

Review Article

Comparative Analysis of Blood Safety Legislation in Pakistan: Evolution, Common Principles, Provincial Variations, Regulatory Gaps, and Future Directions

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Abstract

Blood safety legislation in Pakistan has evolved from a relatively narrow focus on the licensing and inspection of blood banks to a broader systems-based framework covering donor selection, collection, testing, processing, storage, distribution, issuance, clinical use, traceability, haemovigilance, and regulatory oversight. With the exception of Gilgit-Baltistan, all provinces or territories/states examined in this review have enacted specific legal instruments for the regulation of blood transfusion services. These include the Islamabad Transfusion of Safe Blood Ordinance, 2002 and the Islamabad Transfusion of Safe Blood Rules, 2005; the Azad Jammu and Kashmir Transfusion of Safe Blood Act, 2003; the Balochistan Safe Blood Transfusion Authority Act, 2004 and the Balochistan Safe Blood Transfusion Rules, 2005; the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016 together with the Khyber Pakhtunkhwa Blood Transfusion Safety Regulations, 2017 and the Khyber Pakhtunkhwa Blood Transfusion Authority (Appointment and Removal of Chief Executive Officer) Regulations, 2017; the Punjab Blood Transfusion Safety Act, 2016; and the Sindh Safe Blood Transfusion Act, 2017. The later statutes in Punjab, Sindh, and Khyber Pakhtunkhwa replaced earlier enactments, namely the Sindh Transfusion of Safe Blood Act, 1997, the Punjab Transfusion of Safe Blood Ordinance, 1999, and the Khyber Pakhtunkhwa Transfusion of Safe Blood Act, 1999, reflecting a shift from first-generation blood bank laws to second-generation transfusion systems laws. This manuscript provides a comparative legal analysis of these enactments, identifies common features and jurisdiction-specific innovations, and highlights legislative strengths and gaps. All laws share a core commitment to safe screened blood, licensing of blood establishments, and establishment of dedicated regulatory authorities. However, Punjab, Khyber Pakhtunkhwa, and Sindh have moved significantly further by incorporating traceability, haemovigilance, data protection, hospital transfusion committees, responsible person requirements, and stronger inspection and enforcement frameworks. Harmonization of standards across jurisdictions and enactment of legislation in Gilgit-Baltistan remain important priorities.

Key Words: Blood safety, Blood transfusion legislation, Pakistan, Haemovigilance, Traceability, Blood Transfusion Authority

Cite this article as: Waheed U, Umer M, Saba N, Wazeer A, Pasha SK, Ahmad M, Haleem A. Comparative Analysis of Blood Safety Legislation in Pakistan: Evolution, Common Principles, Provincial Variations, Regulatory Gaps, and Future Directions. J Soc Obstet Gynaecol Pak. 2026;16(3):273-279 DOI. 0.71104/jsogp.v16i3.1122



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Introduction

Safe blood transfusion is an essential component of a functioning health system and since 2013, the blood and blood products have been included in the WHO

Model List of Essential Medicines.¹ Effective regulation of blood and blood products is essential to ensure their recognition and management as essential medicines.

Authorship Contribution: ¹Idea conception, ^{1,2}Data collection, ³Literature review, ²Data collection, ³Conception of idea and interpretation, ^{1,3}Final approval and accountable for work, ^{1,4,5}Manuscript writing, ^{6,7}Data collection, ⁸Data analysis

Funding Source: none

Conflict of Interest: none

Received: June 25, 2026

Revised: Aug 12, 2026

Accepted Aug 16, 2026

This requires countries to establish a robust regulatory framework and a well-functioning blood transfusion authority (BTA) to oversee quality, safety, and availability.^{2,3}

Since the establishment of the first blood bank in Lahore, Pakistan in 1942 to meet the needs of World War II, blood transfusion services in the country have evolved through the integration of laboratory technology and scientific advancements.⁴ By 2019, Pakistan had a network of approximately 650 blood banks across the public, private, and not-for-profit sectors. These facilities range from small centres collecting fewer than 500 units annually to large institutions collecting over 100,000 units per year. In 2019, an estimated 2.7 million units of blood were collected nationwide, which has increased to approximately 3.4 million units in 2026. However, only about 18% of these donations were obtained from voluntary non-remunerated blood donors, highlighting a continued reliance on replacement donors and the need for strengthening voluntary donation systems.⁵

Despite significant progress since the 1990s, inequities in the availability and access to blood persist in Pakistan. These challenges stem from the uneven distribution of blood banks, inadequate infrastructure, suboptimal levels of voluntary blood donation, weak supply chain management systems, shortages of functional equipment, and a lack of competent and trained personnel. Additionally, ineffective regulatory mechanisms and poor coordination within and between institutions further exacerbate the situation. The establishment of blood banks in many geographic areas is often not guided by defined criteria or demand-based planning. Instead, blood transfusion services (BTS) in Pakistan tend to favor the development of facilities in urban centres or regions with a high prevalence of thalassaemia,^{6,7} driven in part by economic and operational incentives. This has resulted in an inequitable distribution of services, undermining the fundamental objective of ensuring equitable access to safe blood. Moreover, many facilities operate with limited skilled workforce and suboptimal workloads, which adversely affects both the efficiency and quality of blood transfusion services.

