



**World Health  
Organization**



United Arab Emirates



International  
Haemovigilance  
Network



# **After WHO Global Consultation on Haemovigilance**

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**World Health  
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# Outline of the Presentation

- WHO Global Consultation on Haemovigilance
  - Objectives
  - Agenda
  - Participants
  - Recommendations
  - Priorities for Action
  - Follow up



## Objectives of the Global HV Consultation (1 of 3)

1. Highlight the importance of **national haemovigilance systems** and international **networking** for global blood safety and availability
2. Assess the nature and magnitude of current **challenges** and **barriers** to the implementation of haemovigilance systems, particularly in developing countries
3. Provide a platform for countries to **share experiences** and **learn lessons** for developing national haemovigilance systems in a stepwise manner



## Objectives of the Global HV Consultation (2 of 3)

4. Define **strategies** for developing haemovigilance systems, including
  - harmonized **reporting** of transfusion-related adverse reactions and events
  - **collection, analysis** and **use** of national data for continuous learning
  - improvement in the safety of **blood donors, blood products** and **patients**



## Objectives of the Global HV Consultation (3 of 3)

5. Building on existing international networks, discuss expansion of **global mechanisms** for **networking countries and organizations** to share data, information and experiences on haemovigilance, to
  - advocate and support the establishment of **national haemovigilance systems**
  - harmonize global **data collection**
  - organize **joint activities**
  - function as a **forum** for dialogue, advice and information gathering for all key stakeholders



## Participants of the Global HV Consultation

- About 150 participants, including representatives from 46 countries (developed and developing) representing all regions of WHO, including
  - senior policy makers from ministries of health
  - representatives from main institutions, agencies and stakeholders in establishing haemovigilance systems at national, regional or hospital level
    - blood services, public health institutions, hospitals, regulatory agencies and professional bodies.
- Key international organizations and experts



## Participating Countries

- **AFR:** Burkina Faso, Ethiopia, Ghana, Kenya, Mauritius, Namibia, Niger, Senegal, South Africa, Uganda
- **AMR:** Argentina, Canada, Brazil, Honduras, United States of America
- **EMR:** Afghanistan, Egypt, Iraq, Jordan, Kuwait, Oman, Pakistan, Qatar, Saudi Arabia, South Sudan, Tunisia, United Arab Emirates
- **EUR:** France, Netherlands, Slovenia, United Kingdom
- **SEAR:** Bangladesh, Bhutan, India, Nepal, Sri Lanka, Thailand
- **WPR:** Australia, Cambodia, China, Japan, Korea Lao PDR, Mongolia, Viet Nam

## **WHO Global Consultation on Haemovigilance, Nov 2012, Dubai**







## Agenda of the Global HV Consultation (1 of 2)

1. Opening session
2. International perspectives on haemovigilance
3. Challenges, lessons learnt and strategies for implementation of HV systems: Country experiences
4. Breakout sessions: 4 groups

A: Challenges in setting up HV systems and strategies for developing national HV systems



## Agenda of the Global HV Consultation (2 of 2)

B: Global mechanisms for networking countries and organizations for sharing of data, information and experiences on HV

C: Standardized definitions & tools for global HV reporting

D: Future perspectives: Scope of HV and beyond

5. Tour of the Sharjah Blood Transfusion & Research Center
6. Recommendations and priorities for action
7. Closing session



## Recommendations: Hospital/Institutional level (1 of 4)

**Hospital administrators and clinical staff should:**

1. Implement **clinical guidelines** on transfusion of blood and blood products based on **national standards**, including:
  - positive identification of patients prior to transfusion
  - transfusion triggers
  - standard blood ordering schedules
  - appropriate documentation of the transfusion process
  - blood utilization review
  - audit of clinical transfusion practice
  - traceability requirements



## Recommendations: Hospital/Institutional level (2 of 4)

2. Establish **policies and procedures** for all steps in blood transfusion chain including those for haemovigilance. These should be:
  - based on local, national or international standards
  - non-punitive
  - reviewed on regular basis
3. Define **quality indicators** as measures of clinical practice and traceability, and collect and analyze the indicators data on regular basis for quality improvement



## Recommendations: Hospital/Institutional level (3 of 4)

4. Develop mechanisms of reporting of adverse transfusion events (reactions and incidents), including
  - adverse transfusion reaction forms and incident reporting form
  - protocol for further investigations of transfusion reactions
  - clear roles and responsibilities for reporting and follow up
  - regular review of adverse reactions and incidents by the hospital transfusion committee



