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Research Article

**International Soft Law and Safe Blood Transfusion Systems: WHO Standards
and National Implementation**

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Abstract

Introduction: The article explores how international soft law has developed national blood transfusion safety systems by utilizing the normative frameworks of the World Health Organization (WHO). Although there is currently no binding treaty for blood safety in place globally, the WHO has developed a multi-layered governance pathway that creates norms through various forms of documentation, including: World Health Assembly (WHA) Resolutions; Strategic Action Plans; Technical Guidelines; and Benchmarking Mechanisms.

Method: Using legal doctrinal analysis, norm-diffusion theory, and regulatory-governance analysis, and drawing on comparative case studies of China, India, and Bangladesh, this article examines how non-binding WHO standards shape domestic blood legislation, institutional design, and regulatory practice.

Results or Findings: The study finds that there is a significant degree of normative convergence around 5 core principles including: (1) Voluntary and Non-remunerated Blood Donation; (2) Universal Testing for Infection; (3) Centralized Blood System Governance; (4) Hemovigilance; and (5) Quality Management Systems. However, due to issues such as structural inequality, fragmentation of institutions and limited resources, the implementation of these principles has been uneven.

Discussion or Conclusion: The study concludes by stating that the WHO utilizes its authority through an epistemic form of legitimacy, technical expertise, benchmarking and norm entrepreneurship and does not rely on coercion to enforce compliance. By framing blood governance as a hybrid model of transnational administrative regulation, this study advances the scholarship on global health law and regulatory governance and highlights the efficacy of soft law as a form of de facto regulation in highly technical environments.

Keywords: international soft law, global health governance, blood regulation, World Health Organization, voluntary blood donation

JEL Codes: K32, K33, K38

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Araştırma Makalesi

**Uluslararası Yumuşak Hukuk ve Güvenli Kan Transfüzyon Sistemleri: DSÖ
Standartları ve Ulusal Uygulama**

ASM Mahmudul Hasan^a

Öz

Giriş: Bu makale, uluslararası yumuşak hukukun, Dünya Sağlık Örgütü'nün (DSÖ) normatif çerçeveleri aracılığıyla ulusal kan transfüzyonu güvenliği sistemlerinin gelişimine nasıl katkıda bulunduğunu incelemektedir. Küresel ölçekte kan güvenliğine ilişkin bağlayıcı bir uluslararası antlaşma bulunmaması birlikte, DSÖ; Dünya Sağlık Asamblesi (WHA) kararları, stratejik eylem planları, teknik kılavuzlar ve karşılaştırmalı değerlendirme (benchmarking) mekanizmaları gibi çeşitli belge türleri aracılığıyla normlar üreten çok katmanlı bir yönetim mekanizması geliştirmiştir.

Yöntem: Hukuki doktrinal analiz, norm yayılımı teorisi ve düzenleyici yönetim yaklaşımından yararlanan bu çalışma, Çin, Hindistan ve Bangladeş örnek olayları üzerinden, bağlayıcı olmayan DSÖ standartlarının ulusal kan mevzuatını, kurumsal tasarımı ve düzenleyici uygulamayı nasıl şekillendirdiğini incelemektedir.

Sonuçlar ya da Bulgular: Araştırma, beş temel ilke etrafında önemli ölçüde bir normatif yakınsama bulunduğunu ortaya koymaktadır. Bu ilkeler: (1) gönüllü ve karşılıksız kan bağıışı, (2) enfeksiyonlara yönelik evrensel tarama, (3) merkezi kan sistemi yönetimi, (4) hemovijilans ve (5) kalite yönetim sistemleridir. Bununla birlikte, yapısal eşitsizlikler, kurumsal parçalanma ve sınırlı kaynaklar gibi faktörler nedeniyle bu ilkelerin uygulanması ülkeler arasında eşit düzeyde gerçekleşmemiştir.

Tartışma ya da Yapılan Çıkarımlar: Çalışma, DSÖ'nün uyumu sağlamak için zorlayıcı araçlara dayanmak yerine epistemik meşruiyet, teknik uzmanlık, karşılaştırmalı değerlendirme ve norm girişimciliği yoluyla otoritesini kullandığını ortaya koymaktadır. Kan yönetişimini ulusötesi idari düzenlemenin hibrit bir modeli olarak kavramsallaştıran bu çalışma, küresel sağlık hukuku ve düzenleyici yönetim literatürüne katkı sunmakta ve yüksek derecede teknik alanlarda yumuşak hukukun fiili bir düzenleme aracı olarak etkinliğini vurgulamaktadır.

