World Health Organization

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World Health Organization

Vigilance and surveillance in solid organ, tissue and cell transplantation : the role of WHO in the management of transplant activities

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World Health Organization

Health topics | Data | Media centre | Publications | Countries | Programmes | Governance | About WHO | Search

About WHO

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

WHO Constitution

Who we are

WHO began when our Constitution came into force on 7 April 1948 – a date we now celebrate every year as World Health Day. We are now more than 7000 people working in 150 country offices, in 6 regional offices and at our headquarters in Geneva.

Our Constitution and basic documents
Our history
Our structure and presence
Reform of WHO
Multilingualism
Employment
Contact us

What we do

Our primary role is to direct and coordinate international health within the United Nations' system.

These are our main areas of work:

Health systems
Promoting health through the life-course
Noncommunicable diseases
Communicable diseases
Corporate services
Preparedness, surveillance and response.

Read more about what we do
Read about our current leadership priorities

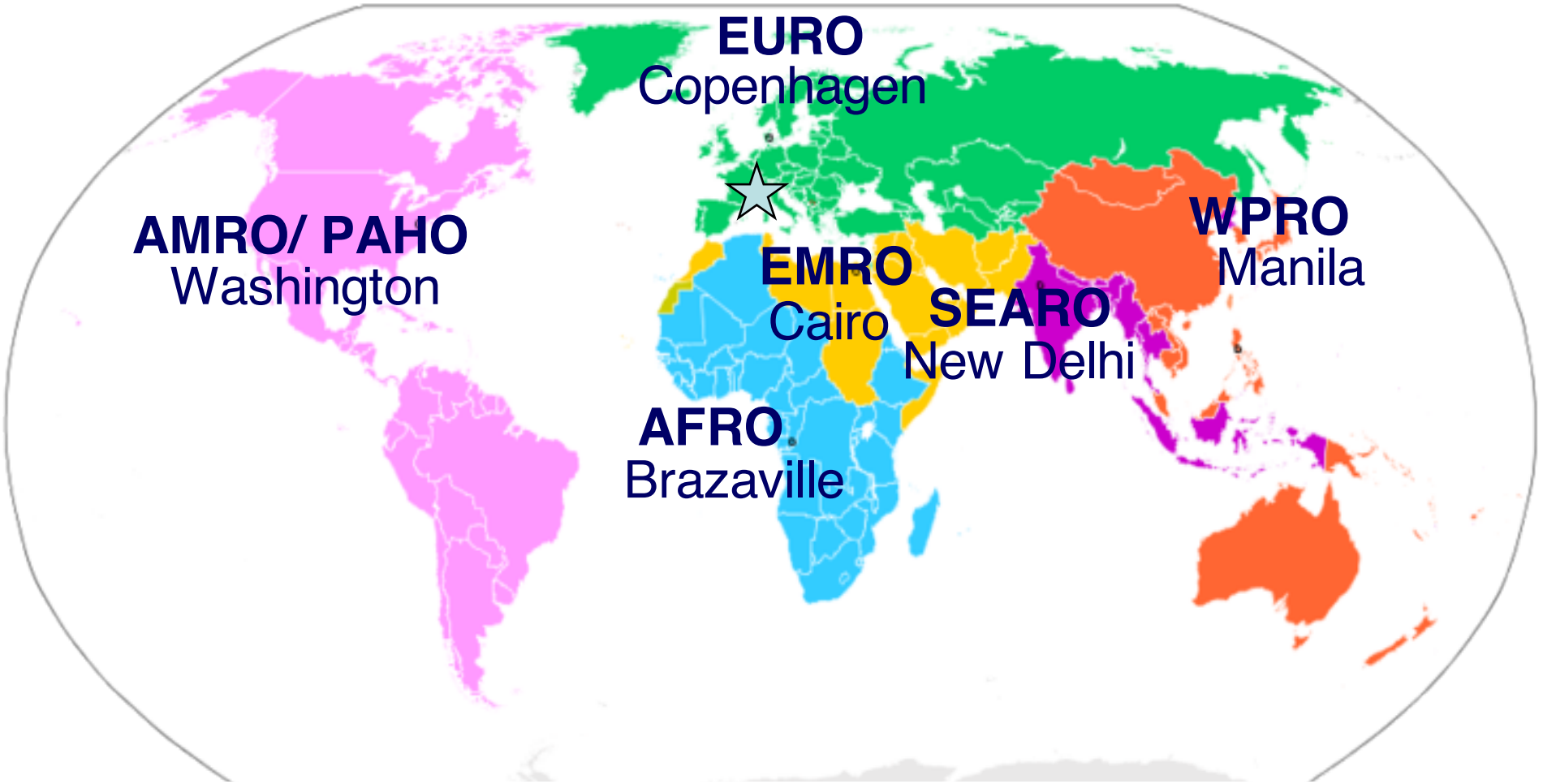
Where we work

We support countries as they coordinate the efforts of multiple sectors of the government and partners – including bi- and multilaterals, funds and foundations, civil society organizations and private sector – to attain their health objectives and support their national health policies and strategies.

Stories on our work in countries
Working with countries
Country specific health information

HQ Geneva

6 Regions of the WHO



W.R. (WHO Representative)

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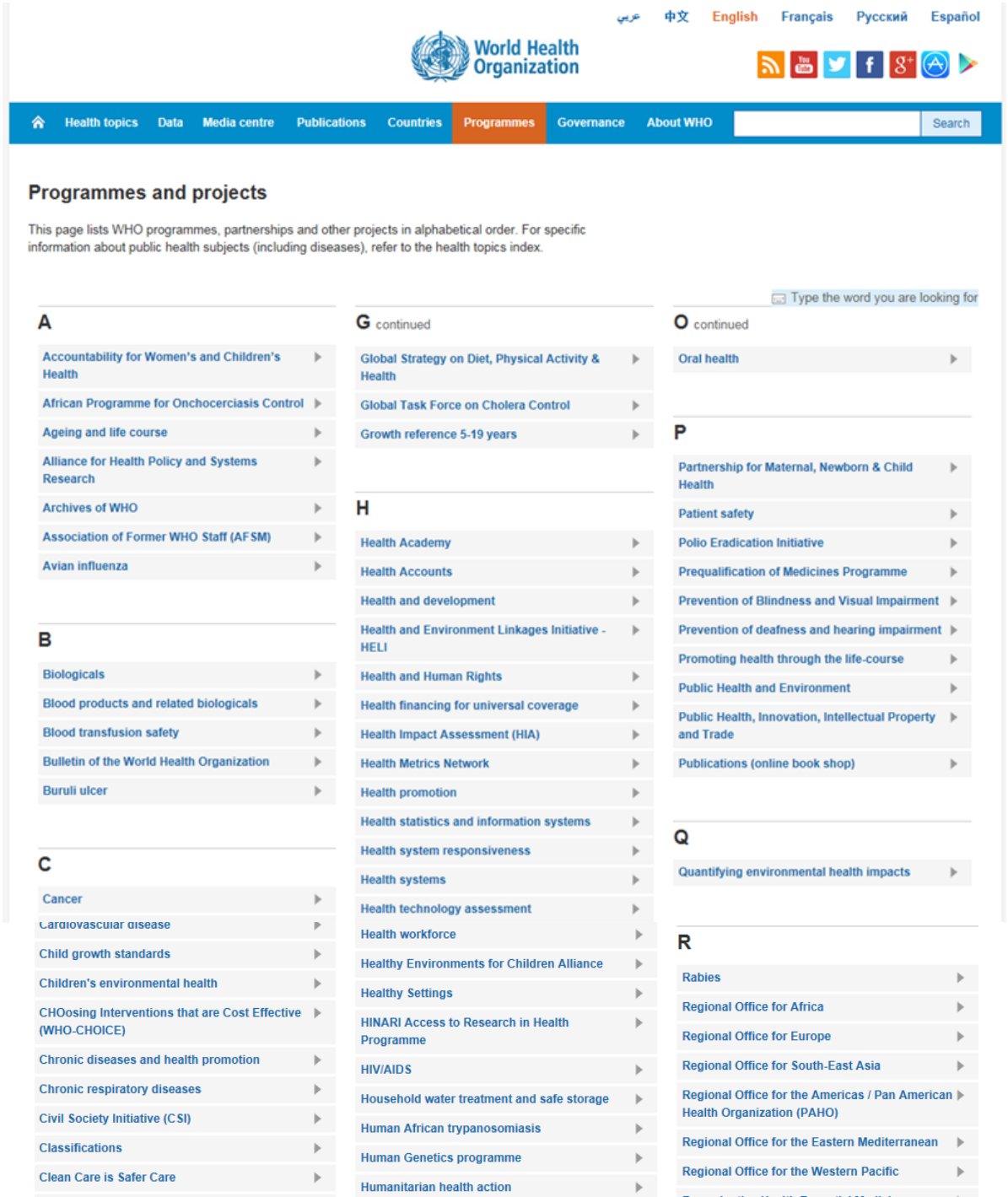

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World Health Organization

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Programmes and projects

This page lists WHO programmes, partnerships and other projects in alphabetical order. For specific information about public health subjects (including diseases), refer to the health topics index.

