



APEC Blood Supply Chain 2020 Roadmap

A Framework to Assist APEC Economies to Work Together to Build the Capacity of Their Blood Services, Infrastructure and Governance and Promote the Achievement of International Safety and Quality Standards for Blood

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Introduction

Transfusion of blood and blood products helps save millions of lives every year. The demand for blood and blood products is increasing at a rapid rate throughout the Asia-Pacific region due to many influences including aging populations, increased disease risk and greater access to healthcare services. Despite the growing demand, wide disparities in access to safe and reliable blood exist. In developing APEC economies in particular, blood supplies are rarely sufficient to meet local demand as well as inadequate to meet international quality and safety standards.

Many challenges, such as governance alignment, appropriate resources (i.e., funding, infrastructure) and achievement of international safety/quality standards obstruct APEC economies' efforts to improve the safety and sustainability of the blood supply chain. In spite of these challenges, there are clear opportunities for implementation of plans by APEC economies to achieve a well-organized, quality driven nationally-coordinated blood transfusion service. For example, emphasis on areas such as process control through quality systems; infrastructure improvements for collection, processing, and distribution of blood and blood products; and development of testing strategies that match the disease risk could provide immediate paths to safer blood systems.

The APEC Life Science Innovation Forum (LSIF) will continue its collaborative commitment to improve blood safety in APEC economies. Multi-sectoral, multi-lateral involvement and public private partnerships (PPP) can and should play a role in driving blood safety improvements in the future.

This APEC Blood Supply Chain Roadmap (the Roadmap) has been developed and reviewed by the participating economies to provide a practical framework for APEC economies to apply at local, national and regional levels to improve the safety of the blood supply. The Roadmap pulls from content discussed and conclusions reached at the APEC Policy Dialogue and Workshop on Attaining a Safe and Sustainable Blood Supply (Manila, Sept 30-Oct 1, 2014). It is the hope of the APEC LSIF that government, academia and industry will work together on this Roadmap to enhance the safety of blood and blood products in the Asia Pacific region.

Background on APEC Blood Safety Initiative

The demand for human blood is increasing at a rapid rate throughout the Asia-Pacific region. Growth in demand is driven by rising incidence of disease, attention on maternal and child health, population growth, aging population, a steadily growing middle-class population with greater access to medical care as well as government focus on improving healthcare infrastructure.

Wide disparities in access to safe and reliable blood exist in APEC. Where blood is available, the blood and blood products supply chain and quality systems may fail to ensure on-time access to safe blood. Every stop along the blood supply chain is critical – from the point of collection to providing product to the recipient. The complicated process requires synergy of multiple factors ranging from adequate volunteer blood donors, blood processing, testing strategies, and distribution to patient blood management and hemovigilance. All of these factors are embodied in the Quality System. The vein-to-vein (donor-to-patient) synergy also requires collaboration of many stakeholders including patients, healthcare providers, blood banks, hospitals, and ministries of health. Alignment of roles and responsibilities within government ministries (e.g. health, education and finance) is required.

Many challenges obstruct the path of APEC economies' efforts to improve the safety and sustainability of the blood supply chain to achieve a well-organized, quality driven nationally-coordinated blood transfusion service. However each challenge also offers an opportunity for improvement. For example, many national governments prioritize improving access to blood collected from regular, voluntary non-remunerated blood donors to ensure blood is available when needed. Additional opportunities for improvement include, but are not limited to process control through quality systems, appropriate resourcing (human, infrastructure, monetary) for recruiting resources (donors and staff), training, collection, processing of blood, testing strategies, appropriate patient blood management, and hemovigilance.

Success by APEC economies to recognize these challenges as opportunities to improve the national transfusion services is enhanced through heightened collaboration among all stakeholders, including private, academic, community, health and non-health public sectors. Multi-sectoral, multi-lateral collaborations and model PPP – built on best and innovative practices appropriate to local environments – support the ability of all APEC economies to operate a fully centralized National Blood Service with consistent quality standards to provide optimal blood safety for improved patient outcomes. Through increased collaboration, patients will be assured timely access to blood, as well as confidence that the

transfusion is free from infectious viruses such as hepatitis and HIV. National governments also benefit from the economic impact of a healthy individual who leaves the hospital to return to the workforce and actively contribute to society.

On 4 July 2013, the APEC Life Sciences Innovation Forum (LSIF) and APEC Health Working Group (HWG) convened in Medan, Indonesia to discuss Healthcare-associated Infections (HAIs). It was during this dialogue that APEC economies' leadership discussed the important challenge of blood-borne infections from transfusions. Due to interest in the health and economic impact of transfusion transmitted infections such as HIV, hepatitis B and hepatitis C, APEC approved funding to fully explore the safety and sustainability of blood supply chains in developing economies across the region.

