment of haematological conditions (cancers such as leukemia, non-malignant disorders and genetic diseases such as haemoglobinopathies, sickle cell anemia).

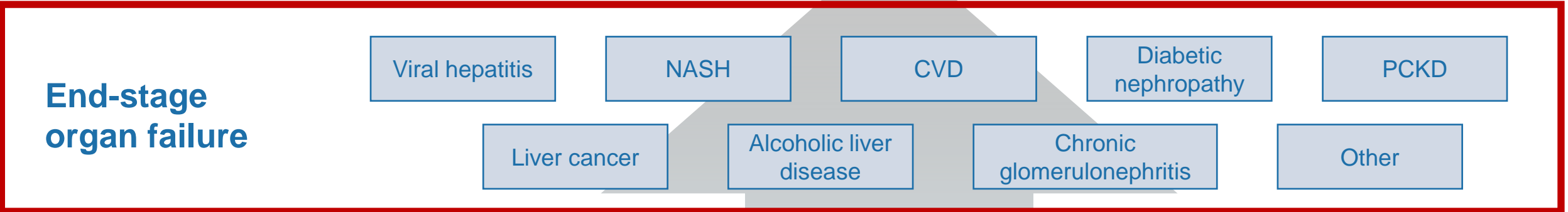
# Increasing Conditions Relevant to Transplantation