Type the word you are looking for

A

- Accountability for Women's and Children's Health
- African Programme for Onchocerciasis Control
- Ageing and life course
- Alliance for Health Policy and Systems Research
- Archives of WHO
- Association of Former WHO Staff (AFSM)
- Avian influenza

B

- Biologicals
- Blood products and related biologicals
- Blood transfusion safety
- Bulletin of the World Health Organization
- Buruli ulcer

C

- Cancer
- Cardiovascular disease
- Child growth standards
- Children's environmental health
- CHOosing Interventions that are Cost Effective (WHO-CHOICE)
- Chronic diseases and health promotion
- Chronic respiratory diseases
- Civil Society Initiative (CSI)
- Classifications
- Clean Care is Safer Care

G continued

- Global Strategy on Diet, Physical Activity & Health
- Global Task Force on Cholera Control
- Growth reference 5-19 years

H

- Health Academy
- Health Accounts
- Health and development
- Health and Environment Linkages Initiative - HELI
- Health and Human Rights
- Health financing for universal coverage
- Health Impact Assessment (HIA)
- Health Metrics Network
- Health promotion
- Health statistics and information systems
- Health system responsiveness
- Health systems
- Health technology assessment
- Health workforce
- Healthy Environments for Children Alliance
- Healthy Settings
- HINARI Access to Research in Health Programme
- HIV/AIDS
- Household water treatment and safe storage
- Human African trypanosomiasis
- Human Genetics programme
- Humanitarian health action

O continued

- Oral health

P

- Partnership for Maternal, Newborn & Child Health
- Patient safety
- Polio Eradication Initiative
- Prequalification of Medicines Programme
- Prevention of Blindness and Visual Impairment
- Prevention of deafness and hearing impairment
- Promoting health through the life-course
- Public Health and Environment
- Public Health, Innovation, Intellectual Property and Trade
- Publications (online book shop)

Q

- Quantifying environmental health impacts

R

- Rabies
- Regional Office for Africa
- Regional Office for Europe
- Regional Office for South-East Asia
- Regional Office for the Americas / Pan American Health Organization (PAHO)
- Regional Office for the Eastern Mediterranean
- Regional Office for the Western Pacific

Cardiovascular disease

Child growth standards

Children's environmental health

CHOosing Interventions that are Cost Effective (WHO-CHOICE)

Chronic diseases and health promotion

Chronic respiratory diseases

Civil Society Initiative (CSI)

Classifications

Clean Care is Safer Care

Climate change and human health

Clinical Trials - International Registry Platform (ICTRP)

Codex Alimentarius

Collaborating centres

Commission on Ending Childhood Obesity

Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)

Contracting and performance incentives

D

Dengue control

Diabetes Programme

Diagnostic imaging

Director-General

Disabilities and rehabilitation

Disability Assessment Schedule II (WHODAS II)

Disease Control in Humanitarian Emergencies

Disease outbreak news

Dracunculiasis

Drug information

Drug resistance

E

e-Library of Evidence for Nutrition Actions (eLENA)

Health workforce

Healthy Environments for Children Alliance

Healthy Settings

HINARI Access to Research in Health Programme

HIV/AIDS

Household water treatment and safe storage

Human African trypanosomiasis

Human Genetics programme

Humanitarian health action

I

Immunization standards

Immunization, Vaccines and Biologicals

In vitro diagnostics and laboratory technology

Indoor air pollution

Influenza

Information Centre on Human Papilloma Virus (HPV) and Cervical Cancer

Initiative for Vaccine Research (IVR)

Injection safety

Inter-Organization Programme for the Sound Management of Chemicals

Intergovernmental Forum on Chemical Safety

International Agency for Research on Cancer (IARC)

International Classification of Functioning, Disability and Health (ICF)

International Health Regulations

International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

International Nonproprietary Names

International Programme on Chemical Safety

International travel and health

Ionizing radiation

K

R

Rabies

Regional Office for Africa

Regional Office for Europe

Regional Office for South-East Asia

Regional Office for the Americas / Pan American Health Organization (PAHO)

Regional Office for the Eastern Mediterranean

Regional Office for the Western Pacific

Reproductive Health Essential Medicines (RHEM) Resource Portal

Reproductive Health Library

S

Schistosomiasis

School and youth health

Sexual and reproductive health

Social determinants of health

Soil-transmitted helminths

Strategic Initiative for Developing Capacity in Ethical Review

Strategic Planning and Innovation (SPI)

Substance abuse

T

Taeniasis

Tobacco Free Initiative (TFI)

Trade, foreign policy, diplomacy and health

Transplantation

Tropical Diseases, Special Programme for Research and Training (TDR)

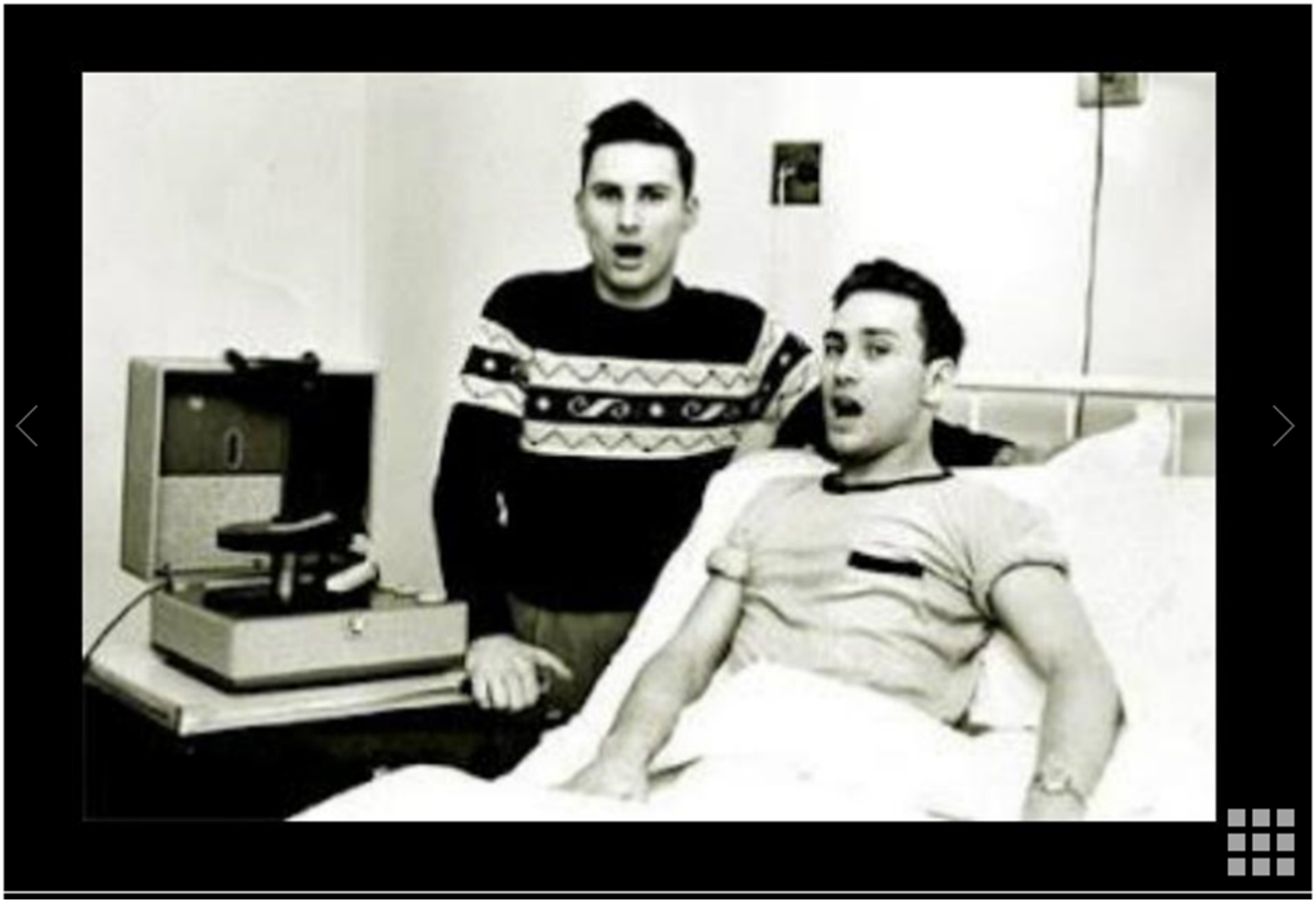
Tuberculosis (TB)

Tuberculosis - Stop TB Partnership

U


PAST

1954



Thomas Starzl

1963

Surg Gynecol Obstet. Author manuscript; available in PMC Feb 2, 2009.
Published in final edited form as:
Surg Gynecol Obstet. Dec 1963; 117: 659–676.

