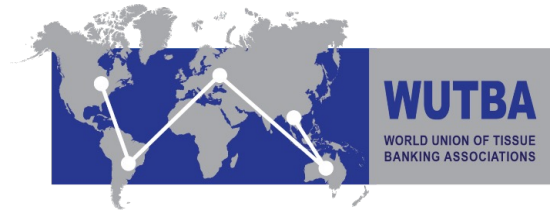




# DGFG

DEUTSCHE GESELLSCHAFT FÜR  
GEWEBETRANSPLANTATION  
GEMEINNÜTZIGE GESELLSCHAFT mbH



SATIBA AGM October 5, 2023

## Ethical issues in tissue medicine

Between short time Need and Long time Development

*Martin Börgel,  
CEO DGFG*

*President elect EATCB*

*General Secretary WUTBA*



## What do we know?

- Ethics  
*ancient Greek ethikos = habit, "custom"*
- moral principles that govern a person's or group's behavior



**World Health  
Organization**

**WHO GUIDING PRINCIPLES  
ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION<sup>1</sup>**

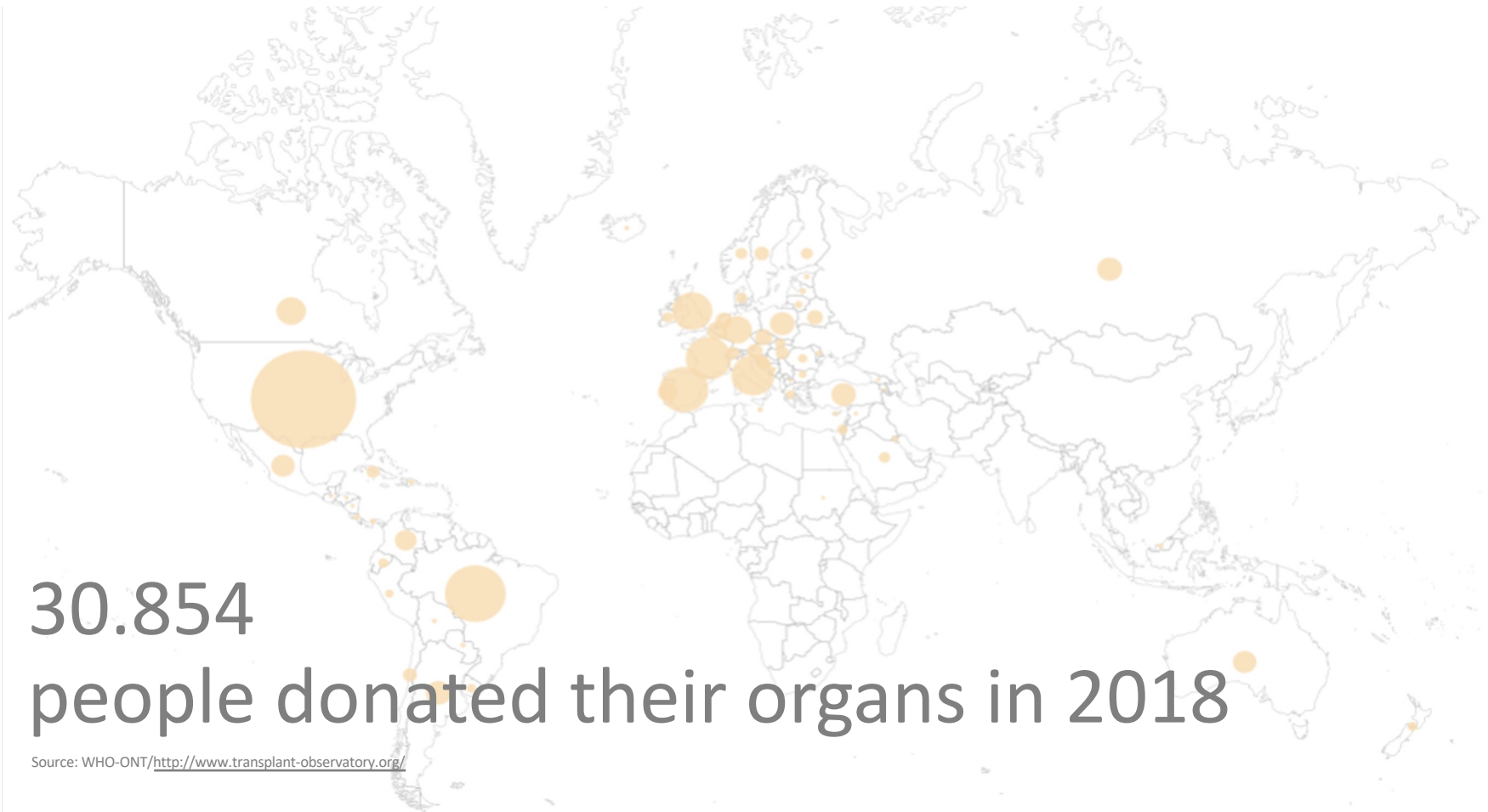


## What do we know?

- about cell, tissue, organ (CTO) Tx?
- involved organisations?
- relevant ethical issues/regulations?
- exchange of CTO?



