

Draft Report

The Regional meeting of National Blood Transfusion Services (NBTS) focal points to review the implementation of "WHO action framework to advance universal access to safe blood and blood products 2020" was held virtually on 26th and 27th July 2022. The two-day meeting took place virtually with 10 of the 11 member states from the region participating including experts in the field of blood transfusion from across the region and WHO Headquarters. The specific objectives of the meeting were:

- To review the status of NBTS in the Member States in the region.
- Implementation of national blood action plans in line with six strategic objectives of the WHO action framework.
- To discuss challenges/gaps and share success stories, especially during the COVID-19 pandemic and progress towards implementation of hemovigilance.
- To discuss a road map to bridge the gaps and strengthen NBTS capacity.
- To sensitize the Member States on the use of Global Benchmarking Tool + Blood to understand and strengthen the regulatory aspect of NBTS.
- To discuss the availability of national data on blood accessibility, availability and safety based on Gender, Equality, human rights and disabilities.

Day 1, 26th August 2022

Day 1 of the meeting commenced with welcome remarks from Dr Aparna Singh Shah, Regional Advisor on Blood, Blood products and products of human origin, WHO Regional Office for South-East Asia, New Delhi.

Mr. Manoj Jhalani, Director of Health Systems Strengthening and Universal Health Coverage (UHC), WHO Regional Office for South-East Asia, New Delhi opened the meeting and presented WHO Regional Director's Address on World Blood Donor Day-2022. Address urged policymakers to create targeted actions ensuring safe, effective and quality assured blood and blood products and working towards the goal of 100% Voluntary non-Remunerated Donations (VNRDs).

Dr. Thaksaphon Thamarangsi, Coordinator, Integrated Health Services, WHO Regional Office for South-East Asia, New Delhi gave the speech on the need for improvement of national blood transfusion services to achieve UHC. This was followed by the objectives and expected outcomes from the meeting and the introduction of the participants.

1st plenary session started with Southeast Asia Regional Perspective on Blood Safety by Dr. Aparna Singh Shah. The presentation used the data from WHO Global Database on Blood Safety" (GDBS), which aims to provide an overview of how countries and blood transfusion services are meeting blood supply, safety, and also gaps and challenges. The presentation highlighted that a safe, equitable, sustainable and secure supply of blood for transfusion remains a key need for all countries. All eleven SEAR member states have a national blood policy. The WHO global report observed the highest percentage increases in voluntary non-remunerated donations in the South-East Asia Region among all the WHO regions. Around 82% of all collected blood in SEAR is VNRDs. All the member states have a national blood policy. All the countries are striving towards achieving a goal of 100% VNRDs. Global perspective was presented by Dr. Yuyun Maryuninsih, Team Leam for Blood and other products of human origin, WHO-HQ. She also described the WHO action framework for improving supply of blood and blood products. She presented a list of new WHO blood safety documents and explained briefly about the WHO Revived Achilles plasma fractionation Project.

After Global and Regional Perspectives, by WHO staff, country status reports were presented by the SEAR member states. Summaries of country presentations are captured as follows.

Bangladesh

The National Safe Blood Transfusion Program (NSBTP) in Bangladesh provide transfusion services through both public (223) and private (203) blood centers. There is a national policy, standard guidelines and legislations regulating this program with proper budget allocation and a cost recovery financial collection system. A total of 0.7 million units of blood were collected in 2021 with 27% being VNRDs and the rest 63% Replacement donors. All the donated blood are screened for Transfusion transmitted infections (TTIs) and the

seroprevalence of TTIs are 0.001%, 0.5%, 0.03%, 0.13% and 0.001% for HIV, HBV, HCV, VDRL and Malarial parasite respectively. 30% of collected blood are separated into components. There is a Day Care Transfusion Service for patients with Thalassemia, Hemophilia, Leukemia, Aplastic anemia and post-surgery chemotherapy patients. Situation varies from centre to centre and major challenges include inadequate infrastructure, absence of use of advanced technology, less numbers of VNRDs, and lack of use of national guidelines at some of the centres. Future plans include establishing a National Blood Center, introduction of national Hemovigilance system, EQAS, establish a plasma fractionation plant and a bone marrow, stem cell and cord blood stem cell transplantation unit.

*Presented by Dr. Supriya Sarkar, Program Manager, Blood Safety & Patient Safety, Directorate General of Health Services, Bangladesh.