PMCID: PMC2634660
NIHMSID: NIHMS79294

HOMOTRANSPLANTATION OF THE LIVER IN HUMANS

T. E. STARZL, M.D., F.A.C.S., T. L. MARCHIORO, M.D., K. N. VON KAULLA, M.D., G. HERMANN, M.D., R. S. BRITTAIN, M.D., and W. R. WADDELL, M.D., F.A.C.S.

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NIHPA Manuscripts

AN IDEAL TREATMENT for several kinds of liver disease would be removal of the diseased organ and orthotopic replacement with a hepatic homograft. Patients with primary carcinoma of the liver, congenital atresia of the bile ducts, and terminal cirrhosis would all be candidates. The application of such therapy depends, first, upon the employment of a satisfactory operative procedure and, second, upon the use of suitable measures to prevent the immunologic rejection of the graft.

Recently, solutions to these problems have evolved which are at least partially satisfactory. The technical requirements for successful canine hepatic transplantation were defined (9). In addition, a regimen of anti-rejection therapy was developed in patients receiving renal homografts which resulted in consistent prolonged survival of the foreign tissue (11, 12).

In the present study, the application of these advances to the problem of clinical hepatic homotransplantation in 3 patients will be described. The first attempt resulted in failure at the operating table. The course of the second 2 patients establishes the feasibility of such an operation in humans, despite the fact that death occurred 22 and 7½ days after transplantation from pulmonary emboli.

METHODS

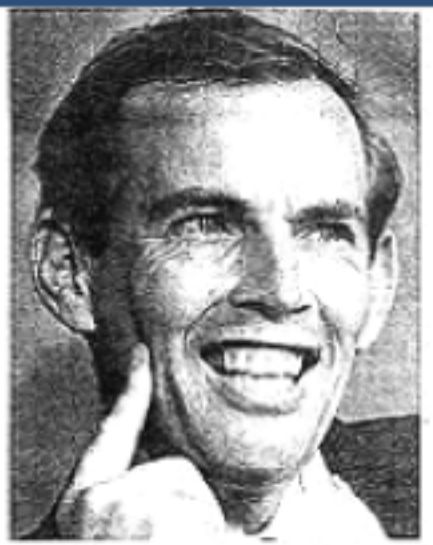
Go to:

Recipient patients

Patient 1 was a 3 year old white male with congenital biliary atresia (Fig. 1A). Physical development had been retarded, preoperative weight being 20 pounds. His general condition was poor, with hepatosplenomegaly, jaundice, and ascites. Total bilirubin was 20.7 milligrams per cent with a conjugated fraction of 16.7 milligrams per cent. Alkaline phosphatase was 12.8 Bodansky units. Serum glutamic-oxalacetic acid transaminase (SGOT) was 160 SF units. The hospital course prior to hepatic homotransplantation on 1 March 1963 was uneventful. On 12 February, the patient underwent thymectomy without complication. For 13 days prior to hepatic transplantation, he was given daily doses of azathioprine of 5 to 6 milligrams per kilogram of body weight.

Moments in History

1967



Professor Chris Barnard, leader of the heart-transplant team, in a characteristic pose during one of his many press conferences.

In December, 1967, a young woman, Denise Darvall, was walking across a street in Woodstock to buy a cake when a car struck her. She died in Groote Schuur Hospital and in doing so achieved immortality by becoming the world's first heart donor when Christiaan Neethling Barnard transferred her heart into the chest of Louis Washkansky.

Cape Town has been witness to many historic moments since the day Van Riebeeck anchored in Table Bay. Few, if any, brought more limelight to the city than the heart transplant. For the surgeon, Dr Barnard, soon to be a household name throughout the world, "the heart is merely a pump". But for those who equated the heart with love and death, the transplant seemed close to a miracle.

First close-up photograph to be taken of Mr Louis Washkansky, who underwent the world's first heart-transplant operation, was taken by a surgeon using an Argus photographer's camera at Groote Schuur Hospital. Mr Washkansky, whose condition was given as good, is being assisted to [illegible] by [illegible]

"Mr Louis Washkansky, the 55-year-old Cape Town man whose life is being sustained today by the heart of a dead 25-year-old woman after the world's first successful heart transplant yesterday, is conscious in Groote Schuur Hospital and in a satisfactory condition." Monday, 4th December 1967

Kuss, R. and Bourget, P. 1991


PAST
NOW

TRES AÑOS DESPUÉS

Las manos de Alba

Vivió 27 años sin ellas. En el 2006 las recuperó. Nunca antes una mujer había recibido un doble trasplante de manos. Hoy Alba vuelve a sentir con sus propios dedos, lleva una vida casi normal en Castellón.

2006

«Son preciosas». Fueron las primeras palabras de Alba al ver sus nuevas manos. El 30 de noviembre cambió su vida. Ella misma se labró el camino con una emotiva carta al doctor Cavadas para pedirle que la operara.

2007

Un aparatamento frente al hospital fue su hogar durante casi dos años. Gracias a una hora diaria de rehabilitación vivió sus primeros 'milagros'. Rascarse, soñar con sacar a su madre, con sacarse el carné de conducir...

EL 'DOCTOR MILAGRO'

A Pedro Cavadas es fácil verlo en su clínica con ropa de camuflaje y mordisqueando una barra de pan. Especialista en microcirugía y cirugía craneoencefálica, atiende 50 visitas al día. Su trabajo es su vida, con permiso de África. El continente lo sedujo de joven y varias veces al año opera gratis en Kenia y Tanzania a niños mutilados o víctimas de machetazos.

2009

Superar el miedo a las quemaduras era un reto. A Alba la aterraban los fogones y otras fuentes de calor. En su sosaniño aún cocina con un hornillo eléctrico, pero ya maneja la plancha con soltura. Y no duda en sacar un vaso con agua casi hirviendo del microondas.

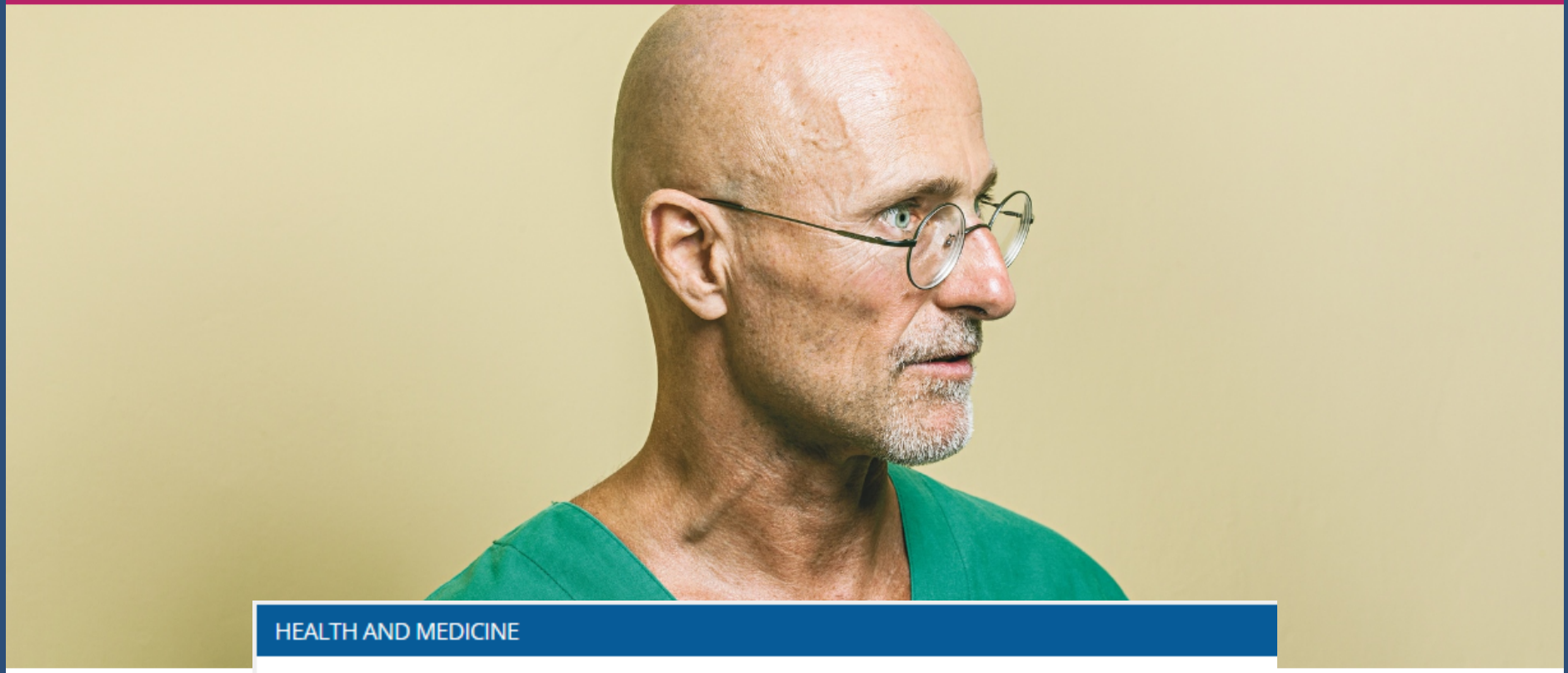

PAST
NOW
FUTURE

home › science

Medical research

'I'll do the first human head transplant'

Italian surgeon Sergio Canavero says he will change medical history as soon as 2017 – he even has a volunteer. Can it be done?



