Coding Systems for Cell, Tissue and Organ

Guiding Principle # 10
Monitoring long term outcomes.
Quality and safety
of procedures and products

This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

Internationally agreed means of coding to identify tissues and cells used in transplantation are essential for full traceability.

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:..

(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:…

(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;

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?

World Health Organization

WHO strategy for safe blood transfusion

Stratégie de l'OMS pour la sécurité transfusionnelle

Voluntary blood donation

Testing of all donated blood

Safe and rational use of blood

Haemovigilance

Quality systems

National coordination of blood transfusion services

WORLD HEALTH ORGANIZATION

Quality Systems for Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

Words of advice

- **Secure the commitment and support of management at all levels**
- **Identify the need for quality in the national blood policy**
- **Develop a national quality policy and plan**
- **Secure adequate resources**
- **Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels**
- **Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank**
- **Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion**
- **Assess the effectiveness of the quality system continually**

Checklist

Prerequisites

- ❑ Nationally-coordinated BTS
- ❑ Management commitment and support
- ❑ Integration of quality in the national blood policy
- ❑ National quality policy and plan
- ❑ National quality manager
- ❑ Adequate resources

Organizational management

- ❑ Clearly defined organizational structure
- ❑ Quality manager in each blood centre and hospital blood bank
- ❑ Quality section in each blood centre and hospital blood bank
- ❑ Culture of quality
- ❑ Commitment and support of all staff
- ❑ Identification of processes and procedures and their critical control points

Standards for quality systems

- ❑ Regulatory or legislative framework
- ❑ Appropriate national or international standards
- ❑ Standards relevant to BTSs

Documentation

- ❑ Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- ❑ Complete, accurate records
- ❑ System for controlling documents

Training

- ❑ Training policy and plan
- ❑ Training of all BTS staff in quality and quality systems
- ❑ Training of other health care professionals involved in blood transfusion
- ❑ Evaluation of training and its impact

Assessment

- ❑ Validation
- ❑ Ongoing data collection and analysis
- ❑ Haemovigilance
- ❑ Regular review of all activities
- ❑ Internal and external audits
- ❑ Error management, corrective and preventive action
- ❑ External quality assessment schemes

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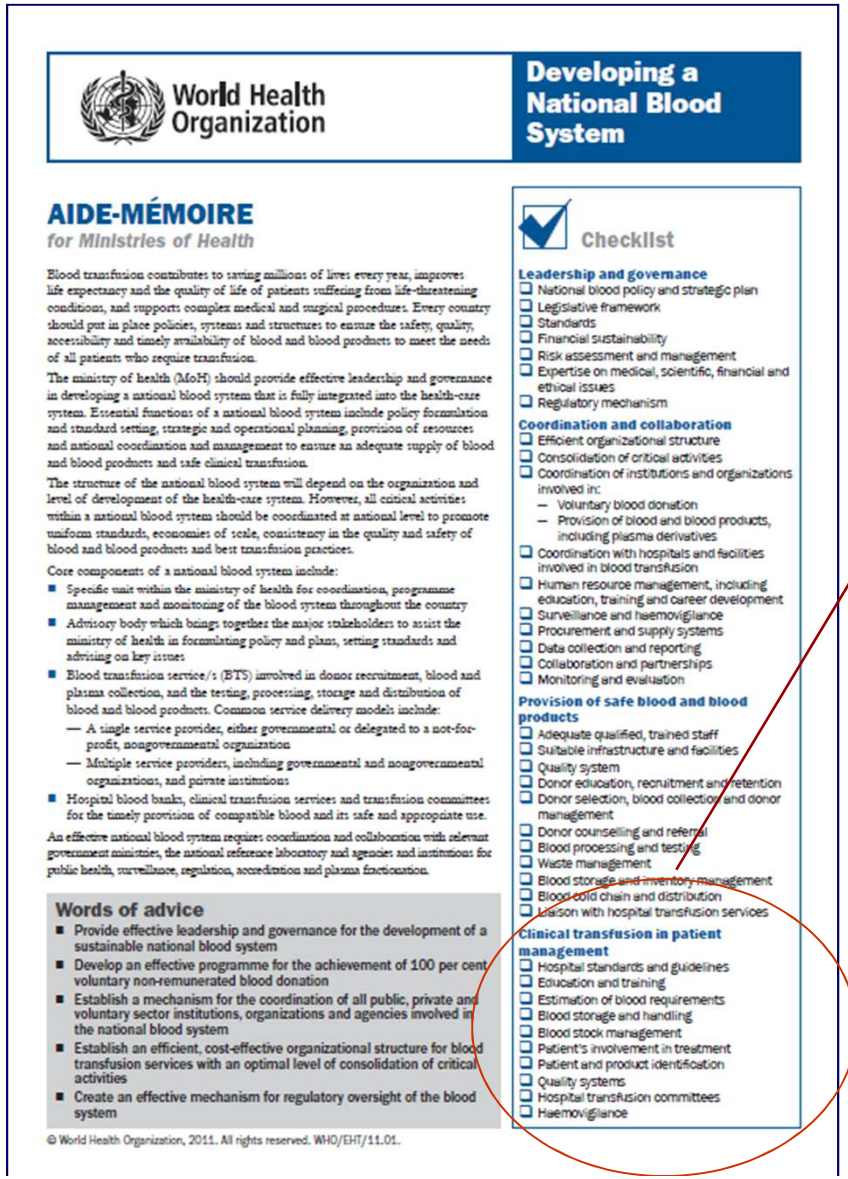
Assessment