Appropriate laws, regulations, policies, and guidelines are essential for establishing a well-coordinated blood transfusion system (BTS) that ensures universal access to safe and high-quality transfusion services.^{8,9} These frameworks play a central role in shaping the

structure, governance, and performance of BTS.¹⁰ Given their critical importance, this article aims to review the evolution and current status of the legal and regulatory framework governing BTS in Pakistan, and to analyze the key issues, challenges, and opportunities for improvement.

Methodology

This narrative review article is based on an extensive review of the literature, including the constitution, laws, ordinances, court judgments, reports, policies, standards, guidelines, government gazette notifications, and peer-reviewed journal articles related to blood transfusion services (BTS) in Pakistan. A systematic literature search was conducted using PubMed, Web of Science, Scopus, and Google Scholar. In addition, general search engines were used to identify relevant grey literature and non-peer-reviewed documents. The search was limited to English-language publications. Relevant documents were selected through screening of titles and abstracts, with additional sources identified from the reference lists of included articles.

Evolution of Blood Safety Laws in Pakistan

In Pakistan, the legal regulation of blood transfusion services emerged in response to the risks of transfusion-transmissible infections, uneven blood banking practices, variable quality standards, and the need for oversight of both public and private sector blood establishments. The earliest laws were largely directed toward preventing unsafe transfusion by mandating screening, registration, licensing, and inspection of blood banks. Over time, however, the legal approach evolved towards regulation of the entire transfusion chain.

In 1995, the Federal Government of Pakistan issued the first national directive mandating the screening of all donated blood units for hepatitis B, hepatitis C, syphilis, and HIV. The directive followed the death from hepatitis of a family member of the Cabinet Secretary in 1994, reportedly following a blood transfusion. This was followed by the enactment of blood safety legislation by the country's constituent units in two distinct phases. The phase one or first-generation laws were promulgated from 1997-2004¹¹ while the second-generation laws from 2016-2017. The Sindh Transfusion of Safe Blood Act, 1997¹² is among the early legal instruments to provide a structured

regulatory model for blood safety in Sindh province. Similar first-generation models were subsequently adopted in Punjab as Punjab Transfusion of Safe Blood Ordinance, 1999;¹³ the North-West Frontier Province Transfusion of Safe Blood Act, 1999;¹⁴ the Islamabad Transfusion of Safe Blood Ordinance, 2002;^{15,16} the Azad Jammu and Kashmir Transfusion of Safe Blood Act, 2003;^{17,18} and the Balochistan Safe Blood Transfusion Authority Act, 2004.¹⁹ These laws primarily focused on licensing blood banks, defining safe blood in terms of screening against major infections, and creating statutory authorities for oversight.

The second phase of legal reform occurred through the German-funded blood transfusion project under the dynamic leadership of Prof. Cees Th. Smit Sibinga (Netherlands), Prof. Hasan Abbas Zaheer (Pakistan), Paul Kohorst (Germany) and Dr. Usman Waheed (Pakistan) along with Provincial Managers of the blood transfusion service.²⁰⁻²² These laws included Punjab Blood Transfusion Safety Act, 2016,²³ the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016,²⁴ and the Sindh Safe Blood Transfusion Act, 2017.²⁵ These newer laws moved beyond traditional blood bank regulation and introduced broader concepts such as blood centres, blood establishments, hospital blood banks, haemovigilance, documentation, traceability, data confidentiality, serious adverse event reporting, rational clinical use, and stronger institutional governance.

Importantly, the later statutes in Punjab, Sindh, and Khyber Pakhtunkhwa also replaced earlier legal frameworks. Punjab repealed the Punjab Transfusion of Safe Blood Ordinance, 1999. Sindh repealed the Sindh Transfusion of Safe Blood Act, 1997. Khyber Pakhtunkhwa repealed the NWFP Transfusion of Safe Blood Act, 1999, which historically represented the earlier North-West Frontier Province-era framework. This legislative progression illustrates a move from facility-based regulation to system-based governance. Table I shows the principal blood safety laws and implementing rules/regulations in Pakistan.

