

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?

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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- ☐ Regular review of all activities
- ☐ Internal and external audits
- ☐ Error management, corrective and preventive action
- ☐ External quality assessment schemes

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

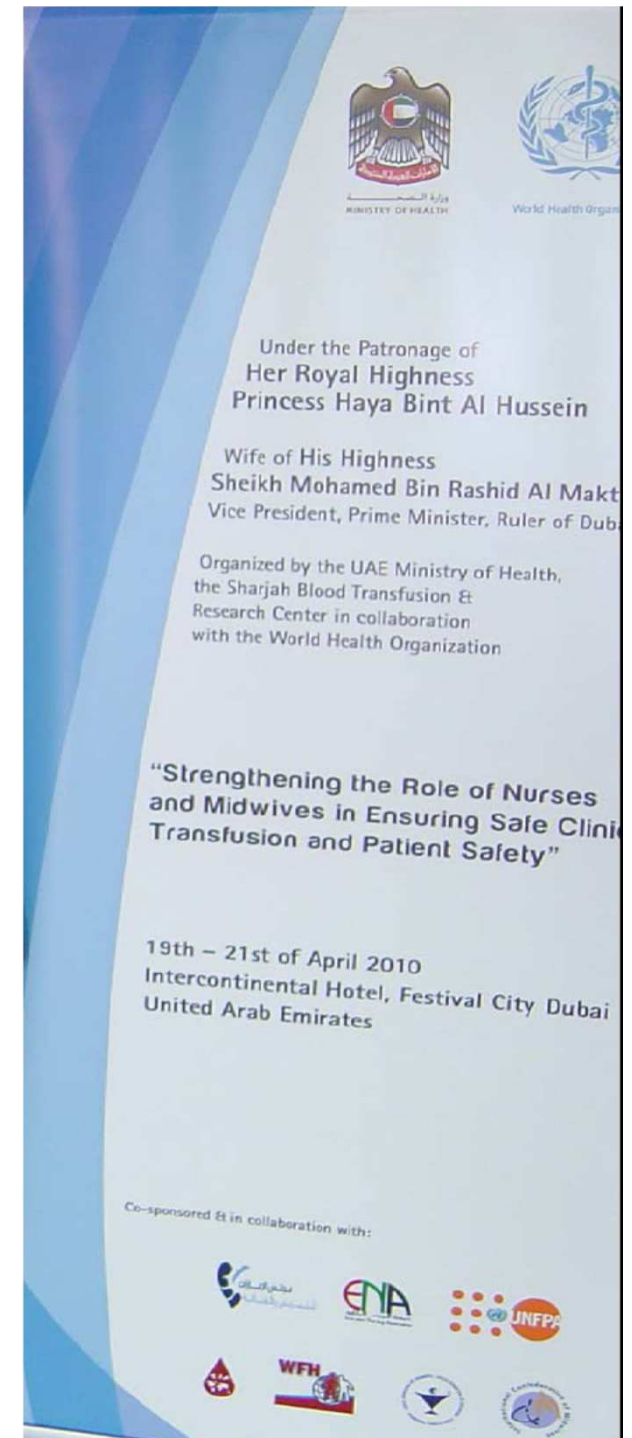
- ☐ Hospital standards and guidelines
- ☐ Education and training
- ☐ Estimation of blood requirements
- ☐ Blood storage and handling
- ☐ Blood stock management
- ☐ Patient's involvement in treatment
- ☐ Patient and product identification
- ☐ Quality systems
- ☐ Hospital transfusion committees
- ☐ Haemovigilance

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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

منظمة الصحة العالمية

إجراءات نقل الدم السريرية وسلامة المريض

World Health Organization

Clinical Transfusion Process and Patient Safety

AIDE-MÉMOIRE

for National Health Authorities and Hospital Management

Blood transfusion is an essential, life-saving intervention in the clinical management of patients. All patients requiring transfusion should have reliable access to safe blood products, including whole blood, whole blood components and plasma-derived medicinal products. Transfusion should be appropriate to patients' clinical needs, provided in time and securely administered.

Patient safety in blood transfusion depends on both the safety of blood products and the safety of the clinical transfusion process – a process that encompasses a series of inter-connected steps including the perception and ordering of blood products; patient identification; collection and labelling of patient blood samples; pre-transfusion compatibility procedures and use of blood; collection and transportation of blood units within the hospital; handling of blood units in the clinical area; blood administration; monitoring of patients; and management of adverse transfusion events.