Ensuring quality is a continual process. Ongoing assessment of the effectiveness of the quality system is essential through:

- Validation of all processes, procedures, equipment and reagents
- Ongoing collection and analysis of data generated from key activities and their use in quality improvement
- Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities
- Regular review of all activities to assess the overall effectiveness of the quality system and ensure continuous improvement

Developing a National Blood System



World Health Organization

Developing a National Blood System

AIDE-MÉMOIRE

for Ministries of Health

Blood transfusion contributes to saving millions of lives every year, improves life expectancy and the quality of life of patients suffering from life-threatening conditions, and supports complex medical and surgical procedures. Every country should put in place policies, systems and structures to ensure the safety, quality, accessibility and timely availability of blood and blood products to meet the needs of all patients who require transfusion.

The ministry of health (MoH) should provide effective leadership and governance in developing a national blood system that is fully integrated into the health-care system. Essential functions of a national blood system include policy formulation and standard setting, strategic and operational planning, provision of resources and national coordination and management to ensure an adequate supply of blood and blood products and safe clinical transfusion.

The structure of the national blood system will depend on the organization and level of development of the health-care system. However, all critical activities within a national blood system should be coordinated at national level to promote uniform standards, economies of scale, consistency in the quality and safety of blood and blood products and best transfusion practices.

Core components of a national blood system include:

- Specific unit within the ministry of health for coordination, programme management and monitoring of the blood system throughout the country
- Advisory body which brings together the major stakeholders to assist the ministry of health in formulating policy and plans, setting standards and advising on key issues
- Blood transfusion service/s (BTS) involved in donor recruitment, blood and plasma collection, and the testing, processing, storage and distribution of blood and blood products. Common service delivery models include:
  - A single service provider, either governmental or delegated to a not-for-profit, nongovernmental organization
  - Multiple service providers, including governmental and nongovernmental organizations, and private institutions
- Hospital blood banks, clinical transfusion services and transfusion committees for the timely provision of compatible blood and its safe and appropriate use.

An effective national blood system requires coordination and collaboration with relevant government ministries, the national reference laboratory and agencies and institutions for public health, surveillance, regulation, accreditation and plasma fractionation.