Common Legal Foundations

Despite differences in drafting style and sophistication, the blood safety laws in Pakistan share several foundational features. First, all laws require that blood or blood products transfused to patients must be safe and screened against major transfusion-transmissible infections, including HIV, hepatitis B, hepatitis C, malaria, and syphilis, with flexibility to add other

infectious agents by notification or regulation. Second, each framework creates a specialized blood transfusion authority responsible for regulation, licensing, inspections, and enforcement. Third, all frameworks prohibit operation of blood banks or blood establishments without registration and licensing by the relevant authority. Fourth, all laws recognize the importance of professional responsibility by assigning duties to physicians, blood bank in-charges, or other responsible personnel to ensure safe transfusion practice. Table II shows the comparative legal features across provinces and territories.

Comparative Analysis of Legislation by Major Themes

1. Scope of regulation

The first-generation laws are narrower in structure and focus mainly on blood banks as the principal regulated unit. Their core purpose is to prevent transfusion of unsafe blood and to require registration, screening, biosafety, and inspection. By contrast, the more recent laws in Punjab, Khyber Pakhtunkhwa, and Sindh regulate the entire transfusion chain. They explicitly cover collection, testing, processing, storage, distribution, issuance, and transfusion of human blood and blood components. Punjab further states that the Act applies to the full transfusion process but not to blood stem cells. This broader scope is a major advance because modern blood safety depends not only on pre-transfusion testing but also on handling, transport, storage, clinical use, and post-transfusion surveillance.

2. Institutional structures and authority composition

All jurisdictions establish a blood transfusion authority, but the degree of detail varies. The Islamabad and AJK laws use relatively open-ended language about technical experts and stakeholders. Balochistan provides a more defined administrative structure, including representation from the health department, academician from haematology, military services, and the private sector. Punjab adopts a more sophisticated governance architecture with a multi-stakeholder authority and separate Technical Committee, Licensing Board, and Appellate Committee. Khyber Pakhtunkhwa also has a strong institutional design, adding a Chief Executive Officer and inspectors, and later regulating the appointment and removal of the CEO through a separate 2017 instrument.²⁶ Sindh uses a hybrid model

that includes the Health Minister, elected representatives, senior health officials, a professor of haematology or pathology, a representative from the Aga Khan University Hospital blood transfusion service, and a representative of a regional blood centre outsourced under public-private partnership.

3. Registration, licensing, and inspection

Registration and licensing are universal requirements across all jurisdictions. The older frameworks in Islamabad and Balochistan are more classical in design: application, committee inquiry, annual licensing, renewal, inspection, and suspension or cancellation after hearing. The more recent regimes are more operationally detailed. Punjab strengthens the licensing framework by establishing a Licensing Board and an Appellate Committee. Sindh introduces the concept of a provisional license where the non-compliance is not critical and can be corrected within a specified time. Khyber Pakhtunkhwa has the strongest operational inspection regime among the reviewed laws, with explicit powers relating to sealing premises, imposing fines, confiscating equipment, putting establishments on probation, and preventing release of unsafe blood or blood components.

4. Blood banks, blood centres, and hospital blood banks

A major distinction between the older and newer laws lies in the regulatory unit. Early legislation primarily regulates blood banks in a general sense. The newer laws separate the system into functional entities such as blood centres, regional blood centres, blood establishments, and hospital blood banks. Punjab clearly distinguishes blood centres from hospital blood banks, assigning them different functions. Khyber Pakhtunkhwa gives statutory recognition to regional blood centres, reflecting a more coordinated and component-oriented blood service model. Sindh also adopts a modern multi-tiered structure, including blood centres, blood establishments, and hospital blood banks. This differentiation is significant because it aligns the law with current transfusion service practice.

5. Traceability, haemovigilance, and adverse event reporting

This is perhaps the clearest dividing line between first-generation and second-generation legislation. The earlier laws require screening and inspection but do not provide a fully developed statutory framework for traceability and haemovigilance. In contrast, Punjab,

Khyber Pakhtunkhwa, and Sindh expressly define traceability and serious adverse events or reactions. Punjab and Sindh define haemovigilance, while Khyber Pakhtunkhwa goes further by giving haemovigilance its own specific statutory section. These laws also require notification of serious adverse events and reactions to the authority.

6. Data protection, confidentiality, and responsible persons

Punjab, Khyber Pakhtunkhwa, and Sindh include more modern provisions relating to donor data security, anonymity, confidentiality, and controlled disclosure while preserving traceability. Sindh expressly requires data protection safeguards and procedures to prevent unauthorized disclosure while guaranteeing traceability. Khyber Pakhtunkhwa and Sindh also embody the idea of a designated or responsible person who is accountable for compliance with the legal framework. These provisions are largely absent or less developed in the earlier laws and reflect a more mature understanding of regulatory accountability.

