Ministry of National Health
Services Regulations & Coordination
GOVERNMENT OF PAKISTAN

The National Blood Transfusion & Blood Products Policy Pakistan 2025-30

National Blood Transfusion and Blood Products Policy

2025–2030

Ministry of National Health Services, Regulations and Coordination,

Government of Pakistan

Citation

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Nadeem Akhtar
Assistant Director (Programme-II)
Tuesday, 30 September, 2025, 3:52:07 PM

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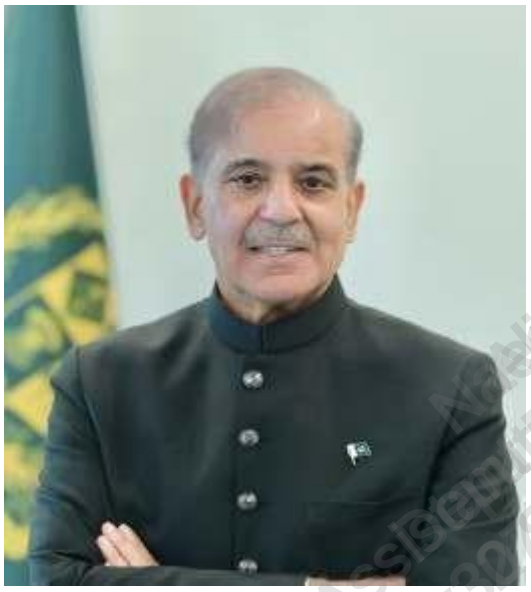
MESSAGE BY THE PRIME MINISTER



I am very glad to see the comprehensive National Blood Policy formulated by the Ministry of National Health Services Regulations and Coordination and Departments of Health to address Pakistan's critical blood transfusion needs. This policy is a crucial roadmap that outlines our strategy for ensuring safe, quality blood transfusion services in the coming years. With a rapidly growing population, Pakistan faces an increased demand for blood derived plasma products due to inherited diseases, surgical procedures, accidents, and chronic illnesses. Additionally, our vulnerability to natural and man-made disasters further underscores the need for a robust blood transfusion system.

I strongly believe that the initiatives and interventions proposed in this National Blood Policy will be instrumental in improving the health and safety of our citizens. This policy is a significant step forward in completing the reform process started in 2008 and enhancing the standard of healthcare in Pakistan. The Government of Islamic Republic of Pakistan is committed to actualize the Vision and Objectives stated in the Policy and all efforts shall be made for its implementation.

I would like to appreciate the efforts of the Health Ministers and their team for this excellent endeavor. I congratulate the team that was tasked to develop the new policy for their untiring efforts. I hope and pray that these policy initiatives are implemented within the specified time limits and lead to the development of a robust blood transfusion system in the country that could meet the demand of the nation in providing safe blood and its component.

Mian Muhammad Shehbaz Sharif
Prime Minister
Islamic Republic of Pakistan

JOINT MESSAGE FROM HEALTH MINISTERS

Blood transfusion is a critical component of a healthcare system, and its importance cannot be overstated. It is estimated that millions of lives are saved annually through blood transfusions, making it an essential component of medical practice. With a rapid population increase in Pakistan, the demand for blood transfusion and its products is also rising mainly due to the increased number of inherited diseases, surgical procedures, accidents, and chronic illnesses. Moreover, Pakistan is considered a highly vulnerable country for natural and man- made disasters. Currently the country is facing both national and complex emergencies.

There are several challenges faced by the country's blood transfusion services including inadequate infrastructure, substandard blood screening services, lack of storage facilities for blood products and a need for revision of regulatory frameworks in line with changing priorities and vulnerabilities.

The last blood transfusion policy for Pakistan expired in 2020 (2014-2020) and the country now needs to revise its policy and align it with changing needs especially the need for Plasma Derived Medicinal Products for the general population.

This policy provides comprehensive plan for National Blood Transfusion System including clinical use of blood and its products in Pakistan in line with international best practices. The policy aims to improve access to safe and quality blood transfusion services and universal access to blood products while protecting health of citizens of Pakistan and rights of all stakeholders. It encompasses the entire blood transfusion system including the collection, processing, storage, distribution and use of blood components and products. This policy also comprehensively focuses on specific objective covering self-sufficiency in Plasma Derived Medicinal Products (PDMPs), which was not touched upon in previous policy. It addresses the governance initiatives, coordinating mechanisms, implementation plans, regulatory capacity and role of health departments at the federal and provincial levels. It also addresses the ethical and legal aspects of blood transfusion including the rights of patients, donors, and healthcare providers.

We the Health Ministers endeavors that this policy will be instrumental in completing the reform process started in 2008 and provides a clear road map that aims to achieve the goal of providing safe and efficacious blood to the population. This goal is in line with the Sustainable Development Goals to which the country is a signatory.

Declaration by Federal and Provincial Ministers of Health

National Blood Transfusion & Blood Products Policy 2025-30.

This National Blood Transfusion Policy (2025-30) is a unified national document with agreed priorities covering 15 objectives along with their subsequent action plans, form a comprehensive framework aimed at enhancing the safety, availability, and accessibility of blood and blood products. We pledge to work together for better health of all especially for women and children of Pakistan and therefore we endorse this document.

Syed Mustafa Kamal

Mr. Khawaja Salman Rafique
Minister for Specialized Healthcare & Medical Education Punjab

Mr. Khawaja Imran Nazeer
Minister for Primary and Secondary Health Department, Punjab

Dr Azra Pechuho
Health Minister, Sindh

Syed Qasim Ali Shah
Health Minister, Khyber Pakhtunkhwa

Sardar Faisal Khan Jamali
Health Minister, Balochistan

Haji Gulbar Khan
Chief Minister, Gilgit Baltistan

Mr Nisar Ansar Abdali
Health Minister, Azad Jammu & Kashmir

Message from the Federal Secretary Health

It is matter of great satisfaction that National Blood Policy 2025-2030 has been finalized with extensive Federal and Provincial stakeholder consultations and improvements in drafts after in-depth deliberations. Pakistan has successfully completed many milestones in the Journey of reforming National Blood Transfusion System but there are still several gaps to be filled in achieving our national goal of providing safe and efficacious blood to the population of Pakistan. The Government of Islamic Republic of Pakistan is committed to actualize the Vision and Objectives stated in the Policy and all efforts shall be made for its implementation.

I congratulate the team that was tasked to develop the new policy for their untiring efforts. I hope and pray that these policy initiatives are implemented within the specified time limits and leading to the development of a robust blood transfusion system in the country that could meet the demand of the nation in providing safe blood and its components.

Secretary
Ministry of National Health Services Regulations &
Coordination, Govt. of Pakistan

Message from Director General Health

I extend my heartfelt gratitude to all the stakeholders, experts, and contributors who have played a pivotal role in shaping the National Blood Transfusion Policy for Pakistan (2025-2030). This policy represents a significant milestone in our commitment to ensuring safe, efficient, and equitable blood transfusion services across the nation. Recognizing its critical importance of a National Blood Policy, the Government of Pakistan has embarked on a journey to establish a nationally organized and coordinated blood transfusion service that caters to routine and emergency blood requirements for the population of this country.

This policy document was formulated in an effort to refresh and further harmonize the priorities for the transfusion services from 2025-30 after the expiry of previous one. The new document provides fundamental principles and identifies clear priority areas that need to be focused on a coordinated manner by all the partners both at the National and Provincial levels.

I am pleased that all of our transfusion medicine stakeholders have actively participated in the whole process of policy formulation, especially CEO IHRA deserves credit for consolidating and strengthening this initiative and under his leadership the Ministry of National Health Services Regulations and Coordination has finally achieved another milestone for the country. I am quite confident that the National Technical Committee with membership from all stakeholders and provinces will periodically review the progress on the implementation of this policy and will ensure that it is implemented in its letter and spirit.

Thank you, Team, for your continued commitment and support to this vital cause.

Dr. Ayesha Isani Majeed
Director General (Health)
Ministry of National Health Services
Regulations & Coordination,
Govt. of Pakistan

Acknowledgement

The IHRA would like to express its sincerest gratitude to all those who contributed to the formulation of the National Blood Policy. The policy provides a framework, intent and will of government on achieving universal access to safe blood and its products. A roadmap is provided for financial sustainability and access to quality blood products.

We sincerely thank the Ministry of National Health Services Regulations and Coordination for their unwavering support throughout the process. Their commitment and dedication to formulating the policy and improving the country's blood transfusion and healthcare system. We pay our special thanks to Secretary, M/o NHSR&C and Director General (Health), M/o NHSR&C.

IHRA would like to extend profound gratitude to all the reviewers of the policy, healthcare professionals, policymakers and patient advocates who participated in our provincial consultation workshops and shared their insights and expertise in developing this policy. Their contributions were invaluable in shaping the policy and ensuring that it is evidence-based, practical and responsive to the needs of patients of Pakistan. We would also like to acknowledge the contribution and dedication of the IHRA team that worked tirelessly throughout the policy formulation process and provided the much-needed support.

We would also like to acknowledge the support provided by both national consultants namely Prof. Nuzhat Mushahid TI(M) and core technical committee, Dr. Jasim Anwar and our international consultant Dr. Paul Strenger from Netherlands. We sincerely thank Roche Pakistan for their administrative support in organizing provincial consultations.

Finally, we thank all the stakeholders including provincial departments of Health, provincial blood transfusion authorities, NGOs and line departments and ministries for their participation and inputs in the policy. We are confident that this policy will ensure that safe and effective use of blood in healthcare settings is making a real difference in the lives of patients and their families. Once again, we thank all stakeholders for their contributions in the formulation of the blood transfusion policy.

Dr. Syed Ahmed Raza Kazmi
Chief Executive Officer Islamabad Healthcare Regulatory Authority

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Abbreviations

DS	Drug Substance
AJK	Azad Jammu & Kashmir
BDO	Blood Donor Organization
BE	Blood Establishments includes RBCs, hospital blood banks and source plasma centers
BECS	Blood Establishment Computer Software
BTS	Blood Transfusion Services
CLIA	Chemi-Luminescence Immuno-Assay
ICCBBA	International Council for Commonality in Blood Banking Automation.
DRAP	Drug Regulatory Authority Pakistan
FBTS	Federal Blood Transfusion Services
GB	Gilgit and Baltistan
GIZ	Deutsche Gesellschaft fur International Zusammenarbeit
IBTS	Institute of Blood Transfusion Services
ISBT	International Society of Blood Transfusion
IVD	In Vitro Diagnostics
KFW	German Development Bank
M/o NHSR&C	Ministry of National Health Services, Regulations and Coordination
NBTP	National Blood Transfusion Programme
NGO	Non-Governmental Organization
NTAC	National Technical and Advisory Committee
PE	Plasma establishment
PBTS	Provincial Blood Transfusion Services
PDMPs	Plasma Derived Medicinal Products
PIC/S	Pharmacological Inspection Coordination Scheme
PPP	Public Private Partnership
PTAC	Provincial Technical Advisory Committee
RBC	Regional Blood Centers
SBTP	Safe Blood Transfusion Programme
WHO	World Health Organization

Introduction

The Islamic republic of Pakistan is the fifth-most populous country, with a population of over 241.5 million as reported by Pakistan Bureau of Statistics. Pakistan's gross national income per capita is $ 1,560 and the total expenditure on health constitute 2.95% of the country's GDP (World Bank Report, 2022). The country is one of the most vulnerable countries for both natural and man- made disasters like climatic changes. In the past it has faced major earthquakes, floods, cyclones, drought and major man-made disasters such as wars and conflicts in neighboring countries, political instability and terrorism, regular disease outbreaks, extreme weather events resulting from climate change. The country is also facing challenges of rapid urbanization and poverty that is adding to other vulnerability factors.

Public sector healthcare system comprises of primary, secondary and tertiary levels, primarily governed by provincial departments of Health. Basic Health Unit (BHU) serves as the first point of contact of patients, which has a referral system to Rural Health Centers (RHC) that offers more extensive health services. The Secondary level consists of Tehsil Headquarter Hospitals that provide more specialized services including inpatient care. District Headquarter Hospitals (DHQ) a tier above THQs, cover whole of the district offering a broad range of medical services. Finally, there are Tertiary Care Hospitals which are affiliated with medical universities and are equipped to handle complex medical cases. However, these are entertaining all types of patients because of urban location. Added to this public sector healthcare is a significant, growing private sector, that vary from small family centers to large highly specialized tertiary level hospitals. Under the constitution, health services delivery is primarily responsibility of the provincial government. However, after 18th Amendment, there are certain only Federal domain areas that have impact on the provincial healthcare delivery and blood system of country, as well access to resources
e.g. The ministry of planning, development and special initiatives, the medical education, drugs and therapeutic goods regulation (DRAP), interprovincial trade, defense, international commitments and arbitrations. This also underscores the importance of one National Blood Policy with help and with the consensus of provinces and areas.

Blood transfusion service is an essential pilar of the healthcare system. Blood safety remains a significant public health problem in developing countries. The 63rd World Health Assembly (WHA) emphasized the importance of establishing reliable quality assurance systems for blood collection, processing and distribution of blood components in blood establishments in Resolution WHA
63.12 on blood product availability, safety and quality. Pakistan is a signatory to the WHO resolutions and to Sustainable Development Goals, and several targets are directly or indirectly related to safe blood transfusion, including Target 3.3, which calls to end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases; and Target 3.8, which calls for universal access to safe, effective,

In Pakistan, donated blood is required to be tested for hepatitis B and C, human immunodeficiency virus (HIV), syphilis, and malaria. However, the uniform standards of Transfusion Transmissible Infections (TTIs) screening could not be implemented, and blood transfusion remains significant source of transmission of Hepatitis and HIV in the country. Even today most blood banks are using rapid screening kits for blood screening. This lack of standardized screening is the first most significant cause of spread of Hepatitis C (13% of total HCV transmissions) and second largest cause of HIV and contributes 12 per cent of HIV infections in Pakistan (World Health Organization, 2022). The estimated prevalence of HIV in the country is underreported as stated in Country Progress Report - Pakistan by Global AIDS Monitoring. Pakistan also ranks first in world with highest prevalence country for HCV after Egypt has successfully eliminated HCV. National Hepatitis Prevalence Survey was conducted in 2008 by Pakistan Medical Research Council (PMRC) and reported that national prevalence of HBV in Pakistan was 2.5% and HCV was 4.8% Province wise break up showed that the Hepatitis B was high in Baluchistan (4.3%) while it was (2.5%) in Sindh, (2.4%) in Punjab and (1.3%) in Khyber Pakhtunkhwa (KPK). For HCV the disease was highest in Punjab (6.7%) followed by Sindh (5.0%), Baluchistan (1.5%) and KPK (1.1%) From 2015 to 2019, there was a 5% increase in HCV-related deaths and an 8% increase in HBV-related deaths. A large community of thalassemic patients in the country (five per cent carrier rate) has largest disease burden of HBV and HCV infections.

The blood components are prepared from few blood donations only, which leads to wastage of plasma and platelets. This translates into wasting at least 0.2-0.3 million liters of recovered plasma that can potentially be utilized for contract manufacturing and meet public need of PDMPs. Furthermore, the lack of leadership, unsatisfactory governance & capacity, unsustainability, non - utilization of technology and discontinuation of international partnership has systematically undermined the blood system reform agenda, that was started in 2008. The last National Blood Policy was for years 2014 to 2020 and needs revision for which this exercise is undertaken. The last NMP achieved variable, insignificant successes of developing a complete ecosystem for National Blood Transfusion as envisioned by WHO's Action Framework (2020-2023):

"Establishment and maintenance of a national blood system requires a broad range of societal, scientific and medical competencies that span behavioral science, epidemiology, serological and gene- based diagnostic methods, operational and quality systems management, risk-based decision- making, clinical training, surveillance tools, and business skills, all of which must operate under local physical, social, political and financial conditions and constraints. Given the breadth and scope of the issues and challenges, an interactive set of strategies is needed."

With this background, it is required that policy is revised for next five years with clear objectives and practical actions in local context incorporating the lessons learnt, available data & experiences, WHO Strategic Framework document and Aide-Memoire.

Executive Summary

Pakistan is home to 240 million people and faces critical challenges in its healthcare system in provision of quality universal care to its population, on one hand. On the other hand, it has tremendous potential to strengthen its blood transfusion system and become self-sufficient in Plasma Derived Medicinal Products to meet domestic and international needs. Its healthcare system comprises of four types of sectors: public, private, Military and NGO with a considerable contribution in informal healthcare landscape. All these sectors are extending blood transfusion services of variable quality, variably regulated and does not form a cohesive, well managed National Blood System and at best can be defined as fragmented. The services range from poor quality, source of TTIs transmission to some centers of excellence that meet international standards. A significant problem that arose after previous NBP is division of blood regulations among different regulatory authorities e.g. provincial blood transfusion authorities, healthcare commissions, HOTA (human organ transplant authority), while exclusion of most important regulator i.e. DRAP. It stemmed from ignoring the fact that blood and its components are universally considered "biological drugs" and there is only one National Drug Regulatory Authority (DRAP) with the concurrence of provinces. This has created additional regulatory burden, non-coordination, fragmentation, confusion for potential investors, poor capacity development without contributing significantly to improving safety, availability and quality of blood, its components and PDMPs and especially the clinical blood transfusion and patient blood management. It is worthwhile for all stake holders to contemplate regulatory framework similar to European SoHo (substances of Human Origin), or FDA Medicinal Products of Human Origin (MPHO) that encompass all blood, cellular, milk, organs, etc. of human origin to be regulated under one directive and regulator.

Blood Transfusion system of Pakistan, especially in public sector, was neglected for long time, but has finally started improving in the last two decades with construction and operationalization of most of Regional Blood Centers (RBCs) that provide all services from collection to screening and component separation and a network of hospital-based blood banks for limited activity that depend on each RBC. Operationalization of some like Islamabad Regional Centers is still to become functional as envisioned by G to G understandings. Other than these regional blood centers the blood system is fragmented with hospitals running their own blood banks without a uniform and standardized testing for Transfusion Transmissible Infections (TTIs), ultimately contributing to the transmission of Hepatitis and HIV and other blood borne infections. The non control of inputs like blood bags, failure to adopt technology and poor regulatory capacity has promoted corrupt practices as well.

This policy document is prepared following expiry of 2014-2020 National Blood Policy and after reviewing the lessons learnt and addressing some new challenges as well as those that were not incorporated/elaborated in previous policies e.g. the presence of surplus recovered plasma and country's unmet needs for PDMPs and consider plasma as therapeutic good. There was lack of clarity of policy on responsibilities, roles and coordination mechanisms at government level, to create enabling environment and lay down mechanisms for utilizing surplus plasma and undertake source plasma program in the future.

It is also pragmatic that readers of policy have the right information about the domains of Federation after 18th constitutional amendment and what subjects/regulation/commitments are in Federal jurisdiction and what exactly have been devolved to provinces and in what form. All objectives have

been framed carefully by keeping the above-mentioned aspect in mind and with legal advice on the same. This aspect is especially important for framing the Objective 9 on self-sufficiency in PDMPs and development of national plasma economy.

This document is divided into 15 objectives addressing respectively the governance, organization, structural components and service implementation aspects of an effective blood system in Pakistan, incorporating the existing constitutional, legislative, institutional and regulatory structures. These objectives along with their subsequent action plans form a comprehensive framework aimed at enhancing the safety, availability, and accessibility of blood and blood products as well as promoting public awareness and self-sufficiency in Plasma Derived Medicinal Products (PDMPs) and supply chains. The prescriptive nature of this policy stems from the need to provide details on why, who, what, how and when due to peculiar circumstances and context of country and desire to achieve effective implementation. Objectives no. 01 to 03 focus on creating a robust governance structure for the country's blood system. The first objective focuses on the national and provincial government's commitment, support, and ownership for a comprehensive National Blood Policy and System. The second objective stipulates to establish a committee (National and Provincial Technical and Advisory Committee NTAC) to bring experts to gather, who shall be the think tank guiding the implementation of the National Blood Policy (NBP) and the development of a National Blood System, ensuring representation from all regions. The third objective focuses on the strengthening and development of the organizational structure of comprehensive, well- coordinated, Federal and Provincial Blood Transfusion Services (FBTS/PBTS)programs which is essentially formalizing and strengthening the existing weak, provincial safe blood program, organizing and managing the respective blood transfusion services through Blood Establishments (BEs) as service delivery units/facilities and some acting as reference centers with the overall goal of implementing the NBP.

Objective no. 04 focuses on Defining National Policy for the TTIs, screening of all blood donations including apheresis donations and develop screening strategies appropriate for specific situations of the country and what is achievable realistically. **Objective no. 05** focuses on establishing, supporting and organizing Blood Establishments (BEs) on Hub and spoke model, including multiple Hospital Blood Banks (HBB) linked with Regional Blood Centers (RBCs) and regulation of day care transfusion facilities in all sectors (public, private, NGO, military) to meet the demand for safe, effective, and quality blood products under the overall management of FBTS at Federal level and PBTS at provincial level for public sector. The regulation of other sectors is also required to be brought under principles of centralized screening and transfusion services with dependent hospitals. BEs can additionally have the mandate to prevent wastage, ensure availability and contribute towards PDMPs to provide surplus blood products to other sectors following transparent, established mechanisms.

Objective no. 06 aims to strengthen national and provincial safe blood transfusion authorities to effectively regulate blood transfusion services and strive to attain highest maturity level with the help of WHO GBMT-plus maturity achievement initiative. **Objective no. 07** focuses on the development of standardized information technologies for accurate data collection, service delivery and regulatory capacity in blood transfusion through ISBT 128-compliant software and real time dashboards. The data gathered has to be made comprehensive enough for future planning.

Objective no. 08 provides a supportive framework for the blood system by developing skilled human resources in blood transfusion via certifications, training and degree programs, while **Objective no. 09** focuses on meeting the national need for Plasma-Derived Medicinal Products (PDMPs) through collaborative

action and involvement of all relevant governmental departments, regulatory bodies and other stakeholders. It stipulates the involvement of commercial organizations through adherence to international commitments and standards, country's regulatory framework, as well as engagement of a full-time blood transfusion medicine expert. **Objective no. 10** focuses on providing safe blood transfusion and products for patients with Thalassemia and bleeding disorders, specifically focusing on outsourcing blood donor screening, encouraging resource sharing, and promoting cost recovery through plasma and platelet sharing.

Objective no. 11 aims to promote the safe and appropriate use of blood and blood products, introduce patient-based management while developing a national and provincial patient blood management and hemovigilance system. **Objective no. 12** focuses on education and awareness about voluntary blood donation and Thalassemia prevention. **Objective no. 13** aims to promote indigenous production of blood transfusion equipment, reagents and consumable items and reduction of cost of doing business of BEs. with the long-term goal of increasing indigenous capacity, ultimately achieving self- sufficiency and cost effectiveness in production of these items. **Objective no. 14** emphasizes partnerships, collaborations and information exchange at regional and international levels, while **Objective no. 15** outlines the establishment of mechanisms for monitoring and auditing the National Blood Policy's implementation.

The NBP spells out overarching universal principles, international commitments and evidence-based interventions that transcend the geographical distribution of services and constitutional changes over time. It is expected that all provinces including GB and AJK shall be on the same page with this national policy and shall commit in its implementation after consensus and concurrence. It shall be highly desirable that this policy undergoes selective revisions, while retaining same structure, in future based on data and lessons learned during implementation over time, rather than completely rewriting it and interrupt the continuity of plan agreed upon by all stakeholders. This is especially important for this sector including that for future plasma fractionation plans which will welcome the sustainability of policies for intermediate to long-term projects. The investments security is closely linked with the continuity in policy and enabling environment based on it. This requires essential participation of ministries of planning, development and special initiatives, National Economic Council and Federal and Provincial Departments of Health.

In summary, these 15 objectives collectively form a comprehensive strategy to strengthen Pakistan's blood transfusion system. From governance and structural components to public awareness, human resource development and self-sufficiency in PDMPs, each objective addresses a crucial aspect to ensure the safety, accessibility and effectiveness of blood and blood products across the country.

By following our guiding principles of unity, faith and discipline combined with national will for larger good, it is hoped that this policy is instrumental in completing the unfinished reform agenda in this vital area of healthcare.

Prof Nuzhat Mushahid

Guiding Principles

A framework for blood transfusion policy formulation is adapted using National Guidelines provided by National Health Vision 2016-25, existing National Standards and Guidelines and other technical documents and data on Blood Transfusion Services, and National Blood Policy and Strategic Framework 2014–20. Previous policy aimed to enhance and build up Pakistan's blood transfusion services through a coordinated national approach. It provides fundamental principles and priority areas to be focused on. The strategic framework was organized into 4 key clusters: 1) Governance,2) Resources, 3) Core Business, and 4) Process Improvement. Each cluster outlined specific strategic areas to be addressed. The development of this framework was supported by the German government through the GIZ Health Sector Support Programme. It builds on the previous National Blood Policy and Strategic Framework from 2008-2012.The framework emphasizes equity, leadership, quality of care, and monitoring and evaluation as overarching priorities for blood transfusion services in Pakistan. It also highlights the need to integrate blood services with other health programs like maternal and child health, hepatitis control, and HIV/AIDS. The principles and guidance were also adopted from the WHO Guidelines, Aide Memoirs, International Society of Blood Transfusion, FDA, European Commission Guidelines, and Systematic Reviews of the existing literature and applied in local context. An inclusive policy formulation process was adopted to draft the blood transfusion policy for Pakistan.