HEALTH AND MEDICINE

The First Human Head Transplant Has Been Scheduled For 2017

September 12, 2015 | by Amy Lynn

Technical Office


194 Members States

The Executive Board

The Executive Board is composed of 34 individuals technically qualified in the field of health, each one designated by a Member State elected to do so by the World Health Assembly. Member States are elected for three-year terms.

The Board meets at least twice a year; the main meeting is normally in January, with a second shorter meeting in May, immediately after the Health Assembly. The main functions of the Executive Board are to give effect to the decisions and policies of the Health Assembly, to advise it and generally to facilitate its work.

Executive Board members

MEMBERS OF THE EXECUTIVE BOARD AND TERM OF OFFICE

The Executive Board is composed of 34 persons who are technically qualified in the field of health, each designated by a Member State that has been elected to serve by the World Health Assembly. Member States are elected for three-year terms.

The affiliations appear in the style and the language used by the corresponding member of the Board.

ALBANIA 2013-2016
Dr Gazmend Bejtja
General Director of Health Policy and Planning
Ministry of Health
Tirana

ANDORRA 2013-2016
Mr Josep M. Casals Alis
General Director of Health and Welfare
Ministry of Health and Welfare
Andorra La Vella

ARGENTINA 2013-2016
Dr. Rubén Agustín Nieto
Secretario de Determinantes de Salud y Relaciones Sanitarias
Ministerio de Salud
Buenos Aires

BRAZIL 2013-2016
Dr Jarbas Barbosa da Silva Júnior
Secretary of Health Surveillance
Ministry of Health
Brasilia

CANADA 2015-2018
Mr Sylvain Segard
Acting Assistant Deputy Minister
Strategic Policy, Planning and International Affairs
Public Health Agency of Canada
Ottawa

CHINA 2014-2017
Ms Zhang Yang
Deputy Director-General
Department of International Cooperation
National Health and Family Planning Commission
Beijing

CONGO 2015-2018
Professeur Alexis Elira Dokekias
Directeur général des Hôpitaux et de l'Organisation des Soins
Ministère de la Santé et de la Population
Brazzaville

DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA 2013-2016
Mr KIM Chang Min Director-General,
Department of International Organisations,
Ministry of Foreign Affairs
Pyongyang

DEMOCRATIC REPUBLIC OF THE CONGO 2014-2017
Dr Mukengeshayi Kupa
Secrétaire général à la Santé
Ministère de la Santé publique
Kinshasa

DOMINICAN REPUBLIC 2015-2018
Dr. Nelson Antonio Rodríguez Monegro
Viceministro de Salud Pública
Santo Domingo

EGYPT 2013-2016

ERITREA 2014-2017
Mr Berhane Ghebretinsae Ghilagaber
Director-General
Department of Health Services
Ministry of Health
Asmara

FRANCE 2015-2018
Professeur Benoit Vallet
Directeur général de la Santé
Ministère des Affaires sociales et de la Santé
Paris

GAMBIA 2014-2017
Mr Omar Sey
Minister of Health and Social Welfare
Ministry of Health and Social Welfare
Banjul

JAPAN 2013-2016
Dr Shigeru Omi
Special Assistant for International Affairs to the Minister of Health, Labour and Welfare
Ministry of Health, Labour and Welfare
Tokyo

JORDAN 2015-2018
Dr Ali Hyasat
Minister of Health
Amman

KAZAKHSTAN 2015-2018
Professor Maksut Kulzhanov
Kazakhstan School of Public Health
Ministry of Healthcare and Social Development
President of the Medical Chamber of Kazakhstan
Astana

KUWAIT 2014-2017
Dr Ali Saad Al-Obaidi
Minister of Health
Ministry of Health
Kuwait City

LIBERIA 2014-2017
Dr Bernice T. Dahn Minister of Health and Social Welfare
Monrovia

MALTA 2015-2018
Dr Raymond Busuttil
Consultant in Public Health,
Ministry for Energy and Health
Valletta

NAMIBIA 2013-2016
Dr Bernard S. Haufiku
Minister of Health and Social Services
Winhoek

NEPAL 2014-2017
Mr Ramjanam Chaudhary
Minister of Health and Population
Kathmandu

NEW ZEALAND 2015-2018

PAKISTAN 2015-2018
Dr Assad Hafeez
Director General Health
Ministry of National Health Services, Regulations and Coordination
Islamabad

PHILIPPINES 2015-2018
Dr Janette Loreto Garin
Secretary of Health (Minister)
Manila

REPUBLIC OF KOREA 2013-2016
Dr Jeon Man-Bok
Vice President for External Relation & Cooperation
Catholic Kwandong University
Gangneung

RUSSIAN FEDERATION 2014-2017
Ms Veronika Igorevna Skvortsova
Minister of Health
Ministry of Health
Moscow

SAUDI ARABIA 2013-2016
Dr Abdulla bin Mifreh Assiri
Assistant Deputy Minister for Preventive Health
Ministry of Health
Riyadh

SOUTH AFRICA 2013-2016
Ms Precious Matsoso
Director-General of Health
Ministry of Health
Pretoria

SURINAME 2013-2016
Dr Maureen Wijngaarde-van Dijk
Acting Directing of Health
Ministry of Health
Paramaribo

SWEDEN 2015-2018
Ms Olivia Wigzell
Director-General
National Board of Health and Welfare
Stockholm

THAILAND 2015-2018
Dr Somsak Akksilp
Deputy Permanent Secretary
Ministry of Public Health
Bangkok

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND 2014-2017
Dame Sally Davies
Chief Medical Officer
Department of Health
London

UNITED STATES OF AMERICA 2014-2017
Dr Thomas Frieden
Director
Centers for Disease Control and Prevention
Atlanta

Governance

The World Health Assembly is the supreme decision-making body for WHO. It generally meets in Geneva in May each year, and is attended by delegations from all 194 Member States. Its main function is to determine the policies of the Organization. The Health Assembly appoints the Director-General, supervises the financial policies of the Organization, and reviews and approves the Proposed programme budget. It similarly considers reports of the Executive Board, which it instructs in regard to matters upon which further action, study, investigation or report may be required.


40th World Health Assembly, 1987

REQUESTS the Director-General:

1. To study, in collaboration with other organizations concerned, the possibility of developing appropriate guiding principles for human organ transplants

2. To report to the Health Assembly on the action taken in this regard.


WHA 57.18

Transplantation worldwide

Request WHO to establish a data collection system on donation and transplantation activity

- ✓ Evaluate access to transplantation among countries
- ✓ Transparency
- ✓ Equity
- ✓ Legal and organizational aspect
- ✓ Design and implement increasing donation program
- ✓ Develop quality and safety measures for patients
- ✓ Analyze initiatives impact

