



World Health
Organization

ESSENTIAL
HEALTH SYSTEMS
TECHNOLOGIES
GOVERNANCE
AND SERVICE DELIVERY

Identification and Monitoring of
Organs, Tissues and Cells, WHO Perspective



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Coordinator "Clinical Procedures" HSS/HDS/CPR

World Health Organization Geneva

World Health Assembly Resolution WHA57.18

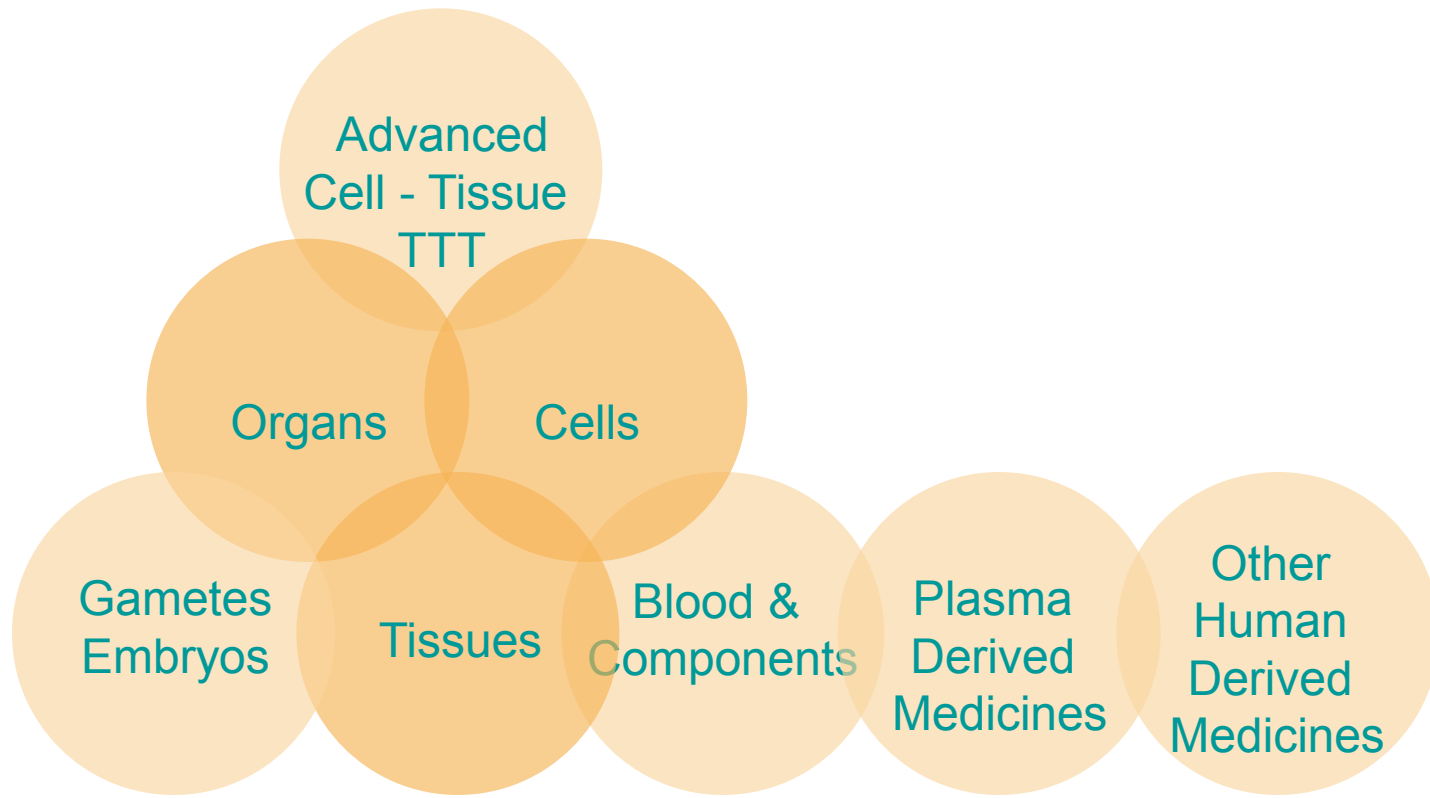
Cell Tissue and Organ Transplantation

URGES Member States:

- 1) to implement effective **national oversight** of procurement, processing and transplantation of human cells, tissues and organs, including ensuring **accountability** for human material for transplantation and its **traceability**;