An appropriate and correct clinical transfusion process ensures patient safety and contributes to improved health and survival. However, transfusion carries the risk of adverse events including errors, transfusion reactions and transmission of infections. The most important cause of serious transfusion reactions and deaths is wrong blood transfusion due to errors during the clinical transfusion process, such as incorrect identification of patients, blood samples or blood units; sampling and labelling errors; laboratory errors; clerical errors; improper storage and handling of blood; failure to perform the final bedside check prior to blood administration; and lack of patient monitoring during transfusion.

Errors during the clinical transfusion process can be prevented by the strengthening of hospital systems and processes for clinical transfusion, the training of hospital staff and the implementation of standardized procedures throughout the clinical transfusion process.

Words of advice

- Ensure an adequate and reliable supply of safe blood products and transfusion alternatives
- Establish policies and systems for safe clinical transfusion and patient safety in all health facilities performing transfusion
- Establish hospital transfusion committees and designate transfusion safety officers in hospitals
- Provide training for all clinicians, nurses, laboratory/blood bank staff, pharmacists and other personnel involved in the clinical transfusion process
- Ensure the implementation of standardized procedures throughout the clinical transfusion process, including patient identification, blood administration and patient monitoring
- Establish haemovigilance systems to monitor, report and investigate adverse events associated with transfusion

Processus clinique de la transfusion et sécurité des patients

Liste de contrôle

Conditions requises à l'hôpital

- Stock suffisant de produits sanguins sûrs
- Effectif suffisant de personnel qualifié et bien formé
- Système d'identification des patients
- Processus clinique de la transfusion intégré dans le système qualité de l'hôpital, y compris les documents et les dossiers
- Comité hospitalier de sécurité transfusionnelle approprié

Directives et protocoles relatifs à la transfusion

- Indicateurs cliniques et biologiques pour l'utilisation des produits sanguins
- Formulaire standard de demande de sang
- Calendriers de commande de sang pour les interventions chirurgicales programmées
- Procédures opératives normalisées pour le processus clinique de la transfusion

Transfusion en clinique

- Usage approprié des produits sanguins sur la base des besoins cliniques des patients
- Collecte et étiquetage précis des échantillons de sang du patient
- Manipulation correcte des unités de sang
- Administration du sang dans de bonnes conditions de sécurité, y compris le contrôle ultime de l'identité du patient, des unités de sang et des documents au lit du malade
- Surveillance du patient avant, pendant et après la transfusion
- Prise en charge des effets indésirables de la transfusion

Service de sang/laboratoire de transfusion de l'hôpital

- Gestion des stocks de sang
- Chaîne de froid pour le stockage et le transport des produits sanguins
- Procédures de compatibilité pré-transfusionnelles, y compris l'épissage et la distribution
- Conservation et stockage des prélèvements sanguins des patients
- Enregistrement et investigation des effets indésirables de la transfusion

Suivi et évaluation

- Système d'hémovigilance pour la surveillance, la notification et l'investigation des effets indésirables de la transfusion
- Indicateurs pour contrôler la qualité et l'innocuité du processus clinique de transfusion
- Analyse des données de l'hémovigilance, suivie de mesures correctives et préventives
- Revues régulières de l'utilisation du sang et des pratiques transfusionnelles

de transfusion clinique peuvent les systèmes et processus, la capacité du personnel et les moyens à la charge du personnel.

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El proceso de transfusión clínica y la seguridad de los pacientes

Lista de comprobación

Requisitos para los hospitales

- Existencia suficiente de productos sanguíneos seguros
- Dotación suficiente de personal calificado y capacitado
- Sistema de identificación de pacientes
- Proceso de transfusión clínica integrado al sistema de calidad del hospital, en particular los servicios de documentación y registros
- Comité hospitalario de transfusiones que funcione
- Funcionamiento a cargo de la seguridad de las transfusiones
- Información al paciente y consentimiento de este
- Infraestructura adecuada del banco de sangre del hospital

Directivos y protocolos para la transfusión

- Indicadores clínicos y de laboratorio para el uso de productos sanguíneos
- Formulario estandarizado para solicitar sangre
- Planes de solicitud de sangre para intervenciones quirúrgicas programadas
- Procedimientos operativos estándar del proceso de transfusión clínica