Words of advice

- Provide effective leadership and governance for the development of a sustainable national blood system
- Develop an effective programme for the achievement of 100 per cent voluntary non-remunerated blood donation
- Establish a mechanism for the coordination of all public, private and voluntary sector institutions, organizations and agencies involved in the national blood system
- Establish an efficient, cost-effective organizational structure for blood transfusion services with an optimal level of consolidation of critical activities
- Create an effective mechanism for regulatory oversight of the blood system

Checklist

Leadership and governance
- ☐ National blood policy and strategic plan
- ☐ Legislative framework
- ☐ Standards
- ☐ Financial sustainability
- ☐ Risk assessment and management
- ☐ Expertise on medical, scientific, financial and ethical issues
- ☐ Regulatory mechanism

Coordination and collaboration
- ☐ Efficient organizational structure
- ☐ Consolidation of critical activities
- ☐ Coordination of institutions and organizations involved in:
  - Voluntary blood donation
  - Provision of blood and blood products, including plasma derivatives
- ☐ Coordination with hospitals and facilities involved in blood transfusion
- ☐ Human resource management, including education, training and career development
- ☐ Surveillance and haemovigilance
- ☐ Procurement and supply systems
- ☐ Data collection and reporting
- ☐ Collaboration and partnerships
- ☐ Monitoring and evaluation

Provision of safe blood and blood products
- ☐ Adequate qualified, trained staff
- ☐ Suitable infrastructure and facilities
- ☐ Quality system
- ☐ Donor education, recruitment and retention
- ☐ Donor selection, blood collection and donor management
- ☐ Donor counselling and referral
- ☐ Blood processing and testing
- ☐ Waste management
- ☐ Blood storage and inventory management
- ☐ Blood cold chain and distribution
- ☐ Liaison with hospital transfusion services

Clinical transfusion in patient management
- ☐ Hospital standards and guidelines
- ☐ Education and training
- ☐ Estimation of blood requirements
- ☐ Blood storage and handling
- ☐ Blood stock management
- ☐ Patient's involvement in treatment
- ☐ Patient and product identification
- ☐ Quality systems
- ☐ Hospital transfusion committees
- ☐ Haemovigilance

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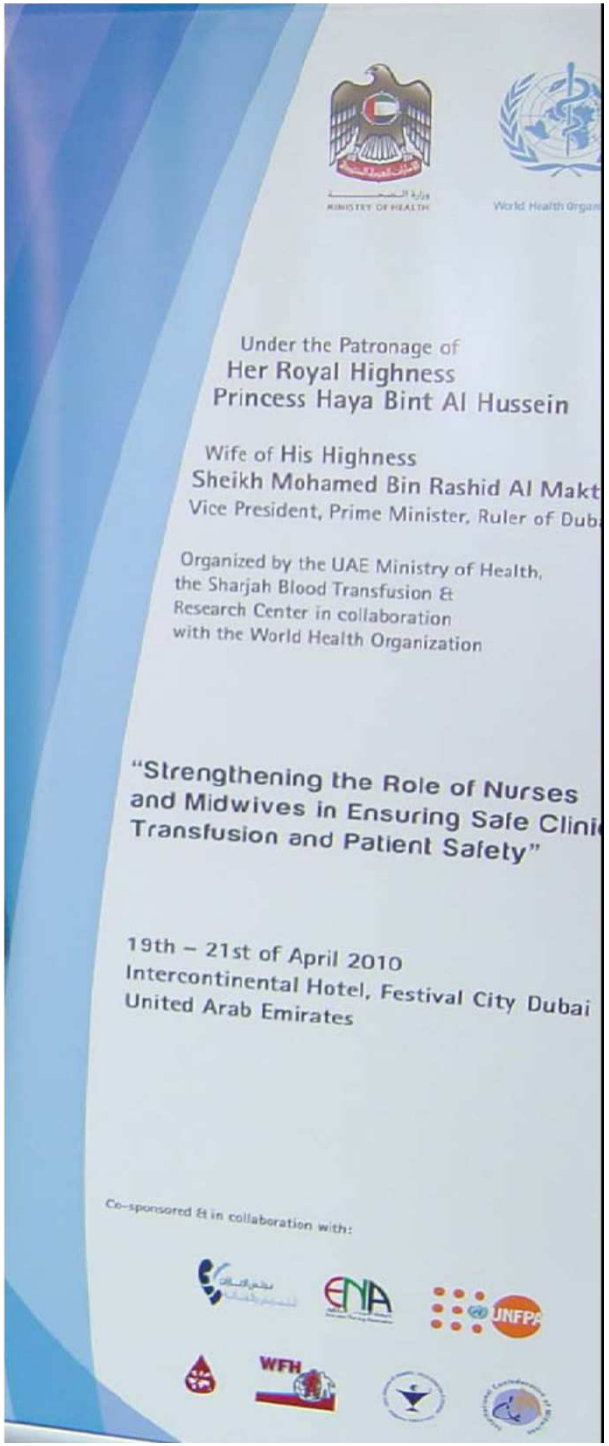
WHO Interregional Consultation