Governments are responsible

Health Products of Human Origin HPOHO

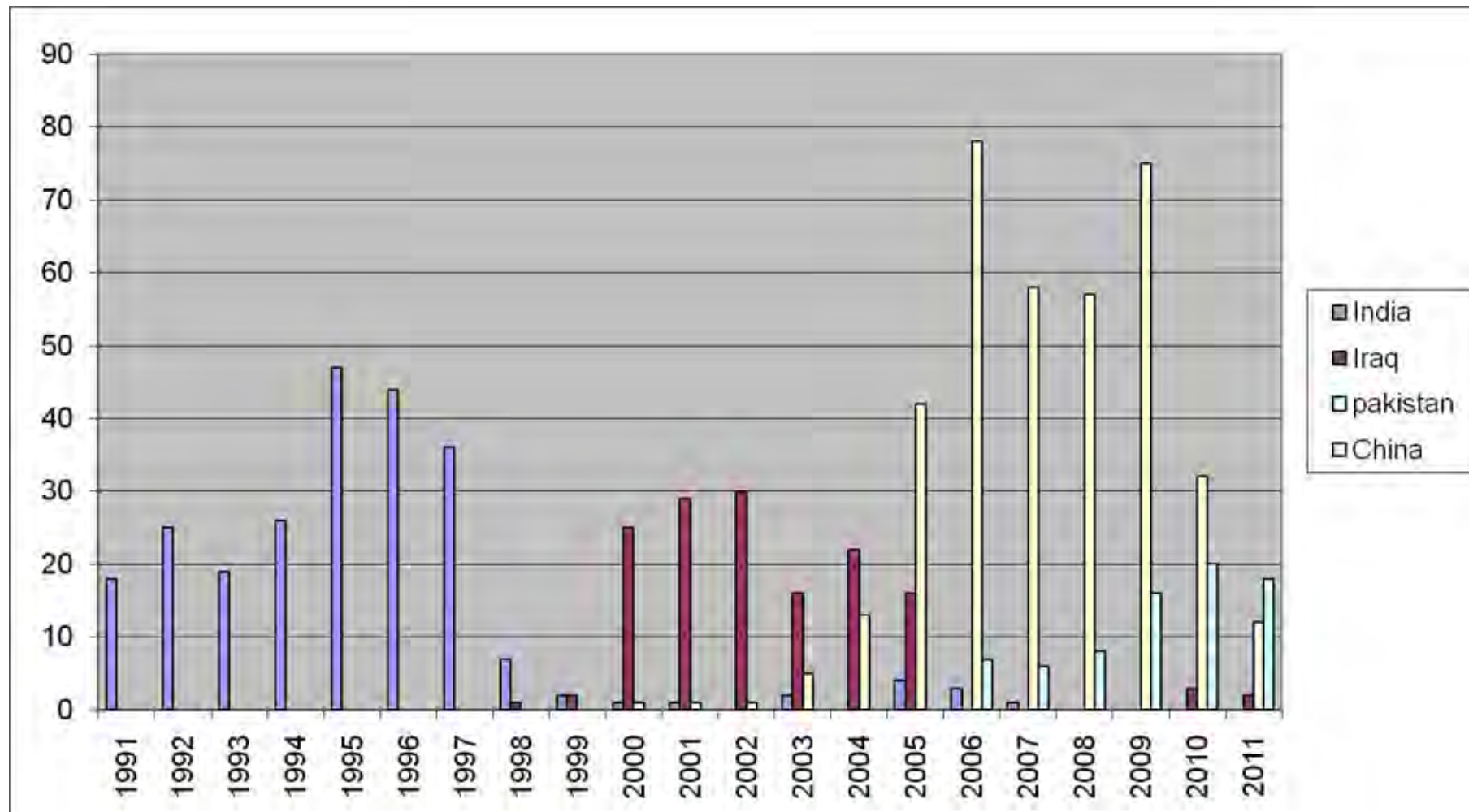


Humanity





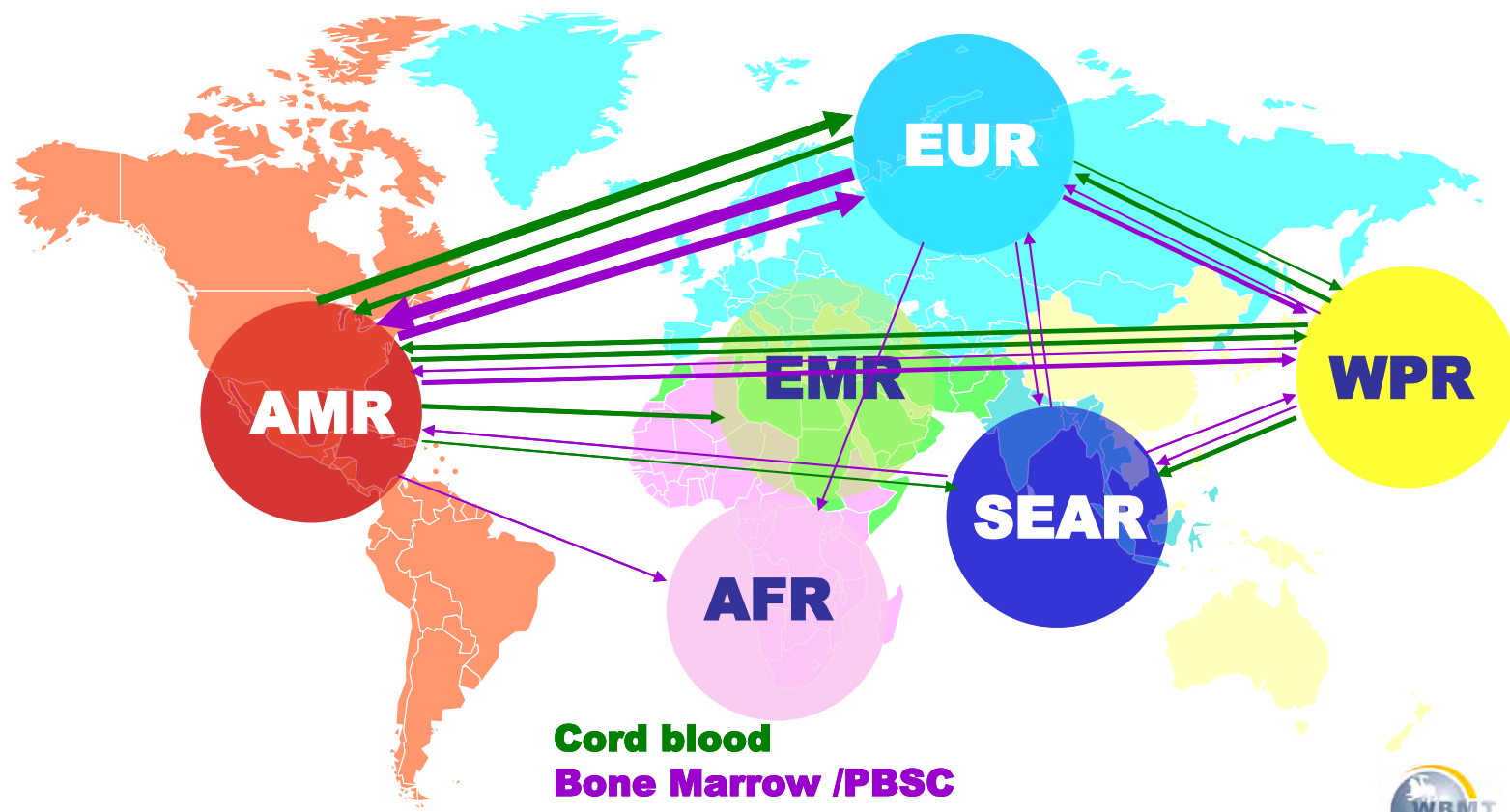
Unrelated Kidney Transplantation in Oman 1991-2011 Country of Transplantation



International Circulation of Hematopoietic Stem Cells per WHO Region

Unrelated Cord Blood, Bone Marrow and Peripheral Blood Stem Cells 2009

A compatible non-related HSC donor is now more frequently identified in another country



FlexiGraft™

Donated Human Tissue

Allowash® Tissue Processed
Using Proprietary Technology

HUMAN FROZEN TISSUE
STORE BETWEEN -40 C AND -80 C

Code: FBPL
Graft ID: 06-4026-005
Description:
BISECTED PATELLAR
LIGAMENT (FR)
Size:
I=1.5 TL=5.4 BB=12.6 CM
Exp. Date: OCT 11 2011

Processed with Bacitracin /
Polymyxin B Sulfate
or Gentamicin



R STERILE

06-4026-005
FBPL
I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet
06-4026-005
FBPL
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Distributed by LifeNet
06-4026-005
FBPL
I=1.5 TL=5.4 BB=12.6 CM
Distributed by LifeNet

SINGLE PATIENT USE ONLY
See Package Insert for Handling

 LifeNet - 5809 Ward Court - Virginia Beach, VA 23455 - 1-888-847-7831

MTF Musculoskeletal Transplant Foundation

Human Allograft Tissue

DESCR: ILIAC CREST WEDGE 10-12mm (ACF)

PROD CODE: 100402

DIMEN: T: 11mm L: 1.8cm W: 15mm W2: 11mm

SERIAL #: MTF 005592290035 EXP. DATE: 07Jan2010

FREEZE-DRIED Store at Room Temperature. Do not freeze.