Bhutan

The Blood Safety Program (BSP) in Bhutan provides transfusion services through 27 hospital-based blood banks. A national blood policy is present with legislations and guidelines with regulation under the Drug Regulatory Authority (DRA). There is a well-functioning hemovigilance system and quality assurance scheme (EQAS and NEQAS). 9614 units of blood were collected in 2021 with 84% VNRDs and 16% Replacement. Collected blood was also separated into components (Platelet concentrates, FFP, Packed red cells). 100% of the donated blood are screened for TTI using rapid testing and seroprevalence of TTIs are 0.07%, 0.26%, 0.04%, 0.9% and 0 for HIV, HBV, HCV, VDRL and Malarial parasite respectively. One of the major challenges is maintaining the quality and safety of blood banks, inadequate implementation of National Standards in the existing centers and a dedicated budget is not available for the day-to-day operations of BTS. Future plans are to consolidate and upgrade the existing blood centers, strengthen the Blood Transfusion Information System (BTIS) and create a National Strategic Plan with an accreditation system in place.

*Presented by Miss Pema Yangzom, Senior Program Officer, Blood Safety & Diagnostic Program, Bhutan.

India

The Blood Transfusion Services in India have 3908 blood collecting centers (1131 public and 2777 private) with 77% being hospital based. There is a national policy with legislations in place for blood safety, licensing is mandatory and regular inspections are conducted to ensure quality and safety with respect to the standard guidelines. There is also a system of accreditation for blood centers. 10.2 million units of blood were collected in 2020 of which 78% was separated into components. In 2019 12.4 million units of blood were collected. 82% of donated blood was VNRDs and 18% replacement. All the donor blood is screened for TTls. The seroprevalence of TTls are 0.13%, 0.73%, 0.32%, 0.25% and 0.04% for HIV, HBV, HCV, VDRL and malarial parasite respectively. All reagents and supplies are through a decentralized procurement. There is a national hemovigilance system. Blood centres participate in NEQAS to assure quality and safety of blood. Success stories include establishment of national hemovigilance system and India's support to Bhutan in developing Bhutan's hemovigilance system. Development of E-Raktkosh app is also an important achievement. Major Challenges at present are data collection, collation, and analysis through national web portal, procurements of blood bank supplies, commissioning metro blood banks, prevention and control of hemoglobinopathies. A road map is being developed for strengthening National blood transfusion services.

*Presented by Dr. Anil Kumar, Additional Deputy Director General, Blood Transfusion Services and National Blood Transfusion Council, India.

Indonesia

There is a nationally coordinated BTS with a national policy, guidelines, strategic plan and budget allocated for it. There are legislations regulating functioning of blood centers with mandatory licensing, regular inspections, quality accreditation and EQAS. There is a national procurement program (BTS) for reagents and supplies. There are 367 blood centers of which 198 are government and 169 are private. A total of 2,185,033 units of blood was collected in 2020 with 78% VNRDs and 22% as Replacement. All the donor blood is screened for TTI's using NAT, CLIA, ELISA, Rapid Tests. TTIs seroprevalence are 0.41%, 1.58%, 0.48% and 0.83% for HIV, HBV, HCV and Syphilis respectively. Blood is separated into components. There is a hemovigilance program. The major challenges include implementing a centralized process for blood processing and patient blood management (PBM), increasing implementation of blood regulation and harmonization for BTs under MoH and IRC. Future plans include a National Strategic plan for blood safety and capacity building for BTS.

*Presented by Dr. Teguh Triyono, National Committee for Blood Service.

Maldives

The Maldivian Blood Services (MBS) provides transfusion services under a national blood policy and committee. There are 104 blood centers (103 hospital based and 1 stand-alone center). There are 5 centers in the capital, 6 in regional hospitals, 13 in the atoll hospitals and in 80 health centers. Central blood establishment participates in EQAS. Each center collects, screen, crossmatch and prepare component to their requirement. In 2020, 6276 units of blood were collected of which 33% VNRDs and 67% Replacement. In 2019 6738 units of blood was collected. 100% of blood is screened for TTIs. Challenges include the geography of the country which also makes it difficult to ensure connection between health facilities providing BTS; lack of resources and trained staff; inadequate VNRDs and no national Hemovigilance component in NBTS. A situation analysis is currently underway and shall provide further understanding of the gaps. A program to increase the voluntary blood donation in the country has also been initiated.

*Presented by Dr. Ahmed Umar, Associate Specialist in Pediatrics, Maldivian Blood Services, Maldives.