- Strengthening the role of nurses and midwives in ensuring safe clinical transfusion and patient safety, Dubai, UAE, April 2010
  - 18 countries from AFR (11) , EMR (4) and SEAR (3)
- Organized by WHO HQ/Geneva and Sharjah Blood Transfusion and Research Centre & cosponsored by the Gov of UAE
- Collaboration with UNFPA, ICN, ICM, WFH and TIF
- Collaboration with WHO programmes on Nursing and Midwives, Injection Safety, Making Pregnancy Safer and Patient Safety



Materials and Tools for Safe Clinical Transfusion Process and Patient Safety

World Health Organization

United Arab Emirates

IHN International Haemovigilance Network

ISBT

Global Consultation on Haemovigilance

20-22 November 2012, Dubai, United Arab Emirates

Jointly organized by WHO HQ/Geneva, Sharjah Blood Transfusion and Research Center and the Government of the United Arab Emirates (UAE), in collaboration with the International Haemovigilance Network and the International Society of Blood Transfusion

WHO Plans and Activities in Haemovigilance

Advocacy and guidance

- An Aide-Mémoire on 'National haemovigilance system'
- Policy and technical guidance on 'Establishing a national haemovigilance system'

Capacity building

- Training workshops for implementation of systems for data and quality management and haemovigilance systems

WHO Plans and Activities in Haemovigilance

Technical support

- Provision of technical support to countries for implementation of WHO guidance and international standards related to HV

International data and information sharing

- Collection and sharing of data using common definitions and standardized data collection tools, based on the WHO Global Database on Blood Safety

Consistent Global Nomenclature and Coding Systems

- Indisputable need for globally standardized description and coding for Medical Products of Human Origin
- Opportunity to work in a harmonized way before individual countries or regions develop disparate systems
- A global review shows that promoting ISBT128 is the best way to achieve global consistency of coding across all medical products of human origin
- Working relationship between WHO and ICCBBA maintaining ISBT 128: global nomenclature, access for LMIC
- **WHO SONG project: Standardization of Organ Nomenclature Globally**

  http://www.who.int/transplantation/tra_song/en/index.html

Globally Consistent Coding Systems

Information Standard for Blood and Transplant 128

- Terminology
- Nomenclature
  - Translations
- Coding
- Unique identifiers
  - Centres
  - Donations
  - (Recipient(s))
- Formatting standards
- Delivery means
- Inter-operability across Medical Products of Human Origin

Engagement of professionals, health authorities and industry

CNT European Projects on V&S 2005-2013 Associating WHO

Centro Nazionale Trapianti

Global Vigilance Tools

3rd Global Consultation on Regulatory Requirements for HCTT, February 2010 Geneva

SAEs - Criteria

CRITERIA FOR REPORTING SAEs
Inappropriate tissues/cells have been distributed for clinical use, even if not used;
The event could have implications for other patients or donors because of shared practices, services, supplies or donors;
The event resulted in a mix-up of gametes or embryos;
The event resulted in loss of any irreplaceable autologous tissues or cells or any highly matched (i.e. recipient specific) allogeneic tissues or cells;
The event resulted in the loss of a significant quantity of unmatched allogeneic tissues or cells.