The *APEC Policy Dialogue and Workshop on Attaining a Safe and Sustainable Blood Supply Chain* was held September 30 to October 1, 2014 in Manila, Philippines. The Workshop convened senior leaders from government, academic institutions, the private sector, civil society, and international organizations to identify how APEC economies can work together to build the capacity of their blood services, infrastructure, and governance and promote the achievement of international safety and quality standards for blood.

Following the 2014 workshop, APEC action will focus on developing and implementing the “APEC Blood Supply Chain 2020 Roadmap”, included in the overall scope of the APEC project. Activities will focus on several areas, including: 1) promoting harmonization and implementation of international standards for blood and blood products; 2) optimizing the efficiency of the blood supply chain through capacity building for blood processing, testing, and distribution systems; 3) sharing best practices to improve the safety and quality of the blood supply and the sustainability of the blood system; 4) identifying strategies for optimizing clinical transfusion practices and patient blood management in both developed and developing economies.

Vision

APEC Life Science Innovation Forum (LSIF) includes senior leaders from government, academic institutions, the private sector, civil society, and international organizations, working together to create better health outcomes for the people of the Asia Pacific region. The APEC LSIF recognizes the potential for leveraging the collective strength of these stakeholders to help APEC economies, particularly

developing economies, to build the capacity of their blood services, infrastructure, and governance and promote the achievement of international safety and quality standards for blood.

Mission

For APEC economies to improve the safety and sustainability of their blood supply by working through cross-sectoral, multi-disciplinary, coordinated and collaborative approaches to optimize their blood processing, testing, and distribution systems.

Goals and Actions

- 1. To strengthen cross-sectorial political commitment and national level government leadership for improving the safety and sustainability of the blood supply by optimizing blood processing, testing and distribution systems for the advancement of public health**

Current Situation

Global organizations such as the World Health Organization (WHO), the International Society for Blood Transfusion (ISBT), the International Federation of Red Cross and Red Crescent Societies (IFRC), and AABB (formerly known as the American Association of Blood Banks) strive to address the safety and accessibility of blood and blood products. These organizations provide significant support to governments and blood banks around the world to improve blood safety standards.

Yet, their efforts don't always translate to political commitment and government leadership at the national level on blood safety matters. In fact, government leadership on blood safety varies greatly across APEC member economies and between agencies within member economies. This is especially true for developing member APEC economies.

For developing economies, competing health issues, alignment of roles and responsibilities, communication between disciplines and lack of resources and expertise all impact governments' commitment to prioritize national blood safety and availability. In order for blood safety to stand out as a priority area in public health, data, case studies and easy-to-understand messages need to be communicated to key decision-makers.

Consultation from APEC developed economies can greatly facilitate development and political leadership in this area.

Actions

- 1.1 Align roles and responsibilities within government for responsibility of the National Blood System.
- 1.2 Understand the health and blood safety gaps in developing APEC economies compared to international standards in quality and safety for blood and blood products for the improvement of public health.
- 1.3 Establish a task force to ensure that clear policies for blood transfusion services are developed and communicated to decision makers at the national level to provide sufficient and timely supplies of safe blood.
- 1.4 Establish a quality system, from which practical guidelines to ensure the quality and continuity of test kits, reagents and other consumables will come.
- 1.5 Create mechanisms for APEC developed economies to assist with training and other areas of guidance to improve government leadership on blood safety.
- 1.6 Design ongoing funding mechanisms.
- 1.7 Share successes by APEC developing economies with other APEC developing economies, for ongoing education and encouragement.

2. To strengthen local policy enactment and implementation of national blood safety policies

Current Situation

Governments at the national level may not be aware of the drivers to ensure safety and availability of blood at the local level. Blood and Transfusion Medicine Key Opinion Leaders believe the key to success is a combination of alignment of roles and responsibilities for the National Blood System, national level policy and sustainable funding (local, provincial, or national). The APEC participants believe that by providing a road map for governments to assess local drivers for blood safety implementation can help improve public health.

A missing element in many developing economies blood safety policies is long term operational funding for local implementation. For example, a national policy can be set up that recommends advanced technologies such as component therapy, testing with serology and nucleic acid

technology (NAT). However, without funding for local implementation, the national level policy will have little impact.