LBL081 Rev. 07/05

Aseptically processed, passes USP <71> for Sterility

Tissue is recovered under aseptic conditions and is aseptically processed. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.

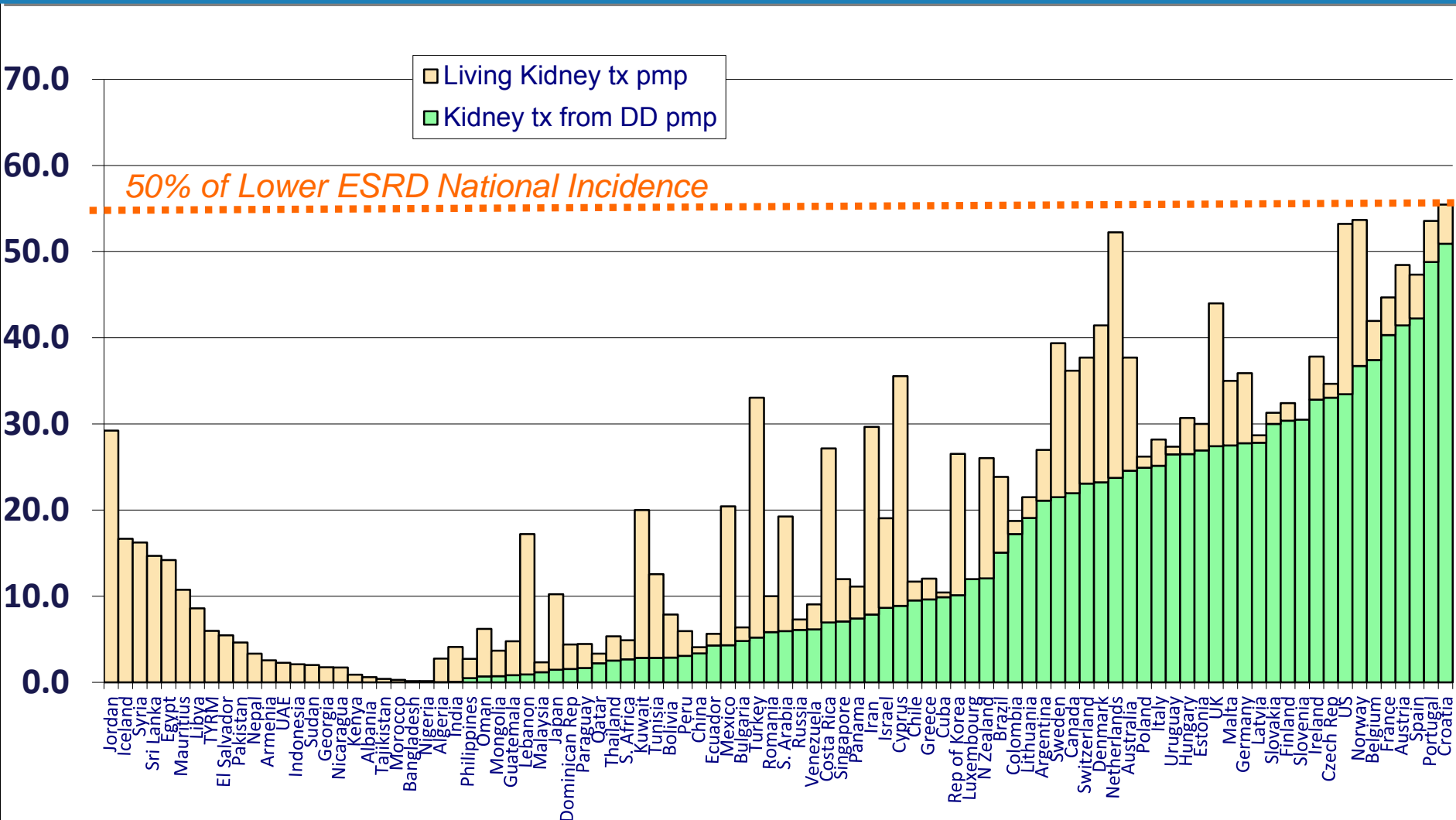
125 MAY STREET
EDISON, NJ 08837
(800) 433-6576