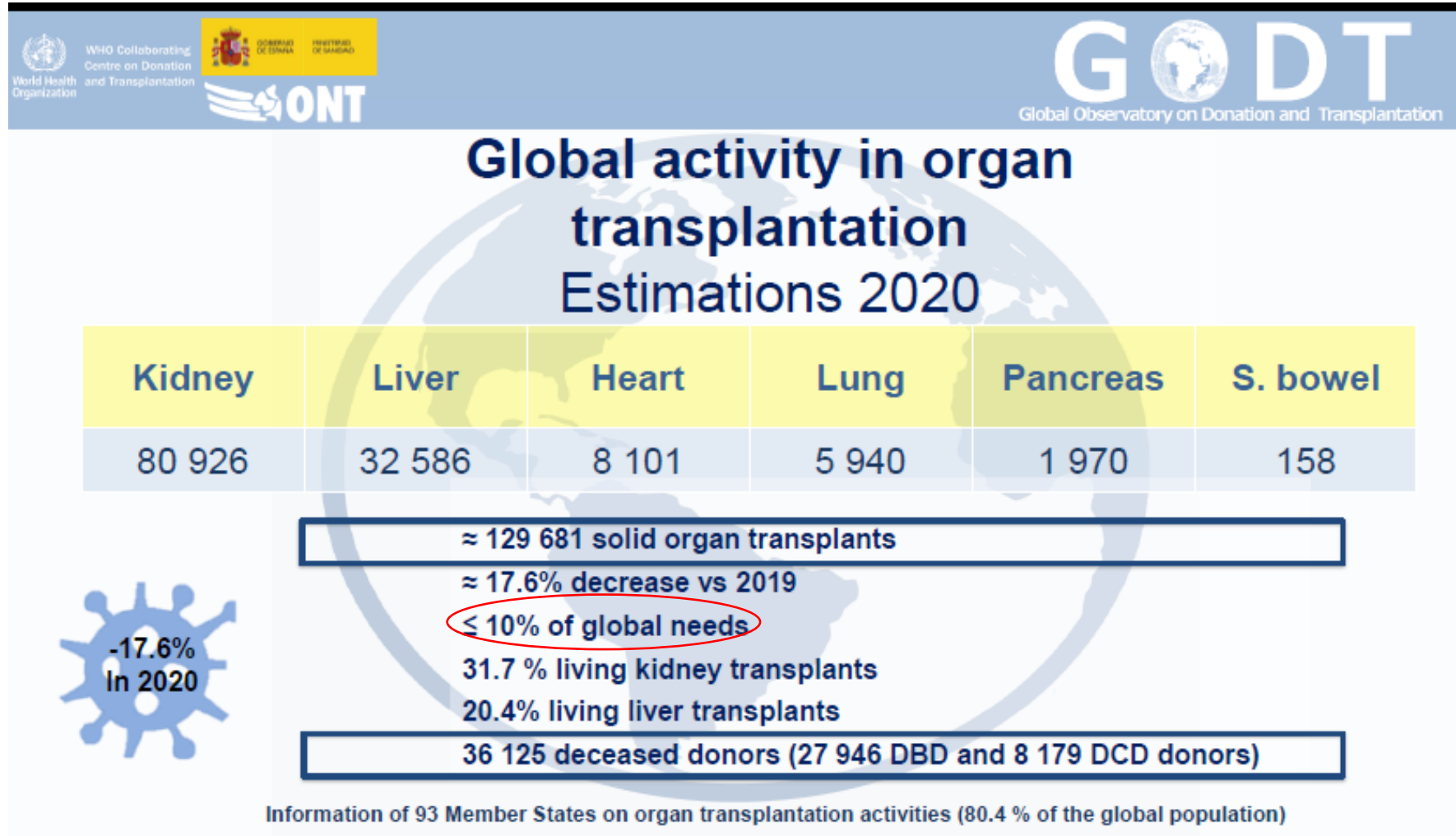


Intervention

Transplantation

Other





# Kidney disease: The case for action

**850 MILLION**  
PEOPLE  
WORLDWIDE  
are now estimated to have some form of kidney disease<sup>1</sup>.

**11<sup>TH</sup>**  
LEADING CAUSE OF  
GLOBAL MORTALITY  
Chronic kidney disease (CKD) causes an estimated 1.2 million deaths per year and is now the 6<sup>th</sup> fastest growing cause of