Anahtar Kelimeler: uluslararası yumuşak hukuk, küresel sağlık yönetişimi, kan düzenlemesi, Dünya Sağlık Örgütü, gönüllü kan bağıışı

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Introduction

Blood transfusions must be made in a safe, effective manner; this is a critical component of our present healthcare system. Millions of people rely on transfusion and/or blood products each year for different medical needs (e.g., trauma or major surgery, obstetric complications, blood disorders, pediatric anemia). There are many issues regarding the way human blood is managed within systems of government. Even with improvements in technology for testing and influencing methods associated with blood transfusions, there are different types of government policies regarding blood transfusions across the world. In some places, blood transfusions are happening through the use of national systems using highly centralized and quality-assured methods; however, there are places that do not operate a comprehensive and coordinated system and instead rely on poorly designed laws, insufficient testing, and reliance on paid or family donors.

Furthermore, there are two questions that arise when discussing blood transfusion systems: firstly, do international laws such as the WHO shape how blood transfusion systems are operated throughout the world; secondly, how does international law affect national blood transfusion systems even when there is no written agreement allowing for the agreement to be enforced within the jurisdiction?

This article examines the role of international soft law in regulating the way each country and territory have developed and operated their blood transfusion systems. The analysis will focus on whether and how the WHO has established normative standards related to blood transfusion systems. Finally, the analysis compares and contrasts the normative values created through medical practice in blood transfusion systems and the normative values created through international law that regulate blood transfusion systems.

This article argues that WHO blood safety standards operate as a form of de facto regulatory governance, even though they are not legally binding as treaty obligations. Their influence arises through technical expertise, epistemic authority, benchmarking, institutional templates, and domestic legal internalization. The article therefore does not merely describe WHO standards; it explains how non-binding international norms are translated into national legislation, administrative practice, and professional standards, and why this process produces uneven outcomes across different institutional contexts.

Global Significance of Safe Blood Transfusion and The Governance Problem

The global significance of safe blood transfusion is both epidemiological and structural. According to the WHO (2025), approximately 118.5 million blood donations are collected annually worldwide, yet 40% of these donations occur in high-income countries that account for only 16% of the global population. Donation rates per 1,000 population vary dramatically: 31.5 in high-income countries compared with 5.0 in low-income countries (WHO, 2025). These disparities illustrate persistent global inequities in access to safe blood.

The risks associated with unsafe transfusion are well documented. Transfusion-transmissible infections (TTIs) such as HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) remain central concerns. In low-income countries, HIV prevalence among blood donors is reported at 0.70%, compared with 0.002% in high-income countries; HBV prevalence is 2.81% versus 0.02%, and HCV prevalence 1.00% versus 0.007% (WHO, 2025). These differences reflect disparities in donor selection systems, screening technology, and regulatory oversight.

Beyond infectious risk, blood availability is closely linked to maternal mortality and pediatric survival. WHO's global consultations have emphasized that severe postpartum hemorrhage is a leading cause of maternal death, particularly in sub-Saharan Africa (WHO, 2008). Safe blood transfusion is one of the essential emergency obstetric interventions required to reduce maternal mortality and achieve global development targets. Accordingly, WHO has integrated blood safety into broader global health strategies, linking it to United Nations Sustainable Development Goal (UN-SDGs) 3 on ensuring healthy lives and promoting well-being (WHO, 2025).

The intersection between blood safety and global health security has been well documented over the last decade and has been highlighted by the emergence of new pathogens, such as HIV and SARS-CoV-2. These new infectious agents illustrate not just the vulnerability of transfusion systems to emerging infectious threats (WHO, 2008) but also that national blood systems provide both clinical services and epidemiological surveillance. Weak transfusion systems pose a significant risk to countries and constitute an international threat. In summary, this information establishes that safe blood transfusions are a global public health priority, health inequity, and a threat to global security.

Despite its global importance, blood transfusion governance remains fragmented and uneven. WHO data indicate that while 73% of reporting countries have a national blood policy, only 66% possess specific blood legislation; among low-income countries, this figure drops to 39% (WHO, 2025). The absence of binding legal frameworks often results in decentralized and inconsistent regulatory oversight.