The policy is hoped to achieve the Sustainable Development Goals' three targets related to blood and blood-related products and effectively apply the WHO's Action framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020–2023. All of above are referenced with links for accessing, as many are open source and full texts or extracts are impossible to be made part of the document. All technical documents previously developed from the platform of SBTP shall also be available for public after the dormant website is activated.

National Health Vision

The National Health Vision Pakistan 2016–2025 recognizes the importance of blood transfusion services in Pakistan and aims to improve the availability, safety and accessibility of these services. Vision sets out several objectives to achieve this goal, including strengthening the regulatory framework for blood transfusion services to ensure the safety of blood products and reduce the risk of transfusion-transmissible infections. The strategic vision mentions that the

- Governments will enforce public health laws related to smoking, drug safety, organ donation and transplant, safe blood transfusion, environmental protection, and food safety.
- Strengthening the Drug Regulatory Authority of Pakistan and effective legislation is required to efficiently regulate drugs, human organ donations, blood transfusions, and all therapeutic goods will be revisited and implemented in spirit.

Universal Access to Blood Products

WHO proposed several actions to achieve the objectives of universal access to safe blood and its products. These include encouraging voluntary, non-remunerated blood donations; strengthening the governance and regulatory frameworks for blood products to ensure that they are produced, processed and distributed in accordance with international standards and best practices; and building partnerships between governments, international organizations, civil society, and the private sector to advance research and development in the field of blood transfusion and to promote the sharing of knowledge and best practices. The Vision and Mission of National Blood Policy is aligned with WHO's guidance.

National Blood Policy Vision

Establishment of National Blood System in the country that meets the needs of society and citizens for blood products including PDMPs, based on good governance, scientific evidence, ethical principles and harmonized with international best practices.

National Blood Policy

Development, organization and implementation of nationally/regionally well-coordinated, well managed, well regulated, sustainable, cost-effective blood transfusion services capable of providing adequate, safe blood products including PDMPs that are based on gradual transition to voluntary blood donations while protecting the rights and safety of all stake holders and promotes optimum utilization.

OBJECTIVES OF THE NATIONAL BLOOD POLICY AND PROPOSED ACTIONS FOR ACHIEVING OBJECTIVES

Objective 1:

Secure Government commitment and support at National and Provincial level

1. A firm commitment and support from the State, governments and concerned institutions for national blood policy and national blood system shall be present all the time. The federal, provincial, regional governments, departments and institutions shall show commitment to International Society of Blood Transfusion (ISBT) code of ethics (non-binding but provides best practice on ethics for blood donation and transfusion) and has been adopted by WHO (Fig 6). Governments shall in collaboration with and under guidance of WHO fulfill its commitments to all of World Health Assembly directives, to which it is signatory.

2. State Institutions and Government recognizes safe blood and blood products as basic right of citizens of Pakistan that save lives and prevents morbidity therefore Governments shall have ownership of National Blood Policy actions under Policy Objectives, Legislations, Acts and Regulations undertaken by any government without undermining these for any exigencies or reasons.

3. For any significant deviations and changes in any prevailing policy and governance initiatives, their functional and financial impact on blood system and patients shall be evaluated and documented and must have ownership of stake holders. This shall include reflection on impact of delaying implementation of NBP on public health including transmission of diseases and creation of enabling environment for inviting investments in safety and PDMP's.

4. Federal and provincial Governments shall initiate, complete and amend governance tools, frameworks and regulatory measures including Laws/Acts/Regulations/Rules, where required, to fulfill the Federal and Provincial government's commitment with National Blood Policy and development of National Blood System (it is the sum of Federal, provincial, AJK and GB Blood Systems). The Fig # 01 is a visual representation of key players and their relationships in the Blood System of Pakistan. It also indicates possible Governance tools that can be utilized by Federal and provincial governments for coordinated implementation of policy.

5. Federal Government shall appoint a domain qualified, competent leader as National Coordinator for Safe Blood Transfusion Programme (SBTP) as this entity at present is not led by domain specialists and does not play active role. The coordinator shall work closely with NTAC and be responsible for coordinating the implementation of National Blood Policy, planning initiatives, guidance, advocacy, monitoring, liaison with federal & provincial authorities, departments, institutions and international partners/organizations. SBTP Coordinator shall continue with reform agenda to consolidate the gains made so far and manage progress until National Blood System is fully functional and delivers its objectives defined in the policy.

6. Federal Government shall devise a consultative and transparent mechanism for establishing National Technical and Advisory Committee (NTAC), to act as a think tank and steering force, for implementation of NBP. The provincial governments shall constitute provincial advisory committees as per their Acts.

The functions of these committees would be financed and facilitated for its activities (not individuals) from suitable heads. This shall be notified and hosted at appropriate government's governance structure.

The Governments may utilize public private partnership models or delegate responsibility of establishing National Blood System (that involves and integrates each provincial blood system) to a non-profit or other suitable entity to fulfill its commitment with NBP.

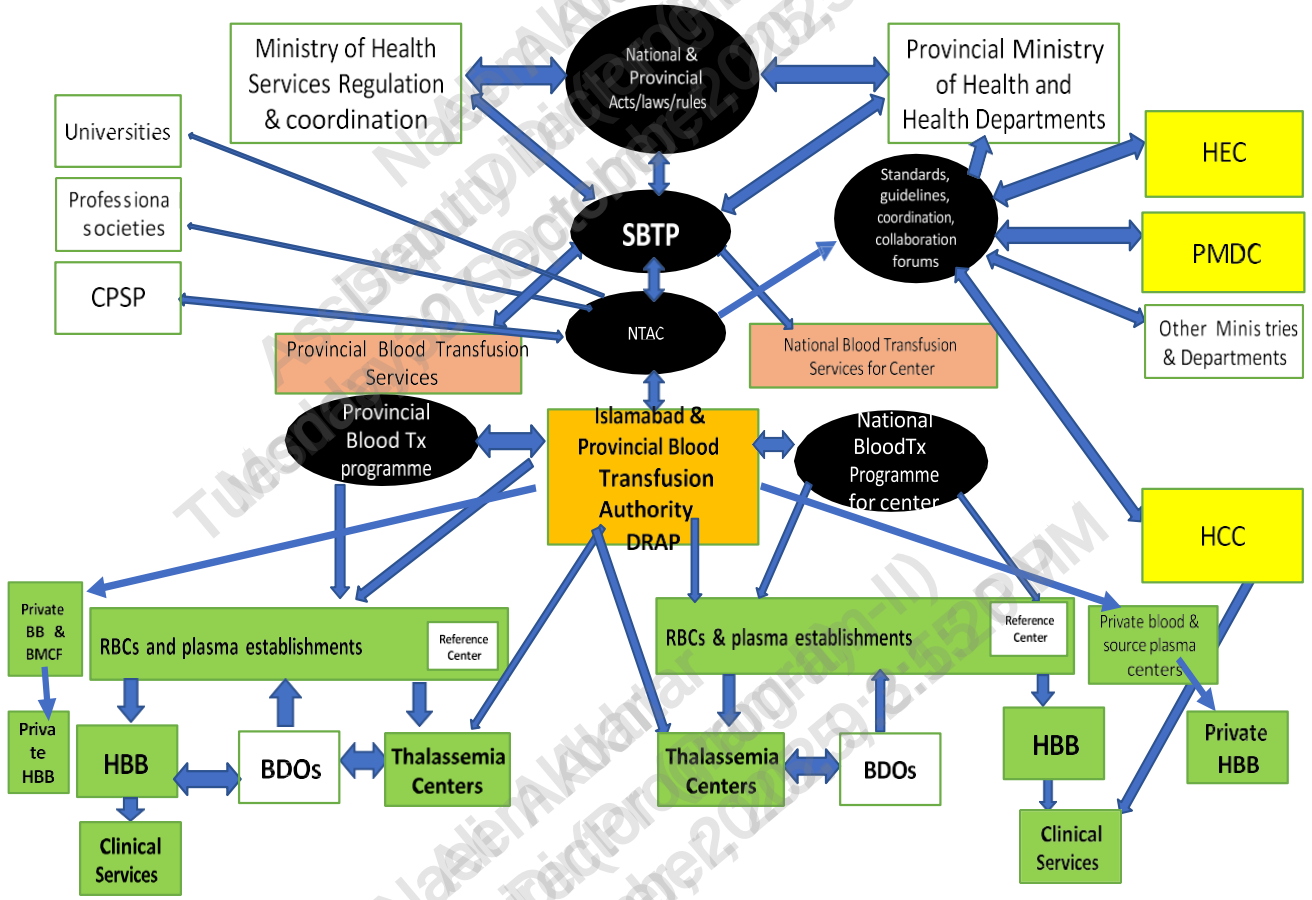


Fig #01: Governance and institutional Framework for the implementation of the national blood transfusion policy of Pakistan

Governance mechanisms/tools:

Responsible Ministries and institutions with role in National Blood System

Regulatory Authorities involved in implementation of NBP Federal and

Provincial Blood Transfusion Services (safe blood programmes)

Blood Establishments/ Hospitals as users

RBCs: Regional Blood Centers, HBB: Hospital Blood Bank, BDO: Blood Donor Organization: DRAP: Drug Regulatory Authority Pakistan HCC: Health Care Commission, CPSP: College of Physicians & Surgeons Pakistan, HEC: Higher Education Commission SBTP: Safe Blood Transfusion Pakistan, NTAC: National Technical and Advisory Committee

7. Federal and Provincial Governments shall establish appropriate financing framework and provide budgets as per the requirements of National Blood System, coordinated and recommended by SBTP based on objective data and according to implementation strategy. Government at center and provinces shall ensure adequate and sustainable resources for all institutions, organizations, committees, stakeholders, regulators and service delivery mechanisms in public sector to make safe blood products available for citizens throughout the country. Blood Transfusion in all other sectors shall be guided, coordinated and regulated to bring these into fold of National Blood System by gradually transitioning to hub and spoke model of linking hospital blood banks with Regional Blood Centers. (Public, Private, non- profit or hybrid), as deemed fit.

8. Governments should ensure that all concerned departments and personnel at decision making positions are aware and knowledgeable about the role and importance of voluntary blood donation, blood transfusion, blood systems, blood products including PDMPs and international best practices, especially in governance, policy and regulation.

9. Governments shall evolve mechanisms for periodic and systematic review and evaluation of progress on implementation of National Blood Policy by all those assigned for this responsibility. Health departments monitoring SBTP, NTAC, Healthcare Commissions, BTAs, DRAP and other concerned ministries/department/institutions shall be carried out. If found deficient by monitoring cells of health departments then the Governments shall evaluate and consider reducing/merging regulatory activity. Monitoring teams of governments shall ensure yearly feedback from BEs, PEs, Hospitals, patient advocacy groups, professional societies/associations.

10. Governments shall remain transparent and accountable for its policies, implementation strategies and financial support for National Blood Policy.

11. Governments shall make efforts to revive, coordinate, and secure additional funding opportunities from international partners who were instrumental in initiating and helping in blood transfusion reforms. Technical help should be sought for further building capacity, especially the regulatory capacity.

12. Government shall revive and complete the WHO Collaborating Center at RBC Islamabad or outsource to PPP which is needed for quality monitoring and referral center of National Blood System, involving Provincial Blood Systems and services.

Objective 2:

Establish a National Technical & Advisory committee of experts with representations from all provinces and areas to provide guidance for the development of National Blood System and implementation of NBP

1. Ministry of NHSR&C in consultation with provincial health departments shall establish, revive and notify a National Technical and Advisory Committee (NTAC) with clear TORs and as envisioned in national and provincial Acts. The NTAC shall be the Governance tool and think tank and steering mechanism for advising Government, SBTP, Blood Transfusion Authorities, other authorities/ departments and stakeholders on NBP and its implementation. It should be approachable for industry investors, academia for guidance.

2. The provinces shall notify Provincial Technical Advisory Committee (PTAC) as envisioned in the provincial Acts. All PTACs of all provinces shall work closely with NTAC and SBTP, to create as much uniformity as possible, which shall ultimately facilitate resource sharing, fractionation programme and securing Federal funding e.g. Planning, Development and Special Initiatives etc.

3. NTAC shall have members with technical, professional and administrative experience in blood banking/transfusion, possessing unmatched integrity and having adequate and fair representation from all parts of the country (Federal, one member from each of PTAC, AJK, GB, representative from Military, DRAP and Pakistan Society of Hematology). NTAC members shall not compromise on ethical, moral, national, patient/donors' interest under any circumstances.

4. The chairperson/director for committee's management shall be nominated from among the members with mutual consensus and all members expressing trust in the leadership.

5. NTAC shall:

   i. Be responsible for advising and making recommendations to reform/revive the National and Provincial Blood System/services and safe blood programme and help all with technical matters referred to it for advice. The recommendations shall be considered by M/o NHSR&C, Provincial health departments, SBTP, Federal Blood Transfusion Services (FBTS), Provincial Blood Transfusion Services (PBTS) and regulatory authorities.

   ii. Technically review and provide advice & guidance on the organizational structure, coordination, management of national blood system (NBS) at center and provinces, covering whole country and any appropriate changes. The data required for this function shall be provided by the center and provincial health departments and M/o NHSR&C and regulatory authorities. NTAC shall proactively seek the data from concerned departments.

iii. Establish and advise on key performance indicators for FBTS and PBTS and their programmes. Provide guidance to SBTP and regulators for monitoring all FBTS and PBTS activities. The SBTP shall act as country wide data collection unit that has to submit country data to WHO and other development and funding partners like German Government, and they frequently inquire about progress. This monitoring activity has no legal status and nor any force.

iv. It shall review the standards of other countries, WHO GMP guidelines and existing national standards and recommend revisions or prepare new standards and other guidance documents and information on TTI screening, reagents, quality assurance, quality management, good manufacturing practices, minimum specifications of blood components & blood products, guidelines for donor management, core operations, clinical blood transfusion, patient blood management, hemovigilance and regulatory frameworks.

v. Make standards, recommendations, advice, guidance for quality, coordination, resource sharing, self-sufficiency and availability of safe, effective and quality blood products. These should cover all types of blood components, modified and manipulated blood components, recovered plasma, source plasma, PDMPs, fractionation and fractionated products. The guidance shall be for all concerned authorities/institutions regarding regulatory frameworks, scientific, professional, legal, ethical, technical, commercial matters. The WHO guidance and precedents of other countries and relevant industry standards, regarding novel components and all above mentioned products prepared within BEs, PEs of all classes and tiers facilities shall be referenced to avoid confusions, overlap, misunderstandings between different National and provincial blood transfusion authorities and other authorities like DRAP and Health Care Commissions etc.

vi. Where necessitated, all relevant clinical specialties, experts and stakeholders shall be consulted for all its activities. It should advise relevant departments, authorities and institutions on curriculum and trainings that shall be used for the purpose of certification and degree awards.

vii. NTAC shall provide guidance and recommend actions for the national and provincial health departments and regulatory authorities (DRAP and HCC as these have overlapping roles with BTAs in the context of PDMPs and clinical blood transfusion) with the help of SBTP. BTAs shall be guided for adoption of WHO Global Benchmark Tool-plus and efforts towards qualification for highest maturity level as regulator. This is advocated by WHO for plasma derived medicinal products self-sufficiency and plasma fractionation programme. NTAC shall review systems of registration, licensing, accreditation of FBTS, PBTS and blood establishments (BEs), Plasma Establishments by the blood transfusion authorities in the country and provide guidance.

viii. NTAC shall develop guidelines and provide advice on phased programme from replacement to volunteer donor recruitment and retention including public education and awareness and use of technologies, marketing and media strategies.

ix. NTAC shall help the government departments, FBTS, PBTS to recommend and acquire the

scientific and technical resources and WHO knowledge regarding products and tools, needed to establish national blood system on scientific and technical basis and implement national blood policy.

x. NTAC shall provide guidance for integration, coordination and resource sharing among blood transfusion services of all sectors i.e. public, private, NGOs, Thalassemia centers and BDOs to align with vision and objectives of national blood policy.

xi. Define the criterions etc. for declaring any BE as center that shall be based on, e.g. expertise of its director, facility for component preparation, screening with at least CLIA, facility for neonatal, pediatric & obstetrical transfusion with help of sterile connection device, using ICCBBA ISBT 128 compliant software, presence of Gel cross match and capable of providing Massive Transfusion Protocols for emergencies. NTAC shall revisit this from time to time.

xii. NTAC shall constantly explore sources and appraise internal and external funding opportunities. The governments should be encouraged to facilitate utilization of funding opportunities.

xiii. NTAC shall work on models with relevant partners where investment in recovered plasma projects can be converted into source of funding TTI testing of blood donations and other safety initiatives for blood transfusion and self- sufficiency in PDMPs. It can recommend policy and procedures and mechanisms for realizing such concepts.

xiv. NTAC shall help to develop a task force of experts at the national level for research and development in transfusion and use of technologies and mobilize grants and work actively to train next generation of NTAC members.

Objective 3:

Strengthen, develop or modify the organizational structure of Federal and Provincial Blood Transfusion Services and their programme and develop reference center within each province.

1. The Federal and Provincial Health Department shall reform/develop/revive and notify the well- defined organizational/institutional, entities called Federal Blood Transfusion Services (FBTS) and Provincial Blood Transfusion Services (PBTS), for provision and management of blood transfusion services for whole of Federal area and provinces respectively. Institute of Blood Transfusion (IBTS) in Punjab is one example of Provincial Blood Transfusion Services entity in Punjab and other provinces may study its functionalities for designing their PBTS.

2. The blood transfusion service organizations/institution/entities may be a public sector entity, or the government may delegate this responsibility to a reputable, nonprofit, non- governmental organization. Guidance on criteria and mechanisms for delegating this responsibility shall be sought from the National Technical Advisory Committee, which shall base the recommendations on fairness, transparency, ethical principles, present and past data/evidence and inputs from political leadership, health departments and stakeholders.

3. The model, mandate and scope of FBTS and PBTS shall have formal government commitment, support and recognition as separate entities/organizations/units of federal and provincial health department with a financing framework, adequate budget, management team, trained staff and all other resources. The best international practices in organizational reforms that promote hub and spoke model, in which blood centers are linked with hospital blood banks shall be emulated by making necessary changes, resource allocations and governance measures by Federal and Provincial health departments through FBTS and PBTS.

4. A competent, qualified & experienced transfusion medicine expert/hematologist shall be appointed by national and provincial health departments/ministries, as medical director (designated as Federal and Provincial Blood transfusion services Director)

5. Blood Services Director of FBTS/PBTS. FBTS/PBTS shall strive to function efficiently and achieve performance indicators and predefined outcomes/KPIs. Appointment and training of all staff for carrying out functions of FBTS & PBTS shall be ensured with the help of NTAC and SBTP.

6. FBTS/PBTS shall perform following functions:

6.1. Develop/reform a national and provincial blood system through comprehensive Federal and provincial safe blood programme for the organization, management, coordination of national, provincial and interprovincial, blood transfusion services/activities for ensuring safety, availability and quality blood products across all sectors and for implementing the national blood policy

6.2. Devise/reform a blood transfusion programme based on model of regional blood centers as producers and hospital blood banks and clinical services as users. This may include regionalization and centralization of blood donor screening for TTIs so that rapid screening, especially pre- donation screening can be substituted with CLIA screening and CLIA screening can be followed by NAT screening for maximum number of blood donations and promotion of donations by VNRBD. Each and every possible solution for this activity shall be deliberated, planned and implemented by arranging, financing/budgeting in coordination with health departments, regulators, institutions, professional societies and experts in NTAC.

6.3. Follow the NTAC criterion for upgrading large public sector blood banks to Regional Blood Centers and make these responsible for compliance with National Standards and guidelines. These public sectors upgraded RBCs can be outsourced to private public partnership entities on competitive basis ensuring transparency.

6.4. Review the existing blood supply system and structure, map out processes involved in blood cold chain and identify the gaps and needs. Establish action plans based on needs and arrange

resources for the same and monitor the system periodically.

6.5. Establish and comply with all national and WHO standards, best practices and recommendations of NTAC for implementing the national blood policy.

6.6. Implementation of standardized blood information management system which promotes coordination, management, safety, traceability, availability of blood products and resource sharing. Data shall be made available to SBTP and regulator as per their structure and guidance.

6.7 Responsible for availability of safe blood transfusion and blood products up to grass root level of districts and tehsils and BHUs in respective provinces.

6.8. Devise mechanisms for cooperation across sectors and seek advice from NTAC in these matters. Discourage small blood banking activities and encourage service contracts and MOUs with larger blood centers.

6.9. Formalize the working relationship between stake holders and utilize capacities of existing institutes/organizations/departments/hospitals/ laboratories in public and any other sector involved with blood transfusion services through government letters, contracts, memorandum of understanding and service level agreements where needed and are appropriate with the approvals of competent authorities. The implementation of these measures must be supported by resource allocation.

6.10. Responsible for planning, requesting budget and procurement of finances that shall ensure sustainability of blood programme, for all blood establishments across the province. This may include annual budget allocation, partial or complete cost recovery, insurance coverage, employee's insurance or any other legal mechanism. The health authorities shall be approached by FBTS and PBTS to allocate funds and budget for the blood system on centralized hub and spoke model, for all public sector hospitals up to grass root level. The processes and mechanisms shall be mutually developed, facilitated and coordinated by SBTP, PTACs and NTAC.

6.11. The financing is primarily responsibility of the government but may be supplemented by developing business model based on utilization of recovered plasma and/or running source plasma programme with contractual agreements with pharma industry or investors, under guidance of NTAC and the regulator. This will help in self-sufficiency in PDMPs and improvement in quality due to mandatory requirement of compliance with GMP for making plasma available.

6.12. Responsible for securing budgeting and resources including marketing and media campaign for recruitment and retention of voluntary Non-Remunerated Blood Donors from low-risk groups. This campaign shall be based on sound plan provided by FBTS and PBTS under guidance of NTAC and SBTP.

6.13. Formalize engagements with all blood donor organization across cities. The BDOs shall be trained in maintaining privacy, confidentiality and safety of donors. The BDOs MOUs with BEs shall be overseen and facilitated by FBTS and PBTS.

6.14. Communicate and coordinate with DRAP and Health care commissions, NTAC, SBTP, wherever safety and quality of blood products and clinical blood transfusion need their involvement.

6.15. Keep records and information about the importers/distributors of blood donor screening kits/reagents/equipment, the principals, their approvals with other countries regulators, the prequalification results, in order to get rid of substandard and poor-quality kits, in coordination with DRAP, NTAC and SBTP. FBTS and PBTS shall devise mechanism for centralized procurement and quality verification of reagents with help of provincial departments and regulators. The procurement agencies shall verify the sensitivity and specificity of TTIs testing kits of all types with the help of referral laboratories using WHO methodology, guidance and recommendations and make informed and transparent choices.

6.16 Work closely with Thalassemia centers and NGOs involved in blood collection and transfusion activity. It shall be ensured that NGOs are brought into fold of National Blood System, and they do not waste any component of volunteer donations collected by them.

6.17 Responsible for quality of blood products and transfusion services extended by blood establishments throughout province at all levels. The quality management and compliance with legislation, regulation, rules, national standards, guidelines and best practices shall be ensured at all blood establishments in their jurisdiction, so that they can qualify for license by regulatory authority.

6.18 Ensure sufficient inventory to meet needs of health care facilities using MIS.

6.19 Responsible for providing sufficiently trained staff to carry out activities of each BEs as per the requirements of the hospital. All the staff activity to be monitored through surveillance and using technology.

6.20 Responsible for ensuring that all provincial BEs of any type and size participate in External Quality Assurance Programme and assessment. Training and guidance on same shall be conducted. The funding shall be sought from health departments against comprehensive plan for whole of the province.

6.21 Assessment of equipment, infrastructure, hardware and shortages at all BEs, to ensure that gaps are filled and all BEs are adequately equipped to qualify for licensing and scaling them up for component preparation and FFP storage with potential use for plasma fractionation.

6.22. Evaluate, analyze and oversee all aspects of blood utilization, hemovigilance and HTC and the blood received from BEs in their management jurisdiction. Responsible for implementing NTAC plan for availability of safe blood during disasters and emergencies and arranging resources, trainings and coordination mechanisms for the same within National and Provincial Blood System, external institutions and organizations.

6.23. FBTS and PBTS shall arrange funds to help develop a reference center for blood transfusion and immunohematology within its area of responsibility and make the services available for all BEs in the province. The centers shall promote research in the field of blood transfusion science with the help of task force organized by NTAC.

6.24. The reference centers shall strive for funding from national/international sources and research projects in multiple places that focus on gaps and evidence requirements of the country.

Objective 4:

Define National Policy for the screening of all blood donations including apheresis donations and develop screening strategy appropriate for specific situation of the country

1. National, Federal and Provincial health authorities FBTS, PBTS and blood establishments are responsible for ensuring that standards, strategies, systems, and infrastructure are in place for the screening of all whole blood and apheresis donations.