Processed by

 **OSTEOTECH**
Innovators in Musculoskeletal Science



Kidney Transplantations from Deceased and Living Donors Per Million Population (pmp)




Value of Coding and Machine Readable and Checkable Labels

Recent case at U of Minnesota: September 2011
Copy of information from UNOS Form accompanying the organ

Donor Summary for *****
(Donor ID: YIF133) (Match ID: 680417)

LEFT LUNG

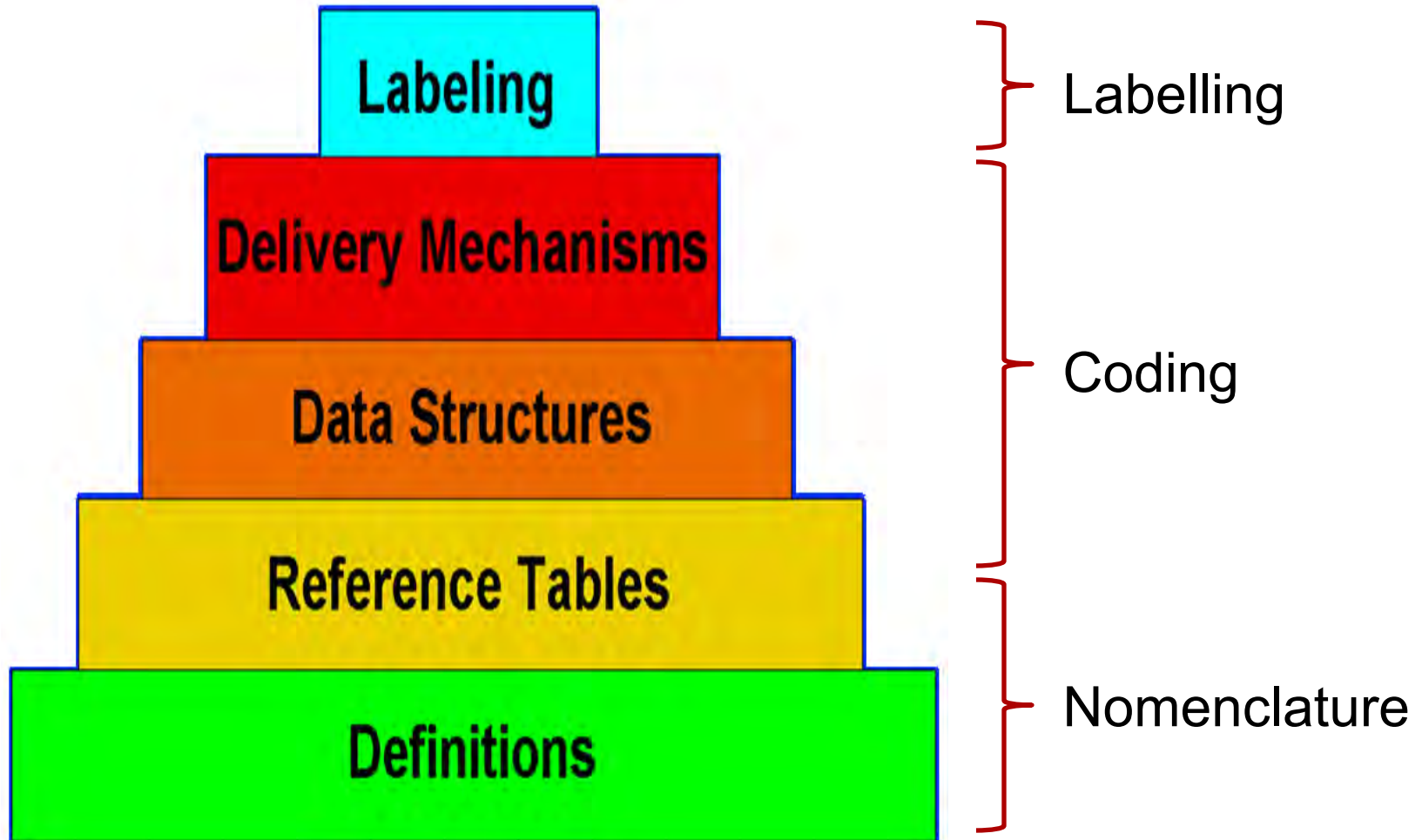
UNOS ID	DONOR ABO
YIF233	O

BIOHAZARD 

20 to 30 % of organ donors are also tissue donors

Courtesy Dr Timothy Pruett

Information Hierarchy



GP 10 Quality safety efficacy of procedures and transplants

High quality, safe and efficacious **procedures** are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.

