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, in collaboration with the International Haemovigilance Network and the International Society of Blood Transfusion

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Acronyms

AE	Adverse events
AR	Adverse reactions
CAPA	Corrective and preventive actions
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTC	Hospital transfusion committees
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
MOH	Ministry of Health
NAT	Nucleic Acid Testing
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TTBI	Transfusion transmitted bacterial infection
TRALI	Transfusion related acute lung injury
WHO	World Health Organization

Executive Summary

Haemovigilance is the systematic surveillance of transfusion-related adverse events (AE) and reactions (AR), encompassing the entire transfusion chain and aimed at improving the safety of the transfusion process. A haemovigilance system is an integral part of quality management in a blood system and is essential for the continual improvement of the quality and safety of blood products and to increase the safety, efficacy and efficiency of blood transfusion. It encompasses all activities of the blood transfusion chain, vein-to-vein, from blood donor to transfused patient.

An effective system of haemovigilance requires traceability of blood and blood products from donors to transfused patients and vice versa (bi-directional tracking), recognition, investigation and reporting of transfusion-related adverse reactions and events and rigorous management of information related to the transfusion process, with timely feedback to ensure appropriate action. Information derived from haemovigilance is key to the introduction of blood safety initiatives, such as the development of transfusion policies and guidelines, changes in the processes in blood transfusion service, better transfusion practices in hospitals, improvements in transfusion standards, education and training, thus increasing safety and quality throughout the transfusion process.

The establishment of a haemovigilance system involves all relevant stakeholders and should be coordinated between the national blood programme under the ministry of health, blood services, hospital clinical units and transfusion laboratories, hospital transfusion committees, professional bodies, public health institutions, regulatory agencies and other stakeholders. It should include the identification, reporting, investigation and analysis of adverse reactions and events in transfused patients and blood donors as well as incidents in manufacturing processes and, eventually, errors and "near- misses". Haemovigilance should be strongly linked to quality management, triggering corrective and preventive actions when required.

The **WHO Global Consultation on Haemovigilance** was held in Dubai, United Arab Emirates on 20-22 November 2012 and was jointly organized by WHO-HQ/Geneva, Sharjah Blood Transfusion and Research Center and the Government of the United Arab Emirates, also in collaboration with the International Haemovigilance Network (IHN) and the International Society of Blood Transfusion (ISBT). This three-day Global Consultation on Haemovigilance involved participants from developing and developed countries, including those with established systems and those with plans to start haemovigilance.

A total of around 150 participants was invited to the consultation from over 49 countries (Afghanistan, Argentina, Australia, Bahrain, Bangladesh, Bhutan, Brazil, Cambodia, Canada, China, Egypt, Ethiopia, France, Germany, Ghana, Honduras, India, Iraq, Japan, Jordan, Kenya, Korea, Kuwait, Lao PDR, Mauritius, Namibia, Nepal, Netherlands, New Zealand, Niger, Oman, Pakistan, Qatar, Saudi Arabia, Senegal, Singapore, Slovenia, Sri Lanka, South Africa, South Sudan, Switzerland, Thailand, Tunisia, Uganda, United Arab Emirates, United Kingdom, United

States of America and Viet Nam) representing all regions of WHO. The participants included senior policy makers from ministries of health, and representatives from key institutions, agencies and stakeholders in establishing haemovigilance systems - at national, regional or hospital level, e.g. blood services, public health institutions, hospitals, regulatory agencies and professional bodies.

Partners from key intergovernmental and international organizations working in the area of haemovigilance were also invited, including the European Directorate for the Quality of Medicines and HealthCare-Council of Europe, European Commission, United States Centers for Disease Control and Prevention, Africa Society for Blood Transfusion, Asia Pacific Blood Network, Arab Society of Blood Transfusion Services, South Asian Association of Transfusion Medicine and Latin American Association of Transfusion Medicine.

The methodology of the consultation included presentations, group discussions, and the identification of priorities for action and recommendations to different stakeholders. Broadly, four groups were constituted for discussion on: 1) challenges and strategies for setting up, developing and maintaining national haemovigilance systems; 2) global mechanism/s for networking countries and organizations for sharing of data, information and experiences on haemovigilance; 3) standardized definitions and tools for global haemovigilance reporting and 4) future perspectives: scope of Haemovigilance and beyond.

Objectives of the Consultation

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.
4. Define strategies for developing haemovigilance systems, including the harmonized reporting of transfusion-related adverse reactions and events, the collection, analysis and use of national data for continuous learning and improvement in the safety of blood donors, blood products and patients.
5. Building on existing international networks, discuss creation of global mechanism/s for networking countries and organizations to share data, information and experiences on haemovigilance; and to advocate and support the establishment of national haemovigilance systems; harmonize global data collection; organize joint activities; and function as a forum for dialogue, advice and information gathering for all key stakeholders.

1. Opening session

1.1 Welcome and opening address

Formal welcome and opening remarks were delivered by Dr Amin Al Amiri, Assistant Undersecretary of Medical Practice and License of the United Arab Emirates and Chairman to the Supreme National Blood Transfusion Committee.

Dr Al Amiri welcomed all the participants; he reiterated the support of the Ministry of Health and of the Government of United Arab Emirates to the activities of WHO in strengthening blood safety and especially to the advancement of haemovigilance systems around the world. He added that government of United Arab Emirates has hosted over 15 international meetings since the Sharjah Blood Centre was designated as a WHO Collaborating Centre and has also allocated significant resources to the advancement of blood and injection safety in the African continent.

Dr Al Amiri stated that efforts were already in place to establish a comprehensive haemovigilance System in the UAE, hence Dubai was the perfect setting for the Consultation, which brought together policy makers, experts and country participants from over 40 countries. He thanked and expressed gratitude to WHO, IHN and ISBT for having organized the consultation to coincide with the 41st National Independence Day celebration and was confident that the meeting will be a success. The faculty and international participants were personally greeted by Dr Al Amiri and staff of the Sharjah Blood Centre and commemorative plaques were awarded as gifts.

1.2 WHO inaugural address – Dr N. Dhingra

Dr. Neelam Dhingra welcomed all the participants and thanked the generous support of the UAE Government, Sharjah Blood Centre for hosting and the support from IHN and ISBT in making the Consultation possible. Dr. Dhingra highlighted that the meeting brought together 150 participants, including representatives from 46 countries (developed and developing) representing all six regions of WHO, including: senior policy makers from ministries of health; representatives from key 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 and key international organizations and experts. She acknowledged and thanked all participating countries for showing their commitment to haemovigilance by attending the conference.

Dr. Dhingra voiced her concern that implementation of haemovigilance systems still remains an important challenge worldwide. Information from the WHO Global Database of Blood Safety (2008) indicates that fewer than 25% of countries report having a haemovigilance system in place. She reminded the audience that haemovigilance systems are an integral part of quality management in a blood system and that its implementation contributes to the ongoing improvement and safety of blood products, blood donation and the transfusion process by identifying and reducing the risk of adverse reactions and unwanted events related to donations and transfusions.

Dr. Dhingra expressed her hope that the consultation would help to:

- Highlight the importance of national haemovigilance systems and international networking for improving global blood safety and availability

- Assess the nature and magnitude of current challenges and barriers to the implementation of haemovigilance systems, particularly in developing countries
- Provide a platform for countries to share experiences and learn lessons for developing national haemovigilance systems in a stepwise manner
- 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

Dr Dhingra noted that the meeting would start with an international perspective on haemovigilance with presentations from developed and developing countries. Participants would then break into groups to discuss the main challenges in the implementation of haemovigilance systems, global mechanisms for networking and collaboration; the need to standardize definitions and tools and one last group that would look on the future perspectives of haemovigilance. The expected outcomes for the meeting are:

- WHO Aide-Mémoire outlining key strategies for establishing national haemovigilance systems reviewed and endorsed
- The report of the global haemovigilance consultation finalized as a WHO publication
- Definitions and tools for global data collection harmonized
- Mechanisms for global haemovigilance networking involving countries and organizations defined
- Publication of an article in a peer-reviewed journal on haemovigilance systems from the data collected from the survey circulated prior to the meeting.

1.3 International Haemovigilance Network– Dr J.C. Faber

Dr. Jean-Claude Faber, President of IHN, expressed his gratitude to the Government of UAE for its generous support, to WHO for taking the initiative and leading the organization of the Consultation and to all the countries participating in the event. He added that IHN was particularly proud to join again its forces and spirits with the ISBT, more precisely with the Working Party on haemovigilance, the close partner of IHN in many years of fruitful collaboration.

Dr. Faber expected that the Global Consultation on Haemovigilance would bring together exciting presentations from participating countries and inspiring discussions from all participants resulting in an international consensus and tangible deliverables. He emphasized the importance of participation from developing and transitional countries and explained that IHN was ready to support financially some of these countries to make it possible for them to attend the meeting. Dr. Faber reiterated that the IHN would do its utmost to move haemovigilance forward, always keeping in mind to avoid duplication of effort and ensuring that the work of all partners would be adequately acknowledged.