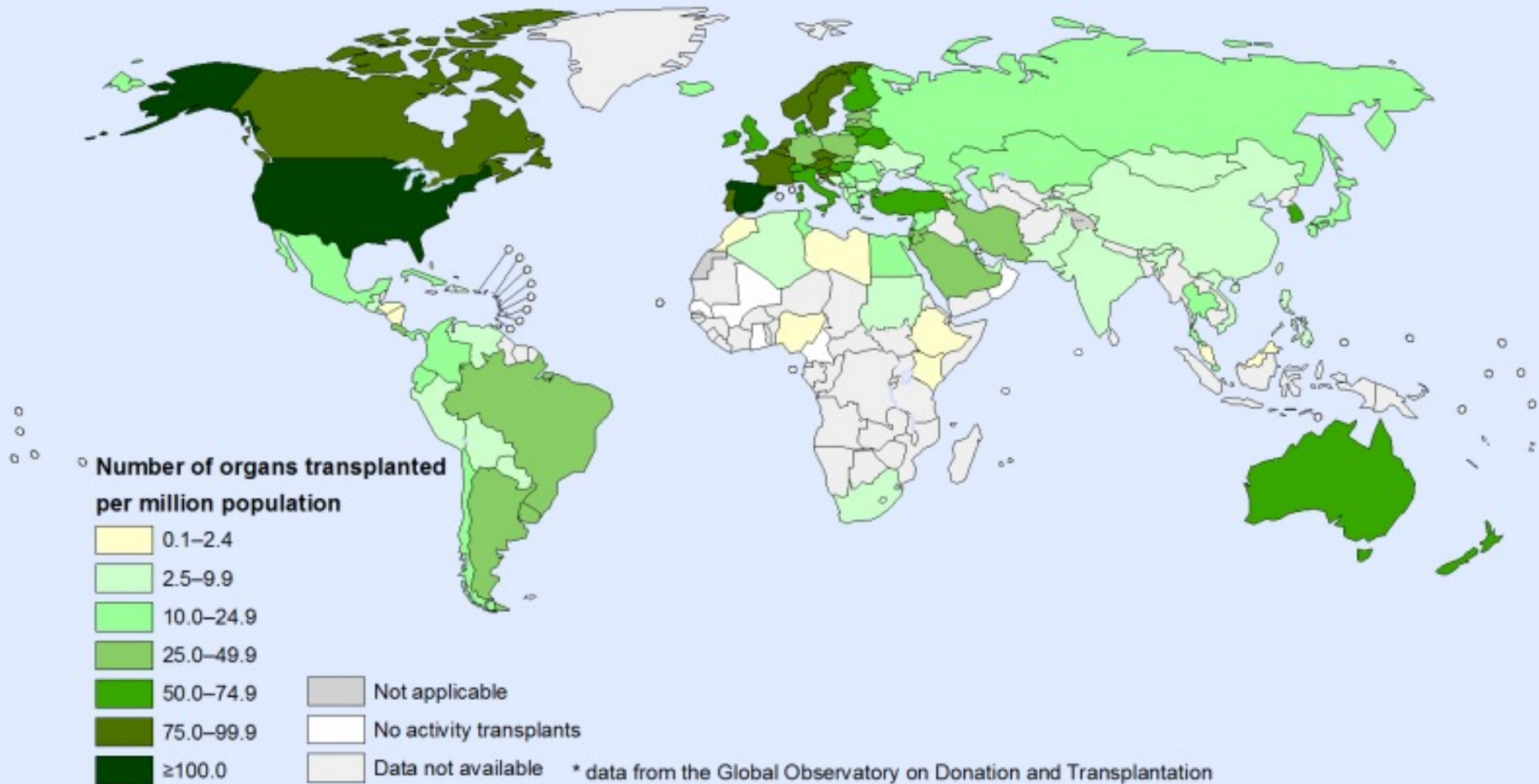
# What do we know?