The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health **products of an exceptional nature**, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

GP 10

Quality safety efficacy of procedures and transplants COMMENTARY

Transplantation of human material which does not involve maintenance treatment may not require active, long-term follow-up, though traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed means of coding to identify tissues and cells used in transplantation are essential for full traceability.

II- URGES Member States:

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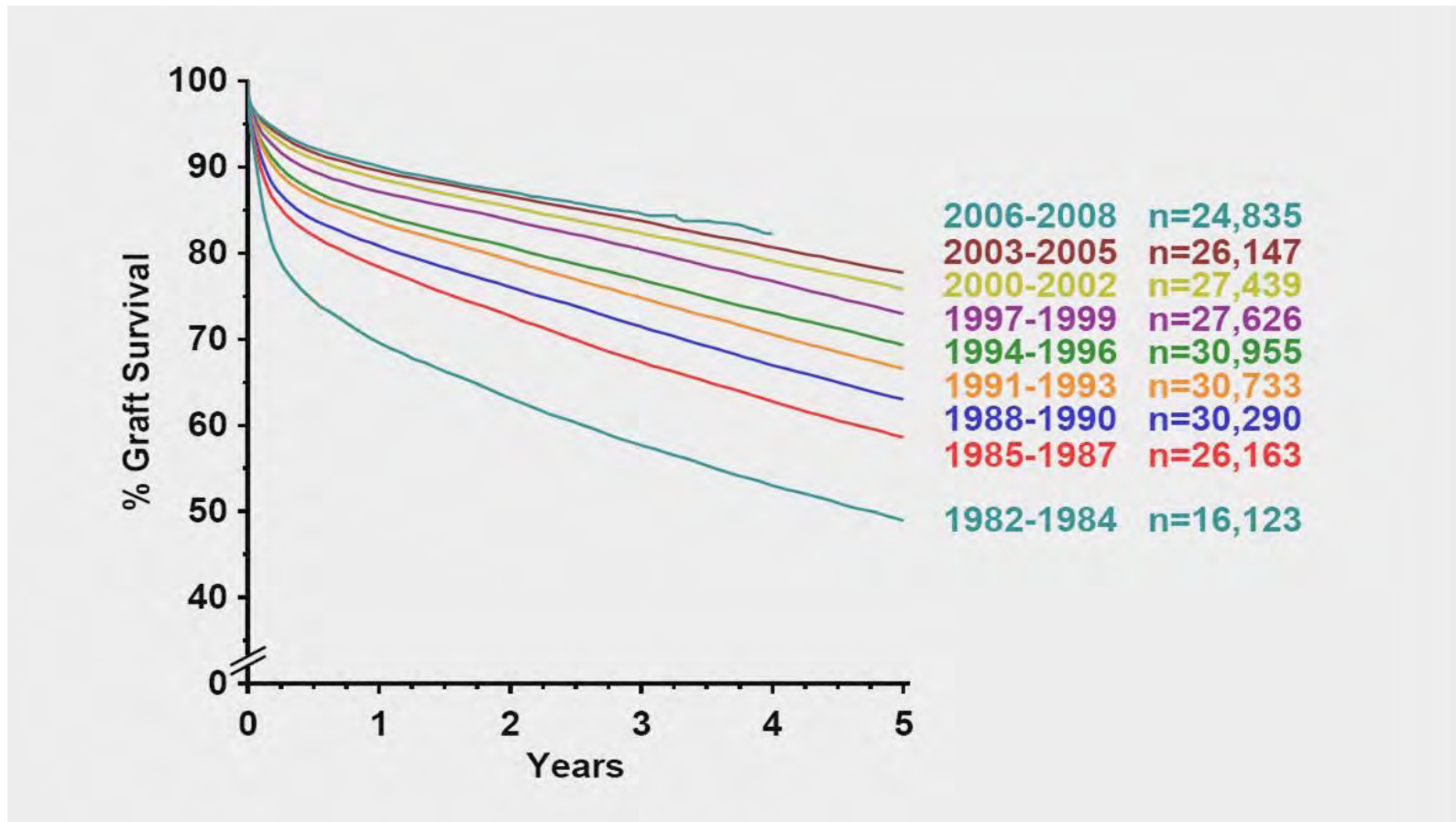
- 5) to improve the safety and efficacy of donation and transplantation by promoting international best practices;
- 6) to strengthen national and multinational authorities and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protecting the health and welfare of living donors with appropriate health-care services and long-term follow up;
- 7) to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation;
- 8) to encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation;