Fragmentation can occur in various ways. Blood services in low and middle-income countries are typically provided through hospitals and do not have a cohesive nationwide coordination structure, resulting in inconsistent screening policies, as well as lost opportunities for economies of scale (WHO, 2021). The 2021 WHO *Guidance on Centralization of Blood Donation Testing and Processing* outline how small, decentralized blood centers will have difficulty adopting more technologically advanced testing methodologies, such as nucleic acid test (NAT) procedures, as well as comprehensive Quality Management Systems (QMS). (WHO, 2021).

Conversely, centralized countries (e.g., the United Kingdom) have a more comprehensive and integrated system of regulation, including licensure, inspection, hemovigilance, and traceability processes that support the effective operation of their blood transfusion services (Joint United Kingdom Blood Transfusion Services/National Institute for Biological Standards and Control (Joint UKBTS/NIBSC), 2005)

The international governance issues associated with blood transfusion also derive from how this area of regulation operates on an international level. Although WHO standards are trustworthy in that they are established by international consensus, they are not put forth as legally binding in the form of a treaty. For example, WHA resolution WHA58.13 (WHO, 2005). encourages Member States to promote the use of voluntary non-remunerated blood donation (VNRBD) and to eliminate the practice of paid blood donation through legislation where appropriate (WHO, 2005).

Therefore, while WHO guidelines are the basis for the establishing of national blood systems, ultimately, the implementation of these policies will depend on whether countries have political will and the capacity to put these requirements into effect domestically. These relative advantages of blood transfusions in decentralized versus centralized systems highlight that blood transfusions are subject to the international soft law separate from hard law; they are the outcome of normative frameworks that do not include formal coercive powers yet impose normative obligations to shape the behavior of countries offering blood transfusion services.

Research Questions and Methodology

Existing scholarship on blood transfusion has developed primarily within clinical medicine, epidemiology, transfusion science, and public health. This literature has examined transfusion-transmissible infections, donor selection, screening technologies, voluntary blood donation, patient safety, and national service-delivery problems. For example, recent work on India's blood transfusion system identifies legal, regulatory, licensing, quality-control, voluntary-donation, and access-related challenges, but it remains mainly focused on domestic regulatory reform rather than the international legal status of WHO standards (Mammen et al., 2021). WHO's global blood safety and availability reports also provide extensive empirical data on donation rates, testing, processing, hemovigilance, and national blood policies, but these documents are primarily technical and institutional rather than theoretical legal analyses (WHO, 2025).

The Global status report on blood safety and availability is particularly relevant because it provides systematic evidence on national blood policies, donation systems, testing coverage, processing capacity, and haemovigilance, thereby supplying the empirical foundation for assessing the implementation of WHO standards (WHO, 2022).

Global health law scholarship has examined WHO lawmaking, global health governance, soft law, health security, and international health regulation more broadly. Recent scholarship emphasizes that WHO has historically functioned as a normative agency and that soft law remains central to global health law because it allows flexible standard-setting in technically complex and politically sensitive areas (Sekalala & Masud, 2021; Gostin et al., 2024). However, this literature has paid limited attention to blood transfusion safety as a specialized field in which WHO resolutions, guidance documents, benchmarking tools, and technical standards produce practical regulatory effects without treaty enforcement.

This article fills that gap by conceptualizing WHO blood safety standards as international soft-law instruments that operate through norm diffusion, epistemic authority, benchmarking, institutional modelling, and domestic legal internalization. Its contribution is therefore twofold: first, it situates safe blood transfusion within global health law and regulatory governance scholarship; second, it explains why WHO soft law produces significant but uneven convergence in national blood transfusion systems.

The research questions that this article will address are as follows:

1. In what ways does the WHO exert normative authority through mechanisms other than legally binding power? This question seeks to identify the means by which WHO-developed standards (e.g., resolutions, guidance documents, and policy frameworks) guide the implementation of blood governance at the national level without using formal coercive measures.

2. What kind of influence do soft law instruments have on the development of national blood transfusion systems? The focus here will be on empirical outcomes including adoption of the principles of VNRBD; legislative reform; centralization; quality management systems; and the use of hemovigilance (WHO, 2005).
3. What accounts for the differences observed in the implementation of these policies by nation-states? The purpose of this comparative analysis is to identify the structural, economic, institutional, and political factors affecting compliance rates across jurisdictions.