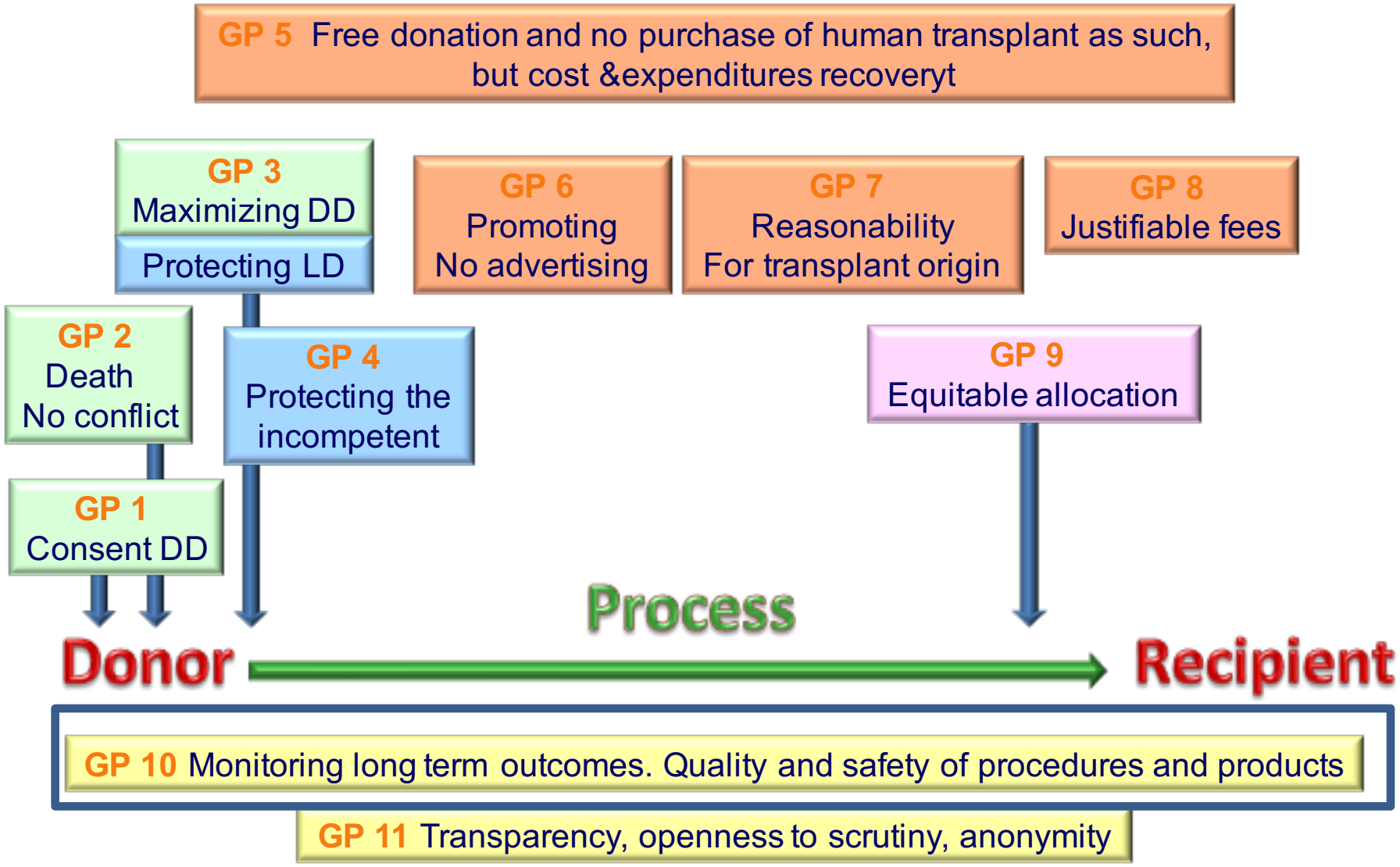

63th World Health Assembly, 2010

World Health Organization

WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION[1]

[1] As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation



WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

Guiding Principle 10

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.

“vigilare”

to stay awake or to care for and is the process of paying close and continuous attention

surveillance .

Is the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary.

vigilance,

vigilance, &

are used in association to underline that the attitude of vigilance needs to be associated to the methods of surveillance

TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 FROM A SERONEGATIVE ORGAN AND TISSUE DONOR

R.J. Simonds, M.D., Scott D. Holmberg, M.D., M.P.H., Richard L. Hurwitz, M.D., Theresa R. Coleman, B.A., Scott Bottenfield, R.N., Lois J. Conley, M.T., M.P.H., Sherry H. Kohlenberg, M.H.A., Kenneth G. Castro, M.D., Beverley A. Dahan, B.A., Charles A. Schable, M.S., Mark A. Rayfield, Ph.D., and Martha F. Rogers, M.D.

Abstract *Background.* Since 1985, donors of organs or tissues for transplantation in the United States have been screened for human immunodeficiency virus type 1 (HIV-1), and more than 60,000 organs and 1 million tissues have been transplanted. We describe a case of transmission of HIV-1 by transplantation of organs and tissues procured between the time the donor became infected and the appearance of antibodies. The donor was a 22-year-old man who died 32 hours after a gunshot wound; he had no known risk factors for HIV-1 infection and was seronegative.

Methods. We reviewed the processing and distribution of all the transplanted organs and tissues, reviewed that received them. Of the 48 identified recipients, 41 were tested for HIV-1 antibody. All four recipients of organs and all three recipients of unprocessed fresh-frozen bone were infected with HIV-1. However, 34 recipients of other tissues — 2 receiving corneas, 3 receiving lyophilized soft tissue, 25 receiving ethanol-treated bone, 3 receiving dura mater treated with gamma radiation, and 1 receiving marrow-evacuated, fresh-frozen bone — tested negative for HIV-1 antibody. Despite immunosuppressive chemotherapy, HIV-1 antibody appeared between 26 and 54 days after transplantation in the three organ recipients who survived more than 4 weeks.

Recall involving 28,000 tissue grafts distributed worldwide in 2005 – donor consent and histories falsified

Transplants

Organs, tissues, cells

- ✓ Welfare of the donor is protected
- ✓ Are collected safely

Ethical concerns are common to all transplants

The fundamental ethical criterion is respect for the human being, to their inalienable rights, to the person's dignity


IMPORTANT


Ethics


SAFETY


RISK
RISK

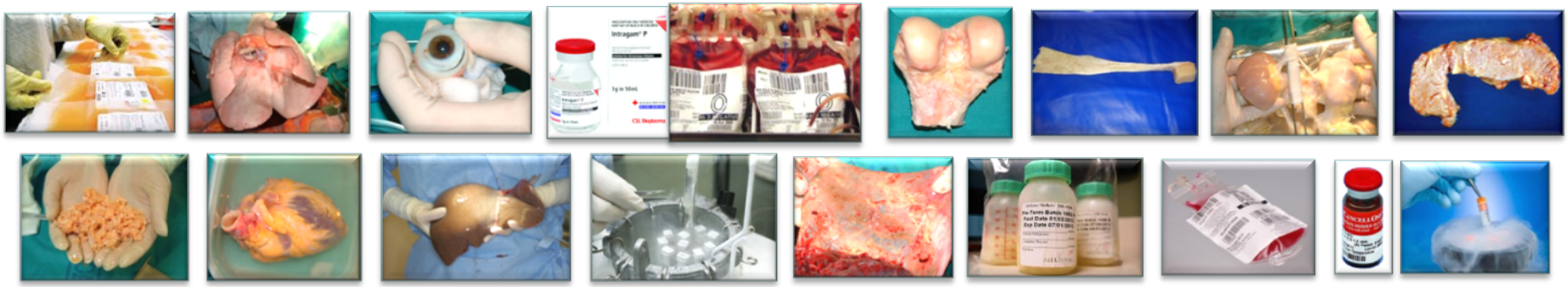
have been exacerbated by the fragmentation of these products into sub-classes obtained in different ways, used by different medical specialties, carrying different relative risks, benefits, and alternatives, and regulated by different national authorities.

Medical Products Human Origin

Include all substances derived wholly or in part from the human body and intended for clinical application.

Medical Products Human Origin

they include cells, organs and fluids irrespective of their fate in the recipient.



Global Activity in Organ Transplantation
2015 Estimates

Kidney	Liver	Heart	Lung	Pancreas	Small bowel
81479	25946	6485	5170	2841	206

≈ 122,127 solid organs reported to be transplanted in 2015

≈ 1.88 % increase over 2014

Information of 112 Member States on organ transplantation activities is included in the **GODT**:

Medical Products Human Origin

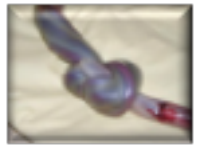
103 million whole blood donations

23 million plasma donations

>5000 cornea transplants in Italy each year

2,1 million tissue grafts distributed by AATB accredited tissue banks

> 40.000 childrem born from donor gametes



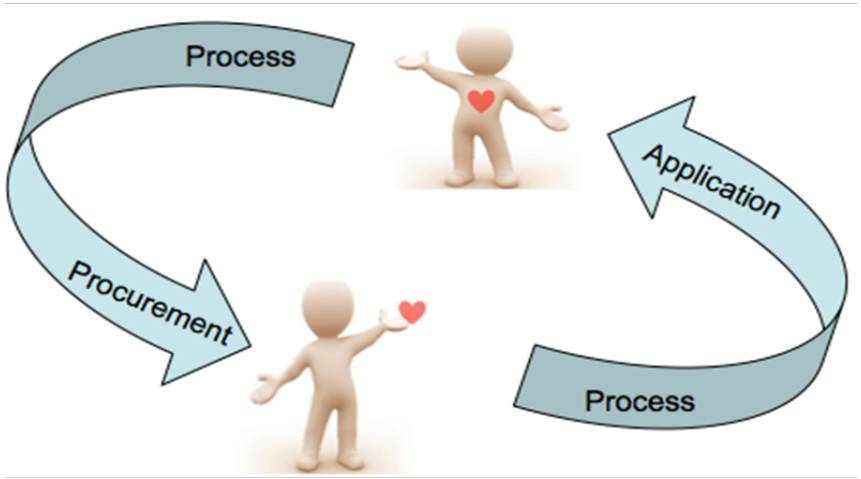
61,000 umbilical cord blood units added to the registries