Myanmar

The country has a national policy, NBTS guidelines and budget allocation. Legislations on blood safety are present with regular inspections of blood banks. There is no licensing or accreditation system of BBs. EQAS and NEQAS is well implemented. The reagents and supplies are centrally procured and distributed. Data management system of NBTS is at places digital or manual. There are 335 centers with 1 stand-alone, 333 hospital-based centers and 1 storage center. 434,311 units of blood were collected in 2018 of which 72% was VNRD and 28% Replacement of which 62% were converter to blood components. 100% of blood is screened for TTIs. NAT, ELISA, and RDTs are various methods of TTIs testing and differs from Centre to centre. Hemovigilance is successfully implemented in central blood establishment. Mobilization of donors and continued safe blood supply during COVID 19 pandemic were challenging. Nationally coordinated blood transfusion services can ensure blood accessibility and safety.

*Presented by Dr. May Thu Aung Hsan, National Professional Officer, WCO-Myanmar.

Nepal

The National Blood Program works in line with National blood policy and follows standard guidelines. There is also a blood strategic plan. There is a hemovigilance system, licensing and regular inspections of blood centers. There are no legislations and an accreditation system in place. There is NEQAS for TTls but not for Immunohematology. There are 121 blood centers of which component separation occurs at 31 centers. 24248 units of blood were collected in 2019 of which 80% VNRD and 20% replacement. 100% of blood is screened for TTls. Methods used for TTls testing differs and spans from ELISA, CLIA, e-CLIA, Rapid testing

(PCR done at reference laboratory). The seroprevalence of TTIs in 2018 are 0.04%, 0.25%, 0.15%, 0.45% for HIV, HBV, HCV and Syphilis. Challenges include inadequate infrastructure at places, need for additional staff, strengthening of reference lab capacity. There is need for expansion of hemovigilance system. Future plans include establishing a revised national program in new federal system, strengthening hemovigilance system and installing a national integrated web-based data management system.

*Presented by Dr. Rekha Manadhar Shrestha, Senior Consultant Pathologist, Coordinator for National Bureau for Blood Transfusion Service, Nepal.

Sri Lanka

The National Blood Transfusion Service is centrally coordinated having a national blood policy. It is the sole supplier of blood and blood products to all public and majority of private hospitals. Standard guidelines are there with legislations, licensing, regular inspections and accreditation system in place with EQAS. There are 106 hospital-based and 2 stand-alone blood centers. 385,054 units of blood was collected in 2021which were 100% VNRD and they were all processed and separated into components. In 2020, 397,833 units of blood were collected. 100% of blood is screened for TTI's and seroprevalence of TTI's in 2021 are 0.01%, 0.2%, 0.13%, 0.39% for HIV, HBV, HCV and VDRL respectively. Adverse reactions in 2020 were 3341 of which major reactions were 556 and minor reactions were 2785. NBTS Sri Lanka acts as a WHO CC providing training and education on Transfusion medicine, preparation of IEC materials and assisting in quality system BTS. Major challenges are regulatory gaps; providing transfusion services during crisis; difficulty in establishing and implementation of software system. Success stories include Implementation of Patient Blood Management program, local production of reagents required for serology testing, implementation of a new stock management guide, maintaining VNRDs during Covid-19 pandemic and post Covid economic crisis.

*Presented by Dr.Lakshman Edirisinghe, Director, National Blood Transfusion Service, Sri Lanka.

Thailand

The Thailand Blood Center works with the Thai Red Cross Society in providing transfusion services in the country. There is a National Blood Center (NBC), 12 Regional Blood Center, 166 Blood services branches and a plasma fractionation center. There is a national policy, standard guidelines, strategic plan, legislations, and regulation, and regular inspections. Accreditation of establishments, participation in EQAS and NEQAS, and a well-functioning hemovigilance system are the strengths of NBTS. A total of 2,645,284 blood donations (all VNRDs) were made in 2020. In 2019, the collection was 2,399,266 units. All donations are screened for TTls. Blood component separation and plasma fractionation is done along with manufacturing of blood group reagents, blood bag, blood products and PDMP in the country. There is an HLA lab for organ and stem cell transplantation with a National Stem Cell Donor Registry.

*Presented by Dr. Pawinee Kupatawintu, Deputy Director, National Blood Center, Thai Red Cross Society, Thailand.

Timor-Leste

Timor Leste has a national blood policy, a blood program and a strategic plan. There is also a dedicated budget allocated for NBTS. There are national standards for NBTS. Regular inspections and external audits are conducted to assure the implementation of standards. There are no legislations covering NBTS. Data management is both digital and manual. Reagents and supplies are centrally provided. There is only one blood bank and the total units collected are from 3000-4000 donors of which 18% VNRD and 82% Replacement. All blood donations are 100% screened for HIV, HBV, HCV and Syphilis. Success stories include increased VNRDs and rational use of blood products. Major challenges are limited human resources, regular training of staff, and equipment. Future plans include the provision of training of staff, establishing a strategic plan

supporting the blood policy; upgrading methods of testing and quality control; advanced technology and equipment, and further increasing numbers of VNRDs.