**30.854**  
people donated their organs in 2018

Source: WHO-ONT/<http://www.transplant-observatory.org/>

## Global transplantation activities of solid organs, 2016\*







# What do we know?



## GLOBAL ALLIANCE OF EYE BANK ASSOCIATIONS





# Eye tissue donation & transplantation

Source: [Global Alliance of Eyebank Association](#)

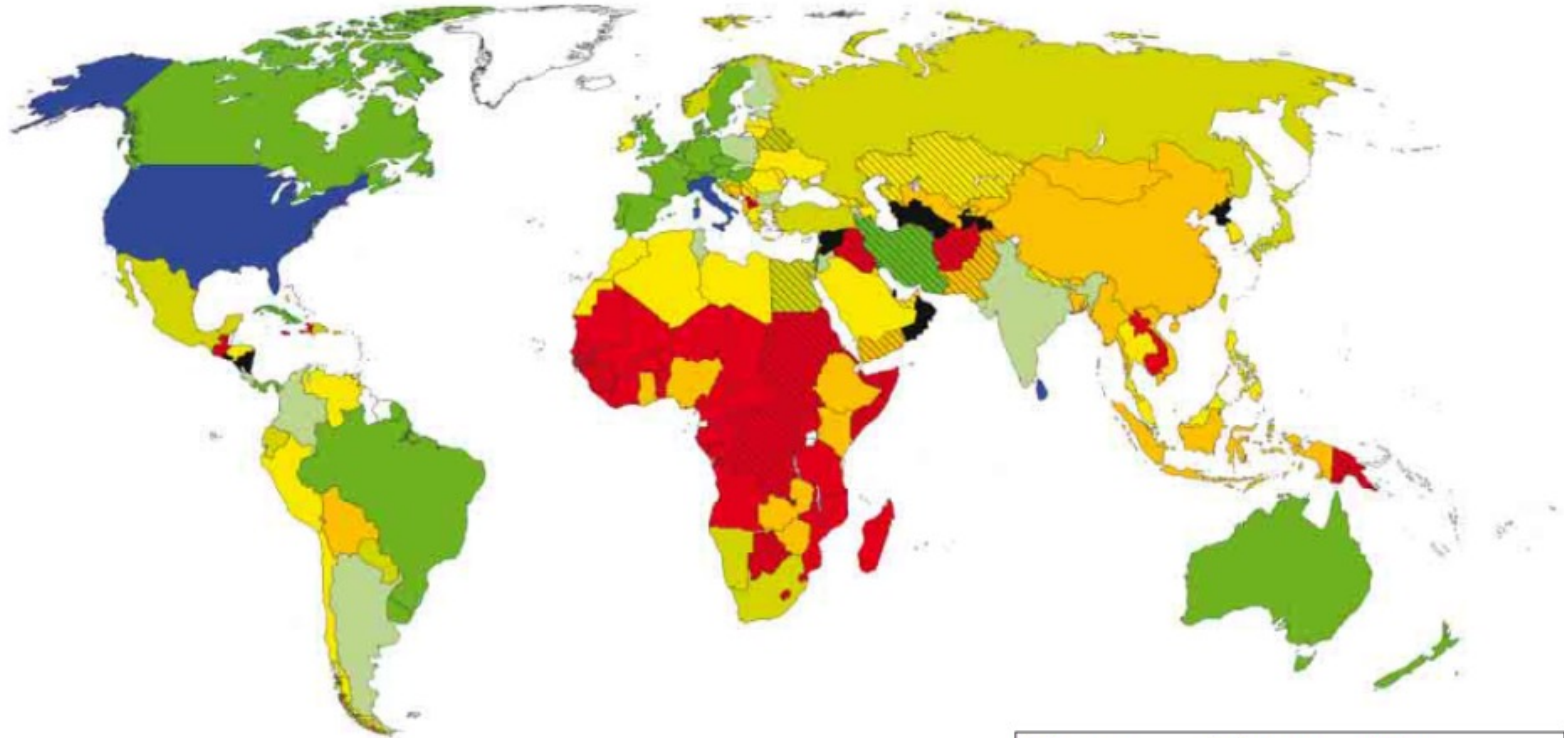
2014	Eye donors	Transplanted corneas
EEBA	18.770	24.026
EBAA	68.956	75.391
EBANZ	1.307	2.204
EBAI (India)	23.434	20.429
<b>TOTAL</b>	<b>112.467</b>	<b>122.050</b>





# Global corneal transplantation – exporters, importers, sufficiency

Source: Philippe Gain, Rémy Jullienne, Zhiguo He, Mansour Aldossary, Sophie Acquart, Fabrice Cognasse, Gilles Thuret, 2016, *Global Survey of Corneal Transplantation and Eye Banking*



