

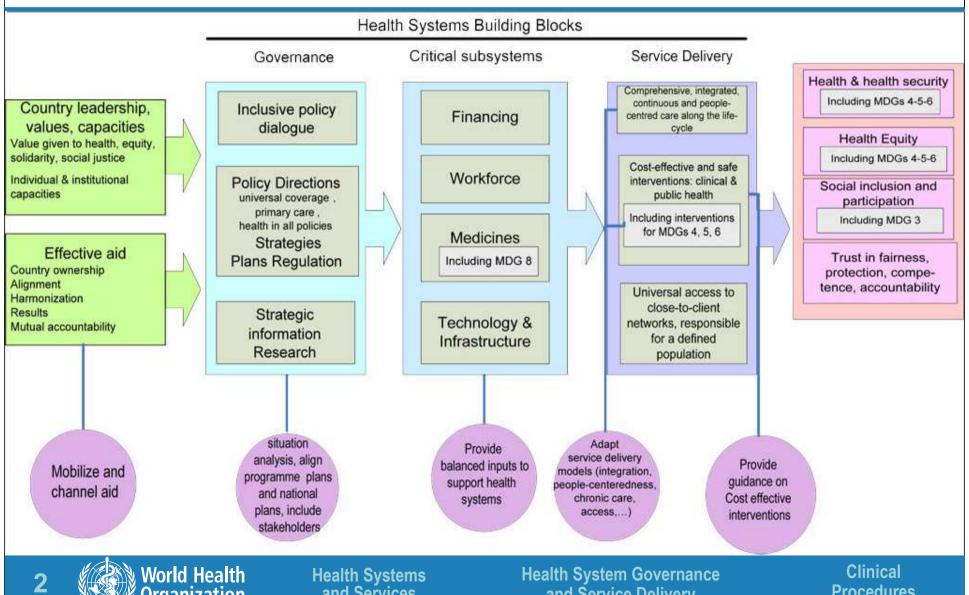
GOVERNANCE AND SERVICE DELIVERY

The World Health Organization and Haematopoietic Stem Cell Transplantation



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WHO Approach to National Health Policy and Plan Development



Health Systems Building Blocks

PHC values and principles

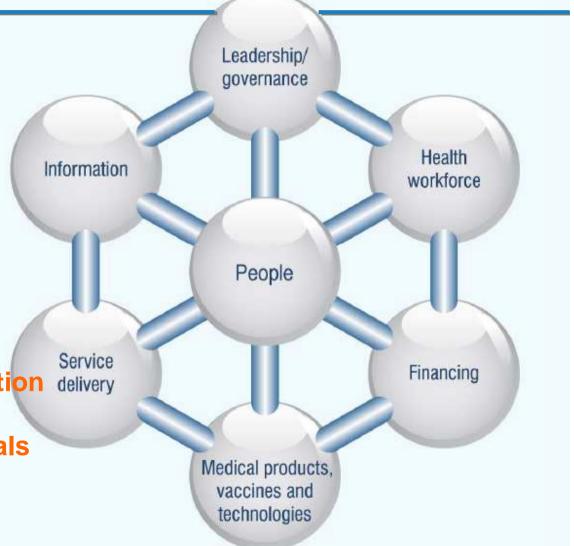
- Solidarity
- Social justice
- Universal access
- Multisectoral action
- Community participation delivery

Health Systems

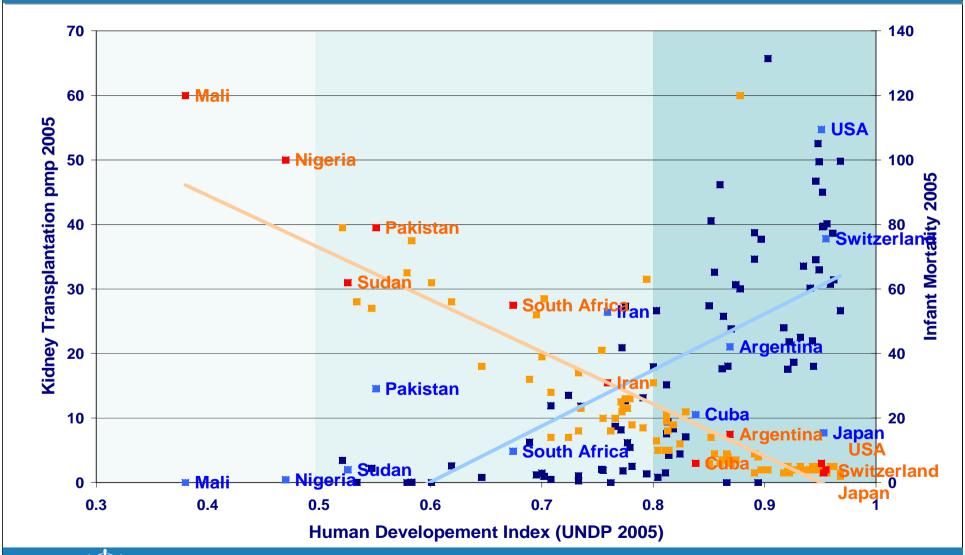
and Services

Millennium Development Goals

(3) 4, 5, 6 and (8)