1.4 International Society for Blood Transfusion– Dr S. Hindawi

Dr. Salwa Hindawi gave the presentation on behalf of Dr. Peter Flanagan, President of ISBT. Haemovigilance is a relatively young part of Transfusion Medicine. It developed in the 1990s in Europe and is now established practice in most developed countries. Information from haemovigilance has contributed significantly to our understanding of the real risks of

transfusion to patients and in particular has highlighted the importance of Transfusion Related Acute Lung Injury (TRALI), bacterial contamination of platelets and the impact of human error in hospital transfusion systems. More work is still needed to ensure global awareness about the appropriate use of blood products and blood transfusion safety.

The ISBT, through its Working Party on Haemovigilance, in collaboration with the IHN, has played an important role in establishing common international definitions for adverse events associated with both blood donation and transfusion. It has also provided a forum for discussion and further development of the scope of haemovigilance. ISBT's participation in this Global Consultation is a natural extension of this work and provides a real opportunity to identify ways to extend the benefits of haemovigilance more widely to low and medium Human Development Index countries. Dr. Hindawi concluded her address by encouraging participants to identify collaborative mechanisms to further strengthen international haemovigilance.

2. International perspectives on haemovigilance

2.1 WHO vision, strategic direction and initiatives on Haemovigilance – Dr N. Dhingra

Dr Neelam Dhingra reminded the audience that the implementation of haemovigilance systems has been recommended by WHO for many years, and the WHO Blood Transfusion Safety programme (WHO/BTS) has joined forces with several partners to highlight its importance. WHO has also emphasized the essential role of surveillance systems in enhancing patient safety by learning from experience in other areas of the health care system. The Global Consultation on Universal Access to Safe Blood Transfusion, 2007 highlighted the need for guidelines, tools and technical support for the establishment of national haemovigilance systems and encouraged WHO to establish Haemovigilance, Surveillance and Alert Networks.

WHO/BTS has defined its strategic direction on haemovigilance as: **strengthening systems for assessment, surveillance, vigilance and alert, monitoring and evaluation** and intends to achieve this by:

Strategy 1: Supporting the development of effective national systems for collection and management of data throughout the transfusion chain

Strategy 2: Building on and strengthening global, regional and national surveillance, vigilance and alert systems and networks for blood safety and availability, and adverse transfusion events and reactions covering the entire transfusion chain from the donor to the patient

Strategy 3: Strengthening global, regional and national monitoring of processes and outcome indicators on blood safety / availability and measuring progress and improvement

2.2 International Haemovigilance Network - Dr J.C. Faber

Dr. Jean-Claude Faber reiterated that haemovigilance is an essential element for blood safety and showed its relation to WHO´s pillars of blood safety. He likened the collaboration between WHO, ISBT, IHN to parts of an engine, fuelled by the generous support of the UAE. The modern concept of haemovigilance includes not only the transfused patient, but also the donor, the processes involved, the reporting of no-harm incidents and near misses and systems for rapid

alert/early warning.

The IHN, although still young, has been 15 years in the making. It has worked hard to standardize terminology, has transformed itself from a European organization into a global one and has developed its own web-based database (ISTARE) that now gathers information from 28 countries. Grants are available to assist developing countries in establishing Haemovigilance programmes but funds are limited and the assessment will prioritize countries with the greatest need. Dr. Faber described the IHN structure, finances and functions and invited participants to join the next IHN Seminar to be held in Brussels in February 20-22, 2013.

2.3 International Society for Blood Transfusion – Dr J. Wiersum

Dr. Jo Wiersum presented the ISBT mission statement: "*Facilitating knowledge about transfusion medicine to serve the interests of donors and patients*". ISBT is a global society with 1500 members in 97 countries. It has a General Assembly and Board of Directors and works through its fourteen (14) Working Parties and Standing Committees. It has close working ties with all major blood safety organizations such as the American Association of Blood Banks (AABB), International Federation of Blood Donor Organizations (FIODS), WHO, etc. ISBT activities include the publication of important technical, administrative and scientific documents relating to blood transfusion as well as setting ethical and technical standards.

The ISBT has its own working party on haemovigilance; it has worked hand in hand with IHN in harmonizing definitions and the development of the ISTARE database. It is currently focusing haemovigilance activities on error and incident definitions, optimal blood use indicators and on potential risks to the donors, e.g. iron depletion and venepuncture related injury.

2.4 Haemovigilance survey – Mr J.P. Yu

The Haemovigilance Survey was developed by the Working Group for Global Consultation on Haemovigilance and had been sent to all 49 (16 high income, 23 middle and 10 low) countries participating in the consultation. This was the first time that data had been collected through the online system and automatically saved in a database in WHO. It had proven to be a very successful effort with 42/49 countries representing all 6 WHO regions completing the survey.

The results of the survey indicated that:

- 28/42 reporting countries had established a HV system
- 16 countries had a HV unit, 25 did not and 1 unknown
- HV was voluntary in 10 countries, mandatory in 13 and mixed in 11
- 22 countries had agreed definitions, standards and guidelines on HV; 15 did not
- 23 countries collect data on adverse donor events; 11 do not
- 32 countries have a bidirectional tracking system between donor and recipient
- 14 countries publish an annual haemovigilance report; 22 do not

He added that the survey identified the following major challenges to implementing a haemovigilance system:

- Fragmented blood transfusion systems (most frequently cited) and health systems (Public, Private Assurance and Unions Security Services)
- Lack of government commitment

- Lack of understanding/ awareness of haemovigilance among clinicians
- Lack of a culture of reporting adverse events
- Fear of punishment
- Lack of experts/expertise on haemovigilance
- Lack of a regulatory framework for haemovigilance
- Absence of well-defined haemovigilance structure and protocols
- Lack of transparency & confidence in government agencies
- Lack of computerized management system and capacity

3. Challenges, lessons learnt and strategies for implementation of haemovigilance systems

3.1 South Africa: experience in implementing haemovigilance – Dr N Moleli

South Africa has a population of 51.8 million. Transfusion services are provided by two organizations: South Africa National Blood Service and Western Province Blood Service which together collect more than 1 million units of blood annually, and serve more than 700 hospitals and clinics. The haemovigilance system was established in 2000 and is modelled on the UK SHOT scheme. It is headed by a medical director, lead consultant and haemovigilance officer, who collect data from hospitals, blood banks and serology laboratories. Annual reports are forwarded to the Director General of the Department of Health.

Implementation of HV has helped in recognition of emerging trends in transfusion hazards. Reports are increasing because of improved awareness through education of blood users and hospital transfusion committees, and there is better understanding of transfusion associated errors. Main challenges are lack of manpower, lack of training and no standardized template or single system common to the two blood services. Future plans include electronic data capture and development of evidence-based guidelines.

3.2 France: experience in implementing haemovigilance – Dr D Bernard

The French haemovigilance system is one of the longest established, and was set up in response to shortcomings in traceability revealed during the HIV epidemic in the 1980s. This led to 'haemovigilance' being formally defined in 1991 followed by legislation in 1993 that required notification of all adverse events in recipients and a high level of traceability of each individual unit from donor to its final destination. The initial purpose of haemovigilance was to reduce adverse reactions and events in the transfusion of labile blood products . In 1998 responsibility for haemovigilance was transferred to the French Health Products Safety Agency (now the ANSM) which has checking and inspection functions at blood transfusion establishments.

With the European Directive 2005/61/EC, transposed into French Law in 2006, came a new definition of haemovigilance – *organised surveillance procedures related to serious adverse or unexpected events or reactions in donors or recipients and the epidemiological follow up of donors - which includes the whole transfusion chain from collection from and monitoring of donors to monitoring of transfusion recipients*. Reporting is mandatory and web-based with very tight observation and regulation. At local level, a haemovigilance focal person is identified in every healthcare facility (1400 in total) and at each local site of the Regional Blood

Establishment (17). At regional level, a haemovigilance coordinator is appointed in each of 29 administrative regions. Nationally haemovigilance is co-ordinated by the ANSM which defines best practice and inspects blood establishments. Adverse events are notified immediately (within 8h locally and within 48h regionally) in writing and notified on a standard form sent electronically to regional and national levels, defining severity and imputability. Success in haemovigilance depends upon involvement of all staff, assurance of absolute confidentiality, absence of blame and regulatory obligation.

Key data from 2011 included: 99.5% blood component traceability; 4287 donor adverse reactions/events; 609 serious transfusion related events and 37 deaths of which 8 were strongly causally linked to transfusion. Safety improvements include a reduction in ABO errors from 21 in 2000 to 3 (but no reduction in mortality: 7 in 2000 and 8 in 2011), a trend of reduction in transfusion transmitted bacterial infection (TTBI) an increase in donor event reporting, reduction in blood component wastage and improved reporting of TRALI.

Challenges include expansion of scope to include all participants, reporting of near-misses expanding of capacity to handle increasing numbers of reports. Future perspectives include development of a national database, computerisation of all hospital blood banks, and making haemovigilance simpler.

3.3 Haemovigilance in Republic of China – Dr J Dandan

China has a population of 1.3 billion in 32 provinces, with 439 blood transfusion services There is currently no integrated haemovigilance programme but several mechanisms are in place for monitoring blood quality and adverse reactions to transfusion. The Blood System framework consists of central government which oversees the provinces, the Red Cross society and the Ministry of Health (MOH). The role of the MOH is to set up legal systems, technical standards and procedures. Since 1999 it has managed blood services, collected and analysed data and set up quality control. The Blood Transfusion Service is responsible for quality management and bi-directional traceability. Hospitals implement clinical guidelines, monitor adverse reactions and set up transfusion committees.