This research uses an integrated doctrinal-comparative methodology supported by normative institutional analysis. First, the doctrinal analysis examines WHO resolutions, technical guidance documents, strategic action frameworks, and benchmarking instruments in order to identify the normative content of WHO blood safety standards. Particular attention is given to voluntary non-remunerated blood donation, universal testing for transfusion-transmissible infections, centralized blood system governance, hemovigilance, and quality management systems.

Second, the article applies normative institutional analysis to examine how these non-binding WHO standards are translated into domestic legal and administrative systems. This approach is appropriate because the study is concerned not only with the formal legal status of WHO instruments, but also with their practical regulatory effects on national legislation, institutional design, professional standards, and compliance behaviour.

Third, the article uses a comparative case-study design focusing on China, India, and Bangladesh. These cases are selected because they are all exposed to WHO blood safety norms but differ significantly in regulatory capacity, administrative structure, resource availability, and enforcement conditions. China represents a case of strong state-led internalization following a public health crisis; India represents partial internalization within a fragmented and federal regulatory structure; and Bangladesh illustrates the gap between legislative adoption and practical enforcement in a resource-constrained setting. This “most different systems” logic allows the article to explain why similar WHO norms produce different domestic outcomes.

Theoretical and Analytical Framework: Soft Law, Regulatory Governance, and Norm Diffusion

To comprehend the unique role of the WHO in the regulation of safe blood transfusions, it is essential to clearly define and situate the concept of international soft law within the framework of global health governance. There is no single comprehensive international treaty regime governing blood transfusions. Instead, there exist numerous resolutions adopted by the WHA, technical guidelines, frameworks for action, ethical codes, and various types of policy instruments. While no individual instrument has any formal binding force, collectively they impact the legislation of individual states, shape the institutional structure of the health system, and establish the professional standards that govern the profession of medicine and other healthcare disciplines across multiple jurisdictions. This section will establish a theoretical foundation for analyzing how the various forms of soft law from WHO create a transnational regulatory framework for global blood governance, drawing insights from legalization theory, theoretical work on the diffusion of normative ideas through constructivism, the theory of transnational legal process, and a body of scholarly work on regulatory governance. This

section will provide an analytical model to understand how soft law created by WHO serves as a global regulatory mechanism for governing blood.

This article connects WHO blood safety standards with five related bodies of literature: global health governance, transnational regulatory governance, global administrative law, compliance theory, and norm diffusion. Global health governance operates in a fragmented institutional environment where WHO often exercises influence through coordination, expertise, standard-setting, and policy guidance rather than direct legal command, a dynamic reflected in contemporary scholarship on global health law and soft law governance. Transnational regulatory governance explains how standards may influence domestic regulation without formal coercion. Slaughter's account of transgovernmental networks is useful here because blood governance depends not only on WHO as an international organization but also on interaction among domestic regulators, ministries of health, professional bodies, laboratories, and international expert networks (Slaughter, 2004). Global administrative law helps clarify how international bodies perform administrative functions such as standard-setting, benchmarking, reporting, and technical assessment. From a global administrative law perspective, WHO's blood safety instruments may be understood as transnational administrative practices because they perform standard-setting, monitoring, reporting, and accountability-related functions beyond the domestic state (Kingsbury et al., 2005). Compliance theory explains why states may follow non-binding standards through reputation, expertise, peer comparison, and institutional incentives. Norm diffusion theory explains how international norms become internalized through repeated interaction, professional acceptance, and domestic legal incorporation. This process is consistent with norm life-cycle theory, according to which norms emerge, spread through persuasion and socialization, and eventually become internalized as accepted standards of appropriate conduct (Finnemore & Sikkink, 1998).

International soft law includes norms, principles, declarations, guidelines, and standards that do not create legally binding obligations under international law but can still have a significant influence over the behavior of states (Hasan, 2025). Soft law is fundamentally different to treaties, which create binding obligations through the process of consent or ratification; soft law instruments rely primarily on persuasive power, legitimacy and technical authority, and reputational pressures to operate.