3. REQUESTS the Director-General:

- (1) to disseminate the updated Guiding Principles on Human Cell, Tissue and Organ Transplantation as widely as possible to all interested parties;
- (2) to provide support to Member States and nongovernmental organizations in order to ban trafficking in material of human origin and transplant tourism;
- (3) to continue collecting and analysing global data on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation of human cells, tissues and organs;
- (4) to facilitate Member States' access to appropriate information on the donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions;
- (5) to provide, in response to requests from Member States, technical support for developing national legislation and regulation on, and suitable and traceable coding systems for, donation and transplantation of human cells, tissues or organs, in particular by facilitating international cooperation;

Graft Survival per Transplant Year

First Deceased Donor Kidney Transplants



Collaborative Transplant Study - Heidelberg

ICCBBA

International Council for Commonality in Blood Banking Automation



- International not-for-profit information standards organization established more than 15 years ago by transfusion specialists to facilitate traceability and the international circulation of blood components
- ISBT128 standards are now being used by more than 3,700 facilities in 67 countries handling blood and blood components, cellular therapies and the whole range of tissues
- ISBT 128 can provide the global solution for identifying organs for transplantation using globally unique donation identification and standard nomenclature
- WHO has engaged in working relations with ICCBBA through a structured collaboration in order to develop:
 - 1. WHO Nomenclature for organ transplants,
 - 2. Global Core nomenclature of cell, tissue and organ transplant suitable for activity reporting at Member State level
 - 3. Increased awareness of the need for global traceability and vigilance,.

The WHO SONG Project: Development of a Nomenclature for Organ Transplants

Collaboration with the International Council for Commonality in Blood Banking Automation (ICCBBA)

3 steps:

1. Creating categories to describe each organ independently of donation / donor characteristics, relevant for transplantation
2. Analysis of relevant characteristics for transplantation purpose, identifying what is relevant for each organ
3. Organizing all information by categories, i.e. creating a structure for 'what is in the box', the essential information that will optimize stewardship of organs donated for transplantation

= Initial framework to stimulate a discussion within the donation/transplantation community.

Standardization of Organ Nomenclature Globally

Towards a coding system for organ transplants



Procurement

- Donation number
- Transplant characteristics
- Processing
- Procurement centre

- Donation number
- Transplant characteristics
- Processing
- Transplantation centre



Follow-up

Transplant ID

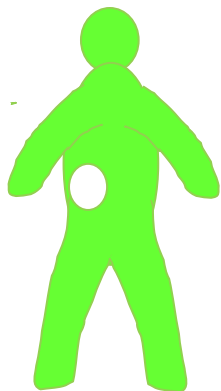
Transplant ID

Transplant ID

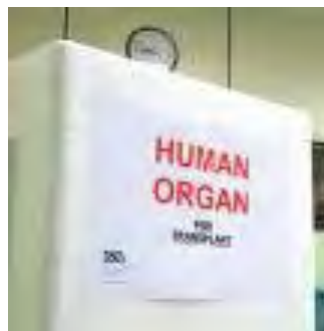
Transplant ID

- Donor ID
- Donation number
- Donor characteristics

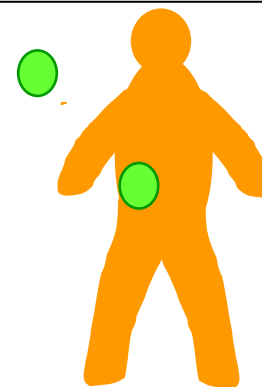
- Donation number
- Transplant characteristics
- Transplantation centre



Donor



In the box:
Transplant ID
Source/ procurement ID
Essential donor and transplant data for (re)allocation
Data on transportation and processing ➔

