Editorial

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Role of Regulations in Improving Quality of Blood Transfusion Services in Islamabad: Recent Developments and Future Strategies

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Blood transfusion services in a country ensure that quality blood and its products are easily available and accessible to the entire population and have all integral components in place, including donor management, processing, storage, screening for Transfusion Transmissible Infections (TTIs), and haemovigilance. These services are critical for patients undergoing surgeries, experiencing trauma, dealing with certain medical conditions, or requiring blood products for various treatments. This integral component of modern healthcare involves a series of interconnected processes to ensure the safe and efficient utilization of donated blood.

The World Health Organization (WHO) suggests that for blood-related procedures such as collection, testing, processing, storage, and distribution, it is advisable to have a well-coordinated national approach. This involves establishing efficient organization and integrated networks for the blood supply. To ensure consistent quality and safety of blood and its products, it is recommended to have a national blood policy and legislative framework governing the national blood system.[1]

Through a number of World Health Assembly (WHA) resolutions passed since 1975,[2] the World Health Organization's member states have vowed to support blood safety in their countries. For many developing countries, putting this promise into action is an enormous task. A significant barrier in this regard is frequently the lack of national policies, regulations, and inadequate healthcare service delivery systems. Without comprehensive legislation and its effective implementation, advances in access and quality of blood services will remain a demanding issue because the legal and regulatory framework is the basis of blood safety.

Ever since the establishment of National Blood Transfusion Programme in sub-continent in 1942 to meet World War II needs, blood transfusion services have been evolving through the amalgamation of laboratory technology and knowledge.[3] The first blood bank started operations in West Bengal while a provincial headquarter was established in Lahore in 1942.

Upon gaining independence in 1947, Pakistan assumed control of the organization situated in Lahore, preserving its original framework. In 1948, this organization was placed under the administrative jurisdiction of the West Pakistan Blood Transfusion Officer. The officer's primary duty was to optimize the infrastructure in order to cater to the needs of patients in need of blood transfusions. In a country undergoing the establishment of post-independence structures, the expansion of the blood transfusion system occurred swiftly, but without the guidance of national blood transfusion standards or adequate oversight from blood transfusion authorities. The foundation of the system relied heavily on "multifunctional" hospital blood banks, which were further supplemented by a growing number of private and non-governmental organization (NGO) sector blood banks.[4]

The blood transfusion system has largely remained demand driven and fragmented, composed of many small-scale blood banks, managed by multiple players and have different levels of performance due to resource and infrastructure limits. In 2019, Pakistan had a comprehensive network of 650 blood banks, encompassing public, private, and not-for-profit NGOs. Approximately 65% of these blood banks were equipped with blood component separation facility. The range of blood banks varied significantly, from smaller facilities collecting less than 500 units of blood annually to larger establishments collecting over 100,000 units per year. In 2019, the total number of blood donations collected were approximately 2.7 million units.[5] Among these donations, approximately 18% were obtained from voluntary non-remunerated blood donors, highlighting the low frequency of voluntary contributions in the country's blood supply.[5] Due to the uneven access to blood in the presence of largely insufficient regulation, exploitation of the patients and families occur and unsafe practices also transpire. In some cases, this involves pilferage of blood especially from the large public sector blood banks

In 2004, the Pakistan's National AIDS Control Programme (NACP) submitted a proposal to the Economic Affairs Division (EAD) within the framework of the Pakistan-German Government Cooperation. The proposal aimed to improve blood safety in Pakistan. In 2007, a joint mission consisting of representatives from NACP and the German Technical and Financial Development Cooperation conducted a feasibility study. The study concluded that it would be beneficial to transition from the existing fragmented system of public and private blood banks to a centralized system of blood collection and processing that aligns with the standards set by the World Health Organization (WHO).

The centralization of the blood transfusion system, especially testing and processing of blood donations, can overcome several deficiencies that often exist in a fragmented decentralized blood transfusion system. There are several advantages attributed to centralization such as optimization of resources, reduction in general costs, improved compliance with standards, enhanced patient access to the appropriate blood components, and increases resilience in disaster situations that affect national or regional blood supply and/or safety. Another key component of blood service centralization is the increased and good quality availability of plasma for fractionation purpose, for example as experienced in Iran.[6]

Despite notable advancements made in the past twenty years, disparities persist in the availability and accessibility of blood, primarily attributable to inadequate distribution of blood banks, insufficient infrastructure, suboptimal levels of voluntary blood donation, ineffective supply chain management systems, scarcity of operational equipment, inadequate training and competence among staff, deficient regulatory mechanisms, and insufficient coordination among institutions. In rural areas, certain blood banks operate with less skilled personnel and face overwhelming workloads, thereby impeding the efficiency and quality of blood transfusion services.