Day 2, 27th August 2022

On day 2, leading experts and eminent speakers gave lectures and presentations on various aspects on blood transfusion services and the objectives and methods to achieving goals in each aspect of blood transfusion. They discussed the gaps, challenges and opportunities present in various blood transfusion services. The sessions were chaired by Dr Surinder Singh, Dr Rati Ram Sharma and Dr Pawinee.

The topics discussed were:

- 1. Towards 100% VNRD—Dr. Rati Ram Sharma.
- 2. Quality Assurance in Serology/TTIs Testing—Dr. Shami Shastry.
- 3. Rational use of blood—Dr. Sita Lakshmi.
- 4. Plasma fractionation—Dr. Surinder Singh.
- 5. Organ Transplant-Products of human origin—Dr. Stratios Chatzixiros.
- 6. Hemovigilance strengthening—Dr. Akansha Bisht
- 1. Dr Rati Ram Sharma talked about the goal of attaining 100% VNRBD, and the various gaps, challenges and opportunities. The challenges to achieving 100% VNRD were in creating better policies, utilization of resources adequately, training manpower, and managing the donor system and post-donation activities. The way toward achieving 100% VNRBD includes a robust hemovigilance system, post-donation donor care system, strategies preventing donor-adverse events, effective communication and use of information technology.
- 2. Dr Shamee Sastry lectured on Quality Assurance in Serology TTIs testing and how important it is to maintain quality standards to control and prevent TTIs. She highlighted the merits, demerits and need for a centralized testing system with regular monitoring, surveillance and gap analysis being done at regional levels. Training is to be provided to staff to improve the existing system in countries. There should also be the promotion of technology innovation and research.
- **3. Dr Sitalakshmi Subramanian** spoke on the Rational Use of Blood, the gaps, challenges and opportunities. She discussed the concept of Optimal blood use and Patient Blood Management (PBM). The major challenges include a lack of guidelines, proper training and education programs, hemovigilance systems, newer technology and awareness of PBM. The way forward is to take a multidisciplinary approach by modifying policies and guidelines, providing regular training, establishing guidelines and standards, and regular monitoring and surveillance.
- **4. Dr Surinder Singh** lectured on Plasma Fractionation. He discussed the essentials of plasma fractionation, the gaps, challenges and opportunities in Southeast Asia and the way ahead in this regard. He discussed the gap between demand and supply at all levels in most countries in SEA. Major issues include high cost of establishment, safety issues related to plasma, erratic supply, cross-border restrictions and self-sufficiency etc. In SEA only a few member states have fractionation plants. The way forward includes (but is not limited to) creating better policies, preparation of safe plasma, improving methods of testing, use of newer tools and technology, using resources judiciously and developing a regulatory system.
- **5. Dr. Estratios Chatzixiros** discussed the principles of donation and management of medical products of human origin (MPHO). Major challenges in member states include limited resources, absence of strategies or policies or lack of proper implementation, and disproportionate focus on organ transplantation/ tissue

transplantation. For a better organ transplant and MPHO system in place there need to be proper legislation and enacted policies, certifying transplant centres and organ and tissue procurement agencies, certifying histopathological laboratories and providing training to staff.

6. Dr Akansha Bisht deliberated on hemovigilance strengthening. She explained the importance of the hemovigilance system and the components which make a robust system. The commitment by authorities with regular funding, uniform data collection with guidelines and documents, providing training, reporting adverse events, analyzing collected data, publishing of reports and having feedback or assessment of the program are important in establishing hemovigilance.

The final session had three presentations including two of WHO's Collaborating Centers (WHOCCs on blood safety) and one on the WHO "Global Benchmarking Tool +Blood" which was chaired by Dr. Ananda Gunasekara and Dr Sita Lakshmi.

National Blood Centre, Thai Red Cross Society, Thailand.

Dr Pawinee, Deputy Director, National Blood Centre, Thailand presented the workings of this WHO-CC. They provide training and expert knowledge on blood transfusion services including establishing a centralized data collection system and monitoring and analysis of data. They also provide onsite training on various aspects of blood transfusion services including managing quality of TTI testing kits. They are currently preparing online training material on Blood cold chain and blood group serology.

National Blood Transfusion Service (NBTS), Sri Lanka.

Dr Lakshman, Director, NBTS, Sri Lanka provided insights into the functioning of this WHO-CC. They provide special training and education courses on transfusion medicine for local and international trainees. The NBTS develop guidelines, manuals and methodologies to improve blood safety and voluntary blood donations. They also assist WHO in implementing quality systems in blood transfusion services.