death. An additional 1.2 million deaths are attributable to reduced kidney function (measured by the glomerular filtration rate (eGFR))<sup>4</sup>.

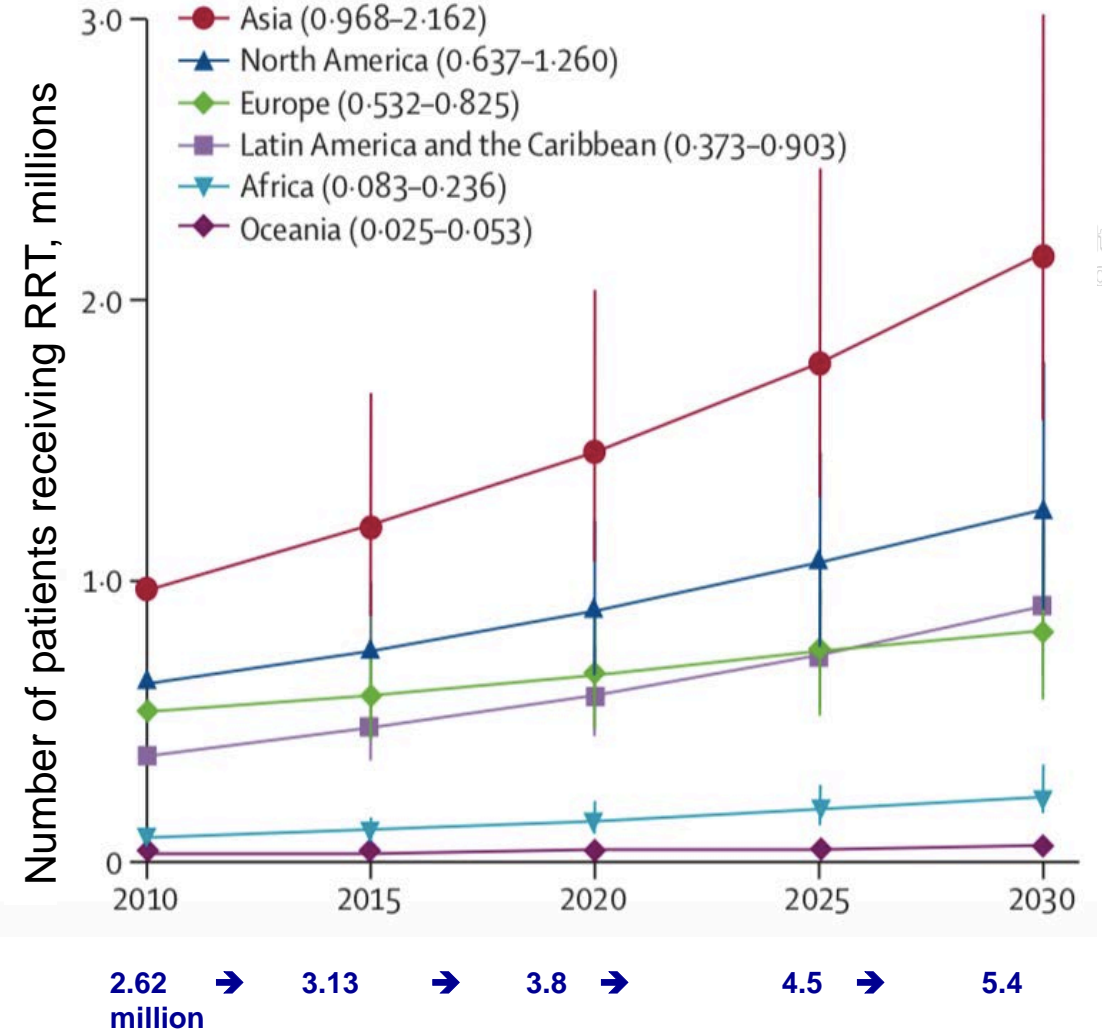
**13 MILLION**  
PEOPLE  
AFFECTED WORLDWIDE  
Acute kidney injury (AKI), an important driver of CKD, affects over 13 million people worldwide and 85% of these cases are found in low and middle-income countries (LMICs)<sup>5</sup>.