## Recommendations: Hospital/Institutional level (4 of 4)

5. Allocate sufficient **human and financial resources** to establish an effective Haemovigilance system at hospital level
6. Put in place mechanisms for providing **training and education** on haemovigilance to all staff involved in the transfusion chain
7. Establish and activate and maintain **hospital transfusion committee**
8. Designate **Transfusion Nurse** or **Haemovigilance Officer** in hospitals to follow up on all reports of adverse transfusion events, to report to HTC and national haemovigilance office



## Recommendations: National level (1 of 5)

**Ministries of Health and state/local health authorities** should

1. Recognize that **haemovigilance is essential** for quality and safety of blood donation and transfusion
2. Enshrine surveillance of the entire blood cold chain in the **national blood policy**
3. Set up and maintain a **national haemovigilance system** where blood collection and blood administration are performed, covering the entire blood chain including **donors and recipients, processes and products**
4. Develop **strategic plans** to set up and maintain a HV system which evolves in a **stepwise manner** from basic to complex



## Recommendations: National level (2 of 5)

5. Provide effective **leadership, direction** and **governance** for the development of a functioning national haemovigilance system
6. Establish mechanisms for **coordination and collaboration of all stakeholders** (institutions and organizations) involved in the blood chain
7. Set up an efficient **organizational structure** for surveillance of the entire blood chain (donors and recipient, products and processes)
8. Advocate, guarantee and assure for a **non-punitive environment** while developing the system





## Recommendations: National level (3 of 5)

9. Provide necessary **resources** both financial and human for effective implementation of HV system
10. Put in place **methods and channels** for data collection, monitoring, analysis, reporting, evaluation and assessment, rapid alert and early warning
11. Ensure that haemovigilance links efficiently into **policy formulation and quality management** and results in improvement of quality and safety of the entire blood chain
12. Facilitate access to current **medical and scientific expertise** in HV system



## Recommendations: National level (4 of 5)

**Blood transfusion services** - national, nationally coordinated or fragmented; and public, private or mixed services should:

1. Define **roles and responsibilities** of blood centres in relation to HV system
2. Develop systems for **reporting** of adverse donor reactions and errors, including data collection, notification and reporting, monitoring and analysis and evaluation




## Recommendations: National level (5 of 5)

3. Establish mechanism for liaison with hospitals, including blood banks/blood transfusion laboratories, and HTC
4. Secure traceability (bidirectional tracking from donor to transfused patient and vice versa –( vein to vein, using appropriate IT, communication tools)
5. Integrate HV into the quality management system



# Aide-Mémoire: National Haemovigilance System

- Leadership and governance
- Components of a haemovigilance system
- Core haemovigilance unit
- Blood transfusion services, as producers
- Hospitals, as users



**World Health Organization**

**AIDE-MÉMOIRE**  
*for Ministries of Health*

Blood transfusion is a life-saving medical intervention. However, the transfusion of blood and blood products may be associated with adverse effects such as the transmission of blood-borne pathogens including viruses, bacteria and parasites. Non-infectious hazards of transfusion can also harm patients. Haemovigilance (HV), the systematic and proactive surveillance of events during and after blood donation and the administration of blood products, helps to detect and identify adverse effects of blood donation and transfusion and can be highly effective in improving the quality and safety of transfusion, as well as providing other benefits, including cost savings. Haemovigilance is a set of surveillance procedures that extend across the entire blood chain from the donors of whole blood and blood components to the recipients of blood and blood products. Additional areas for surveillance include the products and processes along the blood chain and broader clinical transfusion practice, including appropriate prescribing of blood, alternatives to transfusion, and blood administration, and monitoring, the notification of serious incidents with medical devices. Haemovigilance is intended to collect and assess information on adverse events (reactions, incidents, accidents) resulting from the donation of blood and its components, and from transfusion of blood products, and to prevent their occurrence or recurrence. HV should be seen as a continuous and sustained process. The ministry of health (MoH) should provide effective leadership and governance in developing a national HV system that is fully integrated into the blood system and the health-care system and make available the necessary financial and other resources, including the education and training of health care workers in haemovigilance matters. The organization of HV is largely influenced by the existing structure of the national blood system which, in turn, depends on the organization and level of development of the health-care system. The best conditions for setting up and running a HV system may be found in a national blood system where critical activities are co-located at national level to promote uniform standards, consistency in the quality and safety of blood and blood products and best transfusion practice. A HV system should be embedded in the national blood system and be an important structural and functional component of it. Core components of a national HV system include:

