



**World Health  
Organization**

# **WHO's Way Forward with Substances of Human Origin**

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**World Health  
Organization**



## Outline of the Presentation

- Substances of Human origin
- Issues and challenges
- WHO policies and directions as enshrined in WHA resolutions
- What has WHO done?
- What are the next steps?



## Substances of Human Origin

- SOHO - blood, blood products, cells, tissues, organs, gametes and embryos contribute to saving millions of lives every year
- There is **no substitute** for SOHO; obtained only from **humans**; **demand** for SOHO is **growing** globally
- SOHO are interlinked and **intertwined**
  - practices with one impact the others; no national borders for safety or ethical risks
- Yet there are **differences** and particularities between sub-classes of SOHO
- The **self-sufficiency paradigm** applies to all, as SOHO, from humans for humans, involve the community



## Issues and Challenges

- Provision of a safe, sufficient and secure supply of SOHO is a major challenge
- In many developing countries, ineffective policies, structures and systems lead to chronic shortages, unsafe products and unsound practices
- Poor quality assurance and commercial practices jeopardize safety and access to SOHO



## Issues and Challenges

- In absence of government leadership, roles and responsibilities are often unclear, leading to
  - fragmented and inefficient supply systems
  - lack of institutional coordination
  - varying technical standards and capacity
  - limited supervision



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## WHO Policies and Direction

- The World Health Assembly first expressed its concern about unsafe blood and blood products in 1975, when resolution WHA28.72: **Utilization and supply of human blood and blood products** was adopted
- In 1987 the matter of the commercial trade in organs was raised, which led to the adoption of WHA40.13: **Development of guiding principles for human organ transplants**
- WHA Resolution WHA57.18 on **Cell Tissue and Organ Transplantation** (2004)



## WHO Policies and Direction

- WHA58.13: Blood Safety: Proposal to establish **World Blood Donor Day** (2005)
- The **Melbourne Declaration** on 100% Voluntary Non-remunerated Donation of Blood and Blood Components (2009)
- WHA63.12: **Availability, Safety and Quality of Blood Products** (2010)
- WHA63.22: **WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation** (2010)



# Availability, Safety and Quality of Blood Products

## World Health Assembly Resolution WHA63.12

SIXTY-THIRD WORLD HEALTH ASSEMBLY

WHA63.12

Agenda item 11.17

21 May 2010

١٢-٦٣

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WHA63

**Availability, safety and quality of blood products**

第六十三

议程项目

SOIXANT

Point 11.

**توافر منتجات الدم ومأمونيتها وجودتها**

63.<sup>a</sup> A

Punto

**血液制品的可得性、安全性和质量**

**Disponibilité, innocuité et qualité  
des produits sanguins**

ШЕСТЬД  
ВСЕМИР

Пункт 11.

**Disponibilidad, seguridad y calidad  
de los productos sanguíneos**

**Наличие, безопасность и качество  
продуктов крови**



## URGES Member States

1. to establish, implement and support nationally-coordinated, efficiently-managed and sustainable **blood and plasma programmes**, with the aim of achieving **self-sufficiency**
2. to update their **national legislation** to support the national blood system
3. to establish **quality systems** for the processing of whole blood and blood components, GMP for the production of plasma-derived medicinal products



## Preamble Related to Patient Safety Issues

- Recognizing that excessive and unnecessary use of transfusions and of plasma-derived medicinal products, **unsafe transfusion practices, and errors (particularly at the patient's bedside) seriously compromise patient safety**



## URGES Member States

- To establish or strengthen systems for the **safe and rational use of blood products** and to provide training for all staff involved in clinical transfusion, to **implement potential solutions in order to minimize transfusion errors and promote patient safety**, to promote the availability of transfusion alternatives including, where appropriate, autologous transfusion and patient blood management



## URGES Member States

- To ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma- derived medicinal products, including transmissions of pathogens



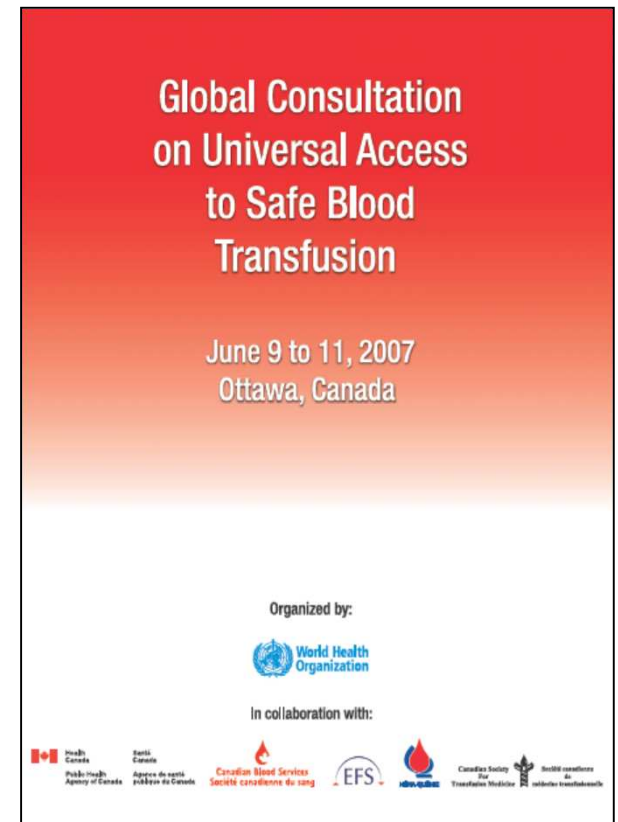
## Requests the DG, WHO

- To provide guidance, training and support to Member States on **safe and rational use of blood products** and to support the introduction of transfusion alternatives including, where appropriate, autologous transfusion, **safe transfusion practices** and patient blood management

# WHO Global Consultation on Universal Access to Safe Blood Transfusion, 2007

## Developing Quality Systems throughout the Blood Transfusion Chain

- Build national and regional capacity for the implementation of quality systems in BTSs
- Encourage national health authorities to establish systems bi-directional traceability of all blood/blood products
- Provide guidelines, tools and technical support for the establishment of national haemovigilance systems
- Foster and support the creation of a Global Haemovigilance, Surveillance and Alert Network



**2004**

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**



**2010**

# WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

Endorsed by the 63d World Health Assembly in Resolution WHA 63.22

**GP 5** Free donation and no purchase of human transplant as such,  
but cost & expenditures recovery

**GP 3**  
Maximizing DD  
Protecting LD

**GP 6**  
Promoting  
No advertising

**GP 7**  
Responsibility  
for transplant origin

**GP 8**  
Justifiable fees

**GP 2**  
Death Δy  
No conflict

**GP 4**  
Protecting the  
incompetent

**GP 9**  
Equitable allocation

**GP 1**  
Consent DD

**Donor**

**Process**

**Recipient**

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

**GP 11** Transparency, openness to scrutiny, anonymity

# V&S for Cell, Tissue and Organ for Transplantation

## Guiding Principle # 10

Monitoring long term outcomes.

Quality and safety  
of procedures and products

**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**

Resolution WHA 63.22

The sixty-third World Health Assembly

1. ENDORSES the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation;

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;

3. REQUESTS the Director-General:...

(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;