**2.6 MILLION**  
RECEIVED DIALYSIS OR  
TRANSPLANTATION  
WORLDWIDE  
In 2010, 2.6 million people with end-stage kidney disease (ESKD) or "kidney failure" received dialysis or transplantation worldwide<sup>6</sup>, a number projected to increase to 5.4 million by 2030<sup>7</sup>.

**\$35,000 - \$100,000**  
DIALYSIS AND KIDNEY  
TRANSPLANTATION  
ANNUAL COSTS  
The cost of treating CKD and its complications is unaffordable for governments and individuals in many parts of the world. Annual costs of dialysis and kidney transplantation alone range between US \$35,000 and US \$100,000 per patient<sup>8</sup>.

**BETWEEN 2.3 - 7.1 MILLION**  
PREMATURE DEATHS FOR  
LACK OF ACCESS TO DIALYSIS  
AND TRANSPLANTATION  
The majority of those deaths occur in countries where resources are insufficient and out of pocket costs are too high<sup>9</sup>.

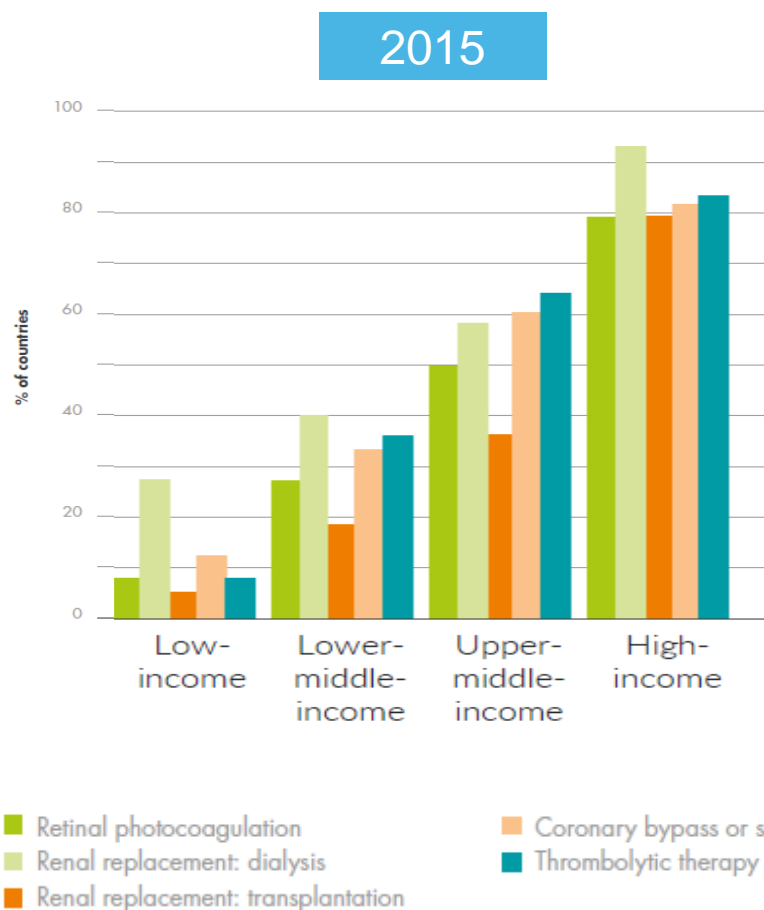
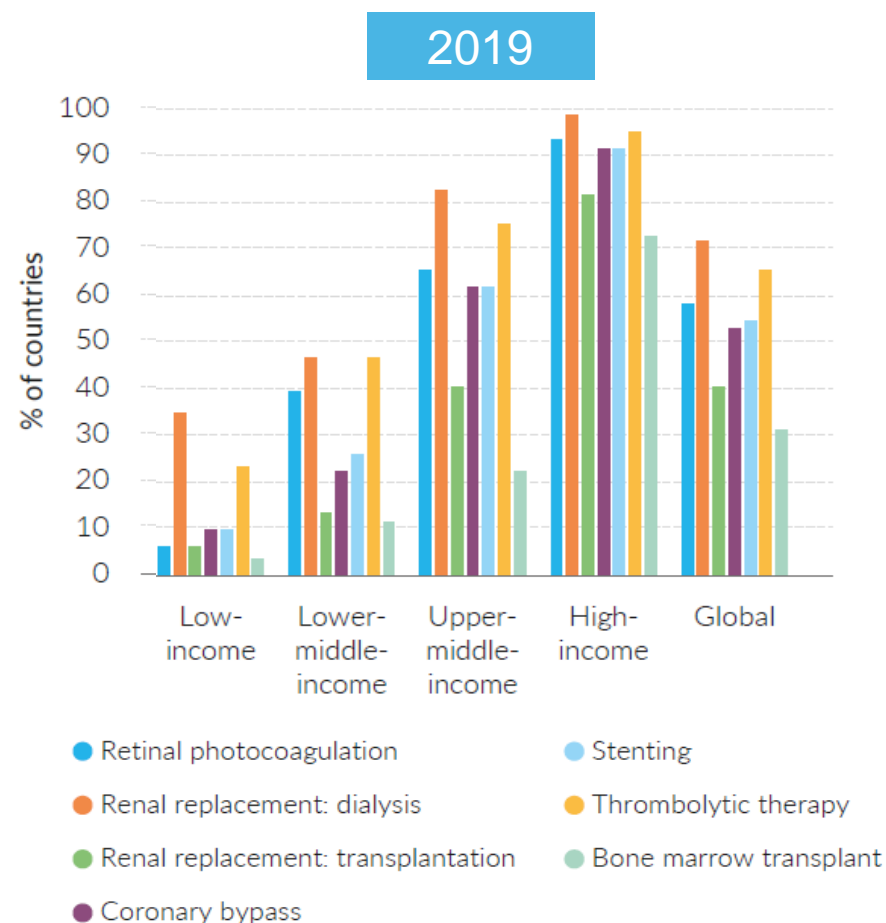
INTERNATIONAL SOCIETY OF NEPHROLOGY  
Report: 2018 UN high-level meeting on NCDs