To ensure the highest standards of quality, safety and availability, robust regulatory framework is necessary. The effectiveness of blood transfusion services relies on the presence of legally authorized regulatory bodies, appropriate laws, regulations, policies and guidelines and above all the implementation of these laws and regulations. The regulatory bodies establish and enforce standards and guidelines for all aspects of blood transfusion, including donor selection and screening, laboratory testing, processing, storage of blood products, transfusion practices, adverse event reporting, and overall governance of blood establishments. By implementing and enforcing regulations, blood transfusion services can maintain high standards of safety, quality, and efficiency. These regulations safeguard the health and well-being of blood donors and recipients, promote public trust, and contribute to the overall effectiveness of transfusion medicine.

Every country, regardless of the economic development level, is trying to regulate the transfusion system through regulatory bodies.[7] A regulatory body may be a separate institution, under the health department (e.g. National Blood Authority in Australia), or integrated in a regulatory institution with a broader scope (e.g. Medicines and Healthcare Products Regulatory Agency in UK). Other examples of regulatory bodies include the Food and Drug Administration (FDA) in the United States, the European Blood Inspection System (EuBIS) in Europe, Health Sciences Authority (HSA) - Blood Services Group in Singapore, and the National Blood Transfusion Council (NBTC) in India.

In Pakistan, for nearly five decades, the key issue in the blood transfusion sector remained a lack of governance and regulatory setup. However, it changed since the system reforms were introduced through a collaboration

with the German Government to improve the blood services in the country.[8] Currently, the blood transfusion system in Pakistan is primarily regulated by the Blood Transfusion Authorities (BTA), which are established under the respective legislations promulgated in each province and federal capital by its legislative assemblies (Figure 1).

After 18th amendment to the constitution of Pakistan in 2011,[9] health has been devolved to the provinces, subsequently all blood transfusion services, regulation and implementation now fall under the control of each province. The multiplicity of the regulatory authorities as each province having its own legislation, leads to the lack of coordination, poor central monitoring, and inadequate standardized regulations. Subsequently, each province is at different stage of regulating its blood banks and improving quality of blood transfusion services. It is important to note that the Gilgit-Baltistan region (earlier called FANA) became a province in 2011 and currently does not have an approved blood safety legislation (proposed legislation is under discussion in the legislative assembly).

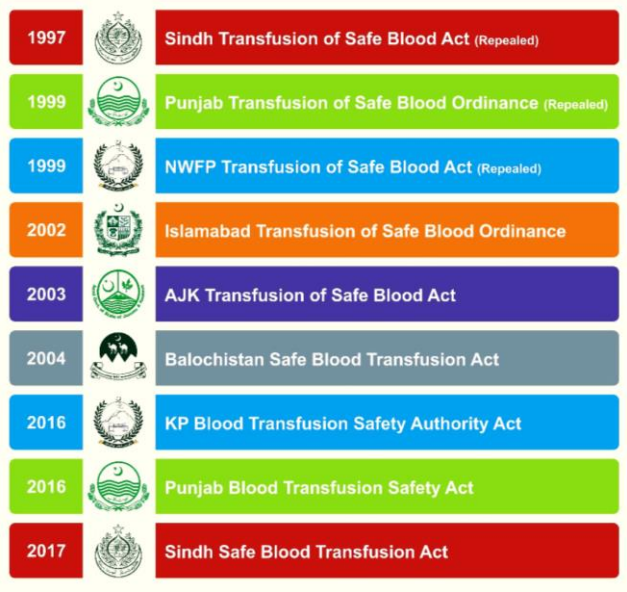

Figure 1: Legislative framework of blood transfusion services in Pakistan.

In the federal capital, Islamabad, the healthcare is relatively well developed compared to rest of the country.[10] The blood transfusions services are regulated by the Islamabad Blood Transfusion Authority (IBTA) functioning under the Islamabad Safe Blood Ordinance No. LXXIII, 2002,[11] and the Islamabad Transfusion of Safe Blood Rules, SRO 307(1), 2005.[12]

The salient features of the legislation include a comprehensive list of definitions and outlines the roles and responsibilities of the Blood Transfusion Authority. It also mentions the functions of the 'blood banks' most notably component preparation, blood grouping, cross matching, antibody screening and identification, implementation of SOPs, screening for five TTIs, and outlawing professional donors, among others. There are separate sections on penalty for contravention and biosafety measures.