7. Rational clinical use and hospital transfusion committees

Another notable advance in the newer legislation is recognition that blood safety is not only a blood bank issue but also a hospital governance issue. Khyber Pakhtunkhwa requires physicians and relevant staff to ensure rational clinical use of blood and blood components through hospital transfusion committees and to document hospital-level transfusion processes. Punjab similarly requires rational and optimal use in compliance with modern good clinical practices. Sindh also addresses the administration and traceability of blood and recognizes the need for structured oversight and awareness mechanisms.

8. Donor policy and voluntary donation

All jurisdictions support the principle of safe, non-commercial donation, though the newer laws articulate it more clearly. Punjab expressly states that blood donation shall be voluntary, anonymous, and non-remunerated, that transfusion is a not-for-profit health sector activity, and that self-sufficiency in blood and blood components should be a governmental priority. Khyber Pakhtunkhwa defines donor in voluntary and non-remunerated terms, while Sindh also defines donor as a person who donates by free will and without compensation, in line with the international standards and WHO recommendations.

Table I: Existing blood safety laws in Pakistan.

Jurisdiction	Current legal instrument	Implementing rules / regulations	Earlier law replaced
Islamabad Capital Territory	Islamabad Transfusion of Safe Blood Ordinance, 2002	Islamabad Transfusion of Safe Blood Rules, 2005	None
Azad Jammu and Kashmir	Azad Jammu and Kashmir Transfusion of Safe Blood Act, 2003	None	None
Balochistan	Balochistan Safe Blood Transfusion Authority Act, 2004	Balochistan Safe Blood Transfusion Rules, 2005	None
Khyber Pakhtunkhwa	Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016	Khyber Pakhtunkhwa Blood Transfusion Safety Regulations, 2017; Khyber Pakhtunkhwa Blood Transfusion Authority (Appointment and Removal of Chief Executive Officer) Regulations, 2017	Khyber Pakhtunkhwa Transfusion of Safe Blood Act, 1999
Punjab	Punjab Blood Transfusion Safety Act, 2016	None	Punjab Transfusion of Safe Blood Ordinance, 1999
Sindh	Sindh Safe Blood Transfusion Act, 2017	None	Sindh Transfusion of Safe Blood Act, 1997

Scope of Legislation in Patient Safety and Preventive Programs

An important consideration is whether the existing legislative framework extends beyond the regulation of blood collection, testing, processing, and distribution to adequately support the surveillance and prevention of adverse transfusion outcomes. Modern blood safety systems require effective mechanisms for the recognition, investigation, reporting, and monitoring of transfusion reactions and transfusion-transmitted infections, preferably through an integrated haemovigilance system. The reviewed legislation demonstrates variable coverage of these areas, with more recent laws generally providing a broader framework for haemovigilance, traceability, and reporting than earlier legislation.

The relationship between blood safety legislation and broader preventive programs also warrants consideration. Carrier screening, genetic counselling, and molecular diagnostic services, particularly for inherited blood disorders such as thalassaemia, can reduce the future burden of transfusion-dependent disorders and consequently the demand for repeated transfusions. Although these services may fall primarily within broader public health and genetic-disease prevention policies rather than blood transfusion legislation itself, stronger coordination between blood safety regulation and such preventive programs could contribute to a more comprehensive national blood system.

Discussion

Globally, blood safety legislation has evolved from the basic regulation of blood banks and mandatory screening for transfusion-transmissible infections toward comprehensive regulatory systems covering the entire blood transfusion chain.^{27,28} Contemporary frameworks increasingly emphasize voluntary non-remunerated blood donation, quality management, traceability, haemovigilance, donor and recipient protection, and rational clinical use of blood.^{29,30} Pakistan's legislative evolution broadly reflects this global transition, although the pace and extent of regulatory modernization have varied considerably across its jurisdictions.

This article demonstrated that Pakistan's blood safety legislation has followed a clear trajectory of legal modernization. The earlier laws were pioneering for their time because they established the principle that transfusion safety must be regulated by statute. They introduced mandatory screening, registration, licensing, and state oversight at a time when blood banking was often fragmented and loosely controlled. Islamabad, Azad Jammu and Kashmir, and Balochistan still reflect this foundational regulatory phase.