Actions

- 2.1 Align roles and responsibilities for safe and available blood for responsibility of the National Blood System.
- 2.2 Enhance the understanding of government at the national level of local public health considerations for addressing blood safety and sustainability.
- 2.3 Make appropriate resources available for consistent and reliable screening.
- 2.4 Make a sufficient number of qualified and trained staff available for blood screening.
- 2.5 Review funding mechanisms to ensure funds can be used by local level implementers for blood safety activities.
- 2.6 Utilize industry expertise through PPP's to educate and mentor local experts.

3. To strengthen donor recruitment, approaches to maintaining a stable volunteer donor base that ensures both availability and safety

Current Situation

The WHO and the IFRC have developed a framework for global action to achieve 100 per cent voluntary blood donation in every economy. The framework is based on the recognition that voluntary non-remunerated blood donation (VNRBD) is the foundation of a safe, sustainable blood supply. The aim is to strengthen national blood donor programs to build a stable pool of the safest possible blood donors.

Actions

- 3.1 Establishment of national blood donor programs based on 100 per cent voluntary donation.
- 3.2 Create a culture of voluntary blood donation through communication and education, and celebration of World Blood Donor Day (WBDD).
- 3.3 Build a stable blood donor pool by motivating and recruiting new donors from low-risk populations, and encouraging existing or lapsed donors to become regular donors and to recognize the contribution to society made by blood donors.
- 3.4 Provide quality donor care, so that blood donation is not onerous.

4. To strengthen quality systems as an essential foundational element for creating a viable National Blood System or Service that requires full government commitment for long-term success

Current Situation

The WHO has established the quality system as a foundation for blood safety and has outlined five pillars of quality systems. Yet, many developing APEC economies still struggle to integrate the quality system into daily practice. There is a significant need to support implantation of quality systems for all elements of the blood screening program, including standards, training, documentation and assessment. With a thorough culture of quality systems in place, blood centers will be prepared to address opportunities for centralization/regionalization, testing strategies, and plasma. Leverage other APEC developed economies that have mastered quality systems in order to build and maintain quality systems in APEC developing economies.

Actions

- 4.1 Develop a culture of quality in the National Blood System.
- 4.2 Develop a national quality policy and plan to embrace Good Manufacturing Practices (GMP).
- 4.3 Focus on the key elements of the quality system: organizational management; standards; documentation; training; assessment.
- 4.4 Secure the commitment and support of the National Blood Transfusion Service to focus on quality systems.
- 4.5 Work with experts from other APEC economies to identify the best approach for prioritizing quality in the national blood policy.
- 4.6 Secure ongoing resources for establishing and maintaining a quality system.
- 4.7 Designate a national quality manager with overall responsibility for the implementation of quality systems at all levels.
- 4.8 Develop a quality section, with appropriate staffing and expertise, in each blood center and hospital blood bank.
- 4.9 Provide training in quality for all BTS staff and other healthcare professionals involved in blood transfusion.
- 4.10 Assess the effectiveness of the quality system continually.

- 4.11 Stay committed to establishing quality systems in order to develop hemovigilance to understand ongoing risk needs.
- 4.12 Train technical staff on best practices for maintaining quality systems and managing resources.

5. To increase government awareness that economies of scale are best achieved through centralization and regionalization to provide quality services at the local level

Current Situation

A decentralized blood banking system and poor infrastructure create challenges for blood banks in developing APEC economies trying to deliver safe blood to patients in remote areas. For blood banks that screen only a few hundred units a month, they are likely unable to invest in testing, information technology (IT) enhancements and other important infrastructure components. Low testing volume prohibits economies of scale. Without economies of scale for testing, blood banks will find it hard to justify investment in needed infrastructure that could improve everything from donation testing to tracking and distribution. One answer to the challenges of the fragmented blood banking system is centralized or regionalized testing.

Actions

- 4.1 Conduct educational awareness activities for decision-makers on how centralization/regionalization creates economies of scale and can help improve safety and quality standards.
- 4.2 Explore which type of centralization and regionalization is best for them, including options for testing, collection, component preparation and therapy.
- 4.3 Perform a healthcare economic analysis to see how economies of scale will drive down costs.
- 4.4 When feasible, pursue consolidation of blood donor testing and/or component preparation in order to drive quality standards and increased oversight of procedures. Blood screening should be consolidated in strategically located facilities at national and/or regional levels to achieve uniformity of standards, increased safety and economies of scale.
- 4.5 Start the blood testing scheme as a pilot program with only two or three hospitals sending samples to a central site. Learn from the pilot experience before expanding the program to a wider area to increase economies of scale.