Kidney Transplantation pmp and Infant mortality per 1000 live births vs Human Development Index



Health Systems

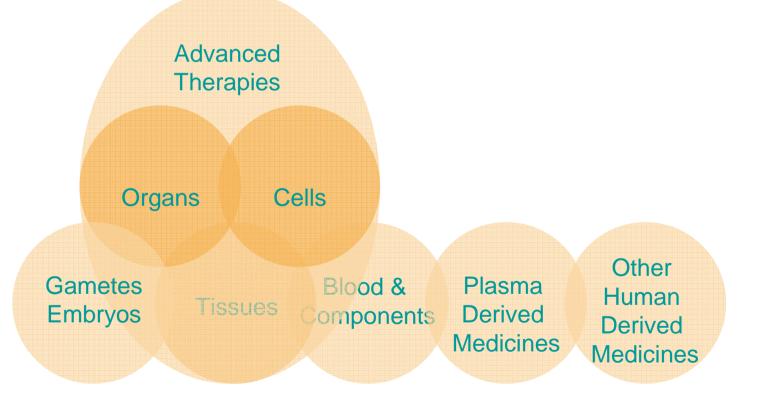
Why is WHO Focusing on Transplantation

- **Ethics** against exploitation of donor and recipient and societal consequences (WHA 40.13)
 - Combatting commercial transplantation trafficking and tourism
 - Self Sufficiency paradigm
- Health products of human origin
 - National Regulatory authorities: safety, quality efficacy and trust of the public in donation
 - Vigilance and Surveillance on ethical and safety risks
- Trends in care for the future
 - Quality and progress of replacement and regenerative therapies to be submitted to same levels of requirements and oversight
- High cost tertiary care yet less expensive than alternatives
 - E.g. haemodialysis and kidney transplantation
- Concept of suitable transplantation ,
 - Equity in the population, tertiary care and public/private partnerships, human resource for health and academia



Health Products of Human Origin HPOHO





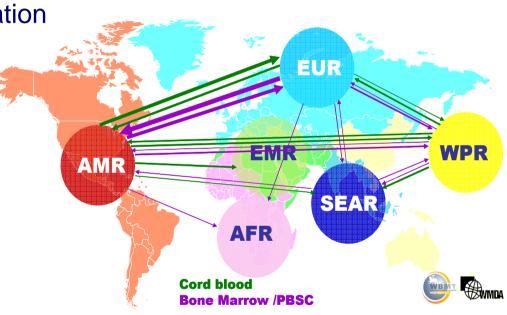
Health Systems

HSCT an Example for Cell/Tissue based Regenerative Therapies

Evidence based haematology

Regional and Global interrelation

- Global circulation of HSC
- Accreditation AHCTA
- Vigilance and Surveillance
 - Donors and recipients
- Coding ISBT 128
- Collaboration with Health Authorities



Stemcell "Therapies"

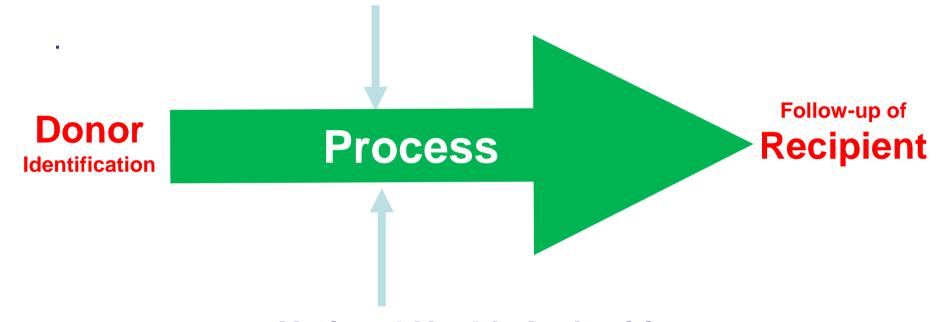
http://stemcelltreatments.org/stem-cell-therapy/ November 2011





Complementary Roles of SPS and NHA

Scientific and Professional societies (SPS): optimal, regional or global, standards and accreditation.



National Health Authorities: minimal, requirements, inspection and licensing

Health Systems

Partnerships, Collaborations and Global Consultations Process

Network





















- National Transplantation Agencies
- National Regulatory Authority
- Policy makers
- Scientific and Professional Societies
- Official relation with The Transplantation Society
- Experts Ethicists, lawyers
- Patients- Donors and Recipents
- Civil society
- Every Region of the Globe and level of

 development

Towards a Common Global Attitude to Transplantation

Health Systems

References

 World Health Assembly resolutions on human organ and tissue transplantation:

• 2004: WHA57.18

2010: WHA63.22

•WHO Guiding Principles on human cell, tissue and organ transplantation (GPs) 2010

