Global Forum for Blood Safety
Organized by WHO Blood Transfusion Safety Programme, in collaboration with WHO AMRO/PAHO and WHO/PAHO Country Office in Brazil, with the collaboration and support of the Government of Brazil
6-8 May 2013, Costão do Santinho Resort, Florianopolis, Brazil

Concept Paper

Background
Member States of the World Health Organization (WHO) have endorsed several World Health Assembly (WHA) resolutions on blood safety and availability, including WHA28.72 (1975), WHA58.13 (2005) and WHA63.12 (2010). These resolutions urged Member States to ensure the provision of adequate supplies of safe blood and blood products that are accessible to all patients who require transfusion, the rational use of blood and safe clinical transfusion practice. Today, many countries still face challenges in maintaining a sufficient supply of safe blood and blood products and ensuring their safe and appropriate use. Increasingly, economic pressures and public perceptions have been driving decision-making in the provision and clinical use of blood products. The following key themes have been identified as requiring the urgent attention of the global community in addressing challenges to ensure universal access to safe blood and blood products and systems for good clinical transfusion practice.

A. Blood System Strengthening for Universal Access
Provision of safe blood and blood products for patients requiring transfusion is a vital component of universal health coverage. All health care system should strive for universal access to blood transfusion services (BTS) as this will lead to equity, social justice and an end to geographical or financial exclusion from access to safe blood and blood products. Protecting, promoting and maintaining the health of the population (for patients and blood donors, in the case of access to safe blood and blood products) is a core responsibility of governments. In exercising this stewardship role, governments should develop, implement and enforce policies that are evidence-based, ethical and effective in strengthening blood transfusion services as an integral part of health systems together with efficient service delivery model, proper financing systems and mechanisms to ensure the availability of adequate resources.

Current blood system challenges include inadequate community education and mobilization on need for voluntary, non-remunerated blood donation, inadequate infrastructures for the provision of quality blood transfusion services, inadequate financing or inappropriate financing systems, poor organization and management of blood transfusion services, unnecessary use of blood, shortages of health workers with the required skill mixes, mismatches between service requirements, and the education provided by health training institutions, poor procurement and supply management systems, limited information systems and lack of good governance. All these contribute to inadequate supply and inequitable access to quality blood transfusion services by patients requiring transfusion.

While reforms in blood system are required for safer blood and blood products, more efficient and cost-effective blood service delivery, they should be supported by wider policy, leadership and stewardship reforms which should be considered as synergistic and tackled concurrently.
B. Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Blood Donation

Major progress has been made in improving the safety of the global blood supply. However, many countries remain unable to ensure that sufficient, sustainable supplies of blood and blood products are available, while also ensuring their quality and safety in the face of known and emerging threats to public health. Large numbers of patients who require life-saving transfusion therapy still lack access to safe blood and blood products.

Despite some successes, self-sufficiency in safe blood and blood products is not yet a reality and many countries with inadequate supplies of blood from voluntary non-remunerated blood donors remain dependent on systems of family/replacement donation and payment to blood and plasma donors to fill the gaps between supply and demand; even systems of family/replacement donation often involve “hidden” payment systems. Increasing global needs for blood and blood products, the complex nature of systems to supply these products and the inability of many national health systems to meet these urgent needs have resulted in a rapid expansion of international commercial activities in relation to blood and blood products, as shown by increasing global markets in commercial plasma collection. Such policies and practices seriously compromise the safety of blood and blood products.

In 2010, the World Health Assembly deliberated on challenges to the availability, safety and quality of blood products and defined self-sufficiency in the supply of safe blood components based on voluntary non-remunerated blood donation (VNRBD), and the security of that supply, as important national goals to prevent blood shortages and meet the transfusion requirements of the patient population. Resolution WHA63.12 urged Member States “to take all necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency”. Countries that have already established policies and systems to achieve self-sufficiency can serve as models by demonstrating the effectiveness of policies, strategies and mechanisms that should be supported and implemented.

C. Quality Management and Haemovigilance

Every blood transfusion service should establish an effective quality management system, based on appropriate national or international standards, to ensure a timely and sustainable supply of blood and blood products of appropriate and consistent quality, and in sufficient quantity. Quality systems should cover all BTS activities and hospital transfusion practices to ensure traceability, from the recruitment and selection of blood donors to the final fate of the donated unit, including its transfusion to patients and their follow up. They should reflect the structure, needs and capabilities of the blood transfusion service as well as the needs of the hospitals and patients that it serves.

Commitment and support from all levels, particularly the government and BTS senior management, are essential for the development and implementation of a quality management system within the BTS with regular monitoring in order to ensure continuous quality improvement. The system should be defined within the BTS quality policy and should be realized through a quality plan. There should be a clear and unequivocal commitment of all BTS staff to the establishment of a comprehensive and effective quality management system covering all aspects of the work of the BTS and an understanding of the importance of quality and the consequences of failure in the quality system. In many BTS, however, gaps still remain in quality management systems, including documentation and information systems; ensuring traceability; appropriate quality standards; quality assessment and accreditation; and haemovigilance systems.
Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse events and reactions (AR/AE) in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. A haemovigilance system is an integral part of quality management in a blood system and is required for the continual improvement of the quality and safety of blood products and the transfusion process. Haemovigilance is essential to identify and prevent the occurrence or recurrence of adverse reactions and unwanted events, and to increase the safety, efficacy and efficiency of blood transfusion. It covers all activities of the blood chain, vein-to-vein, from donor to recipient.