4.6 Develop infrastructure including IT systems to support centralized or regional testing.

6. To increase government focus on blood testing strategies based on the disease burden in the APEC developing economy's population

Current Situation

Even with accelerated policies that support voluntary blood donation, APEC developing economies will still need time before those efforts impact the safety of the blood supply. By matching the most sensitive testing technology to the disease prevalence, APEC economies can advance blood safety and deliver the safest possible blood to patients. It is critical that the blood screening technology and how it is employed (e.g the blood testing algorithm) reflect the prevalence of disease in the general population.

Actions

- 6.1 Establish a baseline for transfusion-transmitted infection risk.
- 6.2 Perform a risk analysis to understand the scope of risk in the blood supply.
- 6.3 Support implementation of serology and Nucleic Acid Technology (NAT). Screening of all donations with serology should be in place before screening strategies utilizing NAT are considered.
- 6.4 Baseline global best practices in blood screening strategies.
- 6.5 Educate policy makers, patient groups and healthcare professionals on safety and identify champions who promote the importance of blood safety.
- 6.6 Measure progress and collect appropriate testing data.
- 6.7 Collect baseline health economic data on testing strategies.

7. To incorporate models such as public-private partnerships and partnerships with non-profit organizations to access resources and expertise and identify advocates for advancing blood safety

Current Situation

Participation in PPP and partnerships with non-profit organizations in areas of healthcare varies across APEC economies. Some economies with limited resources have shown openness to

collaborating with other governments, academia and the private sector to strengthen public health and improve outcomes for patients. Blood safety is an area where there is sufficient experience around the world that numerous public and private sector experts could share information and expertise, thereby helping improve developing economies' access to resources.

Partnerships can be carried out with academic institutions, private corporations, NGOs and hospitals. While many partnerships will be focused on technical expertise, APEC economies can benefit from public affairs partnerships, working with vocal proponents of blood safety to carry blood safety messages to decision makers.

Actions

- 7.1 Review successful PPPs in healthcare and other industries to find a model that fits.
- 7.2 Establish a task force that can make recommendations to Ministry of Health:
 - Establish appropriate legal framework for the partnership model.
 - Set clear, attainable and mutually beneficial goals for the partnership. Communicate widely and have adequate transparency.
 - Incorporate advocates for blood safety from across the continuum of care, including physicians, hospital administration and healthcare workers who can speak to peers and other decision-makers on best practices in testing.
 - Measure the impact of the partnership and share results publically for transparency.
 - Involve outside stakeholders for input on how to improve the partnership.

8. To provide evidence to decision-makers on the value of blood safety policies that facilitate data-based decisions for public health

Current Situation

The decisions that APEC economies are making today on national blood services will require ample time and evaluation. Access to accurate, local data, such as health economic analyses and transfusion transmitted infection rates, will be essential. Without a clear picture of the environment, it will be difficult for decision-makers to make the best long-term decisions for the country.

With a view towards strengthening blood safety in Asia Pacific, there is a real need to devote resources to empower economies to use data to understand and demonstrate ongoing value of blood safety for the region.

Actions

- 8.1 Collect baseline health economic data on centralization/regionalization and testing strategies.
- 8.2 Support standardized data collection and analysis to demonstrate value of blood safety in the continuum of care.
- 8.3 Devote regional resources to health economic analysis to drive policy.
- 8.4 Devote regional resources to plasma strategies to discuss best approaches to meet demand and how to leverage untapped resources of discarded plasma in developing economies.

9. Adopt Patient Blood Management (PBM): a standard of care used to optimize the use of a patient's own blood, thereby reducing or avoiding unnecessary blood transfusions

Current Situation

PBM is a patient-focused, evidence-based and systematic approach to optimize the use of a patient's own blood. It is designed to improve patient outcomes through the safe and rational use of blood and blood products and by minimizing unnecessary exposure to blood products.

Anemia affects approximately 1.6 billion people (25% of the world's population) and is associated with increased healthcare costs, risk of postoperative mortality and morbidity, infectious complications, prolonged hospitalization, and a greater likelihood of allogeneic red blood cell (RBC) transfusions.

Despite the WHO's resolution in May 2010 to adopt PBM, relatively few countries have adopted the approach or the three main elements (3 pillars) that can be applied during the pre, intra, and postoperative stages:

1. Optimize patient's own blood volume, especially red cell mass
2. Minimize the patient's blood loss and bleeding
3. Harness and optimize the patient's physiological tolerance of anemia

Actions

- 9.1 Educate and generate broader awareness of the benefits (patient safety / reduced healthcare costs) of PBM
- 9.2 Create a PBM Taskforce to oversee regional / APEC implementation and sharing of best practice
- 9.3 Create a National PBM Advisory Board with the responsibility to educate, develop national guidelines and oversee the implementation of PBM
- 9.4 Develop metrics for good clinical practice and to benchmark transfusion rates per health facility