Challenges: although multiple strategies have been set up there is no national collation of data. There is concern about the meaning of ‘non-punitive’ and the atmosphere of ‘learning from errors’ has not been established, leading to fear and resultant inhibition of reporting. There is a shortage of funds and human resources, and a lack of structure at the state level.

3.4 Serious Hazards of Transfusion (SHOT), United Kingdom: experience in implementing haemovigilance – Dr P Bolton-Maggs

The UK has a population of 62 million and a national blood service with independent management for England, Wales, Scotland and Northern Ireland which collaborate as the UK Forum. About 3 million blood components are transfused each year. The national confidential haemovigilance system, Serious Hazards of Transfusion (SHOT) was set up in 1996 initially with voluntary reporting but now is required by several professional bodies. Participation has increased from 22% hospitals in 1996 to 98% by 2011. Donor events are collected by the blood services. Hospital reporters (usually transfusion practitioners or laboratory managers) report through an online system. Annual reports are published and widely circulated.

Following the EU directives, the Medicines and Healthcare Regulatory Agency (MHRA) became the competent authority to administer the regulations on behalf of the Secretary of State.

Reporting of serious adverse reactions to MHRA is statutory, whilst SHOT reporting is professionally mandated, The purpose of both is to improve quality and safety for patients by learning from such events. Work is currently in progress to develop a single UK haemovigilance system. Learning from adverse events and SHOT reporting has led to changes in transfusion policies and improvements in practice with a reduction in preventable deaths (e.g. TRALI and bacterial contamination of platelets). There are still underlying problems with basic processes requiring better knowledge in decision making and prescribing. The use of a transfusion checklist is strongly recommended.

3.5 Brazil: experience in implementing haemovigilance – Dr G N. de L. Camara

Brazil's population is 192 million covered by a unified health system with a regulatory framework for blood transfusion underpinned by Federal Law. About 7500 establishments perform transfusion with 2332 blood establishments. The haemovigilance scheme is well established with mandatory confidential reporting since 2010. Numbers of reports have increased, but challenges remain with under-reporting and a need for improved feedback. Currently only recipient events are reported and donor event reporting is being considered. More needs to be done with use of data to demonstrate cost efficiency, analysis of risks using epidemiological tools and to introduce ISBT 128 standards.

3.6 United States of America: model in implementation and coordination of a haemovigilance system – Dr A Marfin

The USA has no national blood transfusion service; blood is collected by multiple organizations, principally the American Red Cross (45%) and America's Blood Centers (45%). About 24 million components are collected and transfused. A National Blood collection and Utilisation Survey (2009) estimates that there are more than 60,000 transfusion reactions annually, of which 16,000 serious. Hospital blood transfusion services and blood centers have regulatory responsibility to report to US Food and Drug Administration, but currently only serious reactions or errors are required to be reported.

The National Healthcare Safety Network (managed by the CDC) has developed a haemovigilance platform with internet based reporting.

Participation needs to be encouraged, definitions need to be harmonised nationally and internationally. At present there are several different entities to which reports are made and establishments have highly variable IT infrastructures.

3.7 Republic of Korea: experience in implementing haemovigilance - Dr S Y Kwon

The population is 48.87 million. In 2011, 2.6 million units of blood were collected, 94% by the Korean Red Cross and the remainder by private blood centres. Screening is performed for all relevant infectious markers including nucleic acid testing (NAT) for hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV. Other safety measures include leucocyte reduction (2004), a donor deferral registry (2003) use of male only plasma and introduction of a diversion pouch (2009). From 1999 there has been mandatory reporting to the Ministry of Health of adverse events leading to death, disability, and transfusion-transmitted infections. A haemovigilance system was set up in 2007 as a research project with voluntary reporting. In 2010 this was taken over by the Korean Society of Blood Transfusion and in 2011 reporting of donor events was made mandatory.

Challenges include the low participation rate (190-458 non-infectious recipient events per annum). This might be improved by providing feedback – currently there is no annual report and no feedback to hospitals about submitted data.

3.8 Thailand: experience in implementing haemovigilance - Dr U Charoonruangrit

With a population of 65.9 million, the blood services are well-organised with national, regional and hospital services. Between 2001 and 2008 there was an attempt to perform voluntary haemovigilance reporting but it was discontinued for several reasons including non-standardization of definitions and no recognition at national level. In addition it was difficult to differentiate the pulmonary complications from each other. New attempts are now being made to re-establish haemovigilance reporting (following a workshop in 2011 led by the president of the ISBT) aided by the international definitions from ISBT, the WHO initiative and adoption of Thai National Blood Policy.

3.9 Tunisia: experience in implementing haemovigilance - Prof K Boukef on behalf of Dr L Ben Hamed and Mrs S Ben Hatira.

Tunisia has a population of 10 million. It has 160 hospitals of which 70 are private owned. Of the 16,659 hospital beds, 3,293 are in private hospitals. The organizational structure of Tunisia's Blood Transfusion Service includes 1 National Blood Transfusion Center, 5 Regional Blood Transfusion Centers, 1 Mobile Blood Transfusion Center and 29 blood banks which collect 200,000 units of blood in total per year. Hemovigilance in Tunisia began in 1980 and included a series of Memoranda from Ministers, directing blood transfusion service to implement documentation in forms of transfusion records, registers of blood component management, transfusion sheets and post–transfusion complication records and a look back system for root cause analysis. An important milestone was the Ministerial decree in 2007 that marked the implementation of hemovigilance system, with defined national, regional and local points in the network, specified procedure to follow in case of a transfusion incident namely submission of Transfusion Incident Sheet and classification based on etiological study. Once done, a pathway of reporting up to the Minister is followed. The hemovigilance incorporates adverse events among both blood recipients as well as blood donors. The national hemovigilance data of 2007 through 2010 were presented.

Among the constraints on haemovigilance system in Tunisia include under-reporting of adverse events by clinicians, late reporting, use of different channels of reporting (e.g. telephones or letters), incomplete information on incident sheets and failure to report the investigation findings and reports the health authority. Government commitment and pro-active technical leadership were identified as two main contributing factors for a successful haemovigilance program in Tunisia.

3.10 Japan: experience in implementing haemovigilance – Dr J Kasamatsu

Japan has a population of 128 million. The Ministry of Health has overall responsibility for the blood supply. The mandate for blood collection and production of labile components is given to Japanese Red Cross (JRCS); production of plasma products is undertaken by the Japan Blood Product Organization and guidance on clinical blood usage is provided by medical institutions.

The haemovigilance system was established in 1993 following transfusion transmitted HIV in haemophilia patients, together with a national policy of storing samples of all blood donations for 11 years. Both labile blood components and plasma derivatives are regulated under the

legal framework of the Blood Law and the Pharmaceutical Affairs Law respectively whereby all adverse reactions or transfusion transmitted infections must be reported. All cellular products are irradiated to prevent transfusion-associated graft versus host disease, which is a high risk in Japan due to a restricted number of HLA haplotypes. All life-threatening serious events are reported directly to the Blood Advisory Council- Ministry of Health (MoH); information on other events is sent to JRC - Blood Safety Head Quarter Safety Vigilance Division through regional centers which then submit the outcomes of investigation to the Blood Advisory Council, with feedback to the hospital that reported the event.

In summary, the haemovigilance system in Japan is tightly regulated by various organisations, with the Surveillance Committee for Safety of Blood Products in the Blood Advisory Council acting as the advisory body to the MoH, which in turn develops national action plans, safety measures and technical guidelines on appropriate use of blood that are implemented by the manufacturers of blood and blood products and clinical users.

The challenges faced are: emerging and re-emerging infections such as Chagas disease, in which safety measures are in the form of revised risk assessment history and introduction of new donor selection criteria and screening tests; regional disparities in the appropriate use of albumin and fresh frozen plasma, and improving awareness among health staff on the reporting system for adverse events. Future plans include conducting clinical trials on Pathogen Reduction Technology for Platelet Concentrates.

3.11 Transfusion Reactions in Patients (TRIP): haemovigilance system in The Netherlands - Dr J Wiersum

The Netherlands has a single blood supply organization- Sanquin - covering a population of 16.7 million. The haemovigilance scheme 'Transfusion Reactions In Patients' - TRIP was set up in 1998, and their definition of haemovigilance is '*the systematic monitoring of side effects and adverse incidents including near misses throughout the chain from blood donor to recipient, and all other activities which can lead to safer and more effective use of blood components*'. All levels of severity and imputability are to be reported.

The flow process starts with the hospital submitting a report to TRIP if a reaction has been noted relating to the blood component. This is the responsibility of the Hemovigilance Officer appointed by the hospital board and is done after all investigations are completed by the transfusion laboratory in the hospital. The Sanquin blood bank also submits a report to TRIP if a problem has been detected after the delivery of a blood component to a hospital. Every six months, TRIP sends national reports to the hospitals participating in TRIP. Annually, an expert panel of board members reviews reaction reports and any discrepancies in the classification of reactions, grading or imputability levels are discussed and resolved with the reporter. Annual reports with findings and recommendations are sent to the reporting hemovigilance officers, blood transfusion committees and governing boards of the hospitals. It is mandatory that all reports of serious reactions are sent to Healthcare Inspectorate.