■ Exporter	■ Adequate	■ Null
■ Self-sufficient	■ Not sufficient	■ No data
■ Almost sufficient	■ Embryonic	□ Less than 1 million inhabitants

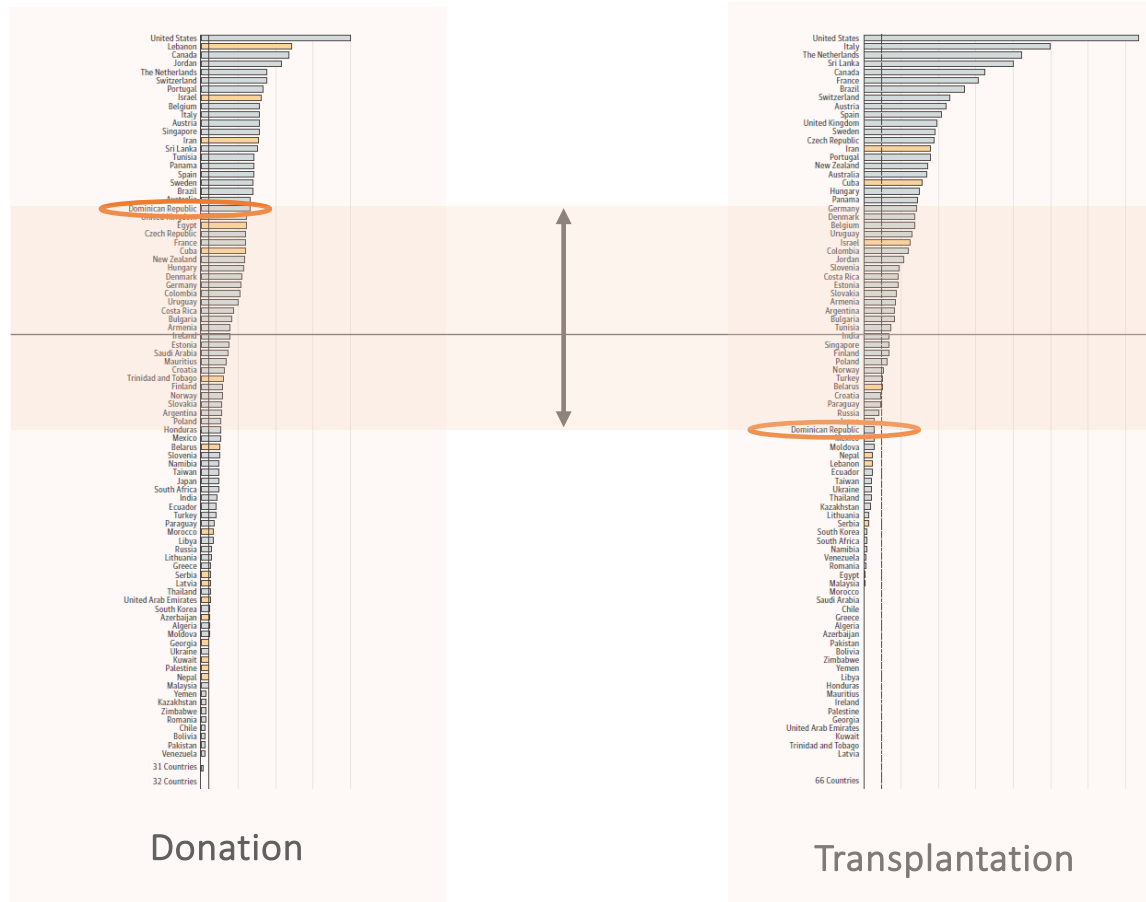
Self-sufficiency?





# Cornea „donor“ vs. „recipient“ countries

Source: Philippe Gain, Rémy Jullienne, Zhiguo He, Mansour Aldossary, Sophie Acquart, Fabrice Cognasse, Gilles Thuret, 2016, *Global Survey of Corneal Transplantation and Eye Banking*