2. The efficient coordination of blood transfusion services at the National and Provincial level is prerequisite for an effective and sustainable screening programme of the country. Federal and Provincial health authorities, after consulting experts and making strategies with their help, shall provide specific and sufficient budget, a suitable infrastructure, with reliable water and power supplies, well-maintained equipment and efficient transportation and telecommunication systems. All blood for transfusion shall be tested for evidence of infectious disease pathogens that at minimum shall include Hepatitis B, Hepatitis C, human immunodeficiency virus (HIV) and Syphilis. Malaria testing shall be made essential, once country specific epidemiological data, risk of transfusion transmitted Malaria and evidence of effective screening strategy is available in the country.

3. The laboratory Tests used should at minimum be ELISA/CLIA or equivalent methodology e.g. ECLIA and if possible supplemented by Nucleic Acid Amplification Testing. Rapid ICT test should only be permissible in special circumstances in primary care (to be specified by regulator) and with RDTs that have been validated for use in blood donor screening by WHO and/or DRAP. These should not be used in secondary and tertiary care hospitals or RBCs.

4. The standards and regulations shall be prepared, that shall provide an overall decision-making process on how tests are to be used and interpreted and defines the outcomes of screening with regard to whether a blood unit will be released or discarded.

5. The relevant authorities and regulators with the help of experts shall ensure that all inputs like IVDs, blood bags, etc. are of satisfactory quality and cold chain is in place to ensure lot to lot fitness. There shall be verifiable mechanisms of validation and verification of quality processes within each blood establishment. DRAP shall devise mechanism to bind retail pharmacies, providing blood bags to patients directly, to only issue against written prescription of same, by licensed blood banks/center and shall provide full traceability and submit data annually to DRAP.

6. The federal and provincial health authorities and regulators shall put systems in place to shift all BEs towards minimum screening with ELIS/CLIA and develop collaborations and coordination with the help of industry and other partners to implement centralized blood donor screening systems.

Objective 5:

Establish and Support Blood Establishments capable of meeting the needs of safe, effective and quality blood products

1. Federal Blood Transfusion Services (FBTS) programme, for Federal areas and Provincial Blood Transfusion Services programme (PBTS) for each province, shall be responsible for development, management and coordination of blood transfusion services in their area/province of responsibility. They are responsible for the quantity and quality of blood services of existing/new Blood Establishments of all tiers and in all geographic areas of their responsibility.

2. The respective health departments shall be responsible for establishing the programme as a formal organizational structure, with new or within existing governance framework.

3. FBTS and PBTS shall provide plan for new/upgradation of existing BEs, prepare PC-1, get approvals, supervise execution of the same and make them functional. All new BEs shall be planned, designed and equipped as per WHO guidelines.

4. Each regional blood center under leadership of FBTS or PBTS shall develop and maintain emergency preparedness plans aligned with national disaster management frameworks. The FBTS/PBTS shall establish mechanisms for inter-provincial coordination of blood supply during emergencies."

5. The BEs shall include all RBCs, HBBs, day care transfusion facilities and shall:

5.1. Devise and follow plan for collection of blood from voluntary non-remunerated blood donors as mandated in Acts.

5.2. Follow and comply with the plans/instructions/directions by FBTS and PBTS and National Blood Policy 2025-2030, honor the linkages that are developed between producing BEs (RBCs and Blood centers) and user entities (HBB and clinical services).

5.3. Comply with all applicable national standards and guidelines for carrying out core business, quality management, blood donation testing, donor management, blood product preparation, storage, transportation, quality, recipient testing and issuance of blood products.

5.4. BEs shall be responsible for creating provision of Plasma Exchange Services, where required and carry out these in coordination with clinical services.

5.5. Obtain licensing from relevant safe blood transfusion authority.

5.6. Provide ownership of blood products and remain an effective member of clinical blood transfusion team and hospital transfusion committee.

5.7. Compile data about blood donation activities, blood transfusion activity, quality, safety, testing in electronic form for submission to FBTS and PBTS and Regulator as mandated in Acts/regulations.

5.8. Ensure availability of all blood products as per requirement of hospitals/clinics and dependent patients on healthcare facility.

5.9. Meet standards for transportation and cold chain maintenance.

5.10. Apply to DRAP to be licensed as "Plasma establishment " if BE plans to use/provide recovered or source plasma for onward manufacturing of PDMPs after complying with standards developed by NTAC and regulation/rules devised by DRAP based on national standards.

5.11. Work according to plans, MOUs and service agreements of FBTS and PBTS, if contract plasma fractionation or local plasma fractionation is planned as federal and/or provincial public sector project. The BEs can have MOUs with legitimate entities/registered companies in the country, for providing recovered or source plasma to them after approval by respective health departments.

5.12. BEs shall be authorized by respective health departments, to provide surplus blood products to other healthcare sectors by following transparent mechanism of approvals. The mechanism in vogue in some other healthcare sectors, blood establishment can be emulated, which includes authorization for issuing blood to user hospitals in other sectors like private, public or NGOs, based on cost recovery. The cost recovered is credited to government accounts directly and auditable. This will help to prevent plasma wastage.

5.13. Provide ownership of blood products and remain an effective member of clinical blood transfusion team and hospital transfusion committee, where the BEs blood products are used.

5.14. Compile data about blood donation activities, blood transfusion activity, quality, safety, testing in electronic form for submission to FBTS and PBTS and Regulator as mandated in Acts/regulations.

5.15. Ensure availability of all blood products as per requirement of hospitals/clinics and dependent patients on healthcare facility.

5.16. Meet standards for transportation and cold chain maintenance.

Objective 6:

Strengthening the national and provincial blood transfusion authorities to effectively regulate blood transfusion services in whole of the country

1. National, Federal and provincial health departments are responsible for:

1.1 Ensuring that their respective blood transfusion authorities are functional as per the Acts/Laws and Policy and all statues of Acts are complied with and paying special attention to appointing right, qualified persons as BTA secretaries with clear KPIs. The minimum qualification required shall be FCPS Hematology or masters in blood transfusion and allowed sufficient time to provide effective leadership. It is of utmost importance that personnel's serving in FBTS/PBTS or IBTS, provincial blood programme is not appointed to carry out functions of regulators, as this creates conflict and regulator shall not be able to secure Global Bench Mark tool - plus status.

1.2 No BTAs shall not be allowed to carry out any activity without existence of technical advisory committee, their documented advice and licensing boards, as per Acts.

1.3 Adequate resource allocation shall be ensured including financial, human resource, logistics and structure so that all of statutes of National and Provincial Blood Transfusion Acts are implemented.

1.4. The BTAS under chairperson/secretary and the management team of blood transfusion authorities shall be responsible for:

1.4.1. Capacity building of the authority to comply with the WHO Global Bench Mark Tool- plus for blood and its components and clinical blood transfusion aspects that are not regulated by Health Care Commissions to qualify for highest maturity level as regulator. This helps to make quality of plasma programme of country successful and qualify for production of PDMPs.

1.4.2. Familiarizing its staff and impart knowledge about the organization, regionalization, centralization of blood transfusion services and clinical usage practices of the country/province, role of SBTP, NTAC, FBTS and PBTS. This shall help it to formulate rules, licensing criteria and accreditations. This will also help in implementation of all statutes of Acts. The uniformity of regulation across provinces shall be made a priority to facilitate exchange and transport of blood products across provinces and center.

1.4.3. Devise rules/regulations based on national standards and with the advice of NTAC and provincial advisory committees for registration, inspection, checking compliance with national standards, licensing the BEs. The BEs encompasses all models including facilities (considered as BEs) carrying out centralized blood donor screening for multiple other BEs (including blood centers, plasma establishments and/or HBB linked in hub and spoke model) or Blood Centers having additional functional HBB within other

hospitals under same responsible person and management team. Technical guidance on these matters shall be sought from provincial advisory committees and NTAC, where clarity is required.

1.4.4. Close liaison with NTAC so that all standards, guidelines and best practices covering all aspects of blood transfusion activity are available with the authority. This shall also include regulating the Therapeutic Plasma Exchange Services.

1.4.5. Frequent formal discussions with experts and NTAC improve the system of regulation.

1.4.6. Register BDOs operating in the country and provinces for ensuring that they comply with standards and regulations and have valid MOUs with licensed Blood establishment and also regulating their activity for blood donor safety, privacy and confidentiality.

1.4.7. Responsible for protecting the rights of blood donors and upholding the ethical standards.

1.4.8. Making use of information management system already available after assessment or by using those produced by provincial information technology boards to produce software/systems in light of standards, instructions and guidance of NTAC and best practices in technology.

1.4.9. Make all regulatory data available in the system and with real time visibility, traceability and activity at all levels. Ensuring integrity, privacy, confidentiality of records that can be verified and accessed by successive secretaries and concerned staff.

1.4.10. Liaison and close coordination with SBTP, NTAC, Healthcare Commissions, BTAs, DRAP and other concerned ministries/department/institutions.

1.4.11. Provincial regulator along with SBTP, NTAC and M/o NHSR&C shall develop international linkages including WHO, for exchange of ideas, sharing of experiences and introducing improvements.

Objective 7:

Development of standardized information systems/technologies for data collection, service delivery and regulatory capacity

1. Federal and Provincial Governments shall prioritize accurate data collection of all blood transfusion activities in their respective jurisdictions, by utilizing all possible mechanisms available and by engaging all capacities e.g. Information Technology Boards or private entities that are developed within the country.

2. Directives and resources shall be provided for procurement of ICCBBA ISBT-128 standards compliant software, and preference to be given those already available in the country. This will facilitate sharing of resources, capable of meeting plasma fractionator demands and availability of uniform data with the regulators and FBTS and PBTS. The donor and patient data base shall be linked to National Identity Card number so that Sero-reactive donors can be deferred across the

country and increase safety of blood.

3. The adoption of IT system for accurate data collection and visibility by the regulators shall be mandated by respective governments as a step towards capacity building of the regulator.

4. The provincial data shall be shared with the Safe Blood Transfusion Programme for consolidated view of National Blood System, undertaking projects like plasma fractionation, future directions of reforms and National Blood Policy. The privacy and confidentiality of data shall be ensured as mandated in Safe Blood Transfusion Acts.

Objective 8:

Develop Human Resource through certification, training and degree programmes and developing HR service structure.

1. Ministry of NHSR&C with the help of SBTP, NTAC, HEC, PMDC and degree registering authorities shall devise mechanism to formulate a data base of personnel's working in BEs and clinical blood transfusion across capital territory and provinces and devise a certification programme for them based on preliminary exam and distant learning to document the competencies of personnel involved in this field.

2. All concerned shall promote close coordination with WHO for guidance and using WHO training tools, programmes and knowledge resources for all tier staff training.

3. NTAC shall create forums for brainstorming with professionals of pathology, hematology, Pakistan Association of Pathologist, Pakistan Society of Hematology, other specialty societies/associations, M/o NHSR&C, HEC, Universities, PMDC, CPSP and Allied Health Sciences regulatory authorities to plan degree programmes, curriculum, training, standard setting and assessment. All concerned shall advocate with health departments to formalize service structures, create positions for trained laboratory technologist/technicians in blood establishments, transfusion safety nurses, blood bankers and blood transfusion specialists.

4. Training places and degree programmes for physicians and nurses shall be developed which is required for carrying out source plasma programme and therapeutic plasma exchange. RBCs shall be encouraged and supported to undertake academic programmes and training.

5. NTAC and M/o NHSR&C shall liaison with post graduate degree awarding institutes like CPSP and universities to introduce/enhance the duration of training in transfusion medicine for all specialties and at undergraduate level and highlight the importance of blood products and bridge gaps by its inclusion in curriculum of undergraduate and post graduate academic programme. The importance of blood transfusion can justify including a complete module and passing of that module as pre-requisite for degree in any clinical specialty of any level.

Objective 9:

To meet National need of Plasma Derived Medicinal products by taking all necessary activities/actions

1. Government shall include PDMPs in essential lifesaving drug list of the country. It shall undertake all policy, legislative, governance, departmental and regulatory actions to facilitate activities in any sector (public, NGO, private), that are planned or undertaken for the availability and safety of PDMPs to fulfill the National needs and/or ensure quality and safety of blood transfusion especially in public sector.

2. Government shall allocate resources and funds in existing health programmes and encourage resource allocation/investment by public sector, industry, corporate sector, NGOs and bilateral/international agencies for mobilization of plasma resources of the country and development of plasma economy. The regulatory framework at the level of DRAP and blood transfusion authorities and relevant ministries, for investment in this sector shall be laid down by the federal and provincial governments primarily to ensure safety of blood donors, meeting the National need of PDMPs and complying with existing legislations of country and international commitments.

3. If registered companies invest in plasma economy, they shall have explicit commitment and transparent process of investing the proceeds of export of plasma of public sector BEs, into safety and availability of blood components/products, in the country in any form, that is stated in National Blood Policy. These commitments shall be after their recovery of cost of doing business and shall include commitment for availability of PDMPs to fulfill all needs of the country/province (once need data is provided by respective governments) and not less than 50% of finished product, according to the yields calculated from the plasma volumes provided or any other terms negotiated. It shall be responsibility of companies to satisfy the governments and regulators about this aspect.

4. For self-sufficiency in PDMPs, NTAC shall consult and formulate guidelines, from time to time with blood transfusion experts, professional societies, representatives of national and provincial regulatory authorities including DRAP, competent lawyers and law department representative, national and provincial health departments members, members from SBTP, FBTS and PBTS, pharmaceutical industry representative, IVD suppliers and distributors dealing with plasma apheresis, TTIs screening instruments/reagents, WFH Pakistan, BDOs, NGOs with significant activity in blood collection in any capacity, Ministry of Commerce, Investment boards, FBR and Customs departments, Large logistics and warehouse companies.

5. Companies already legally registered in the country or future ones and investors in this area, shall respect and shall not violate international commitments of country that encompasses plasma procurement, export, contract manufacturing and import of PDMPs against

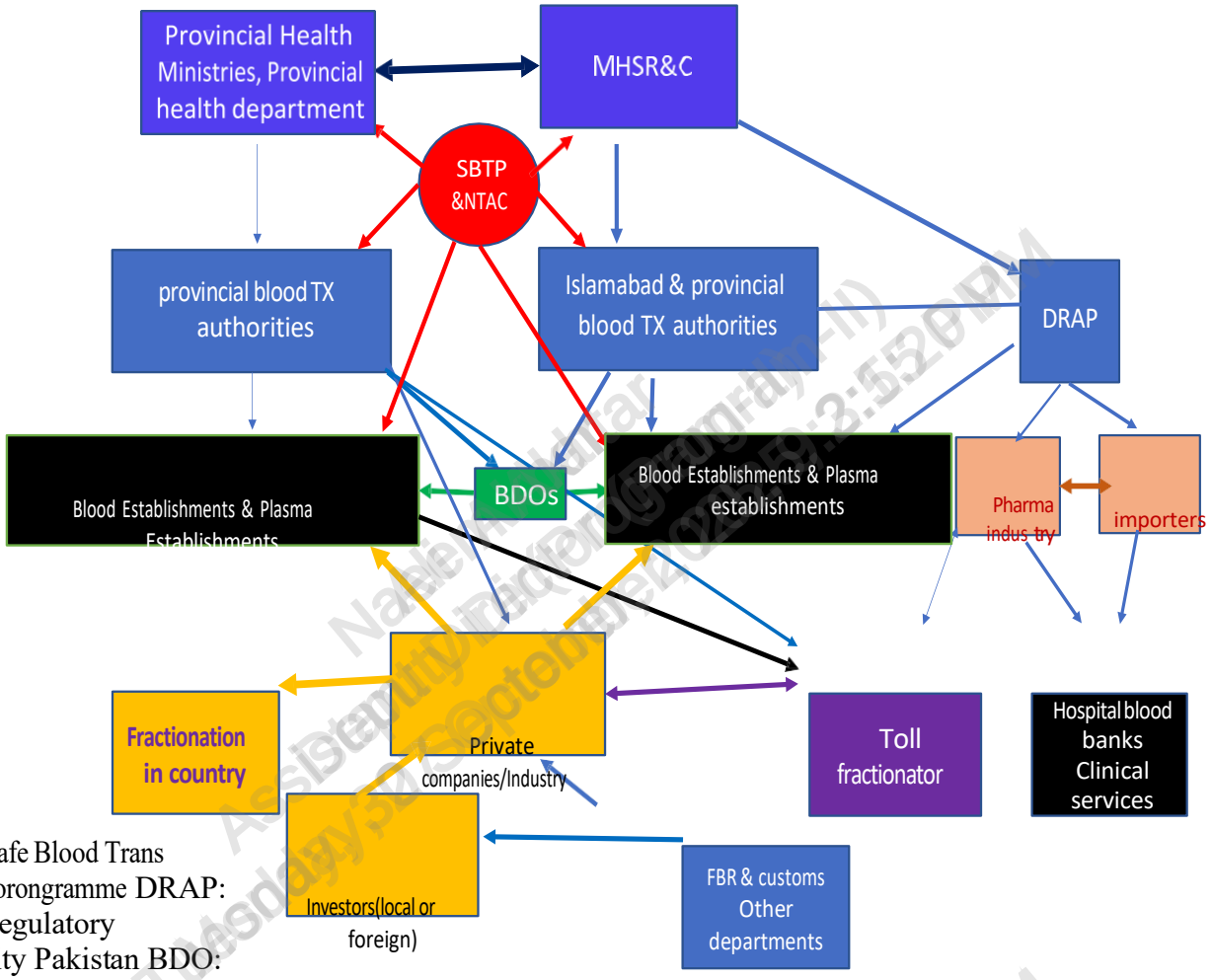
plasma. They must ensure engagement of full-time blood transfusion medicine experts in their structure to fulfill regulatory requirements and technical aspects.

6. The departments concerned and ministries, especially health departments shall follow the laid down procedures for operationalization and navigation by investors, within government departments and machinery to meet legal and regulatory requirements.

7. No drug substance can be exported from any province or area without license and lot release certificate by DRAP and this is essentially required by Ministry of commerce, customs as well as the importers from other countries. Since plasma is considered a drug substance (API), world over so involvement of DRAP is unavoidable. Drug regulation is Federal subject before and even after 18th amendment and DRAP holds offices in every province for its regulatory functions. In view of above any Provincial Blood Transfusion Authority's licensed BE can apply for DRAP license of "Plasma Establishment" for both recovered plasma/source plasma, intended for onward manufacturing of PDMPs, as per national standards, for the same. These BEs shall only inform the BTAs about their PE application to DRAP. It will be responsibility of all and every regulator, directly or indirectly involved with BEs, Plasma Establishments to coordinate with each other and devise processes and procedures to avoid miscommunication, duplication, redundancy and inconveniences for the providers and the patients. All rules/regulations shall be formulated in light of national standards for same by the NTAC. All committees and regulators shall take NBP, national standards, DRAP Acts, BTAs, HCC Acts, national bioethics committee and NIH guidelines or any other applicable legislation into account for doing so.

8. DRAP shall ensure to include national experts in blood transfusion/blood banking in their regulatory divisions to carry out regulation of Plasma establishments in all provinces and areas of the country. DRAP shall communicate with commerce ministry, importing and exporting entities, customs, FBR etc., involving plasma export for onward manufacturing of PDMPs, in appropriate category as recognized internationally. DRAP shall facilitate the export of plasma for onward manufacturing of PDMPs as stated in Para 7, sub para (e) of DRAP Act 2012, if prerequisites are met by Plasma Establishment, based on National Standards and adopted by DRAP for making regulations.

9. A conceptual diagrammatic representation of interactions, coordination of concerned institutions/departments and regulatory authorities for the recovered and source plasma from country is shown in below mentioned Fig#02. This could be the outline for taking initial steps and important to establish the coordination and linkages to facilitate the realization of goals and currently are not practices.



SBTP: Safe Blood Trans fusion Porongramme DRAP: Drug Regulatory Authority Pakistan BDO: Blood Donor Organization MHSR&C: Minis try of Health Services Regulation & coordination

Fig # 02 A conceptual overview of concerned institutions/departments and regulatory authorities for plasma and PDMPs

10. The respective governments may allow the investors, private companies and industry to procure the recovered plasma from licensed public blood establishment or from the public sector operated source Plasma Establishments and with the understandings to return PDMPs for public sector use, as per public needs data by governments and on negotiated terms. The return of finished PDMPs, against public sector plasma shall be regulated by DRAP as registered plasma derived medicinal products, and it shall allow free import for onward utilization as free of charge products for public sector healthcare facilities. Non public sector entities/facilities, operating DRAP licensed BEs or source plasma establishments may export plasma, choose to bring PDMPs to the country for sale as finished product, intermediate product for fill and finish or can use plasma for the export of PDMPs by following relevant regulatory framework of drug regulator of the country.

11. Advocacy for education and awareness of government, institutions, regulators, organization, general public and all stakeholders shall be undertaken by all stakeholders. The aim shall be to realize that only well managed, well-resourced and well- coordinated National Blood System based on Voluntary Non-Remunerated Blood Donations can guarantee the success of recovered or source plasma programme for toll/contract manufacturing of PDMPs and meeting national needs.

12. The guidelines on the appropriate use of PDMPs shall be formulated by NTAC with the help of concerned experts and specialists. The pharmacovigilance shall also be ensured in collaboration with DRAP.

13. The plasma collection programme for PDMPs can be established by any sector BEs after obtaining a license of plasma establishment from DRAP. The Stand-alone Source Plasma Centers without blood establishment activity shall also be allowed, with minimal in-kind support to donors to avoid over- commercialization, as per international practices, if they are licensed by DRAP as 'Plasma Establishments' and do not violate the DRAP Act, the Safe Blood Transfusion Acts of the respective provinces, and National Standards.

Objective 10:

Provision of safe blood transfusion and blood products for Thalassemia and Bleeding disorder patients and facilitate Thalassemia Prevention Programmes

1. The FBTS and PBTS shall bring Thalassemia Centers/Hemophilia Centers and facilities within fold of National and Provincial Blood System so that safe and effective blood components and blood products are available for the patients with Thalassemia and other transfusion dependent diseases. This programme of third-party blood donor screening by involving Public and Private RBCs, Hospital Blood Banks and laboratories that are using approved and advanced blood donor screening technologies by encouraging Service Level agreements. The recovery of cost of blood donor screening with CLIA/NAAT or ECLIA by sharing recovered plasma and platelets with the RBCs and BEs etc. under National & Provincial blood programmes, shall be encouraged.

2. It shall be made mandatory for Thalassemia Centers to collect the blood in triple bags, and they shall not be allowed to waste any component of volunteer blood donations. They shall have MOUs with RBCs, BEs or registered companies to provide components on cost recovery basis.

3. BDOs working with FBTS/PBTS and serving Thalassemia Centers shall be registered by Blood Transfusion Regulatory Authorities and the MOUs/SLA shall be submitted with regulators.

4. The NTAC, SBTP, FBTS, PBTS, BEs, BDOs and Thalassemia Care Centers shall jointly work to facilitate and contribute towards Thalassemia Prevention Programmes in the light of the Thalassemia Prevention policy and Legislations.

5. The RBCs and other BEs shall be encouraged to take responsibility for providing cryoprecipitate and PDMPs to bleeding disorder patients treated at Hemophilia Centers with mutual agreements, until all needs can be met by contract manufacturing.

6. The Thalassemia and Hemophilia Centers shall be regulated by concerned National and Provincial Blood Transfusion Authorities to ensure safety, efficacy and availability of blood for patients they claim to serve.

7. Thalassemia Centers and Hemophilia Centers registered shall remain within their mandate and shall not indulge in clinical blood transfusion in other hospitals, unless they have regulatory authorizations and meet the laid down national and provincial standards and regulations for this activity. This mainly involves complete ownership of the clinical aspects of transfusion of blood products prepared and issued by Thalassemia centers that are used by any HBB or hospital. The Center providing such services shall ensure participation of their consultant in Hospital Transfusion Committees /Hemovigilance of the user hospitals. They shall make a hematologist available for consultation at user hospital, in case of adverse

reactions to their issued products. They shall be responsible for ensuring traceability and hemovigilance as laid down in Acts/regulations and standards.

Objective 11:

Promote safe and appropriate use of blood and blood products and develop national and provincial patient blood management and hemovigilance systems

1. FBTS and PBTS with the cooperation and participation of BEs shall be responsible for promotion, oversight and monitoring of safe and appropriate use of blood and blood components. They shall ensure implementation of comprehensive Patient Blood Management (PBM) at Federal and Provincial level under guidance of NTAC. They will ensure that hospitals should have a maximum blood ordering schedule with them for implementation.

2. BTSs shall use NTAC standards, guidelines and best practices and WHO products on this aspect for implementing them for clinical blood usage in hospitals.

3. NTAC shall write standards and guidelines for plasma exchange procedures and use of blood products. The standards should be implemented by FBTS/PBTS and regulated by blood transfusion authorities. The rational evidence-based practice shall be ensured to prevent patient safety issues and exploitation.

4. FBTS and PBTS shall ensure formulation of effective HTC in compliance with statute of Acts and NTAC guidance and monitor their effectiveness by utilizing technologies for distant meetings etc. The supplier blood

center or BEs shall have the representation in HTC of their respective user hospital. The supplier center shall have a hematologist and/or transfusion medicine specialist who provides ownership of blood products issued from the center. The user hospital shall always consult the supplier center's consultant for any adverse events to blood supplied by the center.