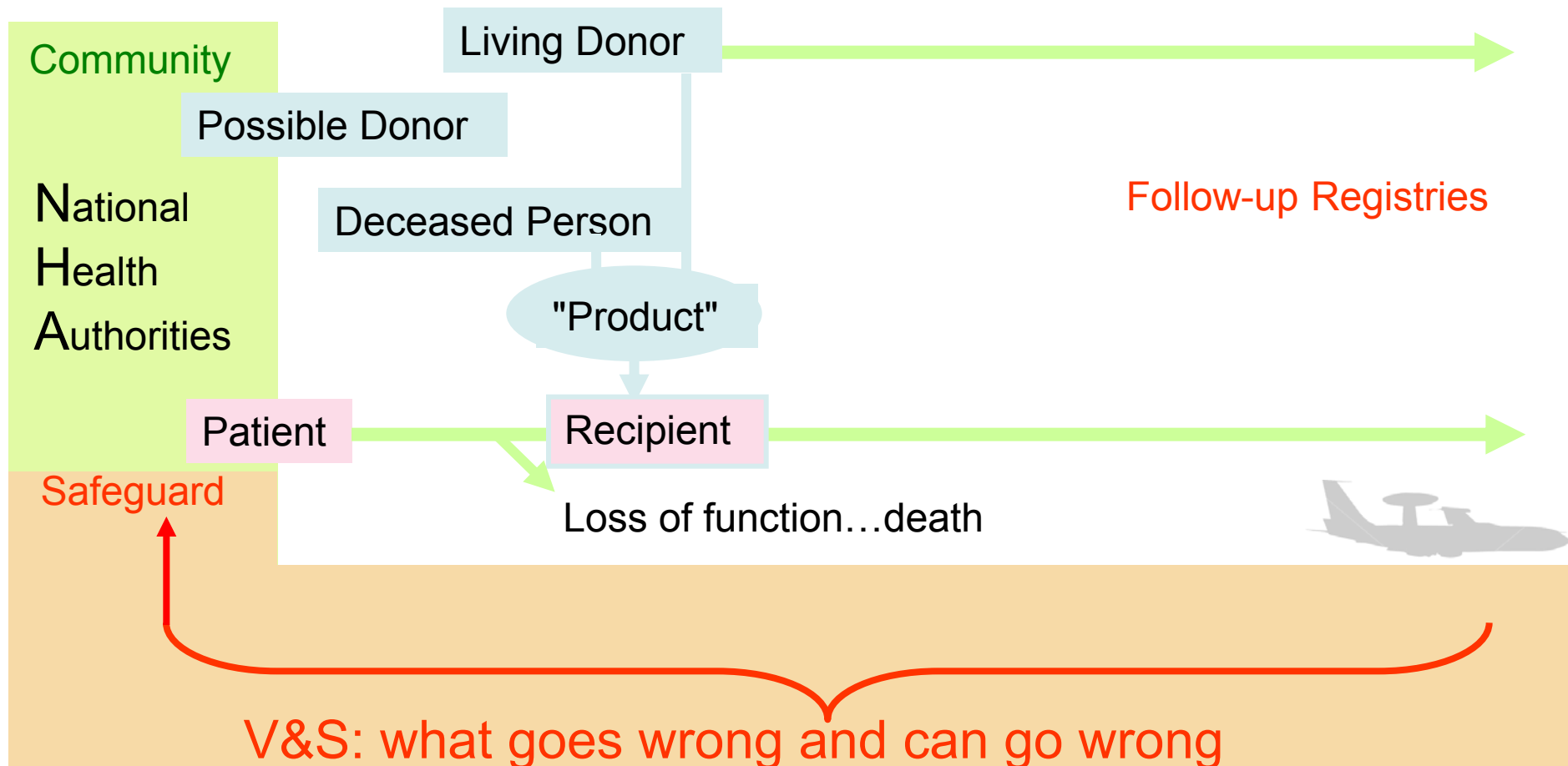


Recipient

V&S: Vigilance and Surveillance

A safeguard of transparency across the donation and transplantation process

Quantitative and qualitative data including non-conformity, failures, risks
Quality Management Systems - Good Practices



US Advisory Committee on Blood Safety and Availability

June 7-8 2011 NIH Bethesda

The Committee recommended the Secretary to establish a task force to:...

4. identify ways to promote adoption of standardized systems (e.g., ISBT-128) for identification and codification of all organ transplants (including country of origin for those acquired abroad) to facilitate tracking and traceability
5. Coordinate with established biovigilance efforts to ensure reporting, tracking and monitoring of transplantation related adverse events to improve outcomes

Conclusions

- Monitoring of patient and live donor outcomes is inherent to HPOHO
- The national and international circulation of CTO requires consistent coding systems to facilitate safety and ethics of procedures and products
- The commonality of ethical and safety risks across HPOHO mandates to strive towards straightforwardly compatible coding systems
- There is an opportunity to achieve consistency of coding systems for HPOHO by building on the existing global ISBT128 system
- WHO is in working relationship for with ICCBBA for the development of WHO nomenclature of organ transplants
- Several national organizations are considering adopting ISBT128 (feasibility assessment by UNOS, National Transplant Committee of China)



Thank you

noell@who.int



**World Health
Organization**