- Haemovigilance unit at national, provincial, state and/or regional level, as appropriate, for central coordination, programme management, monitoring, evaluation and improvement through corrective and preventive actions throughout the blood system
- Blood transfusion services and blood centres involved in blood and plasma collection, testing, processing, storage and distribution of blood and blood products
- Hospitals in which blood transfusion is performed through in: blood banks, operating rooms, clinical wards, transfusion committees in charge for the timely provision of compatible blood, appropriate use of blood products and its safe administration.

An effective national HV system requires balanced coordination and close collaboration of all key stakeholders: relevant ministerial authorities and governmental institutions, suppliers of blood products (producers) and hospitals (users).

**Words of advice**

- Tailor the haemovigilance system to the structure of the national blood system and health system
- Adopt a stepwise approach in building up haemovigilance from a basic to more comprehensive system
- Provide effective leadership and governance for the development of a functioning and effective haemovigilance system
- Establish mechanisms for the coordination and collaboration of all stakeholders involved in the blood chain (producers, clinical users, surveillance and regulators)
- Establish an efficient organizational structure for surveillance of the entire blood chain (donors and recipients as well as products and processes)
- Advocate for a non-punitive environment in the context of blood donation and transfusion

**National Haemovigilance System**

**Checklist**

**Leadership and governance**

- ☐ HV enshrined in national blood policy
- ☐ Legislative framework, specific regulations
- ☐ Strategic plan to establish and maintain HV system
- ☐ Regulatory mechanism
- ☐ Harmonized global definitions and standards
- ☐ Financial sustainability
- ☐ Risk assessment and management
- ☐ Medical, scientific and quality expertise

**Components of a haemovigilance system**

- ☐ Coordination of institutions and organizations involved in production, transfusion, surveillance and regulation
- ☐ Confidentiality, anonymity, non-punitive reporting
- ☐ Human resource development and management, including education, training and career development
- ☐ Traceability (bidirectional tracking)
- ☐ Data collection, investigation, look-back, analysis, reporting and feedback
- ☐ Monitoring and evaluation
- ☐ National and international partnerships

**Core haemovigilance unit**

- ☐ Surveillance of the entire blood chain, from donors to recipients
- ☐ Efficient organizational structure
- ☐ Clearly defined roles and responsibilities
- ☐ Specific tasks (notification handling, data collection, analysis and evaluation, report publishing and dissemination, rapid alert and early warning)
- ☐ Links to public health and regulatory agencies
- ☐ Adequate financial and human resources and authority for implementation to impact changes
- ☐ Trained and experienced personnel

**Blood transfusion services, as producers**

- ☐ Clearly defined roles and responsibilities
- ☐ Education and training of staff
- ☐ Reporting of donor complications
- ☐ Reporting of errors and deviations in processes
- ☐ Liaison with hospitals (blood bank, operating rooms, wards, transfusion committee, quality manager)

**Hospitals, as users**

- ☐ Hospital transfusion committee
- ☐ Hospital policies and guidelines
- ☐ Clearly defined roles and responsibilities: hospital management, and clinical and laboratory staff
- ☐ Education and training of staff
- ☐ Coordination within the hospital (blood bank, clinical wards, transfusion committee, and those responsible for quality management, infection control)
- ☐ Patient and product identification
- ☐ Notification of adverse reactions in recipients
- ☐ Reporting of incidents, accidents and errors



## Recommendations: International level (1 of 4)

**International organizations**, including WHO, IHN and ISBT should:

1. Encourage and provide **high level advocacy** to the national health authorities to establish, implement, evaluate and improve the haemovigilance systems
2. Develop **global technical guidelines, training materials, and standardized/uniform reporting tools and definitions** for the establishment, implementation, evaluation and improvement of the national haemovigilance systems



## Recommendations: International level (2 of 4)

3. Provide **technical support** in:
  - identifying country needs for the development of HV National System
  - assessing gaps and developing roadmaps for establishment of the HV system
  - facilitating the development and implementation of HV plans
4. Facilitate **networking** and support the establishment of partnerships or **twinning** mechanisms for haemovigilance within and between Member States