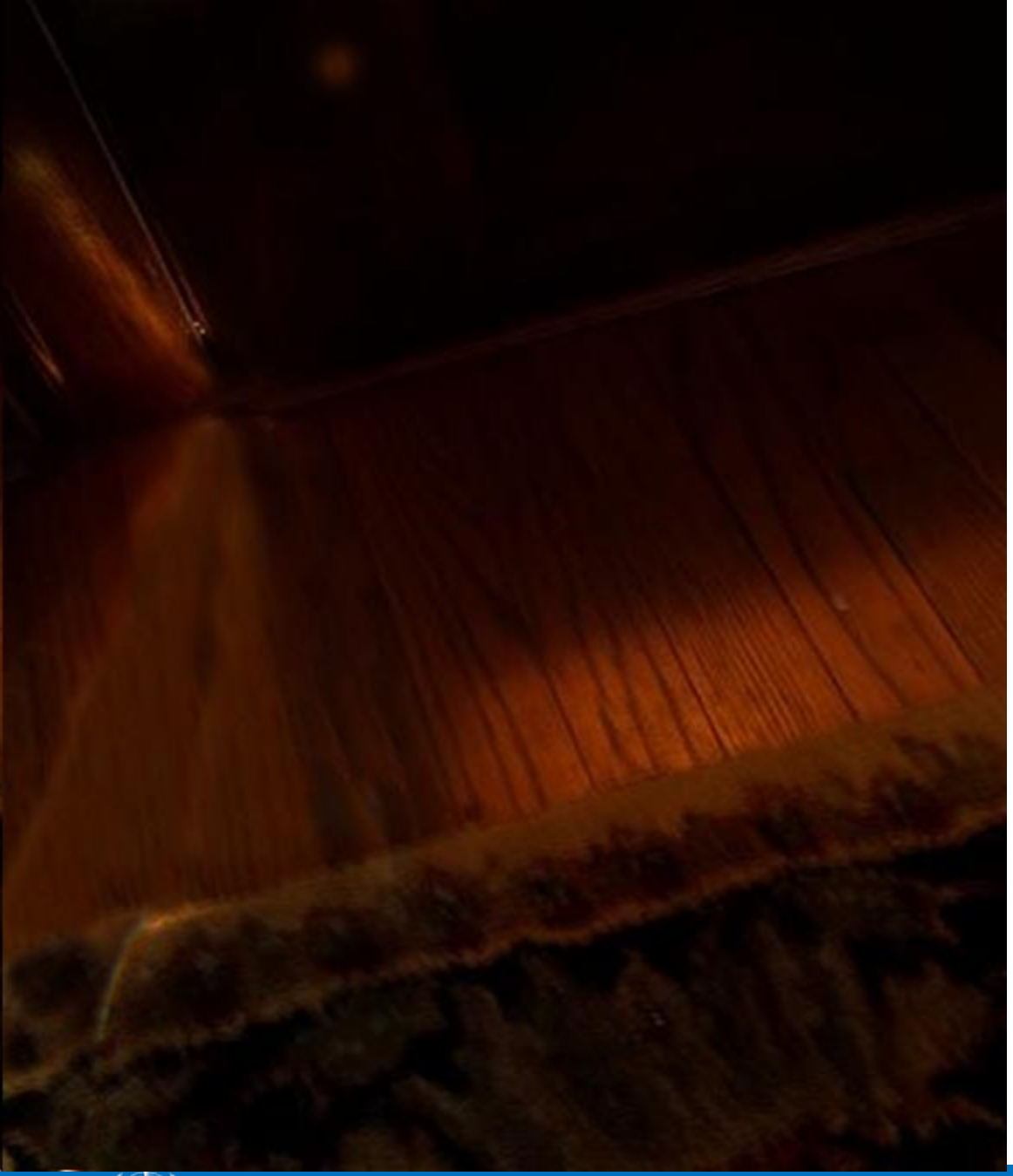
WHO Organization-wide Initiative for Medical Products of Human Origin

“ Health products of an exceptional nature”

Medical Products Human Origin

MPHO have a common origin and destination: human bodies





"There is a crack in everything

That's how the light gets in."

Leonard Cohen

Selected Poems,

1956 - 1968

Courtesy D Fehily


JANUARY
2015

World Health Organization

EXECUTIVE BOARD
136th session
Provisional agenda item 10.6

EB136/32
5 December 2014

Blood and other medical products of human origin

Report by the Secretariat

1. In response to proposals from some Member States to call for strategic guidance on self-sufficiency in blood and blood products based on voluntary non-remunerated donations and the call at the Sixty-seventh World Health Assembly for the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation to be applied to medical products of human origin,[1] the Secretariat has produced this report which covers both blood and other medical products of human origin.

MAIN CHALLENGES

2. Medical products of human origin are derived wholly or in part from the human body and intended for clinical application. They include blood and blood products, organs, bone marrow, cord blood, corneas and tissues. Over the years, their type and use have broadened, and many are widely used. Donors and recipients face a wide range of risks, depending on the type of product used. From donation to the follow-up of recipients, health systems face many challenges, and a global consensus is needed on some guiding principles for the donation and use of medical products of human origin, including the promotion of good and harmonized practices. Most of these principles apply to all public health interventions,[2] but have to be adapted to the particularities of medical products of human origin.[3] The main issue is the existence of a human being at the origin of these products, giving rise to high levels of complexity and responsibility for health systems and health-care providers. Launched in April 2013, the WHO initiative for medical products of human origin aims to create a global framework on common principles for the donation and use of all medical products of human origin, which recognizes the specificities of each product.[4] Three principles concern respect for human dignity, availability and safety, and good governance.

3. **Respect for human dignity.** With special attention to the protection of vulnerable groups, the respect for dignity implies that all donations are based on a voluntary and free informed decision, without coercion or undue inducement. The use of financial or disproportionate incentives and the lack of information provided to potential donors put the validity of the decision to donate at risk. Donors of

[1] See document WHA67/2014/REC/3, summary record of the twelfth meeting of Committee A of the Sixty-seventh World Health Assembly, section 9 K.

[2] See Universal Declaration on Bioethics and Human Rights, resolution 36 adopted by the General Conference of UNESCO at its 33rd session, in 2005.

[3] See for example the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe in 2002.

[4] See document A67/40, para 103, noted by the Sixty-seventh World Health Assembly (document WHA67/2014/REC/3, summary record of the twelfth meeting of Committee A, section 9 J and K).

World Health Organization

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Draft decision proposed by Italy and Spain

The Executive Board, having considered the report of the Secretariat on blood and other medical products of human origin,[1]

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World Health Organization

EXECUTIVE BOARD
136th session
Agenda item 10.6

EB136/CONF./3
27 January 2015

Principles for global consensus on the donation and management of blood and other medical products of human origin

Draft decision proposed by the delegations of Italy, Lithuania, Malta, Slovenia and Spain

Executive Board Decision EB136(2)

January 2015

Principles for global consensus on the donation and management of blood, blood components and medical products of human origin

(7) requested that the Director-General convene consultations with Member States and international partners, to support the development of global consensus on guiding ethical principles for the donation and management of the mentioned medical products of human origin; good governance mechanisms; and common tools to ensure quality, safety and traceability, as well as equitable access and availability, as applicable, to result in a document to be submitted to the Seventieth World Health Assembly for its consideration.

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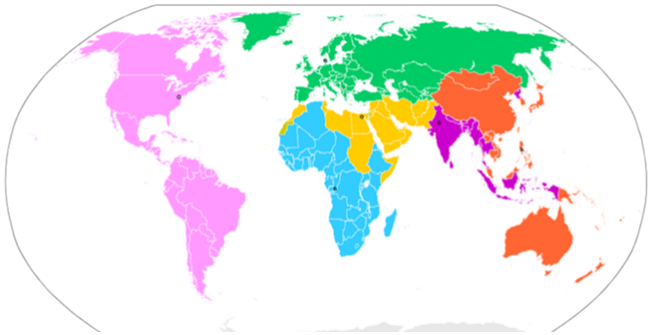
(7) requested that the Director-General convene consultations with Member States and international partners, to support the development of global consensus on guiding ethical principles for the donation and management of the mentioned medical products of human origin; good governance mechanisms; and common tools to ensure quality, safety and traceability, as well as equitable access and availability, as applicable, to result in a document to be submitted to the Seventieth World Health Assembly for its consideration.