Though participation is voluntary and confidentiality is maintained, there has been an increase in number of hospitals reporting to TRIP from a baseline of 70% in 2002 to near 99% in 2011. The ten year experience by TRIP reflects success in one-third reduction in TRALI cases with usage of male-only plasma. However, there has been no reduction in error rates, and main causes of serious reactions include allergic/anaphylaxis, transfusion related acute lung injury (TRALI) and transfusion-associated circulatory overload (TACO). There are 1-2 cases of

transfusion-transmitted bacterial infection per year, and <1 case per year over 9 years of HBV transmission after introduction of HBV NAT, with no other confirmed viral transmissions. One case of post-transfusion malaria was reported in 2011.

Reporting to TRIP is through a user friendly system which also encourages improved bed-side clinical transfusion practice. Harmonization of definitions through collaboration with other organizations is one of the challenges faced. Donor haemovigilance is undertaken by Sanquin.

Discussion revolved around the role of a transfusion safety officer (TSO) with nursing or laboratory background, even if part-time. Such a TSO could contribute towards imparting training of clinical staff, conduct clinical audits and review/revise transfusion protocols and guidelines.

3.12 Regulatory and public health aspects of Haemovigilance in Canada – Dr P Ganz

Canada has a population of 33.4 million; the Canadian Blood Services plus Hema Quebec collect 1.4 million donations annually. The Canadian blood system is mandated to monitor transfusion safety through collection and analysis of surveillance data and to recommend further improvements in the quality and safety of transfused components. Key players in HV in Canada are the Ministry of Health, Health Canada as the regulatory body, the Public Health Agency of Canada (PHAC), the Canadian Blood Services, Hema Quebec and hospitals. The Canadian model for governance of haemovigilance is a blend of mandatory reporting for serious adverse events monitored by Health Canada and voluntary reporting for adverse reactions, accidents and near misses through PHAC. Both government agencies co-operate through established communication links and both are represented in national surveillance data analyses committees. The goals of the HV system are to partner with provinces and territories to establish and maintain an independent system for monitoring adverse events related to transfusion and to conduct targeted research to provide information for risk assessment to further mitigate the risks associated with blood transfusion in Canada.

Several systems are integrated in the haemovigilance system namely:

1. Transfusion Transmitted Injuries Surveillance System (TTISS) which captures data for serious adverse events to blood components
2. Transfusion Errors Surveillance System (TESS) which focuses on collecting data on transfusion errors and near misses
3. Cells, Tissues and Organs Surveillance System (CTOSS) which is currently being developed and serves to collect adverse reaction data in the area of transplantation
4. Targeted surveillance/research system for high-risk population and emerging pathogens.

Dr Ganz shared haemovigilance data showing the highest incidence of 344 in 2006 falling to 172 in 2011. In relation to the data on seven fatalities, three were due to transfusion related acute lung injury (TRALI) but none due to transfusion transmitted infections for the past 15 years. He expressed some concern over the overall number of reports of Transfusion Associated Circulatory Overload (TACO) though only one death was reported.

Areas for improvement in Canadian haemovigilance system include: compliance with reporting, improving quality of reports, consistency in report distribution between blood operators and hospitals, duplication of reporting, incomplete reports and inaccurate assessment and analysis of reports especially in associated fatalities. Outcomes of hemovigilance include: better quality control and processing standards in hospital blood banks, standardized reporting algorithms,

reduced febrile reactions due to leukoreduction and use of single donor platelets and reduced bacterial sepsis by use of blood bags with diversion pouch. The importance of international collaboration and sharing of data were also highlighted. Canada participates actively in building partnerships with organizations such as International Society for Blood Transfusion (ISBT) Working Party on Haemovigilance, the International Hemovigilance Network (IHN) and World Health Organization. The need for a formalized cost benefit analyses to ascertain the cost effective role of haemovigilance efforts in increasing the safety and quality of blood transfusion was also expressed.

3.13 Hong Kong SAR, China: experience in implementing Haemovigilance – Dr C K Lin

Hong Kong has a population of 7.10 million, and a single Blood Transfusion Service as a part of the public hospital system (Hospital Authority) since 1991. A centralized haemovigilance reporting system in all public hospitals with transfusion activities was implemented in 2000, with objectives to: collect, analyze and report data including open disclosure to the medical and public community; encourage reporting of adverse transfusion reactions; ensure proper and adequate investigations and follow-up; strengthen knowledge in transfusion safety and awareness to recognize and report any adverse transfusion reaction; sustain continual quality improvement to maximize blood donor and recipient safety and generate evidence for policy decisions and revision of guidelines.

Key features of the haemovigilance system in Hong Kong include systematic collection of data related to transfusion incidents and adverse reactions by adopting a standardized reporting form; trend analysis and identification of problems in the systems (Blood Bank, hospital transfusion committees, BTS, etc); feedback of the results for education and continued improvement and revision of guidelines, policies and SOPs according to the findings.

Classification of incidents and adverse reactions has been standardized and a Severity Index (SI) has been introduced with SI=0 as no harm caused although an incident occurred and SI=6 being death. Implemented in 2002, Advanced Incident Reporting System (AIRS) has features of a web based system, with centralized data reporting, collating and compilation. Che Kit Lin reflected that more than 90% of the incidents were related to errors in the transfusion request or sampling, mainly blood sample taken from wrong patient.

There have been several changes brought about by the haemovigilance system and this include introduction of Unique Patient Identification System using 2D Barcode in all public hospitals from 2008 to ensure cross-match sample taken from the right patient and the right blood components given to the intended patient; use of male-only plasma and whole blood for clinical transfusion to reduce the incidence of TRALI, and better disinfection and packaging procedure from collection to issue to minimize potential surface contamination of blood bags. Limitations of the system are that reporting is limited to public hospitals and does not include donor haemovigilance, though this is collected by the BTS. The currently used classification system is outdated and not compatible with that of ISBT, making international benchmarking difficult. Future perspectives include: improvement in the quality of reporting through training of staff; revamping of haemovigilance system to adopt the latest international classification; expansion of haemovigilance system to cover donor haemovigilance and private hospitals and sharing of national data and findings with other international organizations. Discussion revolved around the need to include failure of timely availability and accessibility of blood to patients requiring transfusion as one of the adverse events in hemovigilance.

3.14 Sri Lanka: experience in implementing Haemovigilance – Dr S. Jayasekara

This island nation in the Indian Ocean near southern India has a population of 20 million and has impressive socio-economic indicators. Sri Lanka has a centrally coordinated blood transfusion service functioning under the Ministry of Health and fully funded by the Government. It comprises a National Blood Centre and 87 hospital-based blood banks divided in to 16 clusters. The annual blood collection is 330,000 of which 97% is from voluntary non-remunerated blood donors. Screening for HIV, HBV, HCV, Syphilis and Malaria is mandatory and NAT testing will be introduced in 2013.

Sri Lanka has a strong programme of transfusion medicine teaching and training. Reporting of adverse events is mandatory on a monthly basis to the National Blood Centre. Serious events are reported immediately. Systematic analysis of the data has not been streamlined but new data collection forms will be introduced soon. The blood bank officer collects the data and reports to the hemovigilance unit. Currently, 46 hospital transfusion committees (HTC) exist, covering all major hospitals and reporting to the HV system; more HTCs are planned in remaining hospitals. Challenges include under-reporting, resource constraints, failure to recognize adverse events and lack of proper management of the events. Future plans include strengthening of data analysis, inclusion of donor haemovigilance, and capacity building of the involved workforce.

Discussion concerned the relationship between the government and the Blood Transfusion service. The BTS is an autonomous organization but policy is formulated by the government. Soon a National Blood Transfusion Committee will be established and there are also plans to include transfusion medicine in the under-graduate curriculum.

3.15 Evaluation of a national hemovigilance system and estimation of the prevalence and rate of acute transfusion reactions, Windhoek, Namibia 2011 – Dr B Lohrke

The Namibian Blood Transfusion Service (NAMBTS) was established in 1963 and is currently made up of 31 blood banks providing blood supplies and transfusion services to 46 hospitals. 13 of these blood banks supply fully cross-matched blood to about 50% of the Namibian hospitals. Challenges include vast distances and the large amount of O Rh D positive and O Rh D negative blood needed. In 2005 the NAMBTS implemented a hemovigilance system with the objectives of encouraging reporting of all adverse donor and recipient events nationally; training healthcare workers on the importance of monitoring, recognition, and reporting of adverse events and systematically investigating all reports to reduce future reactions. However reporting to the hemovigilance system was very low; in 2011 only 20 adverse events were reported from 20,000 transfusions. To investigate the causes of under-reporting in Namibia, NAMBTS with CDC conducted a study with the following objectives:

- To estimate the true prevalence of acute transfusion reactions
- To compare the true prevalence to the reported prevalence of acute transfusion reactions
- To estimate the rate of transfusion reactions per 1,000 blood units transfused
- To determine the specific diagnoses and severity grade of each acute transfusion reaction detected
- To determine the cause of under-reporting acute transfusion reactions

The project focused specifically on acute reactions occurring within 24 hours of cessation of transfusion. A standardized CDC case definition was used for each acute transfusion reaction.