However, the newer legislation in Punjab, Khyber Pakhtunkhwa, and Sindh is more sophisticated and more consistent with modern blood transfusion governance. These laws no longer view transfusion safety simply as a matter of testing blood for infections. Instead, they regulate the blood chain from donor to recipient and back again through traceability, confidentiality, documentation, haemovigilance, quality

Table II: Comparative legal features across jurisdictions.

Feature	Islamabad 2002	AJK 2003	Balochistan 2004	KP 2016	Punjab 2016	Sindh 2017
Dedicated statutory authority	Yes	Yes	Yes	Yes	Yes	Yes
Registration and licensing mandatory	Yes	Yes	Yes	Yes	Yes	Yes
Primary focus on blood banks only	Mostly yes	Mostly yes	Mostly yes	No	No	No
Recognizes blood centres / regional blood centres	No	No	No	Yes	Yes	Yes
Hospital blood bank specifically addressed	Limited	Limited	Limited	Yes	Yes	Yes
Traceability expressly defined	No	No	No	Yes	Yes	Yes
Haemovigilance explicitly defined	No	No	No	Yes	Yes	Yes
Data protection/confidentiality framework	Limited	Limited	Limited	Yes	Yes	Yes
Hospital transfusion committees	Not central	Not central	Not central	Yes	Yes	Yes
Responsible/designated person concept	Limited	Limited	Limited	Yes	Yes	Yes
Detailed inspectorate powers	Basic	Basic	Basic	Strong	Moderate	Strong
Provisional licensing	No	No	No	No	No	Yes

systems, designated responsibility, and stronger inspection frameworks.³¹

Among the three newer statutes, Punjab stands out for its policy formulation, committee structure, and articulation of principles such as self-sufficiency and non-remunerated donation. Khyber Pakhtunkhwa stands out for operational detail, statutory recognition of regional blood centres, inspectorate powers, and separate CEO regulations. Sindh stands out for integrating a public-private partnership regional blood centre model, adding provisional licensing, and clearly linking traceability to transfusion, manufacturing, or disposal.

Nevertheless, several challenges remain. The laws are not fully harmonized across Pakistan. Terminology differs. Regulatory structures differ. Enforcement tools differ. The degree of attention to haemovigilance and hospital transfusion governance varies. Gilgit-Baltistan still lacks a dedicated blood safety statute, leaving an important territorial gap in the national legal framework.

Recommendations

Governance and regulatory accountability are critical to translating blood safety legislation into effective practice. Regular regulatory audits and inspections, consistent enforcement of prescribed standards, transparent licensing processes, and clearly defined responsibilities of national and provincial authorities are essential for ensuring compliance across both public and private sector blood establishments. Strengthening these mechanisms would also help reduce variations in implementation between jurisdictions and promote greater consistency in blood safety standards across the country.

First, a model framework or harmonized legal template should be developed so that all provinces, territories,

and states use consistent definitions for blood establishment, blood centre, hospital blood bank, serious adverse event, serious adverse reaction, traceability, and haemovigilance. Second, the earlier laws in Islamabad, Azad Jammu and Kashmir, and Balochistan should be reviewed and updated in light of the advances already embodied in Punjab, Khyber Pakhtunkhwa, and Sindh. In particular, these jurisdictions would benefit from explicit provisions on traceability, haemovigilance, data protection, responsible person requirements, and hospital transfusion committees. Third, Gilgit-Baltistan should enact a dedicated blood safety law so that all regions of Pakistan are covered by a formal statutory framework. Fourth, all jurisdictions should adopt uniform minimum standards for licensing, inspection, documentation, adverse event reporting, donor deferral, record retention, and clinical transfusion governance. Finally, implementation capacity should be strengthened through trained inspectors, digital traceability systems, haemovigilance reporting platforms, and regular publication of compliance and performance reports.

Conclusion

Pakistan's blood safety legislation has evolved from an earlier blood bank control model to a more comprehensive transfusion systems model. Islamabad, Azad Jammu and Kashmir, and Balochistan represent the first-generation legal architecture built around safe blood, licensing, and institutional oversight. Punjab, Khyber Pakhtunkhwa, and Sindh represent a more advanced legislative phase that incorporates traceability, haemovigilance, confidentiality, clinical governance, and stronger enforcement. The repeal of the earlier Punjab, Sindh, and Khyber Pakhtunkhwa laws by the newer statutes clearly illustrates this transition. The overall direction is positive and

encouraging. Pakistan now possesses a substantial legal foundation for blood supply and safety. The next step is to ensure legal harmonization, stronger implementation, and complete territorial coverage so that safe blood becomes not only a legal requirement but a consistent health system reality, for expanded voluntary blood donation, universal quality-assured screening, and stricter regulation of blood banks throughout the country.

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