The last presentation was by Mr. Washington Samukange who elaborated on the WHO Global Benchmarking Tool + Blood which evaluates/benchmarks the regulatory programs of blood products including whole blood, components and plasma-derived products. He explained how GBT+ Blood can improve outcomes, create greater consistency in standards and approach and contribute to better resource mobilization in blood transfusion services.

The meeting concluded with a discussion by member states and other participants about achieving 100% VNRD, nationally coordinated blood transfusion services, Quality assurance in TTIs, rational use of blood, component separation, and plasma fractionation. After due deliberations, the following recommendation was drafted. Implementation of recommendations depends on the available resources, country policies and needs.

Draft recommendations to the Member states:

- Member states must ensure accessibility and affordability of safe blood and blood products by establishing nationally coordinated blood transfusion services based on VNRDs.
- Improve and achieve 100% VNRDs by improving awareness among communities, health care providers, and policymakers. Donor mobilization, promotion of VNRDs
- Improving the quality of TTIs testing by ensuring the quality of test kits, organizing NEQAS, and participating in EQAS.

- Ensuring functional legislative framework and regulations overseeing BTS (use of GBT plus as appropriate)
- Implementation of hemovigilance.
- centrally coordinated data management system (collection, collation, and analysis)
- Use of regional/international network for proper utilization of plasma (plasma fractionation), and enhancement of local capacity.
- Reduce plasma wastages.
- Establishing a Centralized blood testing.
- Demand Vs supply calculation.
- Blood council training.

Draft recommendations to the WHO:

- Technical assistance in situational analysis, understanding gaps and challenges, and technical assessment (training/ guidance documents) to strengthen NBTS as per member state's request.
- Technical assistance in improving NEQAS and training for the establishment of testing quality of test kits with help of WHO CCs.
- Technical support and Coordination in plasma fractionation as per country's request and need.
- Technical support is the establishment of the centrally coordinated data management system (collection, collation, and analysis)
- Blood supplies during emergencies; guidance document.
- Technical Support work on blood disorders.

List of participants

Virtual Regional meeting of National Blood Transfusion Services (NBTSs) focal points to review implementation of "WHO action framework to advance universal access to safe Blood and Blood products 2020 (GPHG)", 26-27 July 2022

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Program

Time	Session	Person(s) responsible/					
Day 1: 26 July	Day 1: 26 July 2022						
09:45- 10:00	Registration (check for audio /video connectivity)						
10:00- 10:30	Welcome remarks	Dr. Aparna Singh shah					
	 Health System Director / Coordinator's remarks Regional Director's Address on WBDD Objectives of the Workshop & Introduction of participants & Administrative Announcement Group Photograph (PI switch on Camera) 	Mr. Manoj Jhalani/ Dr. Thaksaphon Thamarangsi,					
10:00- 10:30							
Global/Region	al Update and Country Reports						
10:30-11:00	Overview of Blood Transfusion Services in South East Asia Region/ Global presentation	Dr Yu Yun Dr Aparna Singh Shah					
11:00- 13:45	Country presentations (15 min each)	BAN, BHU, DPRK, IND, INO, MAL, MMR, NEP, SRL, THA, TLS)					
13:45- 14:00	GDBS data	Mr. Yu Junping					
14:00- 14:30	Q-A session	All					

Day 2: 27 July 2022					
Moderator-Dr Surinder Singh/ Dr Ratti Ram Sharma/ Dr Pawinee					
10:00- 10:15	Towards 100% VNRD: gaps/ challenges, opportunities	Dr. Rati ram Sharma			
10:15- 10:30	QA in Serology/ TTIs testing: gaps/ challenges, opportunities	Dr. Shami Shastry			
10:30- 10:45	Rational Use of Blood: gaps/ challenges, opportunities	Dr. Sita Lakshmi			
10:45- 11:00	Plasma Fractionation: gaps/ challenges, opportunities	Dr. Surinder Singh			
11:00- 11:15	Organ transplant-Products of Human Origin	Dr. Stratios			
11:15- 11:30	Hemovigilance strengthening	Dr. Akanksha Bisht			

Moderator: Dr Ananda Gunasekera/ Dr Sita Lakshmi					
11:30-11:45	WHO CC Thailand-activities/possible collaborations	Dr Pawinee			
11:45-12:00	WHO CC Sri Lanka	Dr Laxman			
12:00- 12:15	Regulations in blood transfusion services	THA/ SRL/IND			
12:15- 13:00	Discussions Member states need to strengthen blood Transfusion Services (5-7 minutes representatives of member states)	All			
13:00- 14:00	Next steps and way forward				