The study was designed to be representative of the capital city of Windhoek. In 2010, 8,580 of all 23,744 blood units transfused in Namibia, (36%), were transfused in Windhoek. Data for this study were collected from the six major hospitals which collectively transfuse >99% of all blood in Windhoek.

Of the 1154 events in 2011, 785 were studied and analyzed; the rest were excluded due to inadequate records. Acute reactions were classified into 8 types and 4 grades according to the nature and severity of the reaction. Of these observed 785 events, 28 (3.2% (95% Cl 2.2-4.2)), met the criteria and definition of Acute Reaction, against a reported incidence of acute reactions of 8 /3,721 (0.2%) transfusion events. The difference between observed and reported rates was statistically significant (p value<0.01). As the reporting rate in Namibia was very low compared to international studies a study was designed to determine the cause of underreporting. 46 transfusion facilities were surveyed of which 33 responded. In these facilities, 311 of 1000 estimated eligible health care workers responded. 96% of respondents thought they would recognize an acute transfusion reaction. However when given a list of 15 signs and symptoms of acute transfusion reactions as described in the WHO guidelines for appropriate clinical use of blood, only 5.1% correctly identified all signs and symptoms. 34% of healthcare workers reported that a patient under their care previously had a transfusion reaction but only 12% stated they previously reported a reaction. It was also noted that two deaths related to transfusion were discovered which had not been recognized as such and therefore not reported.

The study made the following recommendations:

1. Modification of training of healthcare workers to reinforce knowledge regarding signs and symptoms of acute transfusion reactions and emphasize the need to report and investigate all acute transfusion reactions

2. Strengthening of blood collection practices including clinical prevention and control protocols to reduce prevalence of bacterial contamination, including uniform skin disinfection at time of donation, and institution of diversion segments to siphon first 20-30cc of the donation

4. Strengthening of better blood transfusion practices in hospitals including more in-service training and close communication with NAMBTS, MoHSS and NIP laboratories

3.16 Australian experience in addressing the needs for education and training for effective Hemovigilance – Dr E Wood

Education and training is required for all those involved directly and indirectly in the transfusion process including on haemovigilance systems. Personnel to be trained will include physicians, nursing staff, midwifery staff, phlebotomists, blood bank scientific and technical staff, porters and other hospital staff. Good information needs to be made available to patients and their families. Others involved indirectly include the government, insurers, and media personnel. Proper education and training programs need to be developed with evaluation to ensure these achieve their desired results. Proper understanding of adult learning principles is a prerequisite and necessary material and manpower resources are essential.

In order to develop the methods and tools for haemovigilance system, due attention should be given to the fact that the target audience includes a diverse range of staff across the transfusion chain, and the patients and families who come from different backgrounds, and experience, and with a varying functional status, knowledge, language and culture. The task-

and site-specific training program developed incorporates haemovigilance policies and procedures, principles of transfusion reaction investigation and follow up, information about storage and handling of blood components and mechanisms of reporting to the hospital risk program and haemovigilance program. For haemovigilance to be effective, staff need training in a range of skills and techniques, including clinical governance, root cause analysis, open disclosure, clinical audit, understanding of human and environmental factors, research and policy implementation/translation, presentation/influencing, epidemiology, databases and statistics.

The Australian "National Safety and Quality Health Service Standards" includes a Standard on Blood and Blood Products, which outlines systems and strategies for safe, effective and appropriate management of blood and blood products. In the Australian national haemovigilance system, hospitals identify, review and report to the regional haemovigilance program. The regional haemovigilance program reviews, validates, and assigns severity and imputability. The same event is then reported to the National framework and data dictionary. The National Haemovigilance Advisory Committee analyses this data and generates reports and recommendations. In different regions of Australia, jurisdictional practice improvement and haemovigilance activities are the responsibility of different organizations: In South Australia; BloodSafe, in New South Wales; Blood Watch, in Australian Capital Territory (ACT): Appropriate Use of Blood Ref Group, in Northern Territories: Transfusion Safety Program, in Queensland: Blood Management Program, in Victoria and Tasmania; Blood Matters and in Western Australia; Patient Blood Management Program.

In conclusion, key factors identified in promoting haemovigilance system were education, basic professional requirement, task- and site-specific haemovigilance training for all participants in the transfusion chain, including patients, assumptions about knowledge and its application, understanding of human and environmental factors, need to target appropriately, and assess effectiveness.

3.17 Present and future of haemovigilance in Kingdom of Saudi Arabia – Dr A Al-Shammari

The country has a population of 28 million served by 408 hospitals in which more than 400,000 blood donation are made every year. The total number of blood banks is 259 out of which 152 function under the Ministry of Health, 67 in the private sector and 40 blood banks are in other government departments. The Directorate of Laboratories and Blood Banks of the Ministry of Health is responsible for policy formulation and decision-making for issues pertaining to transfusion of blood and blood products and is also responsible for the supply of blood and blood products in the country. There is a national blood policy which specifies self-sufficiency as an ultimate goal and defines voluntary non-remunerated blood and plasma donations as the source of national supply of blood and blood products.

Haemovigilance data collection was initiated in 2007. Data on adverse reactions in transfused patients is collected through a questionnaire that is distributed to all health sectors,. At hospital level, this data is generated from records of the Hospital Transfusion Committee and provided to the Directorate manually for compilation and analysis. In 2012, the National Blood Transfusion Service Advisory Committee decided that a 'National Hemovigilance Network' be established to improve the standard of blood safety in the country. The final proposal for this network will be submitted for approval to the Council of Health Services. Several changes have been initiated by haemovigilance including implementation of NAT testing to reduce the risk of

transfusion-transmitted infections (HIV, HBV and HCV) including in the private sector. Universal leukodepletion is also to be mandatory soon.

Challenges faced in implementing hemovigilance include underreporting of adverse events due to fear of retribution and punishment. There are difficulties in communicating with blood banks in both governmental and private sectors and in motivating hospitals to notify events and to have functional Hospital Transfusion Committees. A need was identified to improve the level of awareness of the importance of hemovigilance. In order to streamline data collection, unified software, accredited by CE or FDA, will be applied to facilitate information exchange. The development of a national hemovigilance system and network is currently considered to be one of the most important issues in the national blood transfusion service in Saudi Arabia.

3.18 Slovenia: experience in implementing haemovigilance – Dr M Potocnik

Slovenia has a population of 2 million. The Slovenian National Transfusion Service comprises the Blood Transfusion Centre in Ljubljana and 2 regional centres in Maribor and Celje. These centres also support 10 other blood centres. Collection of blood is from voluntary non-remunerated donors; donation sessions are organized by the Red Cross of Slovenia. There were 101,380 donations in 2011.. The Ministry of Health supervises transfusion via National Council for Blood Supply, while the Blood Department within the Agency for Medicinal Products and Medical Devices is the regulatory body. The Professional Collegium for Transfusion Medicine acts as the expert body in the country. Legislation is in place via a Blood Supply Act in 2000 which requires mandatory reporting of all adverse reactions (only relating to labile blood components). A further Blood Supply Act 2006 passed implemented the EU directive; the Regulations on Haemovigilance were passed in 2007. Haemovigilance began in 2002, with key individuals identified, annual report published and presentations made to staff in hospitals. Reports are made from hospital to the national haemovigilance office (all events) and severe adverse reactions and events reported to the Competent Authority. The majority of adverse reactions and events 2002-2011 were ATRs, allergy and non- haemolytic febrile reactions. TACO reports are increasing. Donor adverse events and incidents during processing, testing, storage, and distribution are reported according to EU regulations.

There have been positive changes and improvements as a result of haemovigilance findings including changes in blood donor selection, introduction of nucleic acid testing, pathogen inactivation for platelets, leukodepletion, and use of male only plasma for transfusion. It proved difficult to prepare for regulations on transfusion without additional resources, because of additional work for staff in hospitals and blood establishments. In future, we aim to further improve adverse reaction and near miss reporting from clinicians, to increase traceability from 70 to 100%, to computerise reporting and to implement better blood transfusion practice.

3.19 Update on ISTARE – Dr J Wiersum

The IHN Database for the Surveillance of Adverse Reactions and Events in Donors and Recipients of Blood Components (ISTARE) was established in February 2008. Its aim is to provide an international tool for reporting and analysing all adverse reactions (ARs) and events (AEs) associated with the donation and transfusion of blood components, irrespective of their severity, and make meaningful comparisons and assessment of trends between haemovigilance systems that use standard ISBT/IHN definitions. Participants in this network can submit

aggregate national haemovigilance data online to the IHN website. ISTARE will automatically provide rates, ratios and charts of the different ARs and AEs.

ISTARE captures the following data

- general information on structure and coverage of the haemovigilance system
- numbers of donors/donations and main categories of blood products
- specific types of blood components issued and transfused
- whole blood and apheresis donor complications,
- incorrect blood component transfused (IBCT)
- adverse transfusion reactions- by blood component, by imputability: "possibly", "probably" and "definitely" and by severity: non-severe, severe, life-threatening and fatal.