5. FBTS and PBTS shall be responsible for implementing NTAC plan and guidance that shall be produced by involving the professional societies, experienced clinicians from different disciplines for establishing systems most suitable and applicable in own circumstances and situations.

6. NTAC shall make a comprehensive plan for training of regulators of Health Care Commissions as well as nurses, paramedics, clinicians, administrators and all personnel involved in the transfusion administration process. All training shall be implemented and documented by FBTS & PBTS and made available to the regulator.

7. NTAC shall develop standardized definitions for a recipient hemovigilance programme including types, severity, immutability and align with International Hemovigilance Network. The standards shall include the data requirements, systems of monitoring, accurate reporting and analysis as well as management responsibilities after adverse reactions. The standards shall be complied with by FBTS, PBTS, BEs and clinical services.

8. PHC shall work in close liaison with blood transfusion authorities to uniformly regulate vein to vein processes. The regulatory authorities, i.e. BTA and HCC shall jointly devise rules for actions involving negligence in blood transfusion and harm to patients.

9. A central database of all reports of undesirable consequences, transfusion reactions, adverse reactions and hemovigilance shall be collected by FBTS and PBTSs and submit to regulator and SBTP as well. The system recommended by NTAC for analysis of data and actions thereafter shall be adopted for learning lessons and making changes in Blood Transfusion and/or blood banking practices, jointly by SBTP, NTAC, FBTS, PBTS and regulatory authorities.

10. SBTP shall coordinate with International Hemovigilance Network for country representation and sharing of data.

Objective 12:

Make efforts for general public, civil society education and awareness about voluntary blood donation National Blood System and importance of Thalassemia Prevention

1. FBTS and PBTS, professional societies, BDOs, Thalassemia & Hemophilia centers and provincial Thalassemia Prevention Programmes under the guidance of NTAC shall make comprehensive plans, formalize forums and use these for public education and awareness about voluntary non remunerated blood donations and need of blood transfusion. The campaign shall be taken to colleges, universities, schools, corporate sector and other sectors of country for sensitization, linking with existing BDOs, encouraging formation of new BDOs and linking these with blood centers.

2. Health departments shall provide budget to FBTS and PBTS, dedicated to this activity and according to plan provided with the help of SBTP and NTAC. This should be used by professional media and digital marketing companies and linked with performance outcomes of BTS.

3. Competitions between BDOs shall be encouraged and they are given recognition at national level.

4. Education and sensitization about PDMPs, plasma programmes shall also be organized so that awareness is of the level that source plasma programme may not appear alien concept in the country.

Objective 13:

Promote and support indigenous production of equipment, reagents, blood bags and other consumable items used in blood transfusion services

1. NTAC shall make recommendations on the products development that are used in blood establishments and blood transfusion and develop links with Ministry of Science and Technology, Ministry of Industry and Production, Private Sector/Industrialists/ Military Production Units and universities for creating awareness, providing motivation, guidance and market analysis to produce these products within the country. Transfer of technology shall be made mandatory for import license of products used in blood establishments and blood transfusion services by DRAP.
2. All efforts shall be made by all concerned for import substitution in this sector and reducing the cost of business to make the safety of blood transfusion viable for the country. Transfer of technology from friendly countries shall be explored.
3. NTAC and SBTP shall collect data on existing engineering capacities and players producing any equipment locally with a view to develop linkages with experts in this science so that production units can improve their products on scientific lines. The collaboration for refurbishing units shall also be promoted.
4. Advocacy by NTAC with Ministry of Commerce, Industries, DRAP, FBR, Customs, NGOs and other institutions to reduce the customs and taxes on products especially for the TTIs screening reagents.
5. NTAC shall produce standards for fitness of purpose for purchase of reagents, IVDs/equipment, calibration/validation requirements and recommend a plan for building capacity in country. There shall be formal communication and collaboration with DRAP to ensure the quality of reagents and consumables used for collection of blood and TTIs screening etc. The WHO collaborating center for quality at RBC Islamabad shall be engaged in this activity after its establishment.

Objective 14:

Develop partnerships, collaboration and information exchange

1. Collaboration with other Governments, regional and international partners shall be established to complete actions in key priorities to jointly address challenges and emerging threats at global, regional and national levels/areas. Institutionalize international technical collaboration framework involving Red Crescent, Red Cross, GAVI, WHO with formal by MoHSR&C and MOFA.

2. Collaborations between WHO member states on regional and international level and relevant organizations shall be encouraged and established by Governments and relevant stakeholders. The establishment of WHO collaborating center for quality shall be undertaken as a priority.

3. NTAC, SBTP and relevant government departments shall engage in international collaboration to learn from global experiences and advancements in blood transfusion practices.

4 Collecting data on any emerging pathogen threats to blood transfusion safety shall be collectively handled by close coordination of Federal and Provincial health departments and institutions.

5. SBTP, Federal and Provincial programmes and regulators shall regularly communicate progress, achievements and challenges to public, stakeholders and international partners.

Objective 15:

Establish mechanisms, technology, tools and KPIs implementation, monitoring and auditing the progress on the implementation of National Blood Policy

1. SBTP with the help of NTAC shall establish processes and outcome indicators to monitor the progress on the implementation of National Blood Policy.

2. SBTP shall compile and share information, progress and appraisal with different governmental and non-governmental departments, institutions and organizations on the progress of implementation.

3. The annual reports on the progress by SBTP, FBTS, PBTS and the relevant data shall also be made available to all concerned.

4. The maintenance of website of SBTP shall be ensured and adequate resources provided by Federal Government for the same. All relevant documents and progress shall be made available for public use.

5. The KPIs for implementation are attached in Annex.

BLOOD TRANSFUSION SERVICES IN PAKISTAN

The Background and Status

Pakistan came into being in August 1947 and it inherited structured blood transfusion services in the province of Punjab in form of Institute of Blood Transfusion Services Punjab (IBTS). IBTS did not keep pace with the population growth, capacity needs, organizational demands and internationally/WHO recommended best practices and models. Within the structure of healthcare, the blood transfusion services grew into a fragmented system which was non uniform, poorly managed and poorly coordinated involving all sectors mentioned. At present, it is estimated that three million blood donations are collected annually countrywide and it remains an estimate in absence of thorough comprehensive data collection.

The National Blood System growth was characterized by absence of National Policy, legislation and regulation. This resulted in nonexistent voluntary blood donations base, non- uniform, incomplete, poor quality TTI screening practices, suboptimal collaboration or coordination and management, unavailability of blood components, wastage, poor clinical usage practices, insufficient participation by stake holders and deficiency of qualified & trained human resources. The data on activity of blood transfusion in country was not collected formally by government except occasionally, so the judgement of the landscape was only through indirect means e.g. the number of annual donations in country was based on the import data of blood bags by their distributors and informal communications with the service providers. This remains an issue to date.

Historically blood transfusion safety efforts started in the country under the AIDS Control Programme during 90s and some efforts were made for introducing blood transfusion safety policy and legislation from 1997 to 2004 and first draft of National Guidelines were prepared in 2006. National Blood Transfusion Reforms and Programme efforts of Pakistan were helped by German Federal Ministry for Economic Cooperation and Development (BMZ), from 2006 onwards. The lead executing agency were the Federal Ministry of Health and Health Ministries of all provinces including AJK after a feasibility study was undertaken by joint mission of GIZ and KFW, the German cooperative bank in 2007. Its recommendations included creation of an internationally well-established model of a nationally coordinated and managed blood system implemented through RBC's and HBB in Hub and Spokes model. The pace of transfusion safety reforms was increased in 2008, through collaboration with joint mission of GIZ Deutsche Gesellschaft fur International Zusammenarbeit GmbH and KFW, the German Cooperative bank.

It was decided at Federal level to establish National Blood Transfusion Programme (NBTP) in 2010, as separate entity from National Aids Control Program and National Blood Policy & Strategic Framework 2008-2012 was formulated. The milestones are shown in Fig #03. The role of NBTP was modified because of devolution of powers after 18th Amendment of constitution in 2011 and the National Blood Policy and Strategic framework 2014-2020 was prepared by the Safe Blood Transfusion Programme (SBTP) operational within M/o NHSR&C. The main role of SBTP was confined to coordination between Centre, Provinces and different National and International Institutions for implementation of National Blood Policy and Strategic Framework 2014-2020. The phased reforms under SBTP included building structures, commissioning and functioning of regional blood centers and upgradation of existing hospital blood banks, as shown in figure 03. The plan was to construct and develop 30 regional blood centers and up gradation of existing 60 large Hospital blood banks.

The collaboration of SBTP with joint mission of GIZ and KFW includes following milestones:

- Enactment of new blood transfusion safety act by all provinces for better alignment, uniformity and support in the implementation of reformed plan.

- Establishment of blood transfusion regulatory authorities for Islamabad and provinces including AJK and GB.

- Commissioning and functioning of RBCs either managed by public sector itself, funded through provincial budget or outsourcing to NGO partners in a private public partnership. The location and status of RBCs is shown in Fig # 04.

- Close liaison for funding and technical assistance from development partners and WHO.

- Data collection from RBCs, Hospital Blood Banks of all sectors and NGOs. Data collection form attached as annex-B and publication of report on this data. Other data made available include National Blood Bank Data Collection Report, 2017 (first edition), IBTA Annual Report, 2019 and Compilation of country wide data base of Blood Donor Organizations across country and of Thalassemia Centers involved in blood transfusion services for Thalassemia and Hemophilia patients.

Development of following technical documents with the help of National and International experts:

- Functional Brief Regional Blood Center, 2011.
- Functional Brief Management Information System for Blood Transfusion
- Services. Country Strategy: Blood Donation screening of Transfusion Transmissible Infections, 2013.
- Standards and Guidelines for Blood Establishments and Transfusion Services, 2013.
- Quality Manual for Blood Transfusion Services, 2016.
- National Guidelines for Quality Control in Transfusion Medicine, 2020.
- Standard Operating Procedures for Blood Transfusion Services, PBTA and Health Department Government of Punjab
- Training Curriculum for Transfusion Medicine, 2015

The National Blood Policy 2014-2020 listed process and outcome indicators for monitoring the progress on implementation of the policy, however these activities of SBTP were interrupted after retirement of previous National Coordinator in 2019. At present the data required for impact analysis and reforms is sketchy, non-uniform, incomplete, non-structured and not thorough enough to be benchmarked against the indicators, that were stated in NBP 2014- 2020. The data collection was never institutionalized by employing relevant technologies and SBTP did not continue this activity properly after 2017. The website maintained by SBTP has also no longer all technical documents that were accessible to stakeholders are no

longer visible except in the departments and individuals. The data and information made available by M/o NHSR&C from RBCs of all provinces including AJK and GB and personal communication with different stakeholders is annexed in this document. The following observations are highlighted:

- The collection of blood in all functioning RBCs combined has reached 0.6 million annually (Table-1, Annex-C). The data from upgraded hospitals as RBCs is shown in tables 2,3,4 & 5.

- All diseases mandated by WHO to be screened are being screened at these RBCs with CLIA. These include HIV, HCV, HBV, Syphilis and Malaria.

- The contribution of Voluntary Non-Remunerated Blood Donations towards total donations collected is less than 15% in all RBCs. Rest is blood replacement and directed donors. Female blood donors constitute less than 2% (Annex C, data from different RBCs),

- There is uniform standard of screening in all RBCs, and it is with approved CLIA platforms and reagents, completed in Phase 1 and Phase 2 of collaborative program.

- There is high prevalence of TTIs in the country reflecting those found in general public. HCV is the largest contributor among the TTIs tested in Southern part of country (Annex- D). The trend of TTIs over three years shows increasing prevalence, especially HCV in three RBCs (Jamshoro, Karachi and Swat) as shown in Figures in Annex-D and rest shows not much change, as the ratio of volunteer donors to replacement/directed donors has not changed much. Syphilis prevalence is high and may be a surrogate marker of HIV as well. There is difference in prevalence of Northern part of country compared to south, (Annex C, Fig # 28 & 29), with less HCV and overall having lower prevalence. The public sector hospitals in Punjab have been predominantly testing TTIs with rapid ICT devices, till 2020. The sensitivity and specificity of these is questionable. In 2021-2022, the upgradation of blood donor screening with CLIA and cross matching with Micro Column Gel was planned and bids were called. These were for the upgraded hospitals, like Lahore General Hospital and Mayo Hospital as shown in Annual report of IBTS (ibts.punjab.gov.pk), (Annex B, table 3,4,5).
- RBCs managed in private public partnership (PPP) model deliver services consistently and efficiently. These RBCs showed upward trend in collection of blood donations and some tangible efforts towards recruitment of VNRBD (Annex C).
- The collection from voluntary blood donor and female participation, however, remains low and do not show significant change in all RBCs (Annex C).
- The private public partnerships were able to manage and train the human resource better with less disruptions compared to RBCs managed in public sector (stakeholder's consultation inputs).
- The private public partnership RBCs were better able to engage the clinical services at hospitals with effective measures, communication and coordination with them (stakeholder's input). These RBC could handle the unhealthy competition from the HBBs (e.g. The RBC Peshawar does not provide blood products to HMC, which has its own HBB running and working separately, despite RBC being located within the complex).

- The data collected by these RBC is more reliable and consistent trends could be ascertained from these private public partnership RBCs (Annex C). All of these are using CLIA for TTIs screening as compared to common practice of pre-donation testing with ICTs at public sector hospitals. The data by IBTS and PBTA show the type of screening practices across the province, and it reflects on the poor quality of data collection (ibts.punjab.gov.pk). (Annex B, table 3,4,5).

- The Regional Blood Centers (RBCs) functioning in the public sector are either non- functioning or functioning sub-optimally. The major reason for that Hospital Blood Banks (HBB's) have not been connected to the RBCs. The critical prerequisite to achieve and exceed targets in regional blood centers is to connect initially the teaching HBB's, followed by District/Tehsil Headquarter (DHQ/THQ) Hospital Blood Banks to the RBC under a single administrative control. There is a lack of this critical understanding regarding the "Hub & Spoke Model" of the RBC-HBB in the policy makers. The "Hub" i.e. RBC cannot function in isolation, without the "Spokes'. HBB. This fact has been proven in the RBC's functioning in the PPP model, which has achieved and exceeded the given targets. In addition, closing the loop for safe blood transfusion from vein of the donor to the vein of the patient in the teaching HBB's controls wastage and pilferage of blood, resulting more than around 20-25% units drawn, which can then be supplied to the THQ hospitals at a very low cost, where blood is not available currently. Consistently, the second major reason for the sub-optimal functioning of the public sector RBC's is insufficient and inconsistent provision of funds.

- The public sector and other sector hospitals especially not affiliated with RBCs and even after upgradation could not control corrupt practices and pilferage of blood, especially because they were not using Blood Establishment Computer Software, poor regulation and controls of clinical practices (stakeholder's input and media reports).

- Unsatisfactory quality, oversight of the serology and cross match practices of hospital Blood Banks are creating patient safety issues (stakeholder's inputs and media reports).

- Despite some significant improvements, the RBCs across the country, even those in public private partnership, did not achieve all the objectives of National Blood Policy, 2014-2020. As per the most recent country wide data on SDGs, shown in Fig 3, the progress in healthcare has stagnated, which is also reflected in the slowing of progress in blood transfusion safety reforms as well.

Some of important deficiencies and gaps that remain in the implementation of NBP & SF, 2014-2020 include:

- Inability to ensure continuity of central function of coordination through SBTP and implementation of policy.

- Slow pace of application of successful SBTP public partnership model to other areas of provinces, sometimes due to litigation by contractual and permanent staff of public sector RBCs. The performance of RBCs in PPP proves that wider adoption of this model is pragmatic way of completing the reform agenda. This will unify the management structure and facilitate coordination. However, the success is limited to honoring contractual agreements, on which track record of provincial governments is area of concern.

- Introduction of comprehensive provincial and national hemovigilance programme and improvement of clinical blood transfusion.

- Deficiencies in optimum sustainable funding and budgeting for the public sector can be reduced by exploring insurance system or employee insurance to finance the input cost of the blood. The possibility of out of the pocket payment by the patient for third party blood products and transfusion services by the public sector can also be explored. The potential of surplus plasma to fund the safety aspects of the blood transfusion and self-sufficiency in PDMPs was also never considered and is worthwhile intervention.

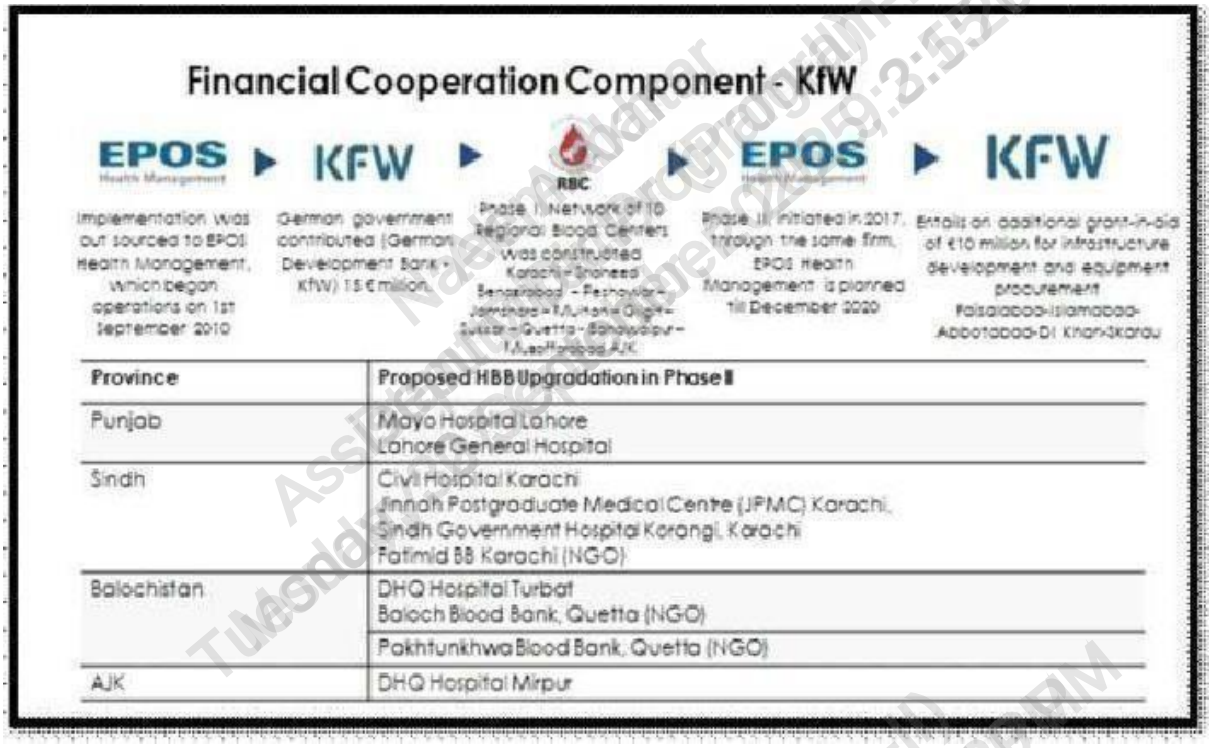
- The innovative solutions, subsequent advocacy, planning and guidance that was never given enough importance may be brought about by forming a group of experts on the form of Advisory committee that offers advice and remains engaged with all components of a "comprehensive National Blood System". This could be akin to a dynamic think tank. The non-remunerated think tank shall be able to sustain its functions beyond the political tenure of successive government and shall have consistency in its advice and plans for long term change. Such a committee is already envisioned in the provincial legislation and previous policies as well.
- The service delivery through appropriately qualified, trained professional staff is one of core issues, especially in public service healthcare delivery.
- Regulatory weaknesses include lack of experienced leadership, ad hoc appointments, poor capacity, insufficient funding and absence of rules. The regulatory authorities of countries are now expected to use Global Bench Mark Tool plus by WHO to qualify for maturity level, so that the regulatory capacity can be trusted by international community and partners. This achievement by regulators would pave way for easier acceptance of recovered and source plasma from the country by the fractionators.
- There is also an overlap of regulatory authorities as well because of varied inputs that are required to make a comprehensive National Blood System and enabling environment towards availability of safe and effective blood products e.g. clinical usage of blood and hemovigilance is completely monitored/implemented by Health Care Commissions. This leads to confusion among health care facilities and also lack of oversight on some essential aspects contributing towards safety and availability of blood products and preventing wastage. In smaller cities, the Healthcare Commissions insistence for MOU with blood establishments registered with regulators pushed the unsafe practices of blood transfusion underground due to lack of options.
- Over the time neglected, non-uniform, ineffective and late Thalassemia prevention initiative resulted in huge healthcare burden of Thalassemia Major children, who consume 0.8-0.9 million annual national blood donations collected. The Thalassemia care services are mainly offered by NGOs and some public sector hospitals, that do not prioritize disease prevention and compete for voluntary blood donations and capitalize on gaps in transfusion services in other sectors. These Thalassemia Centers do not either have facility to make components or they use single or double blood bags to reduce costs which leads to wastage of plasma to the tune of 100000 liters annually. Some of the plasma is used for supporting hemophilia patients. The seroprevalence of TTIs reported among Thalassemia and Hemophilia patients is as high as 60% in some studies from the country, which reflects the safety standards of blood

transfusion services in these facilities. Unless Thalassemia prevention is undertaken on urgent basis, the blood availability and usage shall remain distorted and skewed.

- Based on projection of 1% of population suffering from bleeding disorders, the country should have 24000 patients at least. Due to insufficient facilities and suboptimum primary and secondary care the data is incomplete. The Pakistan chapter of World Federation of Hemophilia has 4700 patients registered and more than 3000 have Hemophilia A. This number of patients would need at least 20 M IU of factor-VIII if they were treated as per average consumption of factor-VIII internationally. There is no national data on use of I/V Immunoglobulins or albumin annually, as many products are smuggled.
- Based on the number of blood donations annually, the country has potentially 0.3 to 0.4 M liters available after meeting domestic need of plasma. With the completion of phase I and II of construction of RBCs and made functional, there is potentially 0.12 M liters of plasma from these RBCs that can meet the GMP requirement for fractionation with some additional investment in quality, storage and logistics. It is important that the new policy facilitates the harnessing of this potential and self-sufficiency in PDMPs by preventing wastage.
- A comprehensive information management system was incompletely developed and utilized for data collection by safe blood transfusion services, and it is now non-utilizable. A standardized Blood Establishment Computer Software (BECS) commissioned at RBCs did not integrate the Hospital Blood Banks and remained unaffordable by hospitals that were planned for upgradation and also by private and NGO blood establishments. The regulator could not assert itself for making this a mandatory requirement, even though majority of statues of Acts cannot be implemented without BECS. It is also essential step towards any recovered or source plasma programme. Additional solutions available or making public sector capacity for developing one is an urgent requirement.
- The important stakeholders, especially the professional societies and degree awarding organizations, remain aloof to the state of blood transfusion services of the country. There are no significant efforts by professional societies for lobbying with policy makers to guide them and contribute in capacity building.
- Much essential local evidence required to guide policy is neither produced nor prioritized.
- The Steering Advisory Committee proposed in previous National Blood Policies was never formalized and if was nominated it never became functional. This has adversely impacted the pace of the programmes of provinces and is required for informing and helping SBTP leadership and the government.
- WHO engagement was no longer actively sought by SBTP, although it has been providing support and help for different aspects of reforms. WHO provides support to the national and provincial blood transfusion programmes in Pakistan in the development of national policies, strategies & standards, conducting capacity-building and training, in addition to; Strengthening blood screening systems to prevent transmission of infections through blood transfusion; conducting national assessment of blood screening system in Pakistan; developing first national testing strategy for transfusion transmitted infections; conducting training on quality assurance in blood establishments based on WHO training module; procuring blood screening kits worth US$ 8.4 million from USAID; conducting training

workshops on national testing strategy for TTIs; implementation of national quality control guidelines; clinical use of blood and hemovigilance; strengthening blood transfusion regulation systems and participating in WHO regional blood transfusion activities.

- The German Development Bank partnership completing in 2023 calls for efforts for extension and this partnership would provide an impetus to sustainability of reforms.



Financial Cooperation Component - KfW

EPOS ▶ KFW ▶ RBC ▶ EPOS ▶ KFW

Implementation was out sourced to EPOS Health Management, which began operations on 1st September 2010

German government contributed (German Development Bank - KfW) 15 € million

Phase I: Network of 10 Regional Blood Center was constructed Karachi-Shaheed Benazirabad - Peshawar-Jamshoro-Multan-Gilgit-Sukkur-Quetta-Bahawalpur-Muzaffarabad AJK

Phase II initiated in 2017, through the same firm, EPOS Health Management is planned till December 2020

Enrolls an additional grant-in-aid of €10 million for infrastructure development and equipment procurement Faisalabad-Islamabad-Abbottabad-DI Khan-Skardu

Province	Proposed HBB Upgradation in Phase II
Punjab	Mayo Hospital Lahore Lahore General Hospital
Sindh	Civil Hospital Karachi Jinnah Postgraduate Medical Centre (JPMC) Karachi Sindh Government Hospital Korangi, Karachi Fatimid BB Karachi (NGO)
Balochistan	DHQ Hospital Turbat Baloch Blood Bank, Quetta (NGO)
	Pakhtunkhwa Blood Bank, Quetta (NGO)
AJK	DHQ Hospital Mirpur

Fig # 03: Financial Cooperation Partners in establishment of RBCs in Pakistan

Fig # 04: Overview of RBCs in Pakistan.