Liyanage et al., Lancet 2015; 385:1975-82

# Current Capacity

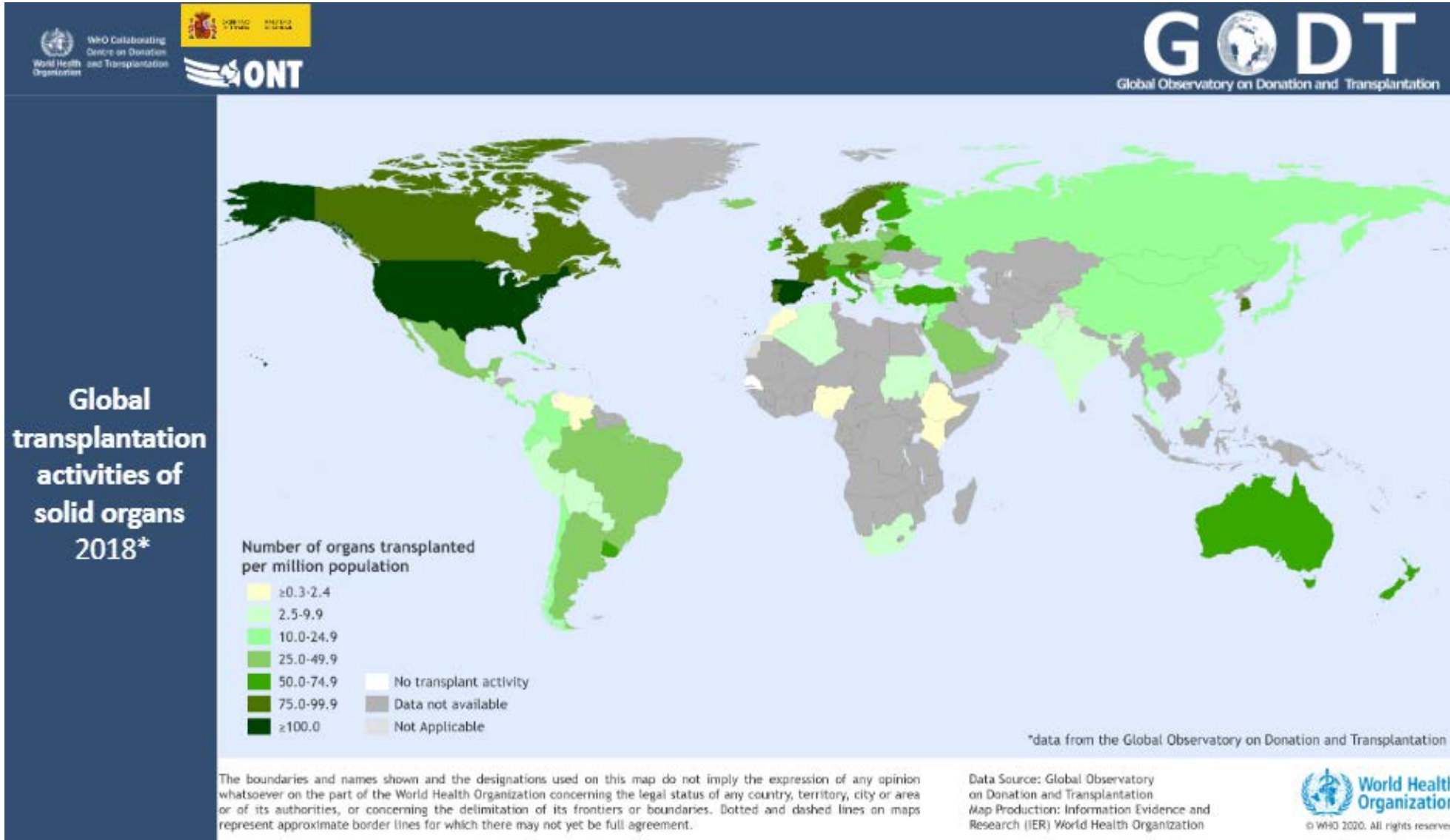
Percentage of countries with procedures for treating NCDs reported as being “generally available” in the publicly funded health system, by WHO region and World Bank income group



Setting	Intervention	2015	2019
LIC	Dialysis	27%	35%
	Kidney transplant'n	5%	5%
LMIC	Dialysis	40%	47%
	Kidney transplant'n	18%	13%
UMIC	Dialysis	58%	82%
	Kidney transplant'n	36%	40%

**Slower progress!**





Deceased donation activity has been reported only in 75 countries (38% of Member States)

# Challenges in Transplantation



- Lack of understanding the burden of disease in order to escalate interventions for preventing end-stage organ failure.
- Limited community awareness, cultural resistance and knowledge regarding donation and the value of transplantation
- Low awareness and engagement amongst the public and healthcare professionals.
- Low organizational and political commitments reflecting in the lack of national strategies for transplantation. This includes deficient Universal Health Coverage (excluding transplantation), low level of activity specific funding (e.g. transplantation, tissue and cell banking, innovation), human resources or infrastructure .
- Inadequate legislation, ethical frameworks, regulatory oversight and governance that may allow for ethically undesirable and inefficient practices, such as coercion of and exploitation of living donors, ‘transplant tourism (e.g. organs) and commercialization (e.g. tissue and cell transplants)
- Deficiencies in deceased donor identification and donation management. Impaired access to living donation programs (e.g. kidneys)
- Limited alternatives in undersupply or emergency preparedness (e.g. mass casualties -burns, trauma)