Transfusión en el área clínica

- Utilización correcta de los productos sanguíneos basada en las necesidades clínicas del paciente
- Identificación correcta del paciente
- Extracción y etiquetado correctos de las muestras sanguíneas del paciente
- Manipulación correcta de las bolsas de sangre
- Administración segura de la sangre, en particular comprobación final de la identidad del paciente, las bolsas de sangre y los documentos a la cabecera del paciente
- Vigilancia del paciente antes, durante y después de la transfusión
- Tratamiento de los efectos adversos de la transfusión

Recibo de sangre y laboratorio de transfusiones del hospital

- Gestión de los stocks de sangre
cadena de frío para el almacenamiento y transporte de productos sanguíneos
- Procedimientos previos de compatibilidad, incluido el epesado y el despacho
- Conservación y almacenamiento de los muestras sanguíneas de los pacientes
- Registro e investigación de los efectos adversos de la transfusión

Vigilancia y evaluación

- Sistema de hemovigilancia para la vigilancia, notificación e investigación de los efectos adversos de la transfusión
- Indicadores para vigilar la calidad y la seguridad del proceso de transfusión clínica
- Análisis de los datos de hemovigilancia, seguido de medidas correctivas y preventivas correspondientes
- Examen periódico de la utilización de la sangre y las prácticas de transfusión

de transfusión clínica pueden los sistemas y procesos, la capacidad del personal y los recursos a la carga del personal.

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مذكرة

للسلطات الصحية الوطنية وإدارة المستشفيات

إن عملية نقل الدم تعد دليلاً أساسياً يلقه الحياة وينقذ في إطار التدبير العلاجي للمريض في العيادة. وينبغي أن تتيح لجميع المرضى الذين يحتاجون إلى نقل الدم وسيلة موثوقة للحصول على منتجات الدم المأمونة، بما فيها الدم الكامل ومكونات الدم المنفوعة والمنتجات الدوائية المشتقة من البلازما. وينبغي أن تكون عملية نقل الدم ملائمة لاحتياجات المريض السريرية وأن تتم في التوقيت المناسب وتضمن أعلى جودة ممكنة.

وتعتمد سلامة المريض في عملية نقل الدم على كل من مأمونية منتجات الدم وسلامة إجراءات نقل الدم السريرية. وهي تشمل سلسلة من الخطوات المترابطة التي تضمن وصولاً وطلب منتجات الدم والتحقق من هوية المريض، وجمع وتوزيع عينات دم المريض، وإجراء التحاليل المتعلقة من توافق فصيلة الدم قبل نقله إلى المريض، وإخراج الدم، وجمع وحدات الدم ونقلها من مكان إلى آخر داخل المستشفى، وصولاً ووحدات الدم في التوقيت السريري المناسب، ونقل الدم إلى المريض، ورسد حالة المريض، ومعالجة الأحداث العارضة التي تقع في عملية نقل الدم.

ومن شأن إجراءات نقل الدم الملائمة والصحيحة أن تضمن سلامة المريض، وتساعد على تحسين صحته، وتقلل من خطر الإصابة. ومع ذلك فإن عملية نقل الدم تتطلب على مدارها العديد من الخطوات التي تشمل الأخطاء والتحديات. ولأنه من الصعب تجنب هذه الأخطاء، فإن من المهم أن تكون الإجراءات المتعلقة بعملية نقل الدم والوقاية من الخطأ في نقل الدم نتيجة الأخطاء التي تحدث في إجراءات نقل الدم السريرية مثل التحقق من هوية المريض أو عينات الدم أو وحدات الدم أو أخطاء أخذ العينات والتوزيع، وأخطاء المختبرات والأخطاء في الأعمال المخبرية، واخترايم وسلامة الدم بصورة غير سليمة، وعدم اتباع الإجراءات الخاصة بالتوافق النهائي عند ترديد المريض قبل نقل الدم، وعدم رصد حالة المريض أثناء عملية نقل الدم.

ويشكل الجولمة من دون أدوية الخطأ، في إجراءات نقل الدم السريرية من خلال تعزيز نظم وإجراءات المستشفيات فيما يتعلق بعملية نقل الدم السريرية، وتدريبات موظفي المستشفيات وتطبيق تدابير موحدة على جميع إجراءات نقل الدم السريرية.

Safe Transfusion Practice (STaP) Training Toolkit

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**World Health
Organization**



International
Haemovigilance
Network



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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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

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 reasonable 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

Recurrent 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
- WHO policies and directions as enshrined in WHA resolutions
- What has WHO done?
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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