Available at: http://www.who.int/transplantation/en/

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

World Health Assembly Resolution WHA57.18 Cell Tissue and Organ Transplantation

- 2. REQUESTS the Director-General:
- (2) to promote international cooperation so as to **increase the access** of citizens to these therapeutic procedures;
- (3) to **provide**, in response to requests from Member States, technical **support for developing suitable transplantation** of cells, tissues or organs, in particular by facilitating international cooperation;

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

GP 5 Free donation and no purchase of human transplant as such,

WHA63.22

(3) to oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking and transplant tourism, including by encouraging healthcare professionals to notify relevant authorities when they become aware of such practices in accordance with national capacities and legislation;

Professionals reporting to authorities

Coi

Donor

Process

recibleut

GP 10 Monitoring long term outcomes. Quality and safety of procedures and products

GP 11 Transparency, openness to scrutiny, anonymity



Joint Council of Europe/United Nations Study

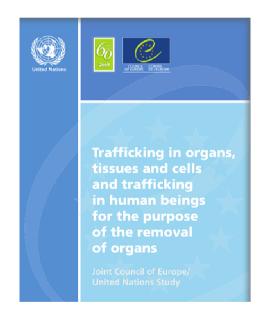
- Prohibition of making financial gain with the human body and its parts as such.
- Identifies the difference between trafficking in human body parts and trafficking in human beings for the procurement of human body parts.
- Recognizes the need for an international binding legal instrument that would prohibit trafficking in human body parts.

Trafficking in cells, tissues and organs:

1. Financial gain on the human body and its parts as such

Health Systems

- 2. Absence of consent of the donor
- 3. Donation and transplantation operating outside of approved domestic system



2011-2013

WHO Plan of Work on Transplantation

Needs Costs/Effectiveness **Costs Containment** V&S BIG V&S **Ethical Watch** Oversight Quality Safer Vigilance and (DICG Istanbul) Surveillance Global NRA Network Guidance for death Inspection Guidance determination Licensing **Assistance** Coding to countries Guidance / Assistance for legal and 4Ds organizational framework Legal Suitable Regulatory **Organizational Transplantation Oversight Framework** Dissemination WHA Global Observatory of Donation and Transplantation

Health Systems



2011-2013

Evidence WHO Plan of Work on Transplantation

Needs Epidemiology Prevention

Costs/Effectiveness **Alternatives**

Costs Containment **Equitable Access**

V&S **NOTIFY**

Surveillance

TULLER SITTLE

Guidance for death determination

Four Informative networks:

Guidance Scientific and Professional Societies and Governmental Agencies

Assistance to countries

4Ds

Guidance / Assistance for legal and

The GODT

organizational framework Activities and practices

or a Legal and Organizational Frameworks

Francyork WHO-ONT Transplantation

Dissemination WHA

WBMT

Global Observatory of Donation and Transplantation



World Health Assembly Resolution WHA63.22 Cell Tissue and Organ Transplantation

1. URGES Member States:

(2) to cooperate in the formulation of recommendations and guidelines to **harmonize global practices** in the procurement, processing and transplantation of human cells, tissues and organs, including development of minimum criteria for suitability of donors of tissues and cells;

World Health Assembly Resolution WHA63.22 Cell Tissue and Organ Transplantation

2. URGES Member States:

- (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;

World Health Assembly Resolution WHA63.22 Cell Tissue and Organ Transplantation

Health System Governance

and Service Delivery

2. URGES Member States:

- (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;

WBMT/WHO Collaboration Plan

- Activity 1 International data gathering and publication
- Activity 2 Promotion of Access to HSCT Donation
- Activity 3 Promotion of Access to HSCT Transplantation
- Activity 4 Provision of Expert Advice to WHO
- Activity 5 Vigilance and Surveillance of HSCT

Health System Governance

and Service Delivery

Transplantation in Health Systems Building Blocks

Solidarity

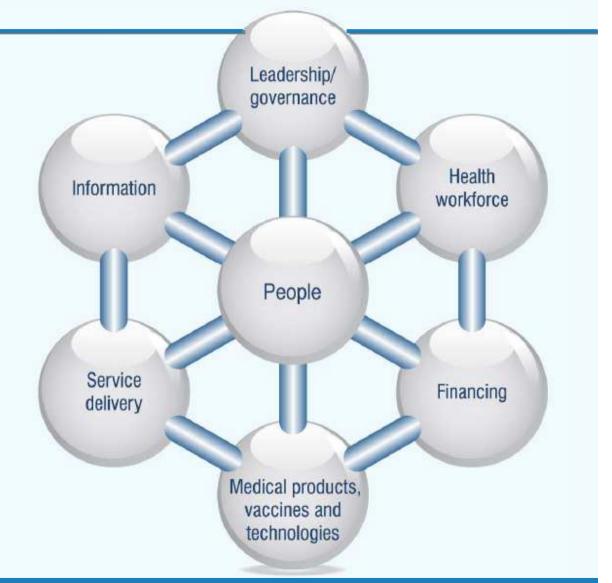
Social justice

Universal access

Multisectoral action

Community participation

PHC values and principles





Thank you