A system of haemovigilance is dependent on the traceability of blood and blood products from donors to recipients and vice versa (bi-directional tracking), the monitoring, investigation and reporting of transfusion-related adverse reactions and events and the rigorous management of information related to the transfusion process. Information generated through this system is a key to introduce required amendments in transfusion policies, to change processes in blood services and transfusion practices in hospitals, to improve transfusion standards, to assist in the formulation of transfusion guidelines and to increase the safety and quality of the entire transfusion process.

D. Risk Assessment and Management for Blood Safety and Availability

There is a public expectation that blood and blood products will be safe, and blood donation and transfusion process do not carry any risk; the public therefore also expects national health authorities to respond effectively to known risks and to anticipate and plan a response. Risks associated with ensuring safety, supply and accessibility to blood and blood products include adverse donor events during or after blood donation; threat to the existing VNRBD system, lack of timely accessibility to sufficient blood; adverse patient events and outcomes; and the risk of known transfusion-transmissible infections, other infections not currently screened for but with a proven or theoretical risk of transmission, and new/emerging infections. Managing and minimizing risk throughout the transfusion chain from donor to recipient is an important part of the responsibilities of national health authorities, blood transfusion services, blood centres and hospitals. The appropriate management of risk ensures improved outcomes for donors and recipients, generates confidence in the system, and has a positive impact on public trust in the blood system.

Establishing a risk management framework is a critical first step in determining appropriate mechanisms and interventions for risk reduction and response. Some risks, such as the residual risk of infection transmission after screening, may be well-characterized and quantified; there is less understanding of other equally important areas of risk, such as the risk of patient mortality or morbidity if blood is not available or the effects of repeat blood donation on donor iron stores. A comprehensive risk assessment should address all aspects of the transfusion chain, including donor, patient and staff safety, and not only blood safety and availability. Anticipating future risks should not be limited to the assessment of emerging infectious diseases but should also include a broader view of social, political, ethical, economic and environmental factors that might impact the blood system and blood availability for patient care. In the event of a local, regional or national emergency or disaster, a risk-based approach to contingency planning is required to ensure safety, availability and adequate continuity of services.

Systems for the identification, prioritization and management of risk should be relevant to the local context. Identifying actual and potential risks requires the expertise of local technical and management staff as well as other relevant stakeholders. Risk matrices should be developed for all major processes to categorize key risks and identify suitable decision makers, actions and resources required.
**WHO Global Forum for Blood Safety**

The WHO/HQ Blood Transfusion Safety team (WHO/BTS) has established the Global Forum for Blood Safety as a mechanism to foster collaboration and enhance communication and information exchange between key international experts, institutions, organizations and other stakeholders. The forum meets once every two years to deliberate on specific topics relevant to global blood safety concerns in order to make structured observations that will identify priorities for action at national, regional and global levels.

WHO/BTS is convening a three-day meeting of this forum in Florianopolis, Brazil, on 6–8 May 2013. The forum is being jointly organized by WHO HQ/Geneva, WHO PAHO/AMRO and the WHO/PAHO Country Office-Brazil, with the collaboration and support of the Government of Brazil. Around 250 participants are expected to attend the forum, including representatives from about 60 developed and developing countries, members of the WHO Expert Advisory Panel on Transfusion Medicine, WHO Collaborating Centres, international organizations and WHO professional staff from headquarters, regional and country offices. Country participants will comprise senior officials from ministries of health and representatives of key organizations, agencies and institutions within the national blood system.

Invitations have also been extended to representatives of other UN organizations (UNFPA, UNAIDS, UNDP and UNICEF) and key intergovernmental, nongovernmental and professional organizations working on matters related to universal access to safe blood and blood products. These include AABB, EDQM-Council of Europe, European Commission, International Association of Blood Donor Organizations, International Federation of Gynaecology and Obstetrics, International Federation of Red Cross and Red Crescent Societies, International Society of Blood Transfusion, International Haemovigilance Network, International Society of Surgery, Medical Society for Patient Blood Management, Network for the Advancement of Transfusion Alternatives, Society for the Advancement for Blood Management, Thalassaemia International Federation and World Federation of Hemophilia.

**Objectives of the Forum**

1. Provide an interdisciplinary and international forum for discussion for key stakeholders in transfusion medicine/science and blood safety from developing and developed countries.

2. Identify major areas of global concern in achieving universal access and self-sufficiency in safe blood and blood products.

3. Review current challenges, barriers and lessons learned from countries’ experience in key areas:
   A. Blood system strengthening for universal access;
   B. Self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation;
   C. Quality management and haemovigilance;
   D. Risk assessment and management for blood safety and availability.

4. Develop structured observations related to the key themes that will guide priorities for action at national, regional and global levels as well as the strategies for their implementation.