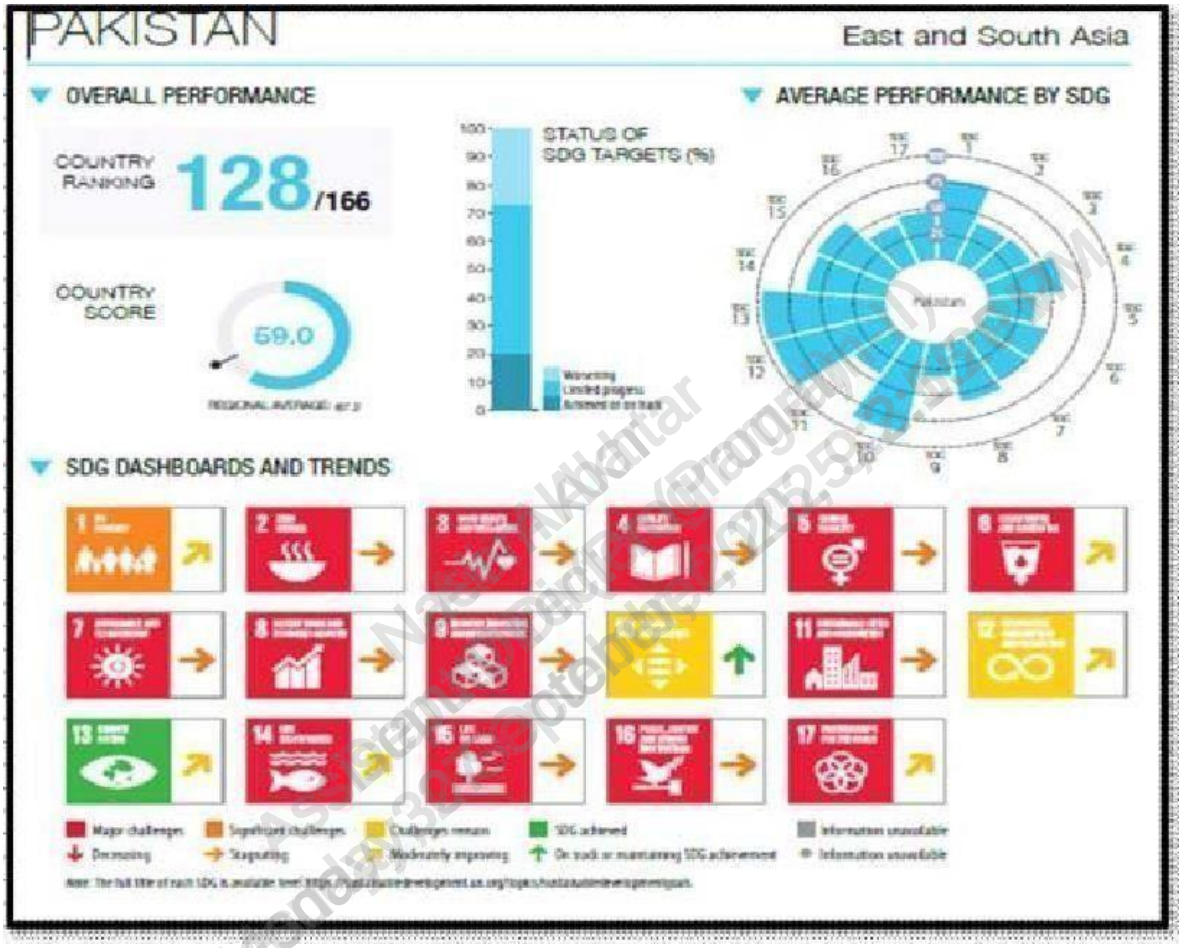


Fig # 05: Pakistan's Average Performance regarding SDG's

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Annexes

Annex – A

A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

The objective of this code is to define the ethical principles and rules to be observed in the field of Transfusion Medicine.

Blood Centers: donors and donation

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor.
   A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.
   The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.
2. A profit motive should not be the basis for the establishment and running of a blood service.
3. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.
4. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
5. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.
6. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.
7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
8. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Hospitals: patients

12. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.
13. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.
14. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.
15. Genuine clinical need should be the only basis for transfusion therapy.
16. There should be no financial incentive to prescribe a blood transfusion.
17. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.

The Code has been elaborated with the technical support and adopted by the WHO.
Adopted by General Assembly of ISBT, July 12, 2000
Amended by the General Assembly of ISBT, September 5, 2006

Fig # 06: WHO Code of Ethics for Blood Donation & Transfusion

Annex – B

Sr #	RBC Name	Avg. Annual Donations in year 2022
1.	RBC Quetta	35000
2.	RBC Karachi	26144
3.	RBC Shaheed Benazir Abad	14829
4.	RBC Sukkur	47438
5.	RBC Jamshoro	68750
6.	RBC Swat	25000
7.	RBC Peshawar	65000
8.	RBC Abbottabad	15490
9.	RBC D. I. Khan	10000
10.	RBC Mayo hospital	84904
11.	RBC Lahore General Hospital	45233
12.	RBC Faisalabad	56302
13.	RBC Bahawalpur	61141
14.	RBC Multan	55522
15.	RBC Islamabad	1887
16.	RBC Muzaffarabad	6830
17.	RBC Gilgit Baltistan	no data
18.	RBC Mirpur	7356
	Total	**626826**

Table # 01: Annual number of donations in Regional Blood Centers Year-2022.

Sr#	Hospital Blood Bank Name	Avg. Annual Donations
1	BU, Mayo Hospital (Emergency + Main,) Lahore	49,521 + 36,312
2	BU, Sir Ganga Ram Hospital, Lahore	44,547
3	BU, Govt. Mian Nawaz Sharif Hospital, Lahore	8,299
4	BU, Govt. Said Mitha Hospital, Lahore	1,543
5	BU, Lady Aitchison Hospital, Lahore	12,740
6	BU, Govt. Teaching Hospital, Shahdara Lahore	5,732
7	BU, Lady Willingdon Hospital, Lahore	20,773
8	BU, Govt. Mian Munshi Hospital, Lahore	1,900
9	BU, Govt. Kot Khawaja Saeed Hospital, Lahore	6,943
10	BU, Lahore General Hospital, Lahore	52,764
11	BU, Jinnah Hospital, Lahore	48,530
12	BU, Punjab Institute of Cardiology, Lahore	14,325
13	BU, Services Hospital (Gynae + Emergency), Lahore	18,345 + 21,811
14	Blood Unit, Benazir Bhutto Hospital, Rawalpindi	12,723
15	Blood Unit, Holy Family Hospital Rawalpindi	33,858
16	Blood Unit, DHQ Hospital Rawalpindi	11,443
17	Blood Unit, Allied Hospital, Faisalabad	56,262
18	Blood Unit, DHQ Hospital, Faisalabad	25,534
19	District Blood Unit, Sheikh Zayed Hospital, R.Y Khan	58,482
20	District Blood Unit, DHQ Hospital, Gujranwala	19,008
21	District Blood Unit, Allama Iqbal Memorial Hospital, Sialkot	15,720
22	District Blood Unit, Aziz Bhatti Shaheed Hospital, Gujrat	13,348
23	District Blood Unit, DHQ Hospital, Sargodha	8,777
24	District Blood Unit, DHQ Hospital, Sahiwal	26,997
25	District Blood Unit, DHQ Hospital, Multan	4,143
26	District Blood Unit, DHQ Hospital, Dera Ghazi Khan	21,532
	TOTAL	**651,912**

Table # 02: Average number of annual donations in Public Sector HBBs, Punjab

Sr#	Name	No. of BBs	2019	2020	2019	2020	Total 2019	Total 2020
			ICT	ICT	ELISA/ CLIA	ELISA/ CLIA		
1	All teaching hospital BBs	26	587,880	481,962				
2	RBCs (Multan & Bahawalpur)	2			115,818	101,475		
3	Children Hospital Lahore, FAD & Multan	3	46,000			30,365		
4	PIC, RIC, CPEIC, FIC, WIC	5			25,000	29,573		
5	DHQ Hospital BBs	26	155,750	172,469				
6	THQ Hospital BBs	7	10,000	31,343				
7	SZH & Anmol BBs	2			21,350	13,471		
8	WAPDA Hospitals	5	Data not available					
	Total	74	7,99,630 (83%)	685,774 (79.7%)	162,168 (17%)	174,88 (20.32%)	9,61,798	8, 60,658

Table # 3 Punjab Blood Transfusion Authority Screening Data 2019-2020

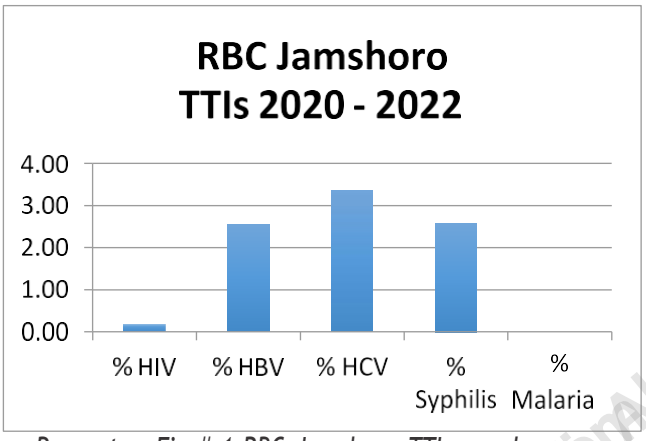
Product Type made	Number
RCCs	69,935
FFPs	51,936
PLTs	
Mega Units	4,089
Total Products Prepared	

Table # 4: Blood Components Data, PBTA

Screening Performed onnumber of donations		Seroreactivity
HIV	569,107	0.02 %
HBV	561,705	1.09 %
HCV	567,736	1.6 %
Syphilis	550,228	1.17 %
Malaria	549,318	0.08 %