## Recommendations: International level (3 of 4)

5. Organize **educational and training** activities in haemovigilance at regional/national level for capacity building to support the development of haemovigilance in countries
6. Strengthen/develop consultation and discussion mechanisms for **global networking, sharing of ideas**, best practices, data, information, experiences and reports of the countries of HV
7. Develop a **web-board or electronic forum** where countries can share publications and knowledge on haemovigilance
8. **Disseminate information** and website addresses and links on different haemovigilance systems



## Recommendations: International level (4 of 4)

9. Encourage and support **publication and communication** of haemovigilance findings and reports at international and other fora (WHO, IHN, ISBT, including other international conferences and meetings)
10. Develop **collaborative partnerships** among international organizations working on haemovigilance





## Priorities for Action (1 of 3)

1. Provide **high level advocacy** for the decision makers in the Ministry of Health for establishing national haemovigilance systems
2. Intensify and expand **networking** with international organizations working in the field of Haemovigilance (HV)
3. Provide information on **technical and managerial matters** necessary to set up and establish haemovigilance system
4. Facilitate access to/develop **protocols and tools to collect, analyse and use** national data for learning and improving the process related to blood donors and blood transfusion



## Priorities for Action (2 of 3)

5. Help define an efficient process to provide **standard case definitions** for data collection
6. Contribute to strengthening the **clinical interface** between the hospitals and the blood banks/blood centres
7. Advocate/encourage setting up and maintaining functional **hospital transfusion committees** (HTC)
8. **Support for IT system** including on:
  - **donor data** management
  - **patient record** systems in hospitals on transfusion
  - database that allows **traceability**
  - staff **training** on IT



## Priorities for Action (3 of 3)

### 9. Strengthen capacity building:

- National **trainings** for all stakeholders in haemovigilance, including clinicians, nurses, midwives and blood bank staff on best transfusion practices and haemovigilance
- Setting up of haemovigilance system at **local (hospital/blood bank) level** (protocols, forms, reporting systems, administrative organization)
- **Assistance** in setting up haemovigilance to **priority countries**
- **Step wise implementation** - to initially start the haemovigilance programmes in **major medical college hospitals** and through regular training further phase it up in other hospitals and health facilities



## Follow up

1. An **Aide-Mémoire** outlining key strategies for establishing national haemovigilance systems
2. **Global strategies** on haemovigilance: Report of the global HV consultation published as a WHO publication
3. Harmonization of **definitions** and **tools** for global data collection
4. Further strengthening of global haemovigilance **networking** involving countries and organizations - WHO EZCollab
5. Publication of an article '**Status of Haemovigilance Systems**' in a peer-reviewed journal

# Building on Existing Expertise and Mechanisms



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## **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



## A Way Forward for HV in Developing Countries

1. National Blood Systems will further develop
2. Quality and safety of blood and transfusion will improve
3. Haemovigilance will play a crucial role for improvement and should be part of QMS
4. Haemovigilance is feasible
5. All actors involved in blood transfusion need to show unconditional will to participate in HV
6. Haemovigilance may be implemented stepwise and it should be primarily bottom-up
7. Setting up a HV system needs time and may not always be straight forward

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## Blood transfusion safety

- Blood transfusion safety
- Blood system strengthening
- Quality systems
- Voluntary donation
- Donation testing
- Blood processing
- Clinical use
- Haemovigilance
- Collaborations and partnerships
- Global Database on Blood Safety

### Haemovigilance



Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse events and reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. It covers all activities of the blood chain, vein-to-vein, from donor to recipient to identify and prevent adverse reactions and unwanted events, and to increase the safety, efficacy and efficiency of blood transfusion. It should include the identification, reporting, investigation and analysis of adverse reactions and events in recipients and blood donors as well as incidents in manufacturing processes and, eventually errors and "near-misses"...

Read more about Haemovigilance...

Global Consultation on Haemovigilance pdf, 150kb

Highlights Haemovigilance Blood donor selection and counselling Self-sufficiency in safe blood and blood products Safe and rational use of blood and blood products

The World Health Organization has been at the forefront of the movement to improve global blood safety since 1975 as mandated by successive World Health Assembly resolutions. The objective of the WHO programme on Blood Transfusion Safety is to ensure provision of

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