# WHA Resolutions on Transplantation



- WHA 40.13 (1987) Development of guiding principles for human organ transplants
- WHA 42.5 (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 and Xenogeneic)
- **WHA 63.22 (2010) Human cell, tissue and organ transplantation (updated WHO Guiding Principles)**



- promote altruistic voluntary non-remunerated donation;
- oppose the seeking of financial gain or comparable advantage
- promote a system of transparent, equitable allocation and equitable access to transplantation services (in accordance with national capacities);
- improve the safety and efficacy
- strengthen national and multinational authorities and/or capacities
- maximize donation from deceased donors
- protect the health and welfare of living donors;
- activity data collection including adverse events and reactions
- encourage the implementation of globally consistent coding systems towards improved traceability

# Recent WHO organization-wide activities for improving availability of and access to transplantation



## 57th DIRECTING COUNCIL

71st SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 30 September-4 October 2019



CD57.R11  
Original: Spanish

### RESOLUTION

#### CD57.R11

STRATEGY AND PLAN OF ACTION ON DONATION AND EQUITABLE ACCESS TO ORGAN, TISSUE, AND CELL TRANSPLANTS 2019-2030



REGIONAL COMMITTEE FOR AFRICA

Seventieth session  
Virtual session, 25 August 2020

Provisional agenda item 15

STATUS OF HUMAN ORGAN AND TISSUE DONATION AND TRANSPLANTATION IN THE WHO AFRICAN REGION

Report of the Secretariat

AFR/RC70/12  
30 June 2020

ORIGINAL: ENGLISH

United Nations

A/RES/75/195



General Assembly

Distr.: General  
28 December 2020

Seventy-fifth session  
Agenda item 111  
Crime prevention and criminal justice

Resolution adopted by the General Assembly  
on 16 December 2020

[on the report of the Third Committee (A/75/479, para. 20)]

75/195. Strengthening and promoting effective measures and 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

## Upscaling the response – focus areas

- **The implementation rate of WHA Resolution 63.22 is slow and great disparity remains between Regions and Member States in regards to the availability of and access to transplantation**
- Some advances have been made – however mostly in UMIC and HIC with a significant impact on donation and transplantation rates.
- There are remaining, and important challenges and gaps in the field between organ, tissue and cell donation and transplantation.
- The WHO sees a role in the establishment and implementation of organ, tissue and cell specific Work Frameworks, where the needs, capabilities and priorities of interested Member States can be considered.

# Development of Workplan for Transplantation (WPT) of Tissues, Organs and Cells in biennial cycles 2022-2030

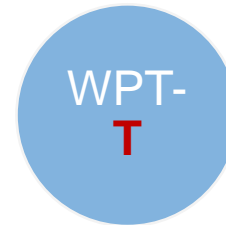


**Phase 1**

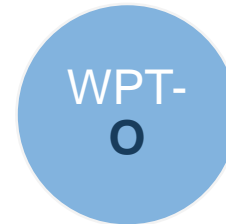
**Phase 2**

**Phase 3**

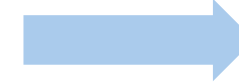
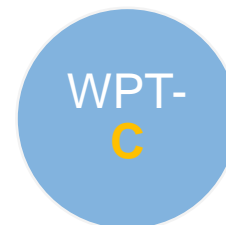
Outline completed.  
To be published  
2<sup>nd</sup> Q 2022



In development, to  
be concluded by  
End of 2022



To be developed  
next biennium  
(2024-2025)



**Regional  
Consultations**

Towards  
implementation,  
reflecting local  
needs, capacity and  
assigned priorities  
by interested  
Member States



**HQ + Regional Offices  
Expert Advisory Groups**

# Variety of actions – WHO output

- Guidelines and best principle in clinical and tissue/ cell banking practices
- Publications / knowledge and information material (reports, fact sheets)
- Tools (registries, web platforms, IT applications)
- Technical support / capacity building (infrastructure, equipment, training)
- Research / innovation (exchange of new technologies, science developments)
- Consultation / expert meetings



The Global Vigilance and Surveillance Database for Medical Products of Human Origin  
TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION

WHO/HTP/EHT/CP/2006.03  
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**World Health Organization**

**Access to Safe and Effective Cells and Tissues for Transplantation**

**AIDE-MEMOIRE**  
*for National Health Authorities\**

Tissue and cell transplantation represent essential and rapidly developing therapies in modern healthcare. It is the responsibility of national health authorities to ensure that the needs of patients are met with a supply of safe tissues and cells of appropriate and consistent quality. A nationally supported legislative framework which defines consent requirements and supports donation and a regulatory system which authorizes tissue and cell banks are prerequisites to achieving this goal. Donation and transplantation activities should be organized in a transparent way with the provision of adequate information and data to enable the public to make informed choices.