There have been 4 rounds of data collection since 2006 in which 25 countries have participated in at least one round, 16 countries have participated at least 3 times, and 11 countries have participated 4 times with 77 total reports. The database includes data on more than 85 million units of blood issued and nearly 20 million units of blood transfused. Total adverse reactions reported were 62,262 (74 per 100,000 units issued), with 233 deaths (0.28 per 100,000 units). Respiratory complications accounted for 60% of deaths. Total donor complication rates were 242,889 (581 per 100,000 donations) of which only 2.5% were severe. Pilot studies have demonstrated the feasibility and value of the IHN database, which is now operational. This web-based system enables collection and analysis of annual data from any country that gathers HV data and will permit comparisons and assessment of trends. There are possibilities for extending this collaboration.

4. Strategies for national and international haemovigilance systems

Four working groups were set up to discuss the strategies for improving the implementation of haemovigilance at national and international level. Each group was chaired by two moderators and background documents were provided to all participants.

Working Group A: Challenges and strategies for setting up, developing and maintaining national haemovigilance systems

This group reviewed the draft Aide-Mémoire which was circulated to all participants of the global consultation prior to the meeting. The group accepted the definition of haemovigilance as a set of organized surveillance procedures covering the entire blood transfusion chain (from the donation of blood and its components to the follow-up of recipients), intended to collect and assess information on adverse events (reactions, incidents, accidents) resulting from donation of blood and its components, and from transfusion of blood products, and to prevent their occurrence or recurrence. The ultimate goal of haemovigilance system is for continual improvement in quality and safety of the blood transfusion chain.

In each country, a haemovigilance system should be set up in each facility where blood donation and transfusion are performed. Haemovigilance should cover the entire blood transfusion chain including blood donors and transfused patients, processes and products and it should be tailored to fit the blood and healthcare system in a country. The participants of Group A discussed the importance of haemovigilance system as an integral part of the national blood system with active participation and ownership of all stakeholders. It is critical that activities in haemovigilance are coordinated, hence the system needs effective leadership and governance. Participants further stressed that haemovigilance should be part of quality management systems of blood centres and health care institutions; and should result in improved policies, procedures and practices in the blood transfusion chain. Key steps in implementing haemovigilance system include; securing political will and support for haemovigilance development, embedding haemovigilance in national blood policy and legislative framework governing quality and safety of the entire blood transfusion chain, covering the entire country with a well-defined and sustainable system and availability of adequate resources.

Effective haemovigilance system relies upon reporting of adverse events, and analysis of what went wrong and why (root cause analysis). It is therefore essential that a haemovigilance system operates in a non-punitive environment and that reporting should be confidential and anonymous. Actions should be taken to rectify identified weaknesses and deficiencies though corrective and preventive actions (CAPA). At national level, the ministry of health should ensure that bidirectional traceability is maintained from donor to patient and vice versa. In addition the MOH or equivalent should ensure that mechanisms are in place for data collection, monitoring, analysis, reporting, evaluation and assessment, rapid alert and early warning. National haemovigilance should also include a rapid alert/early warning system for identification of new infections or problems. There should be monitoring of the implementation of corrective and preventive actions (CAPA) and evaluation of their effectiveness. It was also recommended that standards and definitions be harmonized internationally. Furthermore, it was also suggested that national systems should be linked with international haemovigilance networks to promote international co-operation.

Participants of Group A further elaborated on the roles and responsibilities of different stakeholders in national haemovigilance systems. At national level, a mechanism should be put in place to co-ordinate and ensure collaboration for surveillance of the entire blood transfusion chain (donors, recipients, products and processes) with adequate numbers of trained and experienced staff. In the blood transfusion service(s), the role and responsibility of individual blood centres include in the reporting and investigation of donor and patient complications and the reporting of errors and deviations in processes as well as close liaisons with hospitals. At hospital level, transfusion committees have a significant role to play in implementation of haemovigilance activities and recommendations, including reporting and investigation of patient adverse events and transfusion reactions. Education and training of staff involved in haemovigilance were also discussed. Participants also suggested that in developing countries, implementation of haemovigilance system can be done in a stepwise manner, starting with mandatory notification of serious adverse events in recipients for a period of time in selected hospitals and blood banks. This can be expanded throughout the country with addition of further steps over subsequent period (e.g. mandatory notification of serious AR in donors, other serious AEs in recipients and in blood establishments).

Working Group B: Global mechanism/s for networking countries and organizations for sharing of data, information and experiences on haemovigilance

In 2007, a global consultation on 'Universal Access to Safe Blood Transfusion' were organized in in Ottawa by WHO, working in collaboration with the Public Health Agency of Canada, Health Canada, Canadian Blood Services, Héma-Québec, the Canadian Society for Transfusion Medicine, Établissement Français du Sang and other international partners. The consultation was attended by more than 100 participants, including WHO expert advisory panel members, international experts and representatives of WHO Collaborating Centres, national blood transfusion services, international organizations and developmental partners. One of the key recommendations made by participants to WHO was "to develop a global haemovigilance, surveillance and alert network, which would provide a platform to countries for sharing key information on blood safety and availability issues and build a timely response in addressing emerging threats." This was followed by the World Health Assembly Resolution WHA63.12 on 'Availability, safety and quality of blood products' in 2010, which 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".

Since then WHO has developed bilateral and multilateral collaboration with international partners to take forward global activities in haemovigilance, particularly recognizing the need to support countries in setting up national haemovigilance systems, and also to develop global mechanisms for networking countries and organizations for sharing of data, information and experiences in haemovigilance. There are ongoing international initiatives coordinated by professional organizations including IHN, ISBT and APBN and others, to create haemovigilance networks, primarily involving developed countries. The participants in Group C agreed that there is a need to develop more inclusive networks including participation from countries across all regions globally, representing the developing and developed countries. The haemovigilance networks would promote and facilitate advocacy for haemovigilance, information and experience sharing including on strategies to overcome implementation challenges, development and sharing of alert systems, data-mining, technical support and capacity building including in 'twinning' arrangements and sharing of good practice and lessons learnt. Networking would build on strengths of existing organizations without duplication and promote benchmarking and sharing of norms and standards.

The participants recommended a mechanism for development of an international haemovigilance network, to be done in a phased approach linked to existing formal mechanisms, such as the International Health Regulations (2005) or "IHR (2005)". The IHRs (2005) came into force on 15 June 2007 and are legally binding in 194 countries including all WHO Member States. They aim to prevent, protect against, control and respond to the international spread of public health diseases/emergencies of international concern while avoiding unnecessary interference with international traffic and trade. The IHRs (2005) establish a set of rules to support the global outbreak alert and response system and require countries to improve international surveillance and reporting mechanisms for public health events and to strengthen their national surveillance and response capacities in ensuring global public health security.

Haemovigilance should also be included in the WHO Regional Committee meeting agenda. It was recognized during discussion that there is a need to overcome reluctance to share data in global or regional networks. This could be overcome through agreement on data confidentiality and the use of de-identified and aggregated data in the public domain. The international haemovigilance network (IHN) could also develop cross links with other databases on the WHO website to avoid duplication. The group also suggested several mechanisms for information sharing including the use of electronic networking with online discussion forum using WHO EZCollab.

Participants in Group B proposed an informal coalition to co-ordinate the international network between the three organizations (WHO, IHN and ISBT). Communication would be by means of structured telephone conferences every 3 months to discuss any data needing collaborative immediate action in real time. Administrative responsibility could be taken in rotation. Stakeholders in haemovigilance should be national haemovigilance organizations, ministries of health, and international, national and regional organizations involved in transfusion. Outputs of the network may include the development of norms and standards and the development of guidelines on setting up haemovigilance systems, and mechanisms to address and respond to emerging haemovigilance issues.

Discussion in the group also centred on which databases countries should report to. It was acknowledged that WHO and ISTARE/IHN have different mechanisms of data collection. WHO receives data from Ministries of Health while ISTARE receives data from national haemovigilance schemes. Data from ISTARE/IHN is not shared without consultation with the participants. However, as it is important to avoid duplication, IHN offers collaboration in and access to ISTARE to WHO. Similarly, WHO and CDC has had the experience in sharing national data reported to WHO GDBS with approval of governments of the involved countries and that it is also possible for the data on haemovigilance collected through GDBS be shared with the other partners. Many agreed with this idea of information sharing, but there is still a need for discussion on ownership and confidentiality of the data. All of the participants in Group B agreed on the need for international standardization/harmonization, especially with definitions.

Working Group C: A standardized definition and tools for global haemovigilance reporting

The participants in Group C agreed that international standardized/harmonized definitions are essential to allow comparisons of different haemovigilance systems and facilitate implementation of strategies and lessons learnt from successful haemovigilance systems in different countries. Definitions should be simple yet precise enough to be able to classify most incident, adverse events and reactions in the transfusion chain for purposes of surveillance. They are not intended as strict diagnostic criteria. The following are the suggested to be standardized/harmonized

i) Definition of incidents, adverse events and reactions – it was recognized that these may be difficult to define precisely in different types of health facilities especially in developing countries considering that there are no adequate diagnostic facilities such as chest x-ray or CT scans for the pulmonary symptoms which might be due to transfusion related acute lung injury (TRALI), transfusion-associated dyspnoea (TAD) or transfusion-associated circulatory overload (TACO). It was suggested that perhaps the definition

needs to be grouped to 'reactions with dyspnoea'. It was also stressed that clinical examination and course of the event can be as important as specialised investigation.

ii) Severity of the incident, event or reaction

iii) Imputability – this may not be relevant for incidents where there is no clinical harm. It was also recognized that not all haemovigilance systems assess imputability. Reports where imputability is unlikely or excluded should not be included in comparisons between countries.

iv) Classification of incident, events or reactions – there are several ways that are currently in use for classification and include:
   a) Stage of the process when the incident, event or reaction occurred
   b) Type of error: manpower, machine, material, method, or milieu
   c) Severity of the incident, event, reaction – for example, the Australian system uses a matrix of worst harm x likelihood of recurrence while in the Netherlands, the assessment is based the worst risk that the patient is exposed to.
   d) 'Sentinel' events e.g. incorrect blood component transfused, ABO incompatible transfusion and wrong name on tube (WNOT).