Table # 05: Seroreactivity Data, PBTA

Annex – C



PercentageFig # 1 RBC Jamshoro TTI prevalence 2020-2022

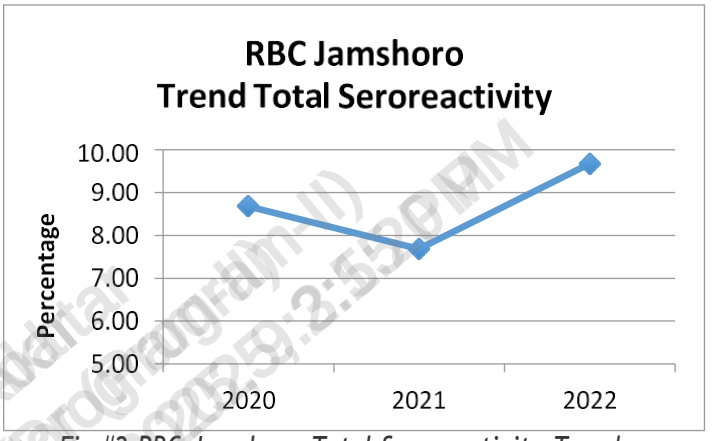


Fig #2 RBC Jamshoro Total Seroreactivity Trend

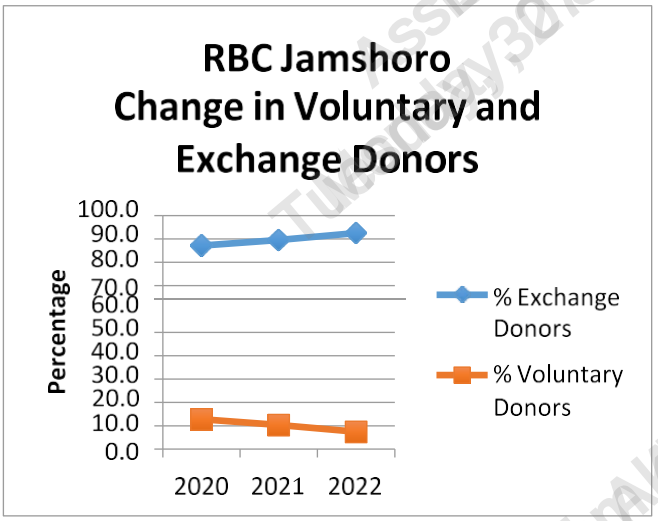


Fig # 3: RBC Jamshoro Voluntary and Exchange Donors

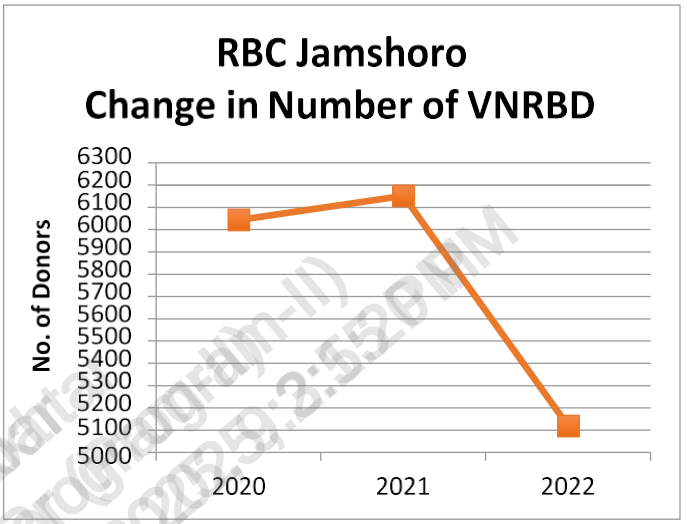


Fig #4: RBC Jamshoro VNRBD Blood Data

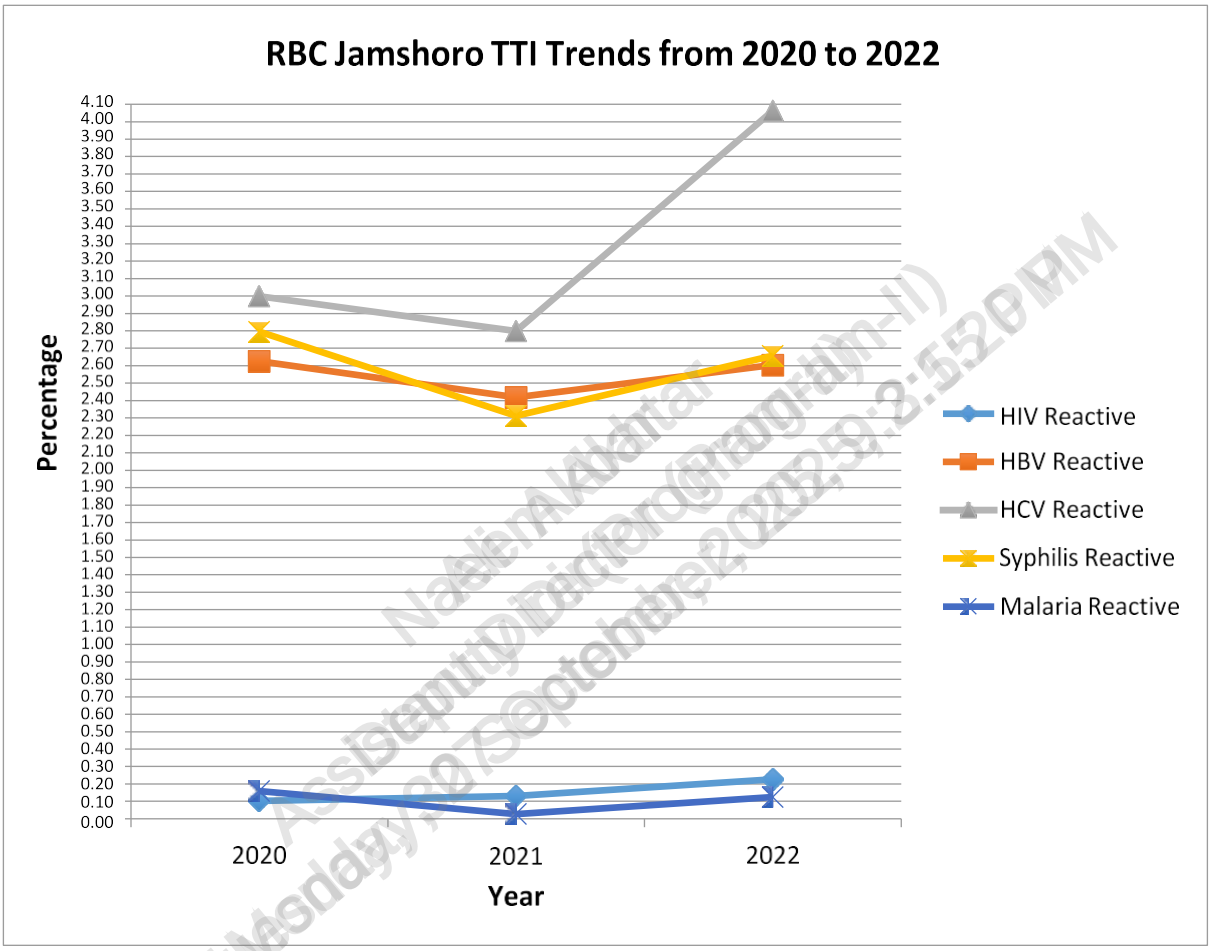


Fig # 05: RBC Jamshoro TTI Trends from 2020 to 2022

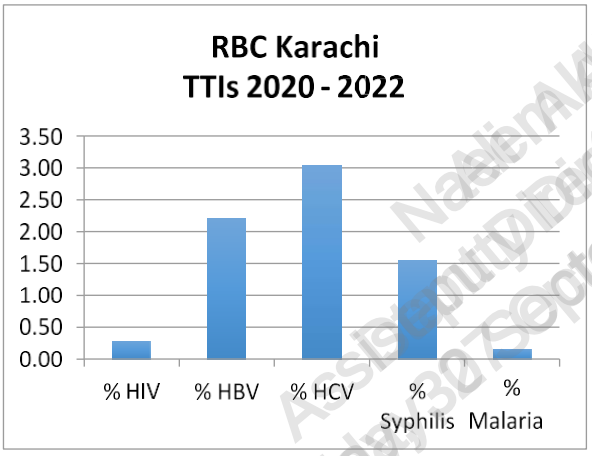


Fig # 6: RBC Karachi TTIs 2020 – 2022

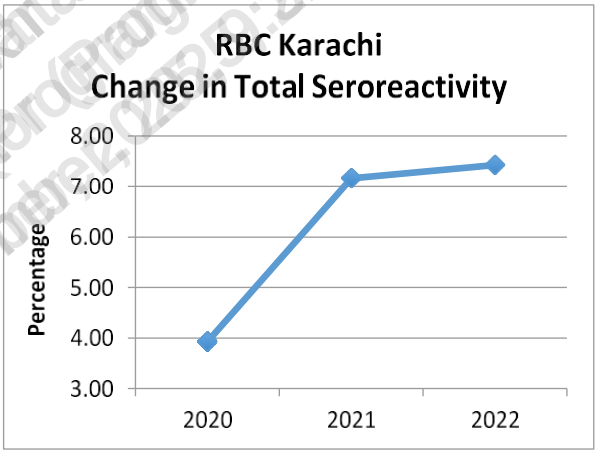


Fig # 7: RBC Karachi Total Seroreactivity Trend

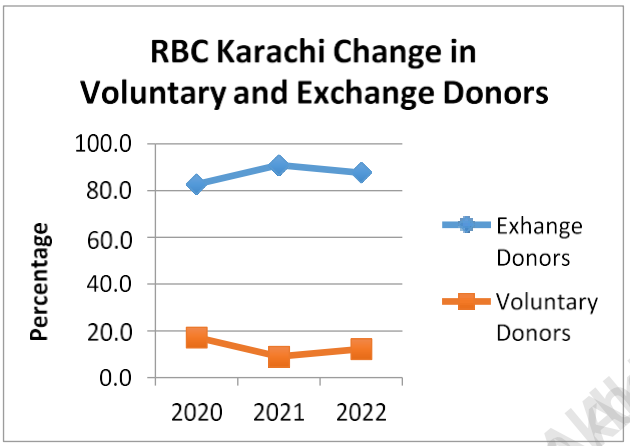


Fig # 8: RBC Karachi Voluntary and Exchange Donors

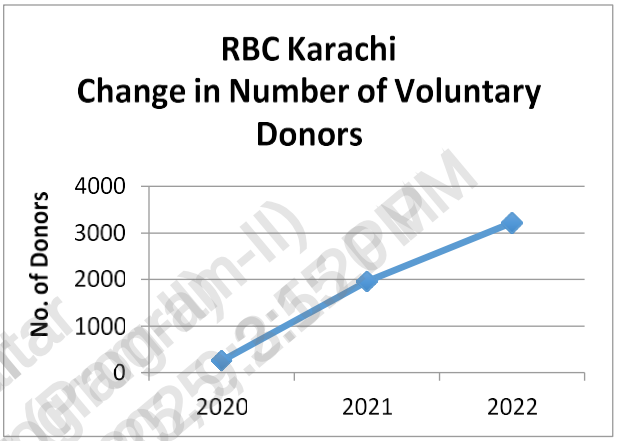


Fig # 9: RBC Jamshoro VNRBD Blood Dat

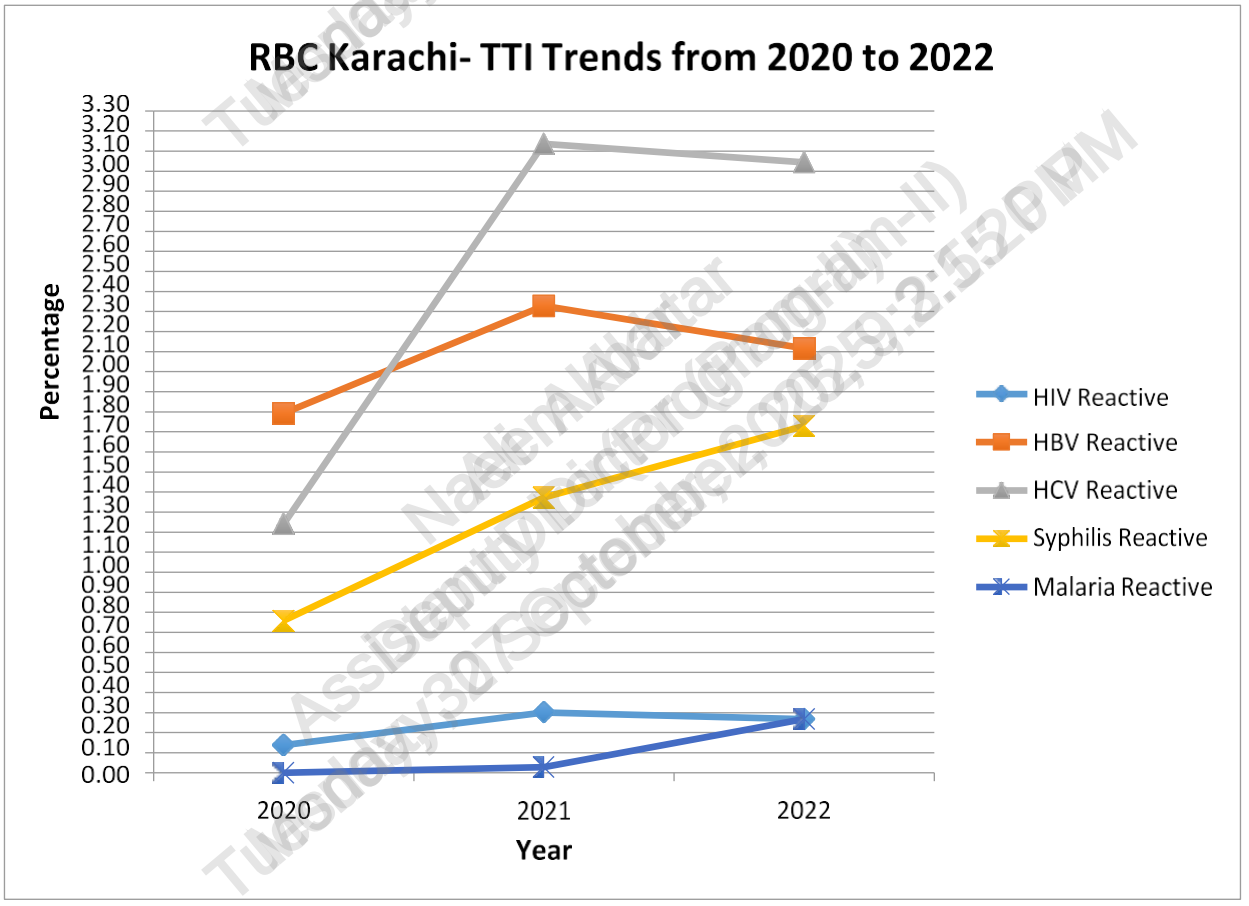


Fig # 10 RBC Karachi TTI Trends from 2020 to 2022

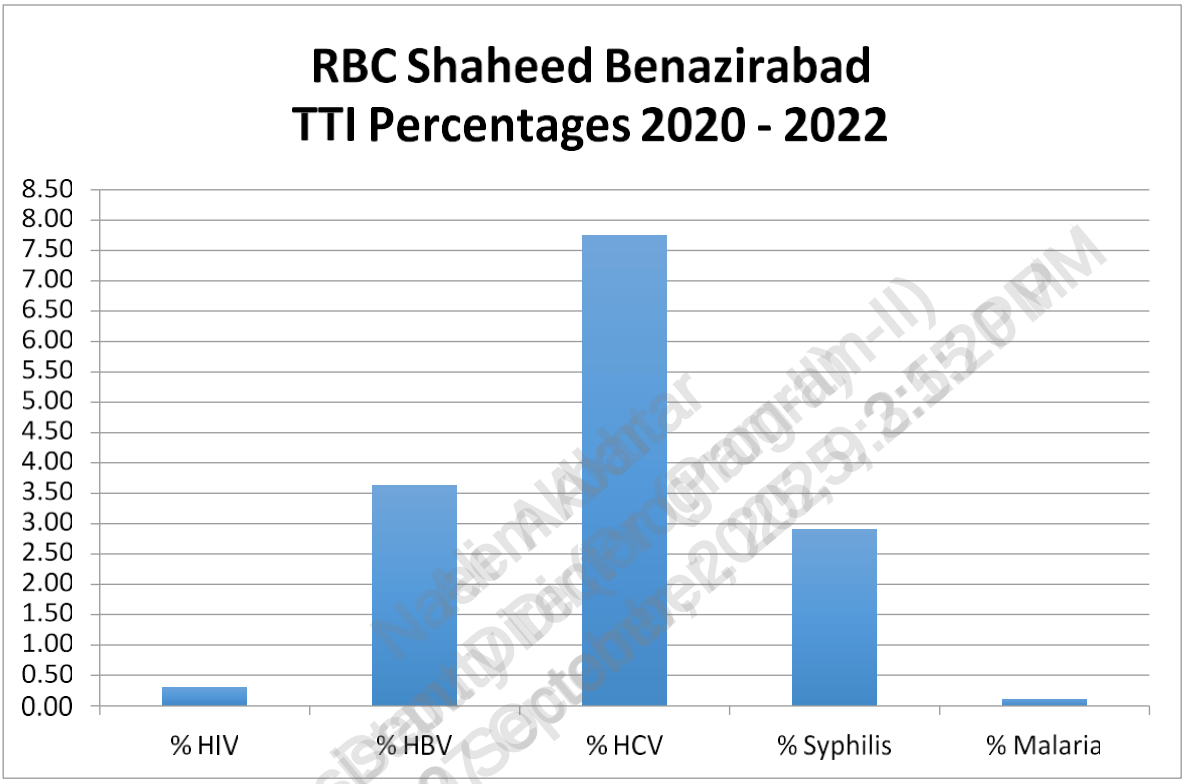


Fig # 11RBC Shaheed Benazir Abad TTI Percentages 2020–2022

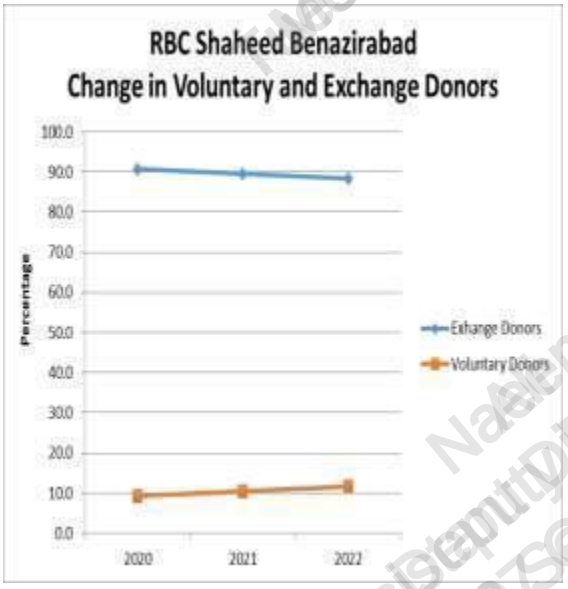


Fig # 12: RBC Shaheed Benazir Abad Voluntary Exchange Donors

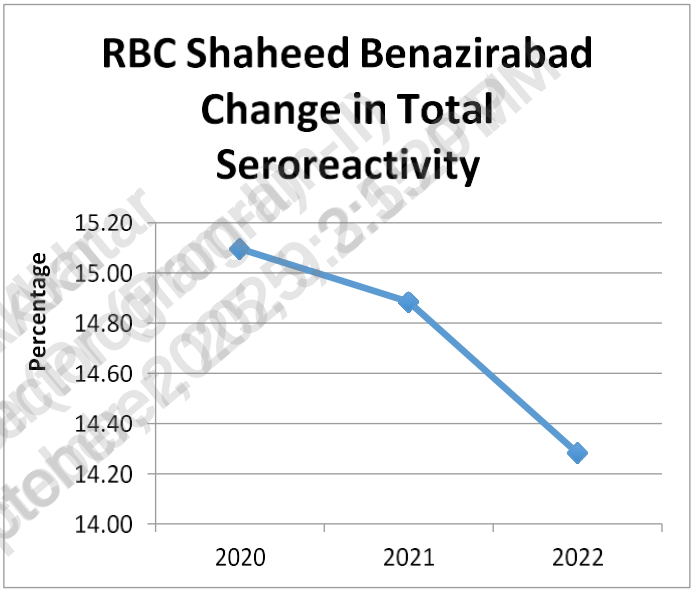


Fig # 13 RBC Shaheed Benazir Abad Seroreactivity Trends

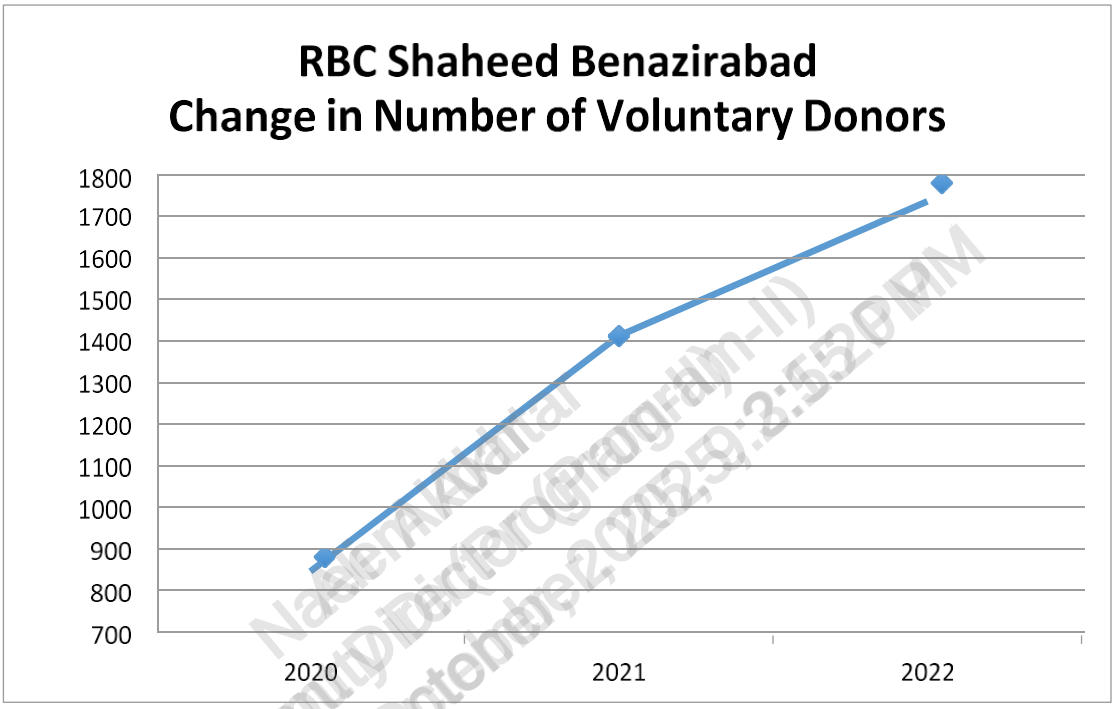


Fig # 14: RBC Shaheed Benazirabad Number of Voluntary Donors

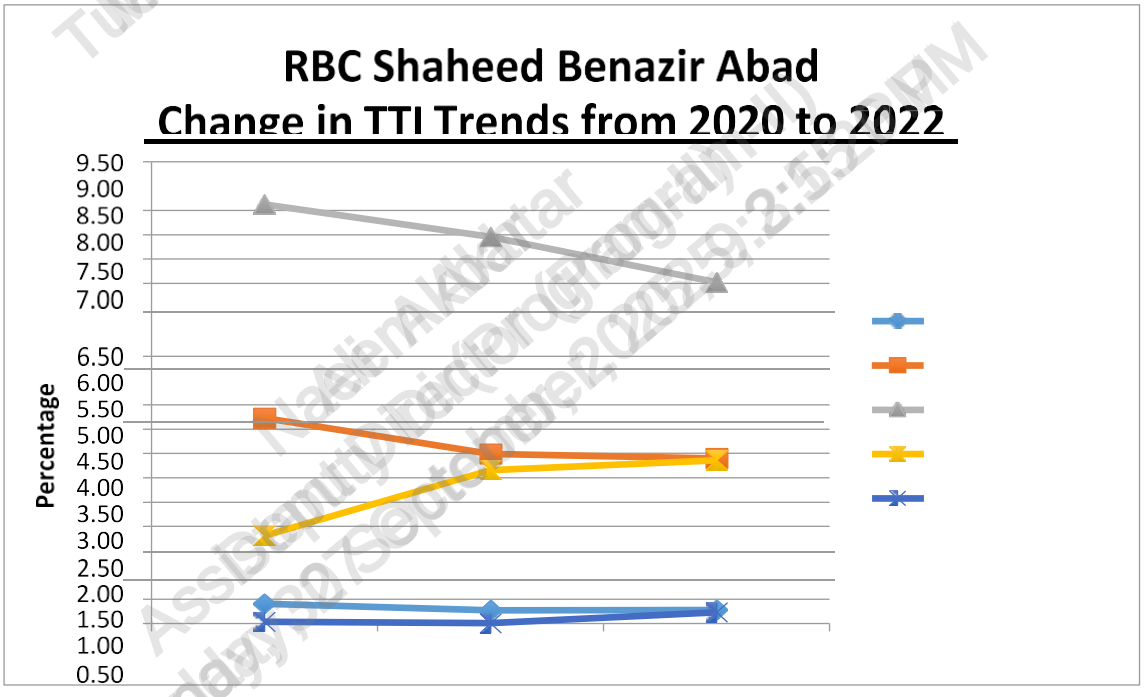


Fig #15: RBC Shaheed Benazir Abad Change in TTI Trends from 2020 to 2022

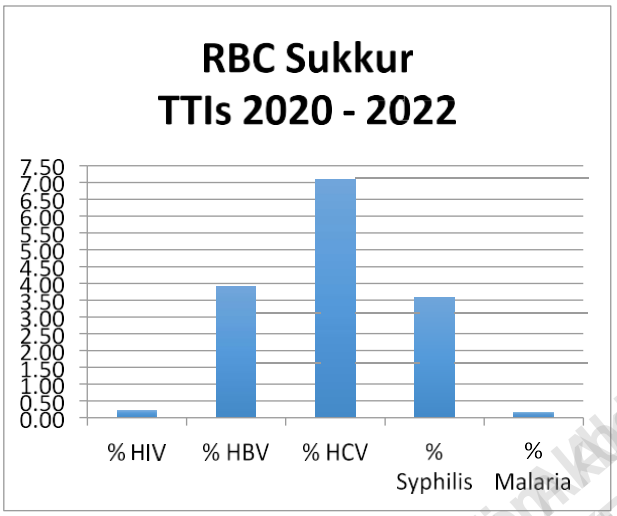


Fig # 16: RBC Sukkur TTIs 2020–2022

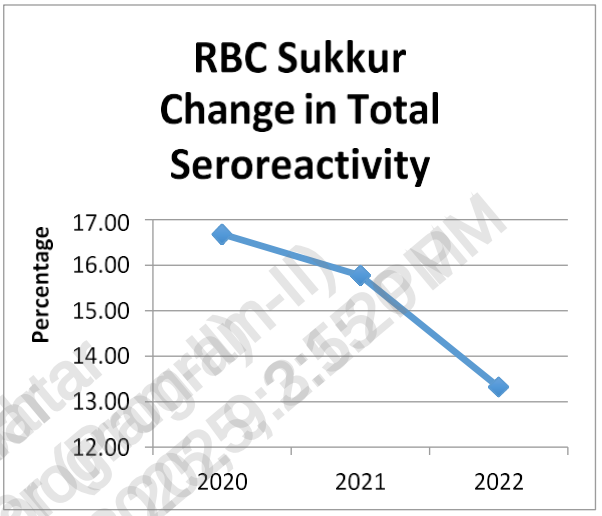


Fig # 17: RBC Sukkur TTI Seroreactivity Trends

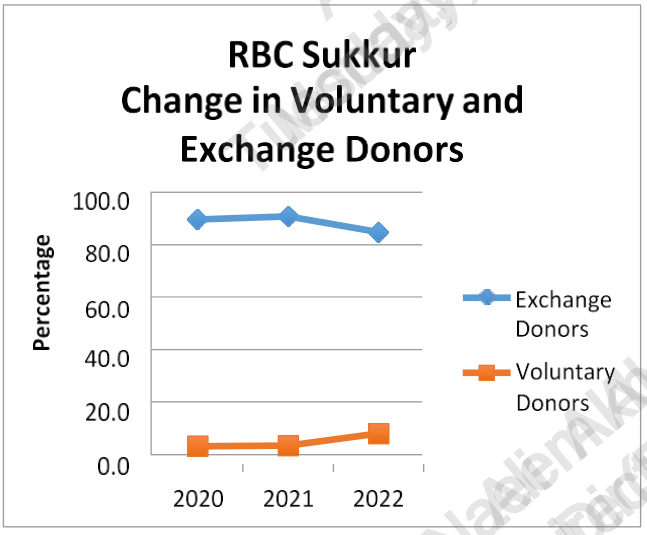


Fig # 18 RBC Sukkur Voluntary and Exchange Donors

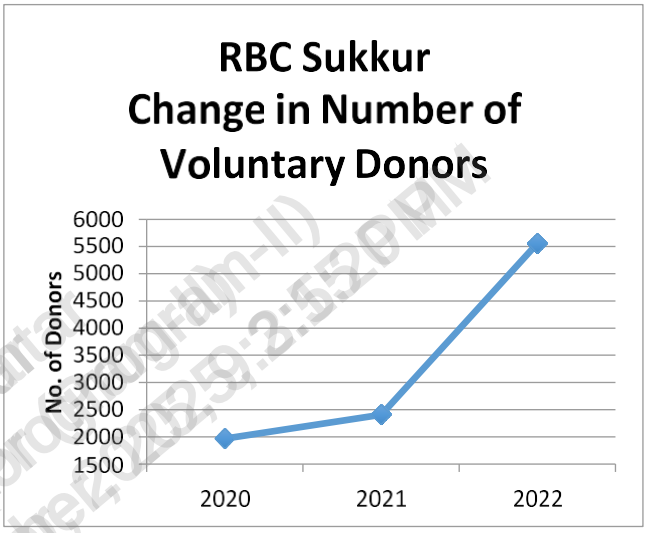


Fig # 19: RBC Sukkur Number of Voluntary Donors

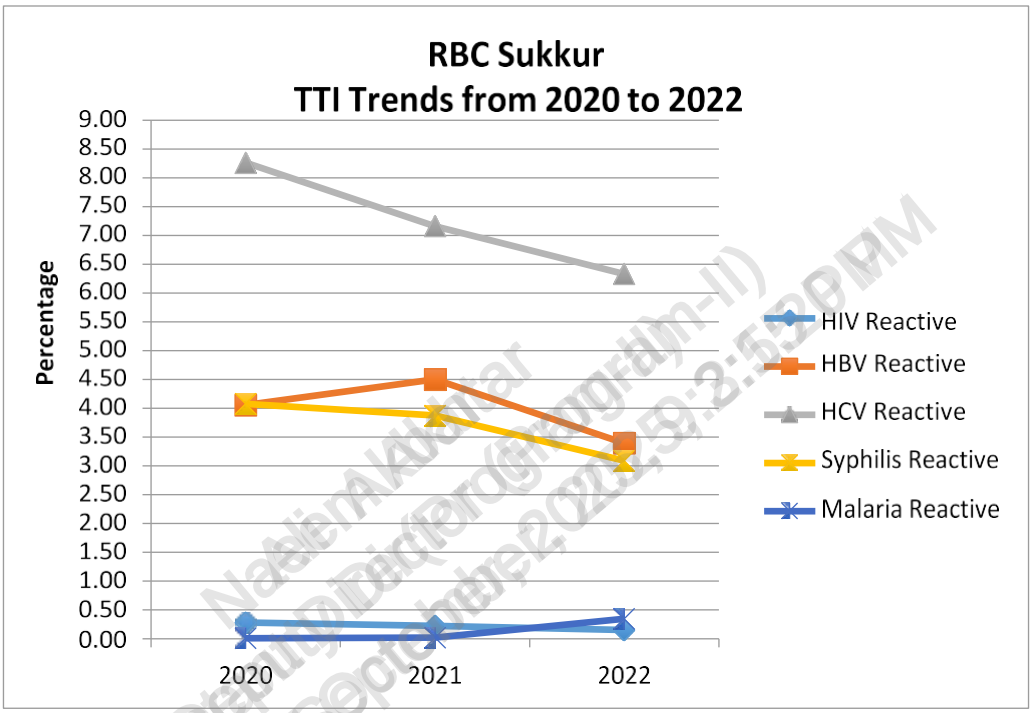


Fig # 20: RBC Sukkur TTI Trends from 2020 to 2022

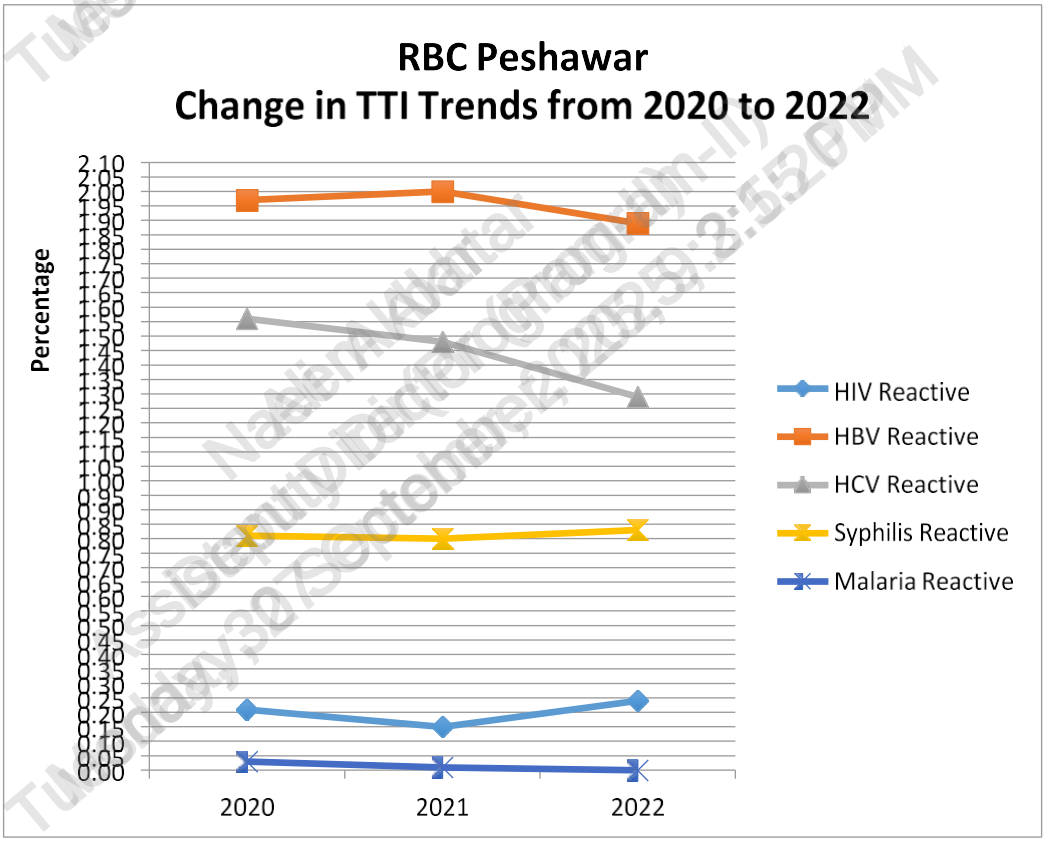


Fig # 21: RBC Peshawar TTI Trends from 2020 to 2022

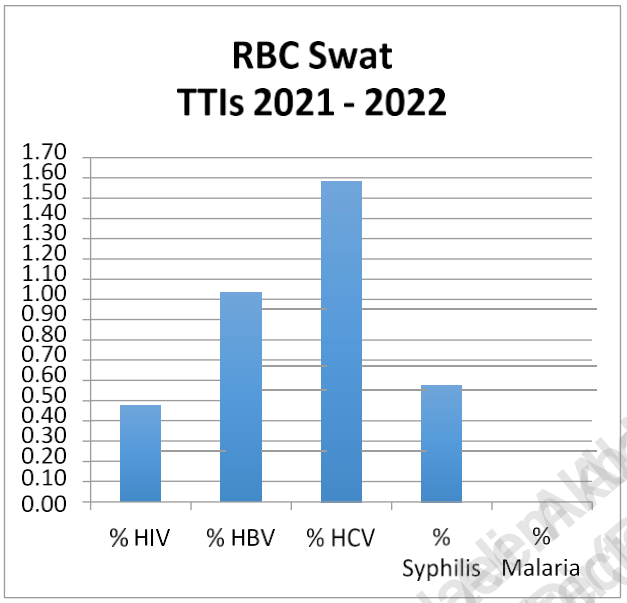


Fig # 22: RBC Swat TTIs 2021 – 2022

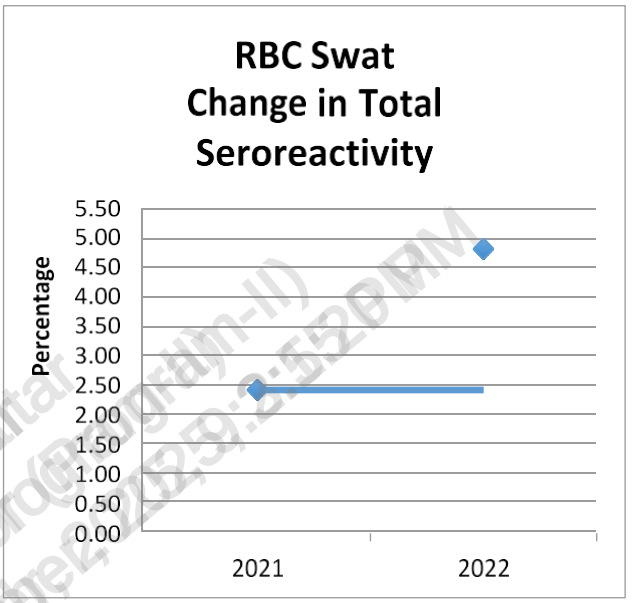
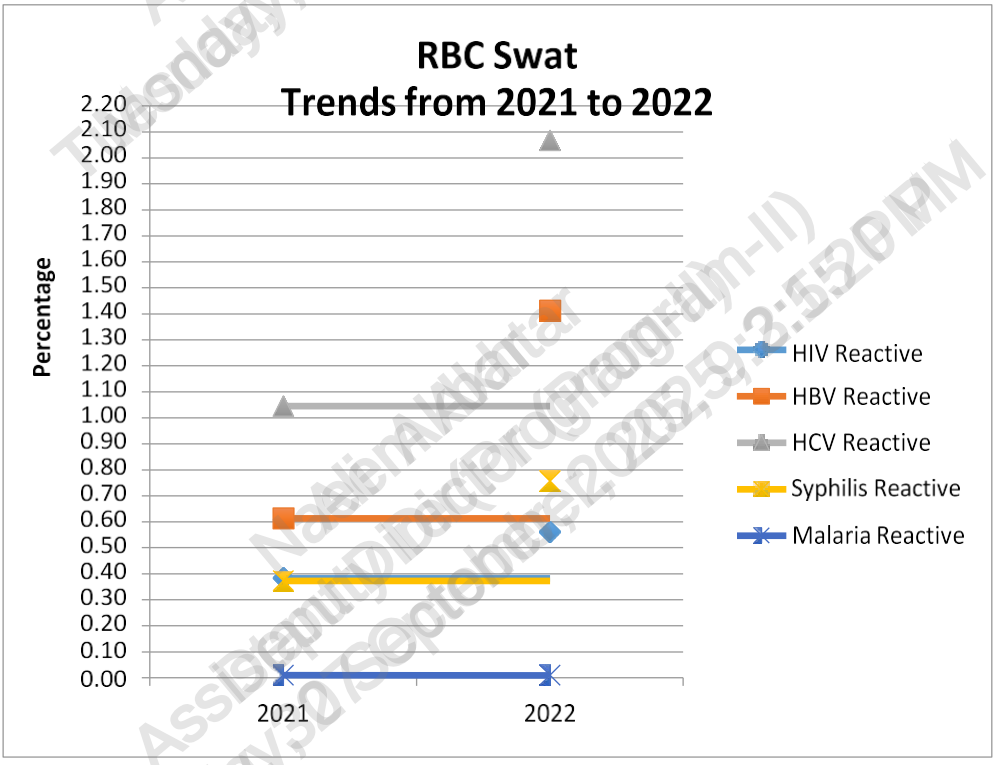