Tissue and cell transplantation carry risks of disease transmission. Viruses (including HIV, hepatitis B and C), bacteria, fungi, parasites and prion agents have been transmitted to tissue and cell recipients causing disease. The safety of tissues and cells for transplantation is assured by the careful selection of donors on the basis of their medical and behavioral history, physical examination and by testing of donor blood samples for transmissible agents. Donations should be procured only from non-remunerated donors from low-risk populations. In addition, whenever possible, validated pathogen inactivation or removal processes should be applied. Transplantation of tissues and cells should only be carried out when there is no option for a safer, equally effective, alternative therapy.

Any organization engaged in the procurement (including donor identification, consent, donor selection testing and tissue or cell retrieval), processing, storage or distribution of tissues and cells for transplantation should implement a comprehensive quality system. The system should cover all aspects of its activities and ensure traceability from the identification of the donor to the transplantation of the product to a recipient. Management commitment and support are essential for the development, implementation and monitoring of a quality system in order to ensure continuous improvement. All staff should understand the importance of quality and their role in achieving it consistently.

**Words of advice**

- Ensure that the legislative framework supports tissue and cell donation and transplantation
- Identify national or international technical reference documents (standards)
- Create a registry of all organizations that screen/test donors, and/or retrieve, process, store or supply tissues and cells for transplantation
- Confirm the implementation of quality systems in tissue and cell establishments
- Designate an authority to control compliance with standards
- Promote the education of health professionals and the public in support of tissue and cell donation
- Publish information and data on tissue and cell donation and transplantation to ensure transparency
- Promote optimal use of tissues and cells

**Checklist**

**National Oversight**

- Legislative/Regulatory framework
- Appropriate national/international standards
- Inspection and authorization of screening, testing, retrieval, processing, storage, distribution, import and export
- Surveillance and vigilance including transplantation transmitted disease
- Monitoring and reporting of donation, processing, distribution, import, export and transplantation activity data

**Education and Promotion**

- Campaigns to promote unremunerated donation
- Education of healthcare professionals to ensure optimal use of the national resource of tissue and cell donations

**Safety**

- Donor selection, deferral, care and confidentiality
- Donor screening and testing for infectious disease markers
- Avoidance of contamination and cross-contamination
- Monitoring of transplantation-transmitted disease

**Quality Systems**

- Clearly defined organizational structures
- Adequate resources (staff and facilities)
- Quality Manager in each cell/tissue establishment
- Comprehensive controlled documentation including Standard Operating Procedures (SOPs)
- Complete and accurate records to ensure traceability
- Appropriate, documented staff training and competency assessment

**Assessment**

- Validation or full verification of each process run and qualification of equipment
- Internal and external audits
- Error management, corrective and preventive action
- External quality assessment schemes

**Clinical Use**

- Traceability
- Appropriate use
- Clinical follow-up of transplant recipients

# Conclusion

The proposed WHO activities under the new workplan will facilitate the advancement of the implementation of WHA Resolution 63.22, taking in consideration the existing Regional Strategies-Plans and in alignment with the WHO 13th General Programme of Work (2019-2023). It is therefore expected to contribute to the following key outcomes:

- Increased priority given to human organ, tissue and cell transplantation within global, regional and national health agendas through advocacy and internationally agreed development goals;
- Established national leadership, governance and oversight through multisectoral action and partnerships;
- Strengthened international cooperation (exchange of best practices, provision of technical expertise, financial support and equipment) in support of low-resource countries, in particular, to enable progress towards self-sufficiency in transplantation.

# Thank you for your attention

You may send us an email at:  
[transplantation@who.int](mailto:transplantation@who.int)  
for further information