The IBTA has over the years developed an ideal regulatory model for inspection of blood banks that has been emulated in the provinces as well.[13,14] Recently, the Ministry of National Health Services, Regulation & Coordination has designated Islamabad Healthcare Regulatory Authority (IHRA) as the focal point to reactivate the IBTA since it remained dormant for a few years. IHRA, an autonomous health regulatory body established by the Islamabad Health Regulation Act of 2018, is implementing evidence-based regulatory standards for the registration and licensing of healthcare establishments in the federal capital. In the blood transfusion arena, the IHRA has earlier led a successful national consultation to formulate a National Blood and Blood Products Policy 2023-2027.

IHRA, with an experienced team of inspectors, commenced the blood banks inspection in the second quarter of 2023. Despite limited resources, the IHRA has made impressive strides within a short timeframe. The IHRA's approach has been highly organized and methodical. The ongoing blood bank inspections have so far yielded noticeable results, with significant improvements being implemented in various aspects of blood bank operations. As a result, several quality measures have been integrated into the standard procedures of these blood banks. In response to these inspections, a few blood banks that previously had inadequate quality standards have chosen to close their operations due to the fear of potential closure. A structured inspection checklist, consisting of objective and standardized questions pertaining to blood banking operations, has been implemented to ensure impartiality. The blood banks showed an initial reluctance to get registered/inspected, however, advocacy and technical guidance ensured cooperation. A non-punitive and facilitatory approach has been adopted due to which trust and cooperation from inspected blood banks is secured. The blood banks are frequently contacting IHRA for guidance and advice.

As per Islamabad Safe Blood Ordinance No. LXXIII, 2002, all blood banks in the Islamabad Capital Territory are mandated to register with IBTA followed by implementation of the required standards as formulated by the Authority. This registration process will now be digitalized and all blood banks will be able to register online. The next step will be assessment of the blood banks against the developed standards and then awarding of licenses to successful blood banks.

The IHRA intends to introduce a rating system, such as the Stars classification, to assess and classify blood banks based on their performance. Recognizing the need for real-time data, the IHRA has planned to establish a system for generating and displaying up-to-date data on the website. Licensed blood banks will be provided with a designated link that enables them to regularly update their blood inventory status online via the official website. These measures collectively contribute to enhancing transparency, efficiency, and accountability within the blood transfusion fraternity.

Establishing suitable legislation, regulations, policies, and guidelines is of paramount importance to ensure the appropriate provision of blood transfusion services in terms of delivering quality assured and correct blood to the right patient, at the right time and location. These regulatory frameworks provide crucial strategic guidance for the comprehensive operation of blood services. However, it is essential for these regulations to be contextually relevant, feasible, and ultimately contribute to the improvement of patient services.[15]

In Islamabad, there is a pressing need for periodic reviews of existing law, regulations, guidelines, and standards pertaining to transfusion medicine. It is crucial to have an updated and revised version of legislation in place, taking into account the rapid advancements and technological progress in this field, as well as the growing complexity of systems and processes involved in transfusion medicine. A review of the existing legislation highlighted limitations including omission of haemovigilance, quality management, sector diversity, hospital interface, and functional separation.[8] Regular assessments and updates ensure that the regulatory framework aligns with current best practices, emerging technologies, and evolving requirements to maintain high standards of quality and safety in transfusion medicine.

It is important to note that while efforts are being made to improve the blood transfusion system, challenges such as ensuring an adequate and safe blood supply, promoting voluntary blood donation, and maintaining quality standards in all blood banks and transfusion centres still exist.

In order to enhance the provision of services and promote blood safety with consistent standards and guidelines that are in line with international best practices, the IHRA has outlined plans to revise blood transfusion standards and then organize a National Consultation on Blood Transfusion Regulations. This event will bring together national health leaders, the Ministry of Health, provincial Departments of Health, Provincial Blood Transfusion Authorities, and stakeholders from relevant non-governmental organizations and private sector establishments. The consultation aims to disseminate the accomplishments of the BTAs, coordination among BTAs and emphasize the crucial role of regulatory bodies in the field of blood transfusion. By raising awareness among policymakers, the objective is to encourage sustained commitment to strengthening the transfusion sector in the country and effectively implementing the government's reforms for blood safety systems.

Conclusion

Strong legislation, regulations, policies, and guidelines form the basis for a safe blood transfusion programme of a country ensuring universal access to quality assured blood to the population. Nonetheless, legislations and policies need to be amended and modified based on the technological advancement and changing needs of the nation. Thus, it is essential that a national legislative framework, and policies be developed which all provinces should either adapt or adopt through their respective forums. Considering the multifaceted implications of safe blood transfusion on public health, blood regulation and safety must be accorded top priority in the health reform agenda under the patronage of senior most national political leadership.

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