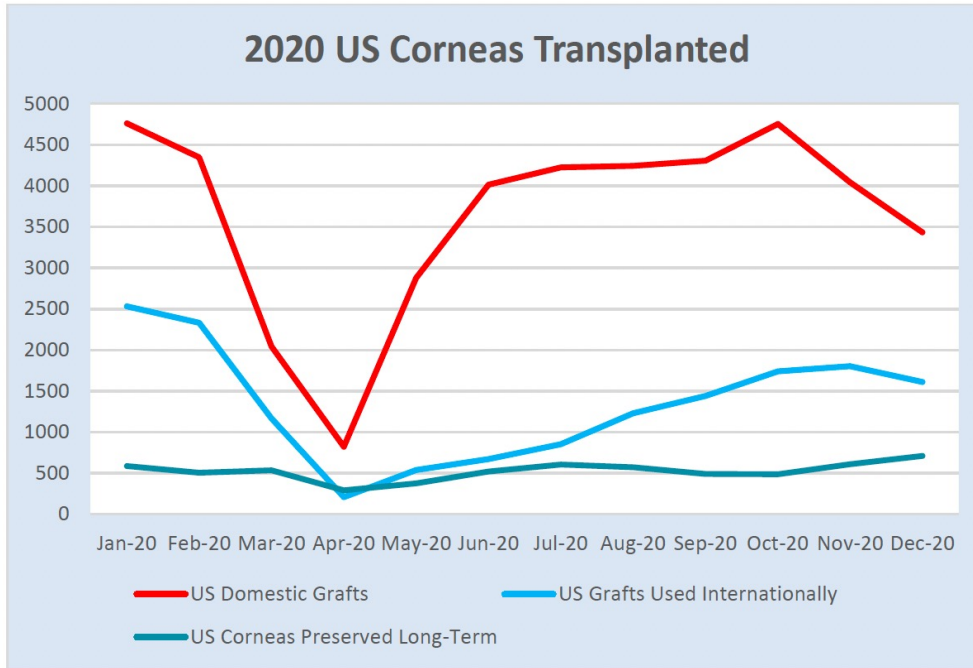


## Why establish local donation programs?

- Become **independent** on imports from other countries
    - Costly and uncertain
  
  - Create **added value** within the country
    - Know how
    - Jobs and infrastructure
    - Local level of expenses and reimbursement costs making tissue medicine affordable on the long term
-

# Effect of COVID-19 on eye bank activity in US

2020 Eye Banking Statistical Report, EBAA



Reduced number of corneas for transplantation – decreased export

# COVID-19 pandemic on cornea donation and donor selection across Europe

Thuret et al. (2020)

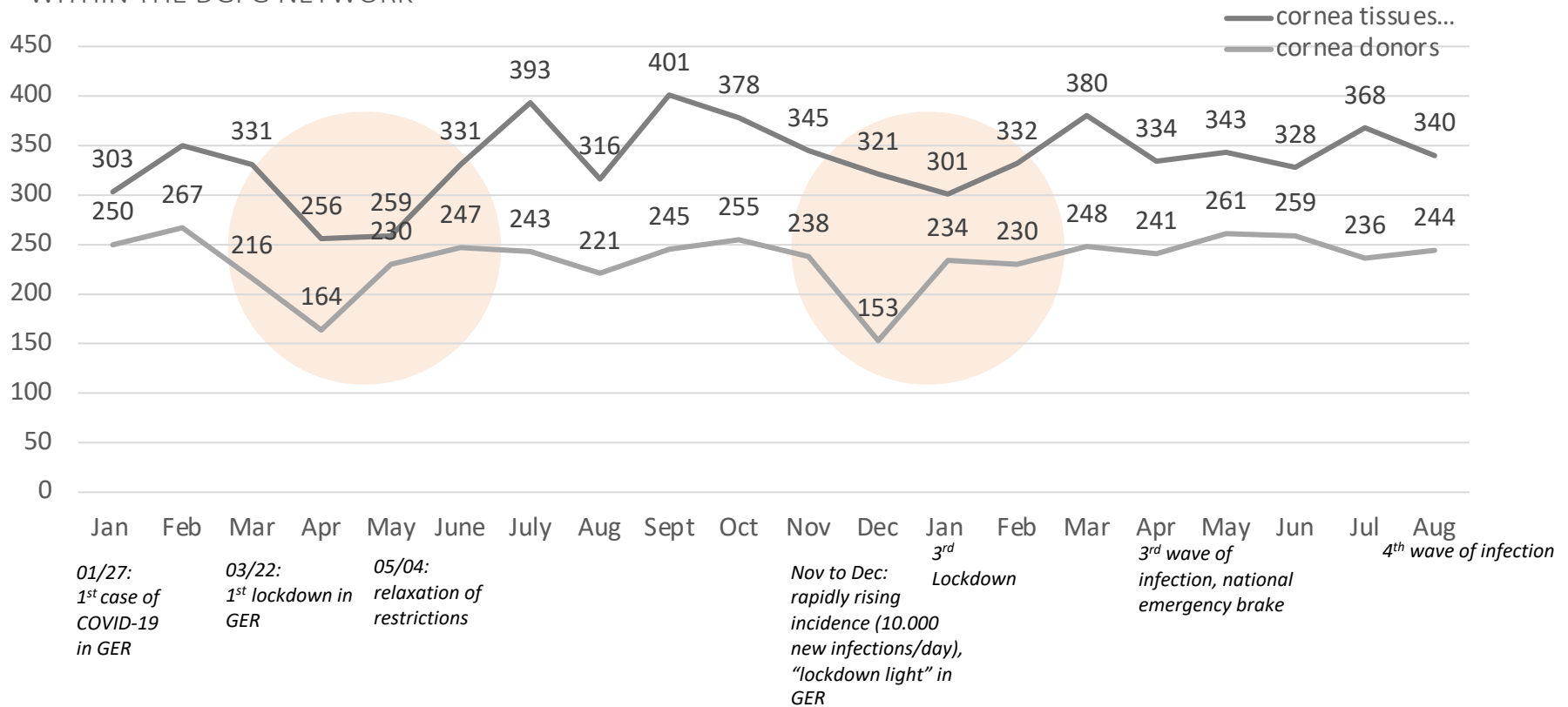
**Table 2** The decrease in the number of corneas procured and distributed in March–May 2020 compared with the mean of the same trimester in 2018 and 2019, expressed in per cent