Objectives

Drafting procedure

- **WHO Secretariat**
  - Service Delivery and Safety department (SDS)
  - Essential Medicines and Health Products department (EMP)
  - Regional offices (RO)
- **Individual Experts** (all types of MPHO)
- **International Societies**




Social network

Service delivery and safety

Service delivery and safety
About us
Areas of work

World Blood Donor Day 2016: Blood connects us all

14 June 2016 -- Voluntary, unpaid blood donations must be increased rapidly in more than half the world's countries in order to ensure a reliable supply of safe blood for patients whose lives depend on it, WHO said on World Blood Donor Day.

Read the press release

Read the campaign essentials

More on World Blood Donor Day 2016

Service Delivery and Safety (SDS)

WHO SDS supports countries in moving their health systems towards universal health coverage, through increased access to safe, high quality, effective, people-centred and integrated services.

– More about us

22 September 2016

Online public consultation on the draft WHO Principles for the donation and management of Medical Products of Human Origin

You are kindly invited to participate in this survey which aims to critically review the document's strengths and weaknesses, with focus being placed on the ethical principles to be applied to medical products, before submission for discussion at the 140th meeting of the Executive Board and thereafter to the 70th World Health Assembly in 2017.
The deadline for receiving responses is 15 October 2016.

To complete the survey please click here

Quick facts

10 facts on patient safety
10 facts on blood transfusion
10 facts on antimicrobial resistance
10 facts on universal health coverage

Contact Information

Service delivery and safety
Health Systems and Innovation
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Public Consultation Results: Acceptance rate

P1 : 94.4%
- *"Government responsibility"*

P2 : 96.0%
- *"Equity in donation"*

P3 : 86.4%
- *"Use only when of proven efficacy"*

P4 : 94.4%
- *"Donation should be an informed and voluntary decision"*

P5 : 89.6%
- *"Financial neutrality – Protection of the vulnerable"*

P6 : 98.4%
- *"Protection against physical and psychosocial risks"*

P7 : 92.0%
- *"Provide information about human origin of the product"*

P8 : 97.6%
- *"Equity in access - Allocation systems based on clinical criteria & ethical norms"*

P9 : 97.6%
- *"Traceability - Quality Management - Vigilance & Surveillance"*

P10 : 98.4%
- *"Transparency while ensuring Anonymity and Privacy"*

Global Acceptance Rate

94.5%

Available at
http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_18-en.pdf

World Health Organization

EXECUTIVE BOARD
140th session
Provisional agenda item 8.2

EB140/18
29 December 2016

Principles for global consensus on the donation and management of blood, blood components and medical products of human origin

Report by the Secretariat

Discussed on 26 January 2016

World Health Organization

SEVENTIETH WORLD HEALTH ASSEMBLY
Provisional agenda item 13.2

A70/19
XX March 2017

Principles on the donation and management of blood, blood components and other medical products of human origin

Report by the Secretariat

New title and amendments following the EB discussion

Common Principles for MPHO

1. **Governments are responsible** for ensuring the ethical and effective procurement, distribution and use of medical products of human origin. This responsibility includes the **obligation to develop and enforce regulations** to ensure the maximum possible level of safety, quality and efficacy, both within and across national borders.

2. **Equity in donation** should be promoted by **engaging all segments of society** in efforts to meet the need for medical products of human origin.

3. Outside clinical research and for the advancement of science, medical products of human origin **should be used** only in situations of **clinical utility** and in the **absence of alternative and affordable therapies** with a comparable or more favourable **balance of risks and benefits**.

Common Principles for MPHO

3 MPHOs should be used only when of proven efficacy and in the absence of alternative therapies of comparable or superior efficacy.

3 Outside clinical research and for the advancement of science, medical products of human origin should be used only in situations of clinical utility and in the absence of alternative and afforable therapies with a comparable or more favourable balance of risks and benefits.

Common Principles for MPHO

1. Governments are responsible for ensuring the ethical and effective procurement, distribution and use of medical products of human origin. This responsibility includes the obligation to develop and enforce regulations to ensure the maximum possible level of safety, quality and efficacy, both within and across national borders.

2. Equity in donation should be promoted by engaging all segments of society in efforts to meet the need for medical products of human origin.

3. Outside clinical research and for the advancement of science, medical products of human origin should be used only in situations of clinical utility and in the absence of alternative and affordable therapies with a comparable or more favourable balance of risks and benefits.

4. Biological materials from living persons for use as medical products of human origin should be taken only with the donor's prior informed and voluntary consent. When biological material from a deceased person is to be used as medical product of human origin, it is imperative to verify that the individual has provided his or her prior consent or has not expressed objections to be a donor, as mandated by national laws.

Common Principles for MPHO

4 Donation of components of the human body for use in medical products should be conditional upon informed and voluntary decision-making by donors or their relatives

4 Biological materials from living persons for use as medical products of human origin should be taken only with the donor's prior informed and voluntary consent. When biological material from a deceased person is to be used as medical product of human origin, it is imperative to verify that the individual has provided his or her prior consent or has not expressed objections to be a donor, as mandated by national laws.

Common Principles for MPHO

5 **Policies governing compensation** to persons who provide biological materials for use as medical products of human origin should seek to **guard against the exploitation of vulnerable individuals and promote equity in donation**. The best way to achieve these goals is to adhere to a **policy of financial neutrality**, in which persons who donate their biological materials for use as medical products of human origin should neither benefit nor lose financially as a result of the donation. Countries should ensure that the burden of donating these materials does not fall primarily on economically disadvantaged groups.

5 **Financial neutrality:** In order to guard against the exploitation of vulnerable individuals and promote equity in donation, persons who provide their biological materials for use in MPHOs should not benefit or lose financially as a result of the donation.

Common Principles for MPHO

5 **Policies governing compensation** to persons who provide biological materials for use as medical products of human origin should seek to **guard against the exploitation of vulnerable individuals and promote equity in donation**. The best way to achieve these goals is to adhere to a **policy of financial neutrality**, in which persons who donate their biological materials for use as medical products of human origin should neither benefit nor lose financially as a result of the donation. Countries should ensure that the burden of donating these materials does not fall primarily on economically disadvantaged groups.

*The Health Assembly has acknowledged **altruistic voluntary and non-remunerated donation** as the cornerstone of safety and quality in medical products of human origin, and as a means to protect the donor against exploitation.*

Payments, reimbursement or coverage of reasonable costs associated with donation, such as transport expenses or documented lost wages, remain consistent with that principle: just as donors should not benefit financially from donation, it should not cause them any financial injury.

Common Principles for MPHO

6 Prospective and actual donors of human biological materials for use in medical products should be protected against physical and psychosocial risks to the fullest extent possible.

7 Depending on the relevant product, and in addition to other information routinely provided when offering medical products of human origin to prospective recipients, the human origin of the product should be disclosed without compromising the confidentiality of the donor's identity.

Common Principles for MPHO

7 Depending on the relevant product, and in addition to other information routinely provided when offering medical products of human origin to prospective recipients, the human origin of the product should be disclosed without compromising the confidentiality of the donor's identity.

7 Information about the relevant product, including its human origin, should be routinely provided when offering MPHOs to prospective recipients.

Common Principles for MPHO

6 Prospective and actual donors of human biological materials for use in medical products should be protected against physical and psychosocial risks to the fullest extent possible.

7 Depending on the relevant product, and in addition to other information routinely provided when offering medical products of human origin to prospective recipients, the human origin of the product should be disclosed without compromising the confidentiality of the donor's identity.

8 Equity in access to the benefits of medical products of human origin should be promoted by sustained efforts to remove barriers to access. Any waiting lists and allocation systems that are developed for medical products of human origin should be based on clinical criteria and ethical norms, not considerations of financial or social status.

9 In order to minimize the risk of harm to donors and recipients and to protect the stability and sustainability of services for medical products of human origin, all steps in the development and use of medical products of human origin should be fully traceable and subject to effective quality-management systems and vigilance & surveillance programmes.

10 The organization and delivery of activities related to medical products of human origin, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the confidentiality of donors / recipients is always protected and adheres to national laws.