Severity (SARs)

Non serious	Mild clinical/psychological consequences. No hospitalisation. No anticipated long term consequence/disability
Serious	- hospitalisation or prolongation of hospitalisation and/or - persistent or significant disability or incapacity or - intervention to preclude permanent damage or - evidence of a serious transmitted infection or - birth of a child with a serious genetic disease following ART with donor gametes or embryos.
Life-threatening	- major intervention to prevent death or - evidence of a life-threatening transmissible infection or - birth of a child with a life-threatening genetic disease following ART with donor gametes or embryos.
Death	Death

Report to CA

Imputability (SARs)

NA Not assessable	Insufficient data for imputability assessment
0. Excluded	Conclusive evidence beyond reasonable doubt for attributing to alternative causes.
1. Unlikely	Evidence clearly in favour of attributing to other causes.
2. Possible	Evidence is indeterminate.
3. Likely, Probable	Evidence in favour of attributing to the tissues/cells.
4. Definite, Certain	Conclusive evidence beyond reaonable doubt for attributing to the tissues/cells

Impact (SARs and SAEs)

1	Rare	Difficult to believe it could happen again
2	Unlikely	Not expected to happen but possible
3	Possible	May occur occasionally
4	Likely	Probable but not persistent
5	Almost certain	Likely to occur on many occasions

Step 1 – Probability of recurrence

Level	Impact Description	Impact on individual(s) Actual (SAR) Potential (SAE)	Impact on Transplant or Fertility System	Impact on Tissue/cell supply
0	Insignificant	Insignificant	No affect	Insignificant
1	Minor	Non-serious	Minor damage	Some applications postponed
2	Significant	Serious	Damage to system – services will be affected for short period	Many applications cancelled or postponed
3	Major	Life threatening	Major damage to system – significant time needed to repair	Significant no. of procedures cancelled - importation required to make-up short-fall
4	Severe	Death	System destroyed – need to rebuild	All allogeneic applications cancelled

Step 2– Consequences of Recurrence

Recurrence probability → / Consequences ↓	Rare 1	Unlikely 2	Possible 3	Likely 4	Almost certain 5
Insignificant 0	0	0	0	0	0
Minor 1	1	2	3	4	5
Significant 2	2	4	6	8	10
Major 3	3	6	9	12	15
Severe 4	4	8	12	16	20

Step 3 - Impact

The NOTIFY Library

- A database of all **types** of severe adverse events and reactions that have been reported arising from procurement and processing to clinical application of cells, tissues and organs for transplantation as well as of medical products of human origin used in assisted reproduction technologies.

1. A reference for professionals focused on **diagnostic and investigation**
2. but also providing evidence for **donor selection**,
3. A source of information for candidate **recipients and living donors**
4. A database for **further study**

Outline of the Presentation

- Substances of Human origin
- Issues and challenges
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- What has WHO done?
- What are the next steps?

Comprehensive Scope of Vigilance for SOHO

	Safety	Ethics	Adverse Reactions	Adverse Events
Cells	✓	✓	✓	✓
Tissues	✓	✓	✓	✓
Organ	✓	✓	✓	✓
Gametes ART	✓	✓	✓	✓
Blood and components	✓	✓	✓	✓
Plasma Derivatives	✓	✓	✓	✓
	Complementarity with pharmacovigilance			
Other SOHO	✓	✓	✓	✓

Value of consolidating vigilance for all SOHO

- Many overlap and similarities despite specificities and differences
- Increased donor, recipient and community protection
- Optimizing vigilance for the “exceptional nature” of SOHO

Need for Global Governance

- Despite more than 25 resolutions adopted by WHO governing bodies addressing the issues of SOHO, the slow implementation of key strategies for blood safety and guiding principles for organ transplantation is a major impediment to achieving safety, self-sufficiency and universal access in many countries
- Need to develop global governance strategies, mechanisms and appropriate legal instruments common to SOHO, pathway to an international binding convention
  - addressing policies on donors, donations, access, equity, ethics, safety, traceability, patients