Country	Cornea procured	Cornea distributed
Austria	-35.0%	-58.3%
Belgium	-81.2%	-72.3%
Bulgaria	7.7%	4.0%
Croatia	-66.0%	-63.1%
Czech Republic	-13.3%	-32.7%
Denmark	-12.4%	-11.2%
Finland	-73.9%	-59.3%
France	-67.5%	-69.4%
Germany	-0.8%	-5.4%
Italy	-50.0%	-55.8%
Norway	-44.3%	-42.9%
Poland	-63.6%	-65.6%
Portugal	-69.0%	-84.0%
Slovenija	-27.3%	-2.3%
Spain	-66.1%	-65.7%
Sweden	-61.3%	-54.2%
Switzerland	-59.7%	-48.6%
The Netherlands	-63.7%	-64.6%
UK	-59.5%	-66.2%
Total (mean±SD)	-47.7%±26.5%	-48.3%±26.2%

Countries are ordered alphabetically.

# DONATED AND DISTRIBUTED OCULAR TISSUES SINCE THE BEGINNING OF THE COVID-19 PANDEMIC

WITHIN THE DGFG NETWORK



Export to Africa  
decreased by  
50%

Country	From US-Eye Banks - transplanted Corneas in 2020	Difference to 2019
Algeria	5	-508
Cameroon	10	10
Cote d'Ivoire	2	-8
Djibouti	870	-539
Egypt	2.980	-2.955
Ethiopia	2	2
Ghana	56	-3
Kenya	157	-108
Malawi	2	2
Mali	3	2
Marocco	213	-203
Namibia	9	-4
Nigeria	37	-105
Rwanda	32	-53
Senegal	3	2
South Africa	612	-239
Sudan	21	-21
Swaziland	11	-5
Tanzania	7	-42
Tunesia	257	-463
Ugnada	2	-38
Zambia	8	-28
Zimbabwe	1	-9
<b>Total</b>	<b>5.300</b>	<b>-5.421</b>