Fig # 23: RBC Swat Total Seroreactivity



Fig# 24: RBC Swat TTI Trends from 2021to 2022

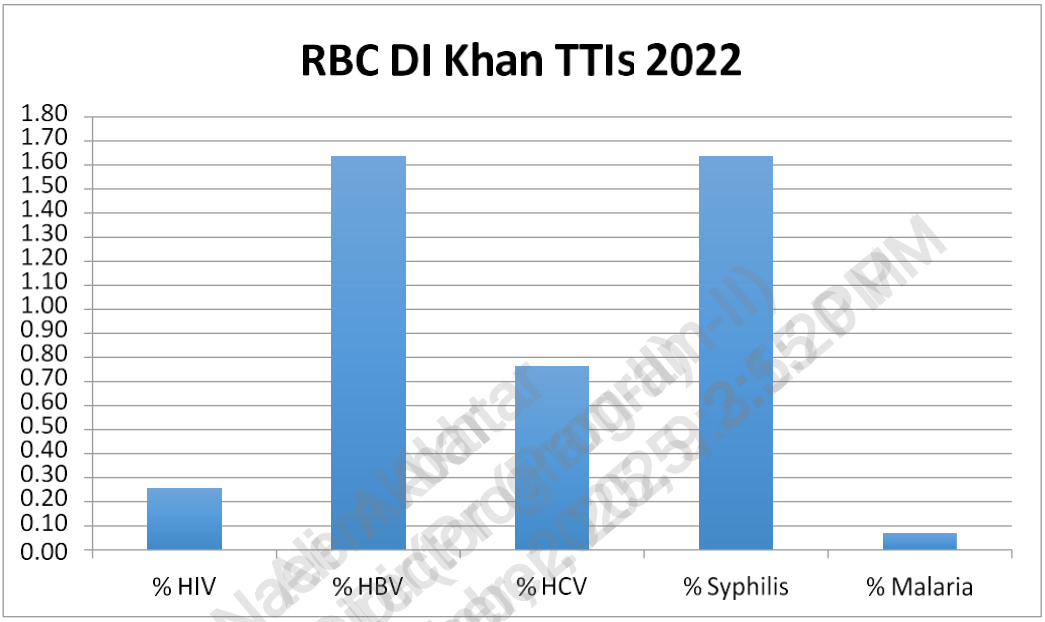


Fig # 25: RBC DI Khan TTIs 2022

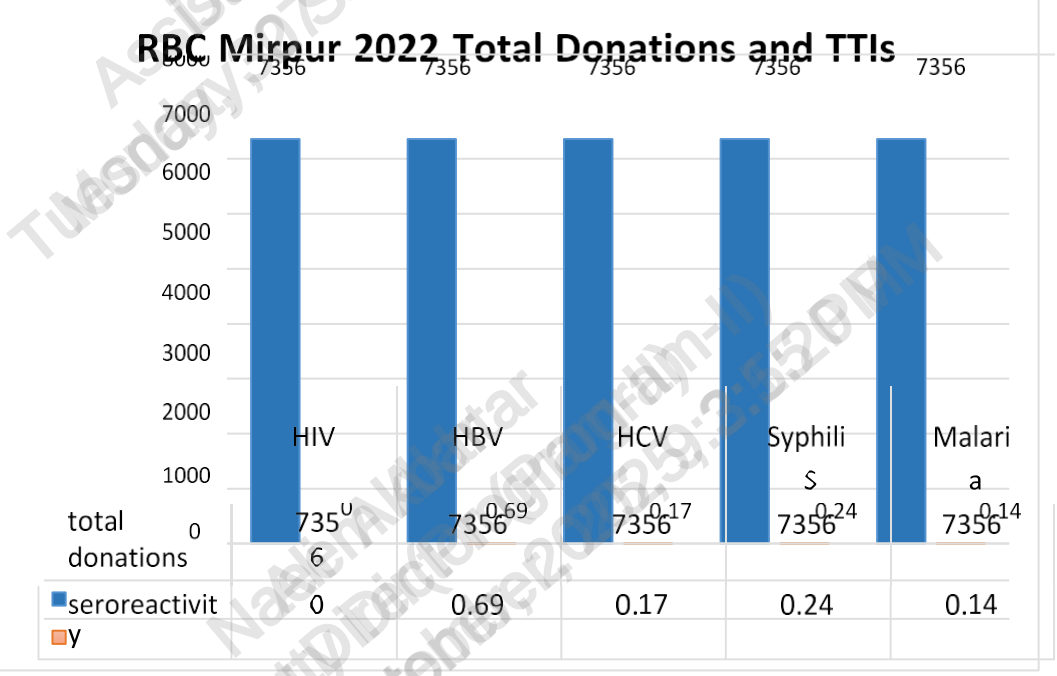


Fig # 26 Total Donations and TTI prevalence RBC Mirpur AJK

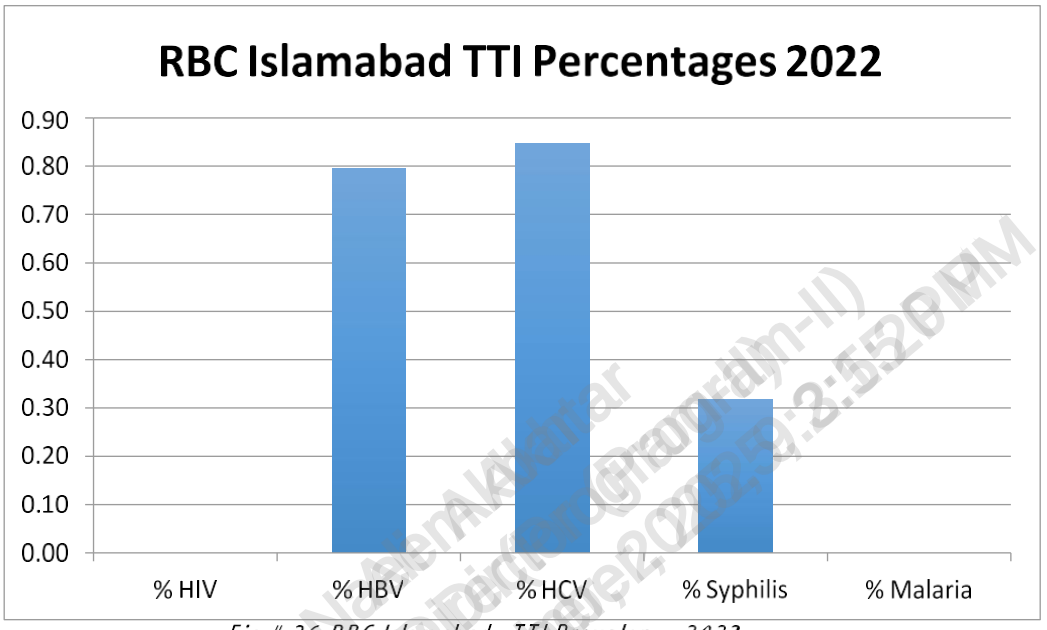


Fig # 26:RBC Islamabad TTI Prevalence 2022

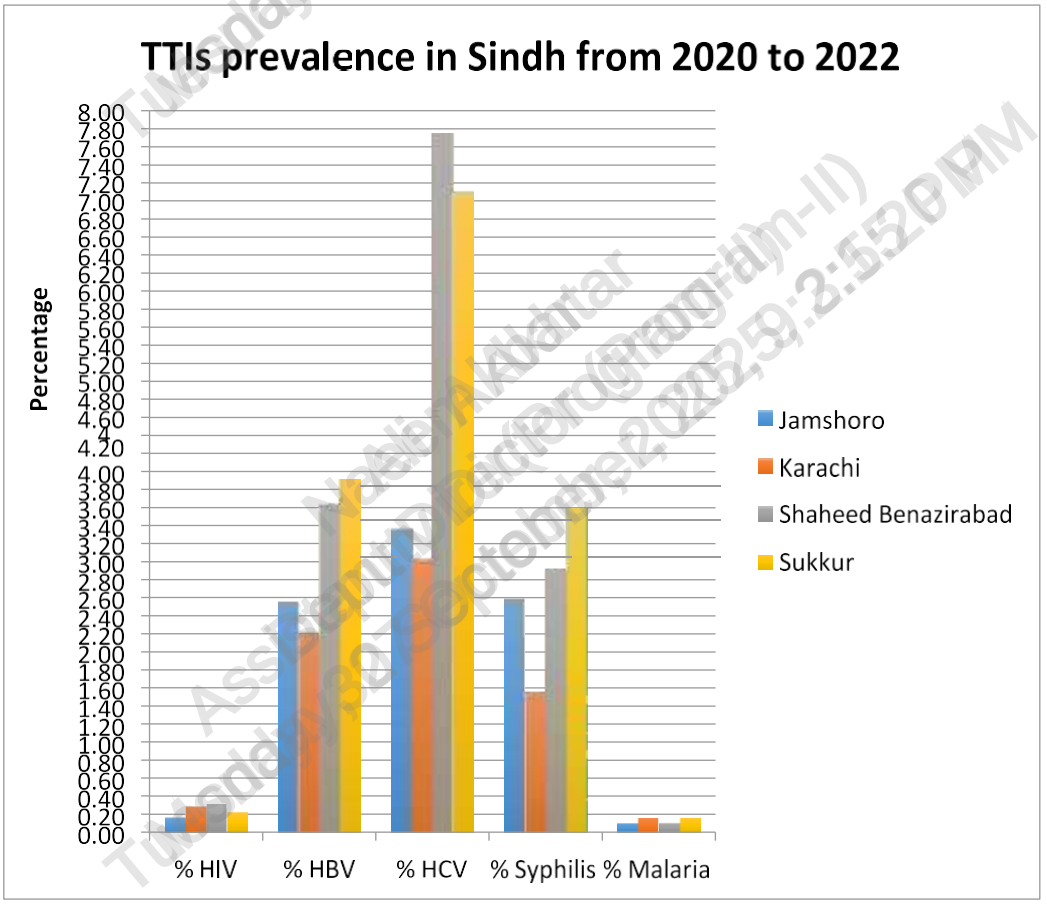


Fig # 27:TTIs prevalence in Sindh from 2020 to 2022

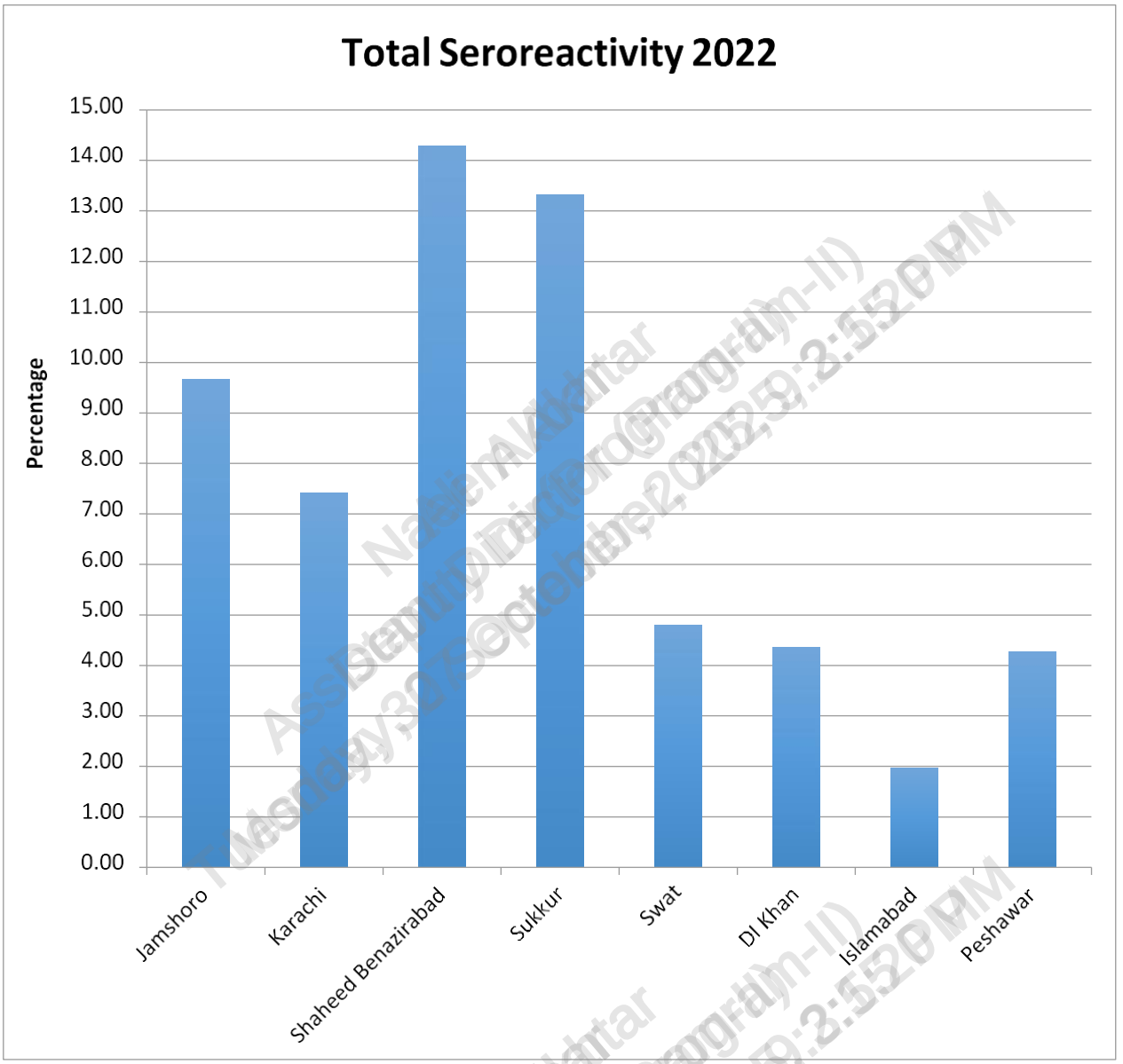


Fig # 28: Seroreactivity of TTIs at different RBCs of Country

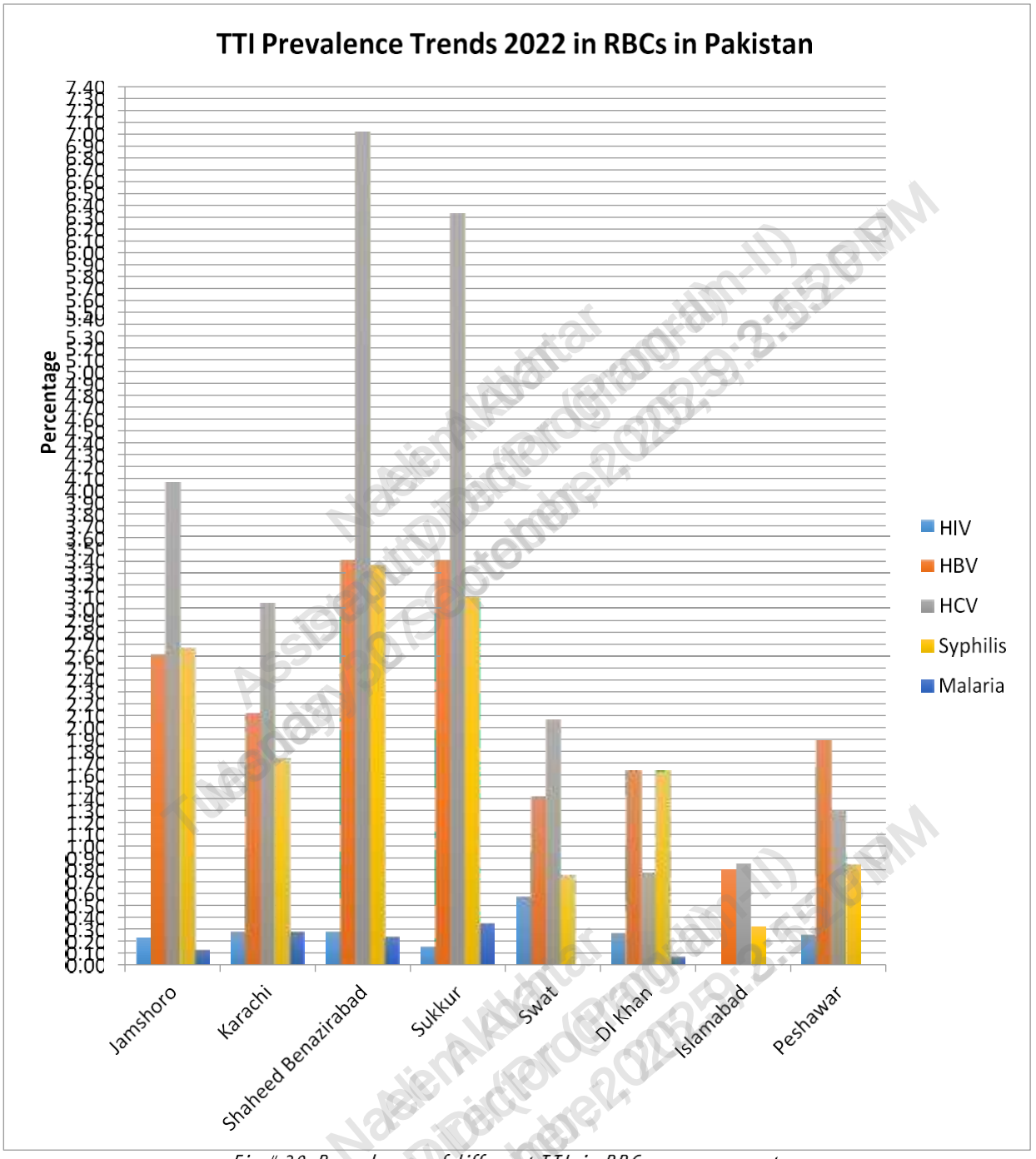


Fig # 29: Prevalence of different TTIs in RBCs across country

Annex-D

Federal Level KPIs

Governance and Coordination	
1. Cabinet approval of policy by Q3 2025 2. **SBTP Revitalization (2024)** • Revival of Safe Blood Transfusion Program and appointment of qualified experienced transfusion medicine specialist / FCPS hematologist as National Coordinator by Q4 2025 • Reactivation of SBTP website with all technical documents by Q4 2025 • Establishment of functional secretariat by Q4 2025 in MoNHSR&C 3. Budget allocation by tracking Federal endorsement and resource commitment monitoring by MoNHSR&C Q 4 2025 4. Establishment of Federal Blood Transfusion Programme Q1 2026 as per policy • IHRA will manage the blood transfusion services under administrative control of M/o NHSR&C • IBTA will be placed under administrative control of IHRA by 2025 5. Implementation of policy timelines and KPIs agreement by federal and provincial ministries, health departments and regulators by Q1 2026	. **National Technical Advisory Committee (NTAC)** • Formation and notification of NTAC by MoNHSR&C by Q4 2025 • Minimum 4 meetings annually from 2024-2030 • Development of standards, guidelines, instruction documents: by Q3 2026 • Guidelines for clinical transfusion by Q4 2026 • Criteria and models for operations/management for RBC Islamabad and effective role in developing hub and spoke model in all sectors by Q2 2026
3. **Regulatory Coordination** • Establishment of formal coordination mechanism between DRAP, Healthcare Commissions and Blood Transfusion Authorities by Q1 2026 • Development of unified regulatory inspection checklist by Q2 2026 • Development of Rules and complete regulatory framework duly published in Gazette by Islamabad Blood Transfusion Authority as part of IHRA. • Registration and licensing of every blood bank in all sectors and at all tiers, ensuring that hub and spoke model is implemented by Q4 2026.	4. **Data Management** • Implementation of national blood establishments, status/ donation/transfusion database by Q3 2026 by SBTP under MoHSR&C • Adoption of Standardized ISBT 128 compliant software and establishment of mechanism for facility identification and donation identification by Q4 2026. • Quarterly data reporting from all provinces achieved by Q4 2026 • Annual national blood system status report publication starting 2026 by MoHSR&C SBTP.
5. Regulatory Capacity • Development of Regulatory Framework by DRAP for registering, licensing Plasma Establishments, export of plasma as per the policy by Q4 2025 • Implementation of Regulatory framework to recovered plasma and source plasma, at Federal and Provincial level by Q1 2026. • Coordination for implementation of DRAP regulatory framework by Provincial Blood Transfusion Authorities, where applicable in coordination with NTAC, SBTP, DRAP. • Achievement of Global Bench Mark Tool Plus by I by Q3 2027	6. National TTI screening standards • Implementation in all sectors of Federal Areas by Q1 2027 • Advanced screening technology adoption (CLIA/ELISA) Q3 2028 • NAT testing capacity development in all sectors with in hub and spoke modal Q1 2030 • Rapid test elimination in appropriate facilities Q2 2030

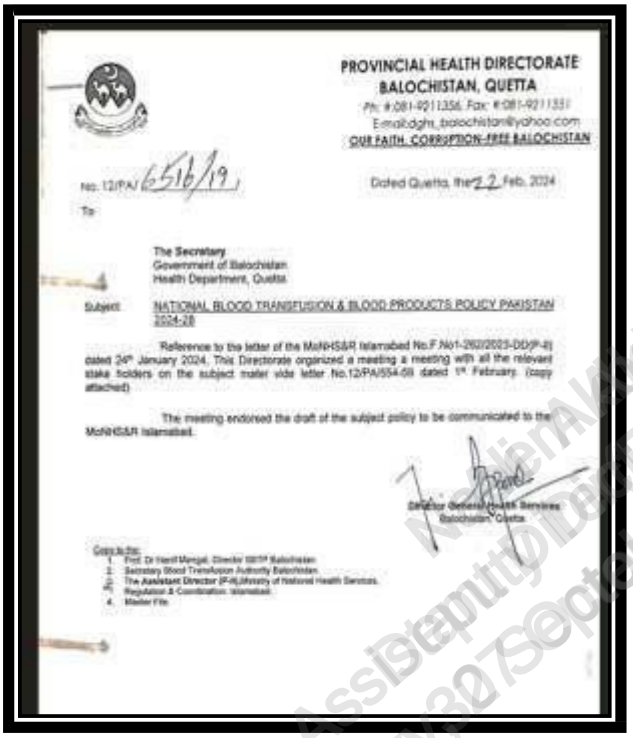
7.MoHSR&C and IHRA to establish Hub and Spoke model of blood transfusion services in Islamabad by operationalization of RBC Islamabad and linking HBB with RBC by Q4 2026 • Voluntary blood donation targets met each year • Complete Hub-spoke model implementation in all major hospitals in Islamabad Q1 2027 • Component preparation capability expansion Q4 2026	1. **International Collaboration** • WHO Collaborating Center at RBC Islamabad established by 2026 • Renewal/extension of German Development Bank partnership by 2026
Policy Implementation and Monitoring	
1. Implementation Progress • Quarterly progress review meetings with provinces and reports published on SBTP website • Annual implementation status report to federal cabinet • Mid-term policy review by 2028	**2. Emergency Preparedness** • National blood emergency response framework developed by Q4 2026 • Inter-provincial emergency blood sharing protocols established by Q2 2026
3. Quality Standards • National External Quality Assessment Scheme established by 2025 • Standard operating procedures for plasma collection for fractionation by Q4 2024	

Provincial Level KPIs

Organization and Management	
1. Blood Transfusion Services Structure (2025-2026) • Notification of revised PBTS structure • Appointment of qualified leadership • Establishment of operational management teams • Annual operational budgets secured	**2. Regional Blood Centers (RBCs)** • Minimum 80% functional capacity of existing RBCs by 2026 • Hub and spoke model implemented in all teaching hospitals by 2027
3. Role in NTAC • Nominate members for NTAC Q1 2026 • Develop provincial advisory committees Q1 2026 • Adopt standards and guidelines developed by NTAC	
4. Hospital Blood Banks (HBBs) • 100% registration with provincial BTAs by 2026 • 70% linked with RBCs and upgraded blood centers in all sectors in hub-spoke model by 2027 • Patient blood management program and Hospital Transfusion Committees functional in all teaching hospitals by 2026	
5. Thalassemia/Bleeding Disorders • Specialized center integration into national system Q2 2027 • Quality mandate compliance (triple bag collection) Q2 2028 • Service level agreements of Thalassemia Centers with other Blood establishment Q2 2026 for preventing wastage of platelets and plasma • Patient registry and treatment protocol development Q2 2027	
Quality and Safety	
1. TTI Screening (2024-2026) • CLIA/ELISA implementation in: • 100% of RBCs by 2026 • 80% teaching hospital blood banks by 2026 • 50% DHQ hospital blood banks by 2027 and 100% by 2028 • NAT testing initiated in at least 2 RBCs per province by 2028 and 100% by 2030	**2. Quality Management** • Quality managers appointed in all RBCs by 2026 • Standard operating procedures implemented in all RBCs by 2026 • Internal and external quality control program in 80% of blood establishments by 2027
3. Hemovigilance • Provincial hemovigilance committees established by 2026 • Reporting system functional in teaching hospitals by 2026 • Quarterly hemovigilance reports from all RBCs by 2026	
Blood Collection and Supply	
1. Voluntary Blood Donation • Increase VNRBD to: • 10% by 2026 • 20% by 2027 • 30% by 2028 • 40% by 2029 • 50% by 2030 • Registration of all blood donor organizations by 2026	**2. Component Preparation** • Component separation in: • 100% RBCs by 2025 • 70% teaching hospital blood banks by 2026 • Wastage reduction to less than 5% by 2027
3. Plasma Program • Recovery and storage of plasma in all RBCs by 2027 • Quality plasma collection system in 50% RBCs by 2026 • Contract fractionation arrangements initiated by provincial governments for recovered plasma 2027	
Regulatory Capacity Building	
1. All provincial blood transfusion regulatory authorities to develop Rules as per the standards and guidelines of NTAC and provincial advisory committees by Q2 2026.	