Key Considerations for Implementation

Paragraph 15

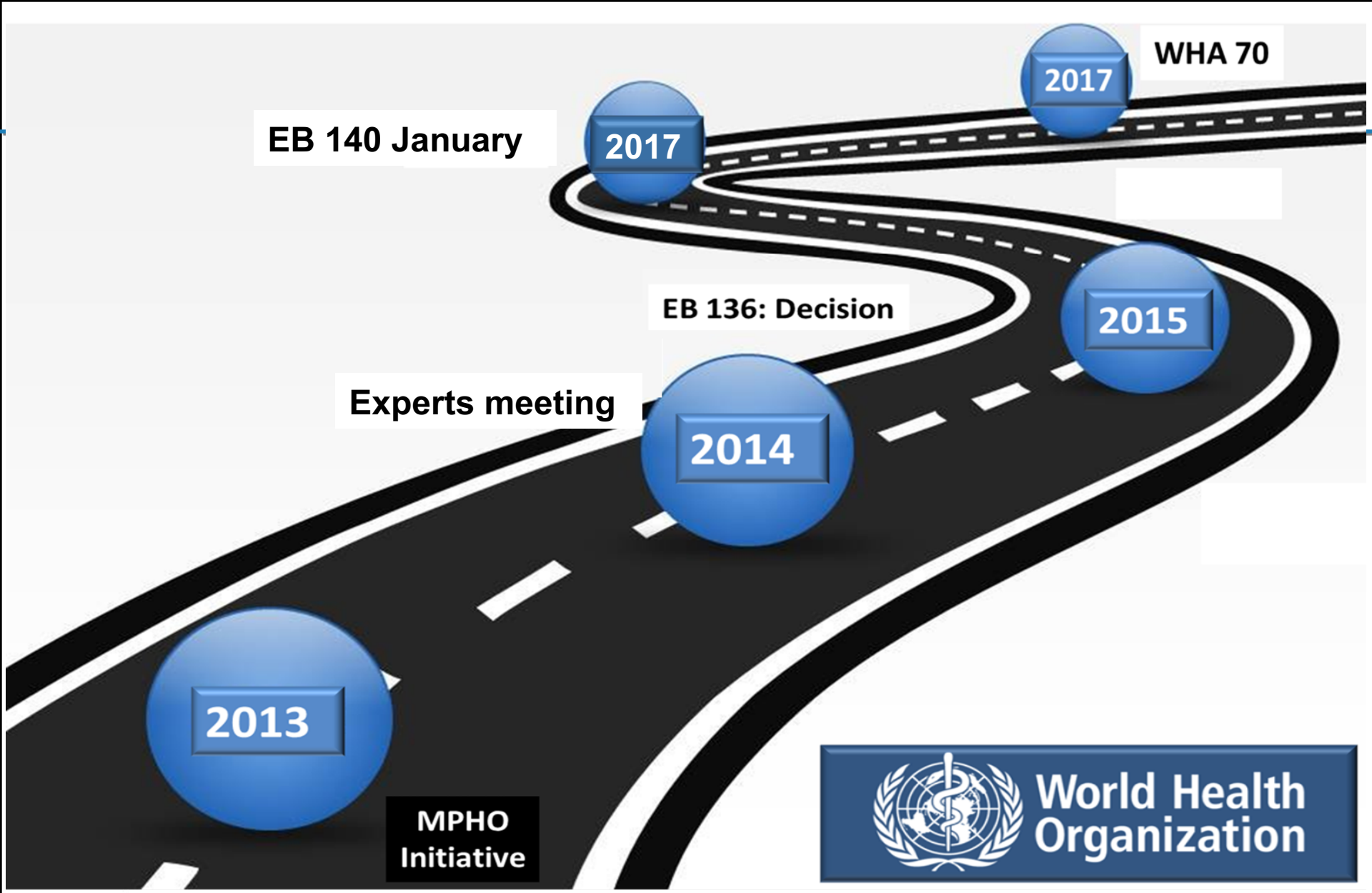
Principles # Guidelines

Governance mechanisms are generally valid for all medical products of human origin, including:

- legislation and regulation;
- policy and strategic planning;
- financial sustainability;
- traceability;
- vigilance and surveillance;
- transparency;
- public engagement;
- crisis response plans.

Each principle should be further elaborated with **strategic approaches** and potential **policy options and interventions** for its attainment. The appropriate mix of policies and interventions to be used at the country level will need to be designed and developed **according to the local context, values and priorities**.

The Secretariat is able to **provide support to Member States** in the implementation procedure through guidance on the basis of input from technical consultations, literature reviews and expert opinion.

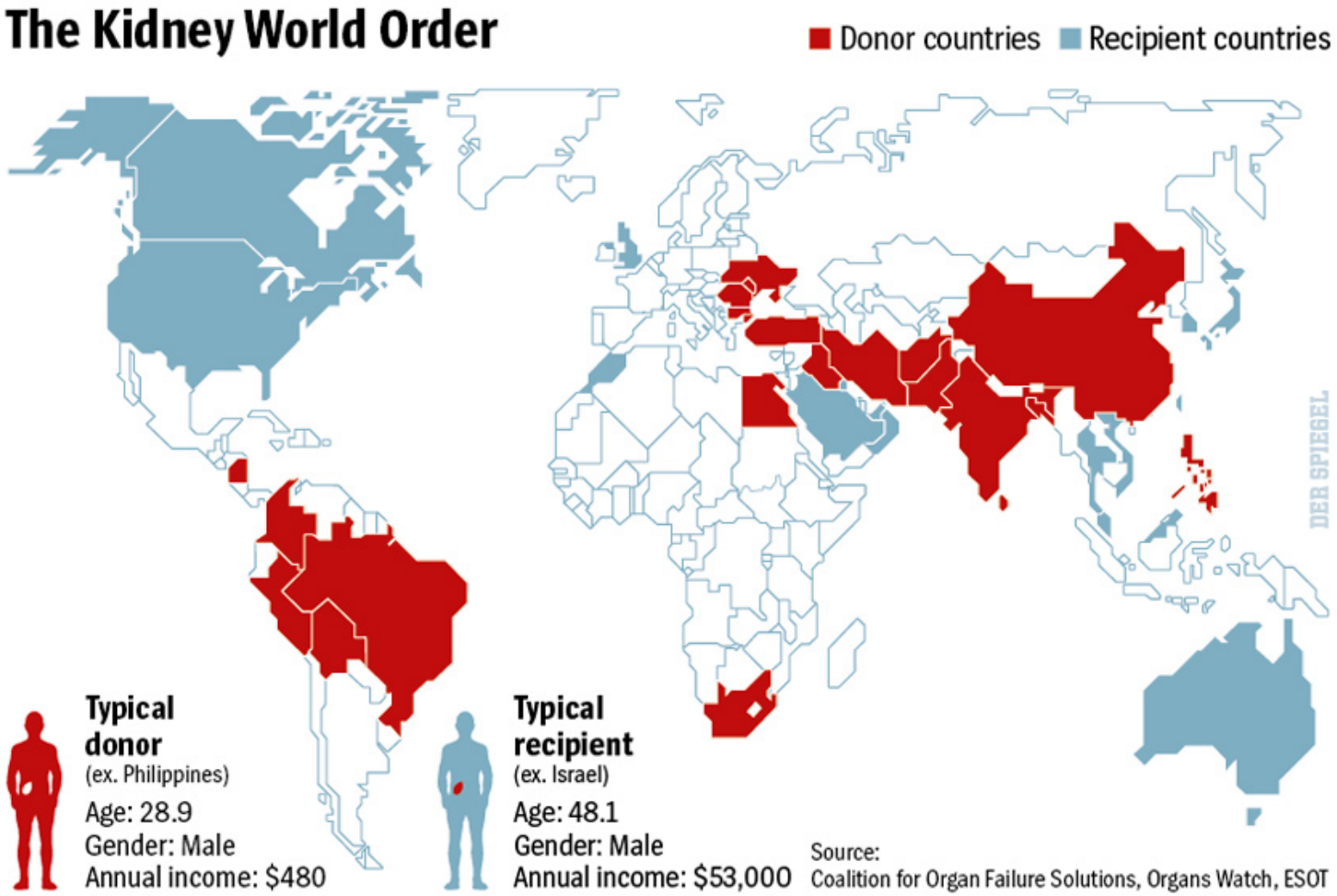

WHA 70
2017
EB 140 January
2017
EB 136: Decision
2015
Experts meeting
2014
2013
MPHO
Initiative
World Health
Organization


70th World Health Assembly, 2017


EMERGENCY
174 KM AHEAD

World Health Organization

Transplant Tourism



5-10% of organ transplants result from some form of commercialization
(year 2005-2006, WHO estimates)

Future project: WHO Transplant Certificate

Draft mock-up

WHO Transplant Registry

KD L GR 005 20171225 001

This is to certify that the (organ) transplant performed on (date) at the (hospital) in (country) has been officially registered by the World Health Organization (WHO) in accordance with the Agreement between (country) and WHO.

Registry Number (alphanumeric)

- Type of organ (XX): **K**i**D**ney
- Type of donor (X) **L**iving
- Country code (XX): **GR**eece
- Authorised Hospital code (000)
- Date (YYYYMMDD)
- Transplant sequence (000)

BLOCKCHAIN

To be generated by the authorised hospital personnel (administration) upon completion of the transplant.
Once data received by the registry, a code will be issued in order to certify the transplant.
The code will be sent back to the hospital and will be provided to the patient with the discharge documents.
Further interactions of the patient with health and insurance services will require the certificate.

Thank you for your attention

World Health Organization