= - 50,6%





# Where are the tissue banks...

Source: International Registry of Tissue Banking Establishments

**AATB**  
American Association of Tissue Banks

**ALABAT**  
Asociación Latinoamericana de Banco de Tejidos

**SATiBA**  
South African Tissue Bank Association

**APASTB**

**WUTBA**  
WORLD UNION OF TISSUE BANKING ASSOCIATIONS

**European Association of Tissue Banks**

**BAA**  
Biotherapeutics Association of Australasia

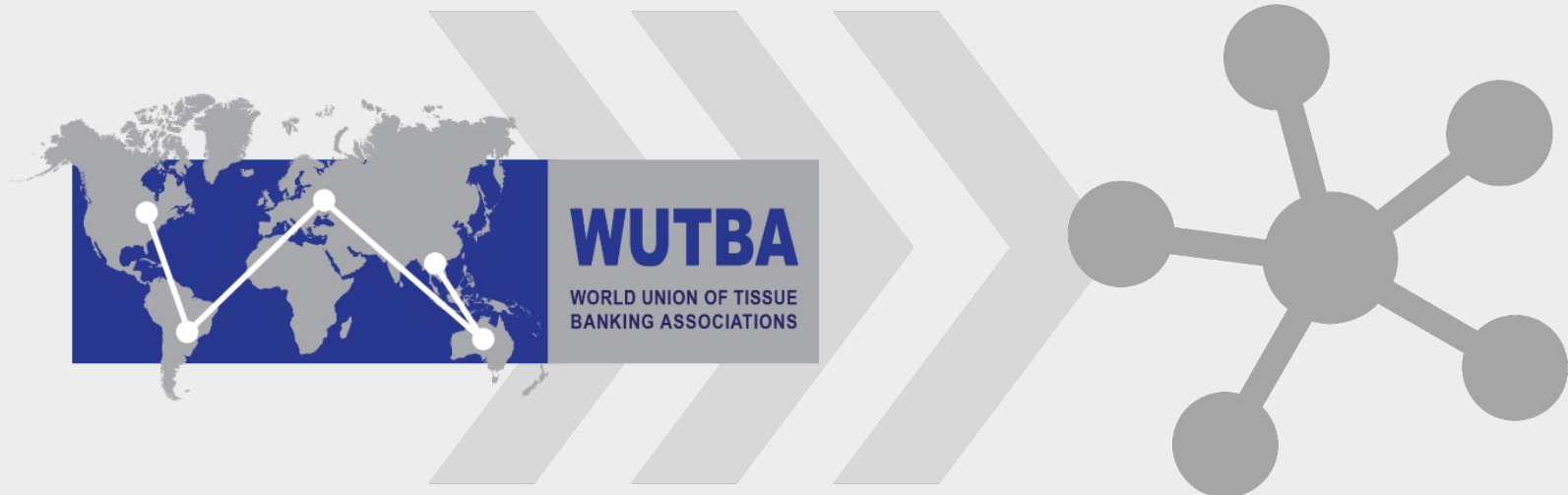
**World Health Organization**

...and what do they do?



WUTBA aiming on...

...bringing together global tissue donation  
and transplantation



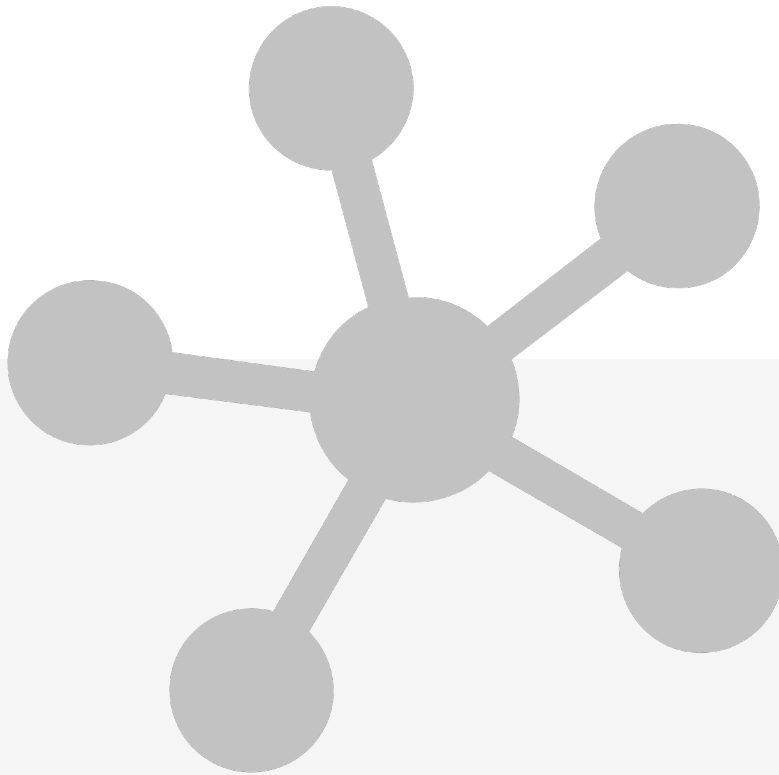


## Aims of WUTBA

- Establish a free association of the world's leading organizations of tissue bank professionals;
- **Support ethical practices in tissue donation and transplantation, and stand against tissue trafficking;**
- Work at harmonizing global practices in the donor screening, procurement / recovery, and processing of human tissues;
- Exchange information on events, activities, standards, regulations, education and research;
- Coordinate meeting schedules and promote scientific programmes (conferences, workshops, etc.) of the member associations;
- Organize, on a regular basis, world scientific meetings and workshops;
- **Establish a global register of tissue establishments;**
- Collect and publish data on tissue donation;
- Collaborate in the establishment of vigilance systems for tissues for transplantation;
- Support universal coding efforts for tissue allografts;
- Act as a global and scientific counterpart in tissue banking for the WHO.



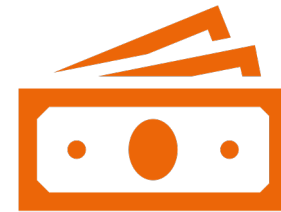
## Tissue traffic



Informed consent?  
Safety?  
Traceability capacity?



Beware of commodification...







Better  
follow...