2. Application and Achievement of WHO Global Bench Mark Tool Plus maturity level 2 by 2027 and maturity level 4 by 2030.	
Training and Capacity Building	
1. Human Resource Development • Training needs assessment completed by Q4 2026 • Standard training modules developed by Q2 2027 • Training of: • 80% RBC staff by 2026 • 60% HBB staff by 2027	**2. Professional Development** • Certification program for blood bank staff initiated by 2027 • Degree programs in transfusion medicine started in at least one medical university per province by 2028
Monitoring and Evaluation	
1. Regular Assessments • Quarterly performance reviews of RBCs • Annual audit of blood establishments • Bi-annual review of implementation progress	**2. Reporting** • Quarterly data submission from all registered blood establishments • Quarterly provincial progress reports to SBTP • Annual provincial blood system status report

Annex – E



PROVINCIAL HEALTH DIRECTORATE
BALOCHISTAN, QUETTA
Ph: #081-9211356, Fax: #081-9211351
E-mail:dghi_balochistan@yahoo.com
OUR PATH, CORRUPTION-FREE BALOCHISTAN

No. 12/PA/ 6516/19 Dated Quetta, the 22 Feb, 2024

To

The Secretary
Government of Balochistan
Health Department, Quetta.

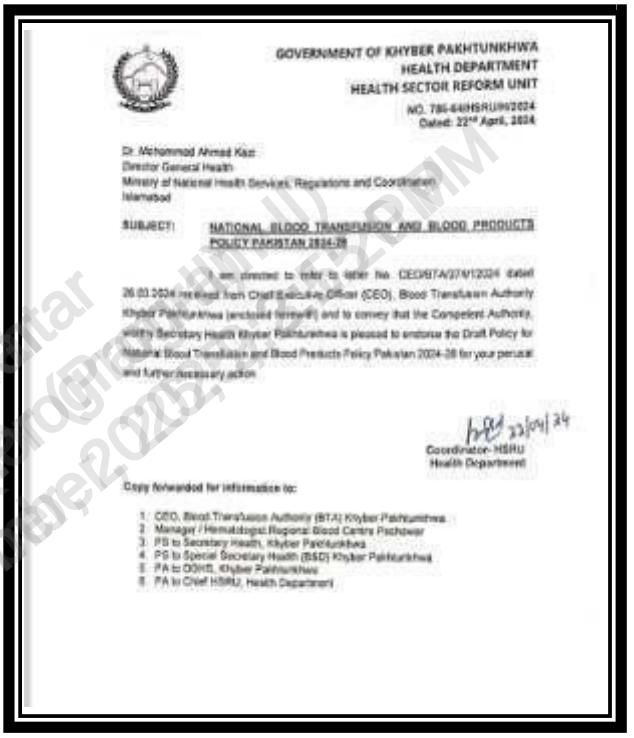
Subject: NATIONAL BLOOD TRANSFUSION & BLOOD PRODUCTS POLICY PAKISTAN 2024-28

Reference to the letter of the MoNHSR Islamabad No.F.No1-262/2023-DD(P-II) dated 24th January 2024. This Directorate organized a meeting a meeting with all the relevant stake holders on the subject matter vide letter No.12/PA/554-58 dated 1st February. (copy attached)

The meeting endorsed the draft of the subject policy to be communicated to the MoNHSR Islamabad.

Director General Health Services
Balochistan, Quetta

Copy to the:
1. Prof. Dr Hanif Mengal, Director SBTP Balochistan
2. Secretary Blood Transfusion Authority Balochistan
3. The Assistant Director (P-II),Ministry of National Health Services, Regulation & Coordination, Islamabad
4. Master File



GOVERNMENT OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT
HEALTH SECTOR REFORM UNIT

NO. 786-64/HSRU/NS/2024
Dated: 22nd April, 2024

Dr. Mohammad Ahmad Kasi
Director General Health
Ministry of National Health Services, Regulations and Coordination
Islamabad

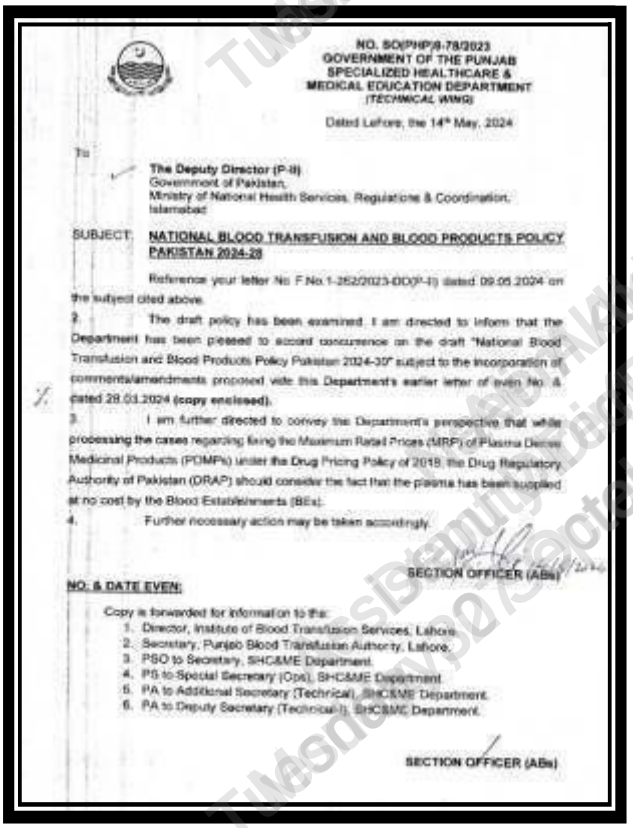
SUBJECT: NATIONAL BLOOD TRANSFUSION AND BLOOD PRODUCTS POLICY PAKISTAN 2024-28

I am directed to refer to letter No. CEO/BTA/374/1/2024 dated 26.03.2024 received from Chief Executive Officer (CEO), Blood Transfusion Authority Khyber Pakhtunkhwa (enclosed herewith) and to convey that the Competent Authority, worthy Secretary Health Khyber Pakhtunkhwa is pleased to endorse the Draft Policy for National Blood Transfusion and Blood Products Policy Pakistan 2024-28 for your perusal and further necessary action.

Coordinator- HSRU
Health Department

Copy forwarded for information to:

1. CEO, Blood Transfusion Authority (BTA) Khyber Pakhtunkhwa
2. Manager / Hematologist Regional Blood Centre Peshawar
3. PS to Secretary Health, Khyber Pakhtunkhwa
4. PS to Special Secretary Health (BSD) Khyber Pakhtunkhwa
5. PA to DD(HS), Khyber Pakhtunkhwa
6. PA to Chief HSRU, Health Department



NO. SO(PHP)/8-78/2023
GOVERNMENT OF THE PUNJAB
SPECIALIZED HEALTHCARE & MEDICAL EDUCATION DEPARTMENT
(TECHNICAL WING)

Dated Lahore, the 14th May, 2024

To

The Deputy Director (P-II)
Government of Pakistan,
Ministry of National Health Services, Regulations & Coordination,
Islamabad

SUBJECT: NATIONAL BLOOD TRANSFUSION AND BLOOD PRODUCTS POLICY PAKISTAN 2024-28

Reference your letter No. F.No.1-262/2023-DD(P-II) dated 09.05.2024 on the subject cited above.

2. The draft policy has been examined. I am directed to inform that the Department has been pleased to accord concurrence on the draft "National Blood Transfusion and Blood Products Policy Pakistan 2024-30" subject to the incorporation of comments/amendments proposed vide this Department's earlier letter of even No. & dated 28.03.2024 **(copy enclosed).**

3. I am further directed to convey the Department's perspective that while processing the cases regarding fixing the Maximum Retail Prices (MRP) of Plasma Derive Medicinal Products (PDMPs) under the Drug Pricing Policy of 2018, the Drug Regulatory Authority of Pakistan (DRAP) should consider the fact that the plasma has been supplied at no cost by the Blood Establishments (BEs).

4. Further necessary action may be taken accordingly.

SECTION OFFICER (ABs)

NO. & DATE EVEN:

Copy is forwarded for information to the:

1. Director, Institute of Blood Transfusion Services, Lahore.
2. Secretary, Punjab Blood Transfusion Authority, Lahore.
3. PSO to Secretary, SHC&ME Department.
4. PS to Special Secretary (Ops), SHC&ME Department.
5. PA to Additional Secretary (Technical), SHC&ME Department.
6. PA to Deputy Secretary (Technical-I), SHC&ME Department.

SECTION OFFICER (ABs)

PROVINCIAL SECRETARIAT
SINDH BLOOD TRANSFUSION AUTHORITY
DEPARTMENT OF HEALTH, GOVERNMENT OF SINDH
Import and Inspection Medical Store Depot (M.S Depot)
Rafiqi Shaheed Road, Near J.P.M.C Cantt, Karachi
(92-21) 35676411-35676412

No. SBTA/376/79 Dated 19/05/2024

To

The Directorate General,
Health Services Sindh,
Hyderabad.

Subject: National Blood Transfusion and blood products policy Pakistan 2024-2028.
Ref: letter No.DGHS/SG-II(STF)/4815/18 dated:31-01-2024

We firmly believe that a uniform and comprehensive National Blood Transfusion and Blood Products Policy is crucial for maintaining consistent standards and minimizing diversification across the country. Apart from blood and blood components, the importance of addressing Plasmapheresis and Plasma-derived medicinal products (PDMP's), is increasingly vital on a regional, national and international scale. Don't fail duly endorse the proposed policy and recognizes its significance in meeting the current and future healthcare needs at large scale.

However, we would like to express our opinion that keeping in view the provincial devolution after 18th amendment, the matters related to administrative issues like managing human resource, blood banks, Thalassemia, Hemophilia centers etc. should ideally be supervised by the specific provincial Blood Transfusion Authorities. This approach ensures a more nuanced and region-specific implementation of the said policy, taking into account the unique needs and challenges faced by each province.

We are committed to collaborating with all the relevant authorities and stakeholders to contribute to the successful implementation of the National Blood Transfusion and Blood Products Policy. We believe that a cooperative effort will strengthen the overall healthcare system in the country.

Dr. Dur-e- Naz Jamal
SECRETARY
Sindh Blood Transfusion Authority

Copy forwarded for information to:
- The Secretary to Government of Sindh Health Department Karachi
- The Director General (Health) Government of Pakistan (MoNHSR) of National Health Service Regulations and Coordination Islamabad
- The PS to Minister Health and Public Health Engineering Department & Government of Sindh Karachi
- Office Copy

Dr. Dur-e- Naz Jamal
SECRETARY
Sindh Blood Transfusion Authority

Core Committee & Contributors

Technical Advisory Team

- Director General Health Ministry of National Health Services, Regulations and Coordination. Chief Executive Officer (CEO) Islamabad Healthcare Regulatory Authority (IHRA)
- Prof. Dr. Hassan Zaheer, Advisor on Blood Products, World Health Organization (WHO). Professor Brig. (R) Nuzhat Mushahid TI(M)

Core Committee

- Dr. Syed Ahmad Raza Kazmi, Chief Executive Officer, Islamabad Healthcare Regulatory, Authority.
- Dr. Hassan Abbas Zaheer, Advisor on Blood Regulations, Availability and Safety, World Health Organization.
- Dr. Ismat Rubab, Deputy Director Inspection, Islamabad Healthcare Regulatory, Authority.
- Dr. Mona Aziz Gillani, Professor of Hematology, Sheikh Zayed Post-Graduate Medical Institute. Dr. Muhammad Athar, Principal Medical Officer, Institute of Blood Transfusion Services, Lahore Dr. Dur e Naz Jamal, Secretary, Blood Transfusion Authority, Sindh
- Dr. Jawad Habib, CEO, Blood Transfusion Authority, Khyber Pakhtunkhwa Dr. Hanif Mengal, Director, Safe Blood Transfusion Program, Baluchistan Dr. Abdul Latif, Provincial Program Manager, Gilgit Baltistan
- Dr. Farwa Sajjeel, Head of Blood Bank, Pakistan Institute of Medical Sciences, Islamabad. Dr. Aamna Latif, Senior Medical Officer, Regional Blood Center, Islamabad.

Consultants

- Professor Brig. (R) Nuzhat Mushahid TI(M), National Consultant.
- Dr Jasim Anwar, National Consultant.
- Dr Paul Strengers, International Consultant.

Coordinator

- Dr Nadeem Akhtar, Chief Executive Officer, Khyber Pakhtunkhwa Healthcare Commission.
- Dr. Ismat Rubab, Deputy Director Inspections, Islamabad Healthcare Regulatory Authority.

Contributors

- Dr Jawad Habib Khan, Chief Executive Officer, Khyber Pakhtunkhwa Blood Transfusion

Khyber Pakhtunkhwa

- Prof Dr Umar Farooq, Dean and Chief Executive Officer, Ayub Medical College, Abbottabad.
- Dr Shams Afridi, Program Director, Safe Blood Transfusion Program, Health Deptt, Khyber Pakhtunkhwa
- Mr. Tariq Khan, Senior Chief Health, Planning and Development Dept Khyber Pakhtunkhwa
- Mr. Rajwal Khan, Strategic Information Advisor, UNAIDS
- Prof. Shahtaj Khan, Professor of Hematology, Hayatabad Medical Complex
- Dr Huma Riaz, Asst Prof Hematology, Hayatabad Medical Complex
- Dr Noore Saba, Manager/Hematologist, Regional Blood Center Peshawar
- Dr Muhammad Kaleem Khan, Pathologist/Manager, District Headquarter Hospital Abbottabad Pakhtunkhwa
- Mr. Zār Muhammad Khan, Section Officer, Law Dept Khyber Pakhtunkhwa
- Mr. Muhammad Ali Khan, Assistant Director, Blood Transfusion Authority Khyber Pakhtunkhwa
- Mr. Usman Khan, Assistant Director, Blood Transfusion Authority Khyber Pakhtunkhwa

- Mr. Muhammad Khalid, Senior Technologist, Regional Blood Center Peshawar

Punjab

- Dr Shaukat Ali, Secretary, Punjab Blood Transfusion Authority
- Dr Shahid Amin, Additional Director, Punjab Health Care Commission
- Dr Muzamil Khan, Dy Secretary (Tech-II), Primary and Secondary Healthcare Department
- Prof Ahsan Waheed Rathore, Vice Chancellor, University of Health Sciences Lahore.
- Ms. Anum Shahzad, Planning Officer Primary and Secondary Healthcare, Planning and Development Board
- Mr. Anwar Sohail, Deputy Director, Law and Parliamentary Affairs Department
- Prof Shabnam Bashir, Professor of Pathology, Fatima Jinnah Medical University (Thalassemia Society of Pakistan)
- Dr. Mona Aziz Gillani, Professor of Hematology, Sheikh Zayed Post-Graduate Medical Institute
- Dr Muhammad Athar, Principal Medical Officer, Institute of Blood Transfusion Services
- Dr Sinaan Mustafa, Senior Blood Transfusion Officer, Institute of Blood Transfusion Services
- Dr Farhana Musheer, Medical Director, Fatimid Foundation Lahore Center
- Mr. Javed Iqbal Malik, Senior Economic Advisor, Industries Department
- Mr. Masood Fareed Malik, Founder and Advisor, Hemophilia Foundation of Pakistan
- Dr Hina Ghous, Blood Transfusion Officer, Institute of Blood Transfusion Services
- Dr Adnan Ahmad Khan, Blood Transfusion Officer, Institute of Blood Transfusion Services
- Dr Amir Salman, Project Coordinator, UPH Sinovac.
- Dr Muhammad Umer Sheikh, Blood Transfusion Officer, Mayo Hospital Lahore
- Dr A Sohail, Medical Officer, Hemophilia Foundation of Pakistan
- Dr Imran Shahid, Manager/Blood Transfusion Officer, Mayo Hospital
- Dr Muhammad Iqbal, Assistant Medical Superintendent, Lahore General Hospital.
- Dr Saira Qaiser, Blood Transfusion Officer, Institute of Blood Transfusion Services
- Dr Asma Hashmi, In charge Blood Bank, Sir Ganga Ram Hospital
- Mr. Aamir Adnan, Deputy Director, University of Health Sciences Lahore
- Ms. Javaria Khan, President, Thalassemia Society of Pakistan
- Ms. Yumna Athar, Post-Graduate Trainee, Sheikh Zayed Hospital Lahore
- Mr. Muhammad Nadeem, Office Superintendent, Punjab Blood Transfusion Authority
- Ms. Shaista Nazir, In charge of Thalassemia Centre, Institute of Blood Transfusion Services
- Mr. Muhammad Nadeem, Technician, Institute of Blood Transfusion Services
- Mr. Farzand Ali, Technologist, Sheikh Zayed Hospital Lahore.

Sindh

- Dr Dure Naz Jamal, Secretary, Blood Transfusion Authority, Sindh
- Dr Ahsan Qavi, Chief Executive Officer, Sindh Health Care Commission
- Dr Zainab Hasan, Deputy Director, Sindh Healthcare Commission
- Dr Arpna Nihal, Women Medical Officer, Sindh Blood Transfusion Authority
- Dr Shabneez Hussain, Head of Blood Transfusion Services, Indus Hospital and Health Network
- Prof Dr Naseem Ahmed, Head of the Department of Pathology, Dow University of Health Sciences

- Dr Naveed Noor, Assistant Professor, Agha Khan University
- Prof Hassan Abbas Zaheer, World Health Organization Advisor on Blood Safety
- Dr Saba Jamal, Senior Director, IHHN (Indus Hospital and Health Network)
- Dr Fahmida, Medical Officer, Jinnah Post-Graduate Medical Center.
- Dr Uzma Ata, Project Head, Regional Blood Center Dow University of Health Sciences
- Dr Ismail Memon, Vice President, Pakistan Medical Association
- Ms. Syeda Madiha Shah, Laboratory In charge, Regional Blood Center Karachi
- Dr Javeria, Asst Professor, Sindh Institute of Urology and Transplantation
- Dr Natasha Ali, Associate Professor, Agha Khan University
- Dr Samra Waleed, Consultant Hematologist, Regional Blood Center
- Ms. Sehrish Fatima, Blood Bank Manager, Patient Welfare Association Civil Blood Bank
- Ms. Saba Khan, Asst Professor, Jinnah Post-Graduate Medical Center
- Dr Ghulam Fatima, Chief Pathologist, Civil Hospital Karachi
- Dr Nida Anwar, Associate Professor, National Institute of Blood Diseases
- Dr Zainab Hasan, Deputy Director, Sindh Healthcare Commission
- Dr Agha Umer Daraz Khan, Chief Pathologist, Hussaini Blood Bank
- Dr Maria Ali, Asst Professor, National Institute of Cardiovascular Diseases
- Prof Saba Sohail, Meritorious Professor, Principal, Dow University of Health Sciences
- Dr Sarfraz Jafry, Vice President, Thalassemia Foundation Pakistan.

- Dr Shahid Shamim, Head of Post-Graduate Learning, Agha Khan University
- Ms. Nousheen Usman, Deputy Director (Admin), Sindh Higher Education Commission
- Ms. Sara Shaikh, Asst Director, Muhammadi Blood Bank
- Dr Ruhul Quddus, Consultant Hematologist, Fatimid Foundation
- Ms. Aqsa Ashfaq, Quality Assurance Supervisor, Fatimid Foundation

- Dr Muhammad Hasan, Senior Instructor, Agha Khan University Hospital.
- Muhammad Hamid, Blood Bank Technician, Sindh Blood Transfusion Authority
- Mr. Arif Khan, Asst Manager, Jinnah Post-Graduate Medical Center

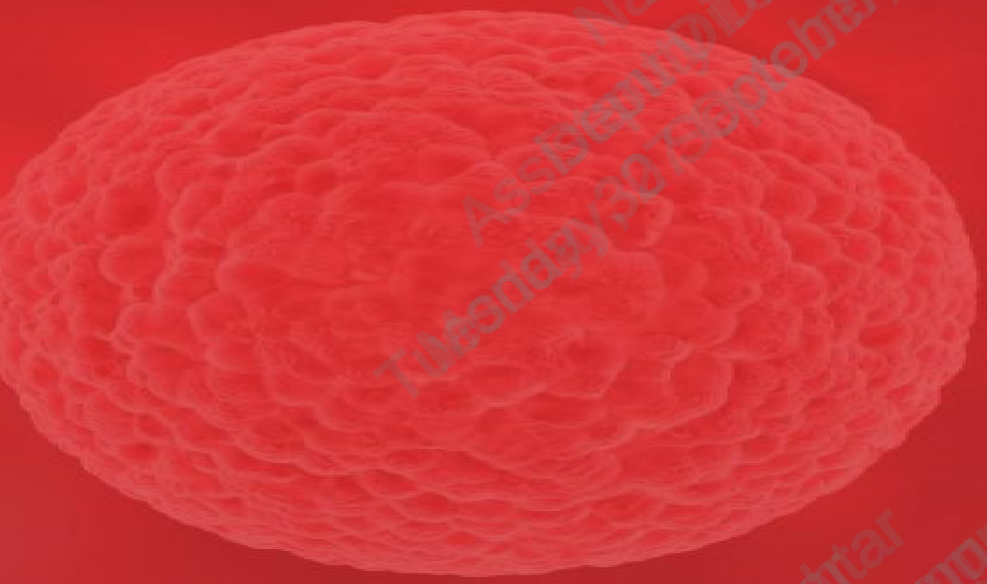
Balochistan

- Dr. Qazi Noor Muhammad, Director General, Health Department
- Dr Syed Yasir, Secretary, Balochistan Blood Transfusion Authority Balochistan
- Mr. Syed Naseer Shah, Additional Secretary, Law Department.
- Dr Muhammad Dawood Khan, Program Manager, Balochistan AIDS Control Program
- Prof Nadeem Samad, Chairman Department of Pathology, Bolan University of Medical and Health Sciences
- Haji Muhammad Akram, Director, Chamber of Commerce.
- Dr Fatima Zahra, Consultant Hematologist, Sheikh Muhammad Bin Zayed Al- Nahyan Institute of Cardiology
- Dr Shafi Muhammad, Manager Regional Blood Center, Bolan Medical Complex
- Mr. Aslam Nasir, Inspector, Balochistan Blood Transfusion Authority
- Dr Muhammad Jahanzeb, Medical Officer, Fatimid Foundation
- Ms. Nazli Naheed, Business Manager, Fatimid Foundation
- Col (R) Nuzhat, Med Director/Admin, Fatimid Foundation
- Dr Kamran ul Haq, Pathologist, Fatma Jinnah Chest Hospital Quetta
- Dr Qayyum Khan, Consultant Hematologist, Civil Hospital Quetta
- Mr. Abdul Hakeem, Technical Team Leader, Regional Blood Center Quetta
- Ms. Syeda Hira Shamsi, Laboratory Technologist, Regional Blood Center Quetta
- Mr. Mohsin Ali, Supervisor, Sheikh Muhammad Bin Zayed Al-Nahyan Institute of Cardiology

- Mr. Javed Iqbal Sheikh, Lab Technician, Benazir Bhutto Shaheed Hospital, Quetta
- Muhammad Anwar, President, Baloch Blood Bank
- Mr. Babar Ansar, Nursing Superintendent, Sandeman (P) Hospital Quetta
- Mr. Saleh Mohammad, Manager Pakhtunkhwa Blood Bank, Quetta.
- Ms. Ghazala, Member, Hemophilia Society of Pakistan
- Dr Amber Munir, Consultant Gynae and Obstetric, Bolan Medical College Hospital, Quetta

Name: Aleem Akhtar
Designation: Deputy Director (Program-II)
Tuesday, 30 September, 2025, 2:52:07 PM

National Blood Policy 2025-2030



Government of Pakistan
Ministry of National Health Services, Regulations and Coordination, Islamabad,
Web: www.nhsrc.gov.pk Email: contact@nhsrc.gov.pk

Ministry of National Health
Services Regulations & Coordination
GOVERNMENT OF PAKISTAN