Considering that there is no internationally accepted definition, the participants agreed to share lists of classifications and consider need for additional definitions. It was proposed that a consultation be held for harmonization and/or standardization of the definitions and classifications to be used in haemovigilance systems. This should include representation from WHO, ISBT and IHN as well as other groups in different countries/organizations to get the widest possible consultation. Several reference materials were also discussed including WHO Patient Safety definitions which the group found to be practical. Once there is agreement on draft definitions and classification, a validation step is required whereby the draft definitions will be tested by experts in classifying real cases from both well established and young systems. Adjustments can be made during the validation exercises, followed by a final consultation. Agreed definitions and denominators should then be published, thus information is easily accessible to different countries and relevant organizations. The importance of having continuity of experts involved in all areas of haemovigilance was emphasised, with accessibility of an expert group for questions or proposals for new definitions. There should be a commitment to review the definitions regularly e.g. every 3-5 years, but not unduly frequently.

Participants in Group C also suggested that additional tools may be required, e.g. a list of minimum investigations. Flow charts could also be developed to assist classification, according to predominant clinical features, and to decide whether and when it is an adverse event, reaction or near miss. Translation of the standardized/harmonized definitions also should be done.

Working Group D: Future perspectives: Scope of haemovigilance and beyond

Haemovigilance systems are now recognized worldwide as an important element in improving the quality and safety of blood products, donation and transfusion practices. Countries are at different stages of awareness, planning, development and implementation of haemovigilance systems. It is recognized that different models of haemovigilance exist and the local circumstances related to blood supply arrangements and delivery of health services influence the model of haemovigilance for a country or region. Most models have the same basic concepts: surveillance of the transfusion chain from blood donors to patients, including

recognition, reporting and prevention of donor-, product-, patient-, and process-related problems. Haemovigilance systems may be based on voluntary or mandatory reporting, and they may include all events (however defined), or only serious ones, via either passive or active surveillance systems. In some systems, near misses are also included.

The participants in Working Group D agreed that the scope of haemovigilance in each country will depends on the priorities of blood safety, the available financial resources, technical capacity, engagement, technology and the level of education and training available. Different solutions may be required in different settings, for example in low income countries, haemovigilance can begin with traceability and monitoring the outcome in the transfused patient. Most haemovigilance systems include blood and blood components, whether allogeneic, autologous, or directed (intended for a specific recipient) in nature. This includes failure of provision of special transfusion requirements (such as irradiated or antigen-matched components). Some systems include salvaged blood and other preparations (for example, platelet-rich plasma gel for topical use, autologous serum eye drops, etc), complications of component-related procedures (for example, intravenous access-related complications of therapeutic plasma exchange) and materiovigilance (adverse events related to use of devices and equipment/instruments during the entire transfusion chain). In some countries, adverse reactions and events due products often used in conjunction with transfusion, such as erythrocyte stimulating agents, recombinant coagulation factors, antifibrinolytic agents and other topical therapies are also covered. Other aspects for consideration in the scope of haemovigilance include surveillance of inappropriate clinical decision-making, monitoring for failure of expected benefit and minimization of product wastage. Haemovigilance should be a dynamic system and be compatible and/or complementary with other vigilance programme in health systems, such as pharmacovigilance, and biovigilance (which may include cells, tissues and organs for transplantation).

Regardless of the model and scope of haemovigilance in a country, some of the prerequisites discussed in the group for haemovigilance systems include quality measurement and the availability of principles, standards and good practice in transfusion chain. There is a need for harmonized national definitions, an agreed list of reportable incidents, reactions, events and/or near-misses to be reported and national coordination of the system in the country. A country setting up haemovigilance system may consider the reduction of risks to patients, cost benefit analysis and health economic evaluation during the assessment process, strategies about communication of data, and multidisciplinary collaboration. Participants also agreed that duplication of activities should be avoided and that haemovigilance system should be practical and sustainable.

Participants also discussed the challenges in setting up haemovigilance as the scope of the system may change over time and decisions need to be made about what to include in the system. This may include unmet needs, including failure to supply products, patient outcomes, wastage, clinical decision making, best practice, issues with the cold chain and equipment. It was agreed that the implementation of haemovigilance system will be enhanced by availability of guidelines on appropriate clinical use; and by training and education which need to be owned by staff involved in transfusion process. It was noted that several countries may need technical assistance in the development of haemovigilance system and that a clear stepwise guidelines by WHO, IHN and ISBT, particularly using checklists and other protocols will be very helpful.

The major stakeholders for national haemovigilance system include hospitals, blood transfusion services and Ministries of Health as well as other groups such as blood donors, patients and clinicians (surgeons, anaesthetists, paediatricians etc.) and blood conservation groups. Media and press can be involved in a positive way. It was recognized that securing government commitment and support for haemovigilance is important and WHO can play a strong advocacy and technical role in this aspect.

In recent years, there has been increasing international sharing of definitions and information, and efforts to ensure standardization of definitions and capture of events, with the aims of facilitating comparison and benchmarking and to evaluate introduction of preventive/corrective measures by blood establishments and hospitals. Participants in the group recommended that haemovigilance systems in different countries should be harmonize with one another to make the results comparable and that lessons can be learned from one another. It was noted that many existing vigilance systems are based on product faults and that countries are at such different stages of development with different challenges. It was agreed that there is a need for data from high, mid and low income countries. Participants also discussed the specific challenges faced in developing countries including under-transfusion and suggested that this issue might need particular monitoring. Considering the limited manpower in developing countries, it might be considered that nurses in this setting may be more effective in leading the haemovigilance activities.

5. Recommendations and priorities for action

The participants of the global consultation have identified, discussed and agreed on the recommendations and priorities for action at different levels for the implementation of haemovigilance system following deliberations in the global consultation. These recommendations and priorities for action are directed hospitals, blood centres, national/regional blood transfusion services, the national health authorities, international partners and WHO as well as to the participants in the global consultation.

5.1 Recommendations to hospital/institutional level

For implementation of haemovigilance at hospital and other health care facilities, **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.

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 including confirmation of transfusion; and collect and analyse the indicators data on regular basis for quality improvement.

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.

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 and transfusion safety to all staff involved in the transfusion chain.

7. Establish and activate and maintain **hospital transfusion committees**.

8. Designate or appoint **Transfusion Nurse or Haemovigilance Officer** in hospitals to follow up on all reports of adverse transfusion events, to report to HTC and to the National Haemovigilance Office, where applicable.

5.2 Recommendations at national level

For implementation of haemovigilance at national level, **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 haemovigilance system which evolves in a stepwise manner from basic to complex.

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

Similarly, for implementation of haemovigilance at national level, **all blood centres and transfusion services** should:

1. Define **roles and responsibilities** of blood centres in relation to haemovigilance system.
2. Develop systems for reporting of adverse donor reactions and errors, including data collection, notification and reporting, monitoring and analysis and evaluation.
3. Establish mechanism for **liaison with hospitals**, blood banks/blood transfusion laboratories, and HTC.
4. Secure **traceability** (bidirectional tracking from donor to transfused patient and vice versa (vein to vein, using appropriates IT, communication tools).
5. Integrate haemovigilance into the quality management system.

5.3 Recommendations at international level

International organizations, including World Health organization (WHO), International Haemovigilance Network (IHN) and International Society of Blood Transfusion (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.
3. **Provide technical support** in:

- identifying country needs for the development of national haemovigilance system
- assessing gaps and developing roadmaps for establishment of the system
- facilitating the development and implementation of haemovigilance plans.

4. **Facilitate networking** and support the establishment of partnerships or **twinning mechanisms** for haemovigilance within and between Member States.

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 haemovigilance.

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.

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.

5.4 Priorities for action

1. Provide **high level advocacy** for the decision makers in the Ministry of Health/National Health Authorities for establishing national haemovigilance systems

2. Intensify and expand **networking** with international organizations working in the field of Haemovigilance)

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 (harmonized international tools)

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/supplying blood centres.

7. Advocate/encourage setting up and maintaining functional **hospital transfusion committees** (HTC)

8. **Support for IT system** including on:
    a. System for donor data management
    b. Improvements of the patient record systems in hospitals on transfusion
    c. Provision of database that allows traceability
    d. Staff training on IT

9. Strengthen **capacity building**:
    a. National **training** for all stakeholders in haemovigilance, including clinicians, nurses, midwives and blood bank staff on best transfusion practices and haemovigilance
    b. Setting up of haemovigilance systems at **local (hospital/blood bank)** level (protocols, forms, reporting systems, administrative organization)
    c. **Assistance** in setting up haemovigilance to priority countries
    d. **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

6. Conclusion and closing address

During the closing session of the 'WHO Global Consultation on Haemovigilance', concluding remarks were given by Dr Amin Al Amiri on behalf of Sharjah Blood Transfusion and Research Center and the Government of the United Arab Emirates and by Dr Neelam Dhingra, Coordinator, Blood Transfusion Safety, WHO-HQ, Switzerland.