## *The Barcelona Principles*

An agreement on the use of human donated tissue  
for ocular transplantation, research & future  
technologies



# The Barcelona Principles

- Global Bioethical Framework for Ocular Tissue
- Eye bank & Ophthalmic communities
  - Both the providers and users
- Management & Utility of altruistic donations
  - Both treatment and research
- Retention as a public resource
  - Custodianship & Stewardship





## The Barcelona Principles

- Declaration of Istanbul on Organ Trafficking and Transplant tourism
- Universal Declaration of Human Rights
- Declaration of Helsinki - Ethical principles for research involving human subjects
- World Medical Association Statement on Organ & Tissue Donation
- W.H.O Guiding Principles on human cell, tissue and organ transplantation (WHA63.22)





contact to the  
family/next of  
kin for consent

- ✓ What has to be the minimum Information?



## 4) Fairness

Promote fair,  
equitable and  
transparent  
allocation  
mechanisms

Implement systems, criteria and standard operating procedures that are based on recipient outcome need/urgency

- ✓ Promote this system to surgeons/transplant facilities
- ✓ Adhere to jurisdictional laws and regulations
- ✓ Promote systems that prevent waste of the altruistic and voluntary donation
- ✓ Prevent donation and allocation systems that restrict the equitable access to CTO





## 5) Collaboration

Uphold the integrity of the custodian's profession in all jurisdictions.

- ✓ Collaborate with other Custodians – both governmental and non-governmental
- ✓ Work harmoniously within the sector, promoting ethical partnerships and good practice
- ✓ Maintain appropriately trained staff through the provision of qualification programs and continual professional development
- ✓ Share knowledge, skills, and resources



## 6) Transparency

Develop high-quality services that promote ethical Cell/Tissues/Organs management, traceability, and utility.

- ✓ partnerships, policy and business/operational activities aligning with the WHO guidelines WHA63.22, 2010 & recommended sector standards
- ✓ reporting, tracking and labelling systems to track CTO movement and utility
- ✓ provide de-identified donor and recipient transplant data to available recognised jurisdictional data tracking registries inclusive of import/export data
- ✓ comply with all relevant jurisdictional laws and legislations
- ✓ no trafficking, tampering, forgery, falsification and counterfeit activities



## 7) Sustainability

Develop  
local/national  
self-sufficient  
services.

- ✓ Prioritise domestic need over exportation
- ✓ Utilise cross-border collaborations/activities while developing own services
- ✓ Comply with jurisdictional laws regarding allocation of domestic tissue to citizens, residents and/or foreign nationals



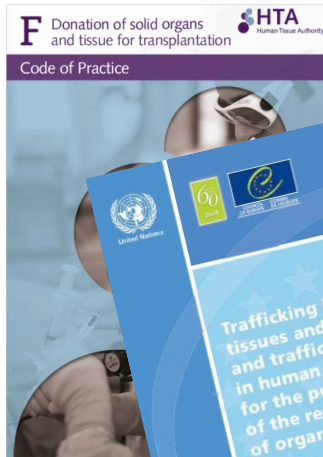
## 8) Control exchange

Recognise and address the potential ethical, legal and clinical implications of cross-border activities.

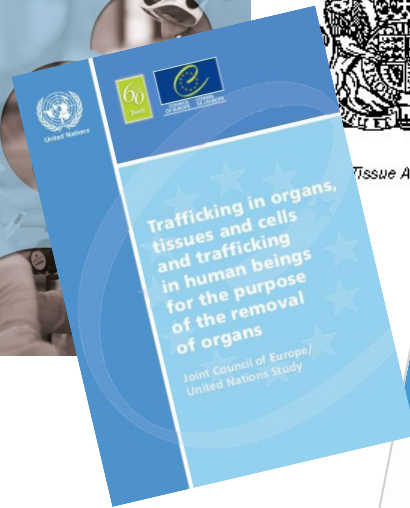
- ✓ ensure rigorous import and export processes are in place to guarantee the ethical, legal and best use of the CTO
- ✓ respect local systems when working in a foreign country/jurisdiction
- ✓ importers and exporters should report issues regarding cross-border activities to local competent authorities/relevant stakeholders



# Ethical framework law & policies



**The Human Tissue Act 2004**



GAEBA Global Bioethical Framework

“Barcelona Principles”



[www.wutba.org](http://www.wutba.org)

Altruistic donation

Rights of donors (informed consent, privacy)

Right of recipients (equality in access)

Respect to the human origin (no trade)

Sharing the load (self-sufficiency)





*Visit us online!*



**WUTBA**  
WORLD UNION OF TISSUE  
BANKING ASSOCIATIONS