Dr Al Amiri appreciated the support provided from WHO, IHN and ISBT on the technical, financial and administrative aspect of the Global Consultation. Dr Al Amiri also thanked all the speakers, chairs, facilitators, rapporteurs and participants for their key role making the consultation a huge success. It was recognized that there is great need for participants in the Global Consultation to further develop and implement haemovigilance in their workplace the Global Consultation had provided the networking opportunities for sharing of ideas and learning from each other.

On behalf of WHO, Dr Dhingra expressed her appreciation to the Government of United Arab Emirates, Sharjah Blood Transfusion and Research Centre and all the partners for their support and thanked the participants for their enthusiastic contributions prior to closing the meeting.

7. Annexes

7.1 Agenda

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

Agenda

1. Opening session
2. International perspectives on haemovigilance
3. Challenges, lessons learnt and strategies for implementation of haemovigilance systems: Country Experiences
4. Breakout Sessions: Four working groups
   A. Challenges in setting up haemovigilance systems and strategies for developing national haemovigilance systems
   B. Global mechanism/s for networking countries and organizations for sharing of data, information and experiences on haemovigilance
   C. A standardized definition and tools for global haemovigilance reporting
   D. Future perspectives: Scope of haemovigilance and beyond
5. Tour of the Sharjah Blood Transfusion & Research Centre
6. Recommendations and priorities for action

7.2 Programme of work

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

Programme of Work

Day 1 - Tuesday, 20 November 2012		
08:30 – 09:30	Registration	
Inauguration and Opening Ceremony		
09:30 – 10:30	Inauguration Address: ▪ Government of UAE ▪ Blood Transfusion and Research Services, UAE and Haemovigilance system in UAE ▪ WHO-HQ, Geneva ▪ IHN ▪ ISBT	 Minister of Health H.E. Dr Amin Al Amiri Dr Neelam Dhingra Dr Jean-Claude Faber Dr Salwa Hindawi
10:30 – 11:00	Group photo & Break	
Session 1: International Perspectives on Haemovigilance Chair: Dr Jean-Claude Faber and Vice-Chair: Dr Che Kit Lin Rapporteurs: Dr Elizabeth Vinelli and Dr Janaki Sonoo		
11:00 – 11.30	Objectives of the Global Haemovigilance Consultation WHO Strategic Direction and Initiatives on Haemovigilance	Dr Neelam Dhingra
11:30 – 12.00	International Haemovigilance Network	Dr Jean-Claude Faber
12.00 – 12.30	International Society of Blood Transfusion	Dr Jo Wiersum
12:30 – 13.00	Discussion	
13:00 – 14:00	Lunch	
Session 2a: Challenges, lessons learnt and strategies for implementation of haemovigilance systems: Country Experiences Chair: Dr Neelam Dhingra and Vice-Chair: Dr May Yassin Raouf Rapporteurs: Dr Elizabeth Vinelli and Dr Janaki Sonoo		
14:00 – 14:30	Overview of haemovigilance systems in participating	Mr Jun Ping Yu

	countries	
14:30 – 14:50	South Africa: experience in implementing haemovigilance	Dr Neo Moleli
14:50 – 15:10	France: experience in implementing haemovigilance	Dr Bernard David
15:10 – 15:30	Haemovigilance in China	Dr Jia Dandan
15:30 – 15:50	Serious Hazards of Transfusion (SHOT), United Kingdom: experience in implementing haemovigilance	Dr Paula Bolton-Maggs
15:50 – 16:20	Break	
16:20 – 16:40	Brazil: experience in implementing haemovigilance	Dr Geni Neumann de Lima Camara
16:40 – 17:00	United States of America: model in implementation and coordination of a haemovigilance system	Dr Anthony Marfin
17:00 – 17:20	Republic of Korea: experience in implementing haemovigilance	Dr Cho Nam-sun Dr So-Yong Kwon
17:20 – 17:40	Thailand: experience in implementing haemovigilance	Dr Ubonwoon Charoonruangrit
17:40 – 18:00	Tunisia: experience in implementing haemovigilance	Dr Leila Ben Hamed Dr Saadia Abdelkefi Hatira
18:00 – 18:30	Summary of day 1	Chairperson(s)
Day 2 - Wednesday, 21 November 2012		
08:30 – 09:00	Report of Day 1 and Discussion	Rapporteurs
Session 2b: Challenges, lessons learnt and strategies for implementation of haemovigilance systems: Country Experiences Chair: Dr Peter Ganz and Vice-Chair: Dr Salwa Hindawi Rapporteurs: Dr Mahrukh Getshen and Dr Hasan Abbas Zaheer		
09:00 – 09:20	Japan: experience in implementing haemovigilance	Dr Junya Kasamatsu
09:20 – 09:40	Transfusion Reactions in Patients (TRIP): haemovigilance system in The Netherlands	Dr Jo Wiersum
09:40 – 10:00	Regulatory and public health aspects of haemovigilance in Canada	Dr Peter Ganz
10:00 – 10:20	Hong Kong SAR, China: experience in implementing haemovigilance	Dr Che Kit Lin
10:20 – 10:40	Sri Lanka: experience in implementing haemovigilance	Dr S. Jayasekara
10:40 – 11.10	Break	
11:10 – 11:30	Evaluation of a national haemovigilance system and estimation of the prevalence and rate of acute transfusion reactions	Dr Anthony Marfin Dr Britta Lohrke
11:30 – 11:50	Australian experience in addressing the needs for education and training for haemovigilance system	Dr Erica Wood
11:50 – 12:10	Present and future of haemovigilance in Kingdom of	Dr Aly Alshammari

	Saudi Arabia	
12:10 – 12:30	Slovenia: experience in implementing haemovigilance	Dr Marjeta Potocnik
12:30 – 13:00	Update on ISTARE, the international haemovigilance database	Dr Jo Wiersum
13:00 – 14:00	Lunch	
Session 3: Working Groups Chair: Dr Peter Ganz and Vice-Chair: Dr Salwa Hindawi		
14:00 – 15:30	**Break Out Sessions: Four Working Groups:** Each group to deliberate on	
	A. Challenges and strategies for setting up, developing and maintaining national haemovigilance systems	**Group A moderators**: Dr Jean-Claude Faber and Dr Noryati Abu Amin **Group B moderators:** Dr Neelam Dhingra and Dr Elizabeth Vinelli **Group C moderators:** Dr Jo Wiersum and Dr Che Kit Lin **Group D moderators**: Dr Erica Wood and Dr Janaki Sonoo
	B. Global mechanism/s for networking countries and organizations for sharing of data, information and experiences on haemovigilance	
	C. A standardized definition and tools for global haemovigilance reporting	
	D. Future perspectives: Scope of haemovigilance and beyond	
15:30 – 16:00	Break	
16:00 – 18:00	Continue Group Work	
19:00	Assembly and departure for the Dubai Heritage Village	Ministry of Health, United Arab Emirates
Day 3 - Thursday, 22 November 2012 Rapporteurs: Dr Neo Moleli and Dr Paula Bolton-Maggs		
07:15	Assembly for visit to Sharjah Blood Transfusion & Research Centre	Organizer: Dr May Yassin Raouf
07:30	Departure for visit to the centre	
08:00 – 09:00	Tour of the blood centre	
09:00	Departure for the consultation venue	
09:30	Arrival to the consultation venue	
09:30 – 10:00	Break	
Session 3: Working Groups (Contd) Chair: Dr Erica Wood and Vice Chair: Dr Noryati Abu Amin		
10:00 – 10:30	Report of Day 2 (Session 2b) and discussion	Rapporteurs
10:30 – 10:50	**Presentation Working Group A** Strategies for setting up or strengthening national	Group Rapporteur

	haemovigilance systems based on appropriate models	
10:50 – 11:20	Plenary discussion WG A	
11:20 – 11:40	**Presentation Working Group B** Global mechanism/s for networking countries and organizations for sharing of data, information and experiences on haemovigilance	Group Rapporteur
11:40 – 12:10	Plenary discussion WG B	
12:10 – 12:30	**Presentation Working Group C** A standardized definition and tools for global haemovigilance reporting	Group Rapporteur
12:30 – 13:00	Plenary discussion WG C	
13:00 – 14:00	Lunch	
14:00 – 14:20	**Presentation Working Group D** Future perspectives: Scope of haemovigilance and beyond	Group Rapporteur
14:20 – 14:50	Plenary discussion WG D	
Session 4: Recommendations and Priorities for Action Chair: Dr Neelam Dhingra and Vice-Chair: Dr Amin Al Amiri		
14:50 – 16:45	Recommendations and priorities for action at different levels: ▪ Hospital level ▪ National level ▪ International level	 Dr Salwa Hindawi Dr JC Faber Dr Neelam Dhingra
16:45 – 17:00	Summary and conclusions Closing address ▪ Sharjah Blood Transfusion and Research Centre ▪ WHO	 Dr Amin Al Amiri Dr Neelam Dhingra
17:00	Refreshments	

7.3 List of participants

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

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7.4 Group photograph

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