The influential "legalization" theory by Abbott and Snidal (2000) views international law as a three-dimensional construct comprised of obligation, precision, and delegation; hard law has high levels of each of these dimensions (binding obligations, clear rules, and delegation of power to other entities to interpret and enforce the law), while soft law has limited levels of two dimensions (e.g. high precision but low obligation) or only one dimension (e.g. high delegation without binding enforcement). The flexibility of soft law allows states to coordinate policy in politically sensitive or technically complex areas without the need to adopt rigid legal commitments.

An example of this phenomenon is the governance of blood transfusion. WHO's technical guidance on VNRBD, quality management systems, and centralized testing may have been expressed very precisely from an operational perspective (WHO, 2021) but are not legally binding obligations as set out in treaties.

Shelton (2000) and Chinkin (1989) argue that soft law is becoming increasingly important in international governance, especially in cases where rapid scientific advancements

and political sensitivity make binding agreements unfeasible. Soft law serves multiple roles: as a precursor to hard law, as an adjunct to existing law, as a platform for coordination in very technical areas of governance, and as a means to develop norms and gradually harmonize practices.

Blood governance fits nicely within this framework. There are no Global Blood Conventions in existence; rather, blood governance develops through WHA resolutions (e.g. WHA58.13), regional frameworks, and technical guidelines that gradually create expectations for national blood systems (WHO, 2005). As a result, blood governance operates in a soft law environment, characterized by low levels of formal legal obligations and high levels of technical precision.

The WHO Constitution grants the Organization authority to act as the “directing and coordinating authority on international health work” (WHO, 2009, Article 2). While WHO possesses limited treaty-making power under Articles 19 and 21, it has historically relied far more heavily on non-binding instruments such as recommendations, technical guidelines, model legislation, and action frameworks (WHO, 2009).

In the field of blood transfusion, WHO has developed a layered normative architecture:

- • WHA resolutions WHA28.72 (WHO, 1975) and WHA58.13 (WHO, 2005)
- Action Framework to Advance Universal Access to Safe, Effective, and Quality-Assured Blood Products
- Technical guidance on centralization (WHO, 2021)
- Fact sheets with global benchmarking data (WHO, 2025)
- Regional publications such as *Blood Transfusion: A Basic Text* (WHO Regional Office for the Eastern Mediterranean (WHO EMRO), 1994)

WHA58.13 urges Member States to promote VNRBD and eliminate paid donation systems (WHO, 2005). While not legally binding, such resolutions carry substantial political legitimacy because they are adopted by consensus or majority vote of Member States.

WHO guidance documents further translate these political commitments into operational standards. The 2021 *Guidance on Centralization of Blood Donation Testing and Processing* provides detailed institutional blueprints for restructuring national blood systems, including QMS implementation, regulatory oversight, and economies of scale (WHO, 2021). Despite its non-binding nature, it functions as a de facto regulatory template.

WHO also acts as a norm entrepreneur. Through technical expertise, epidemiological data (WHO Global Database on Blood Safety), and global benchmarking reports, WHO frames voluntary donation as both ethically superior and epidemiologically safer (WHO, 2025). By linking blood safety to SDG 3 and maternal mortality reduction, WHO situates transfusion governance within broader global development commitments.

Thus, soft law in global health operates through: Political endorsement (WHA resolutions), Technical standard-setting, Data-driven benchmarking, Ethical framing, Institutional modeling. Blood transfusion governance offers a paradigmatic example of this mechanism.

In order to understand how WHO's non-binding norms influence a country's legal system; it is important to examine the broader concept of diffusion and conformity with regard to the international normative system.

Constructivist scholarship argues that state behaviour is shaped not only by material interests or coercion, but also by socialization, persuasion, identity formation, and the internalization of shared norms (Finnemore & Sikkink, 1998). The process of internalizing acceptance of the non-binding norm of VNRBD is an example of this. From 2008 to 2018, there was a rise in voluntary donations by 10.7 million globally (WHO, 2025). This trend illustrates that states were slowly accepting WHO's ethical justification for voluntary non-remunerated blood donations.

Koh (1996) formulated a theory on the transnational legal process. This theory purports that after repeated interaction, interpretation and, incorporation into the domestic legal system, international norms become customary law. In this respect, the WHO guidelines that are cited in domestic policy documents and referenced in judgments (for example, informed consent lawsuits) will be relied upon to provide guidance and incorporated into the licensing process for the blood transfusion industry. This ongoing process is how soft law ultimately acquires a quasi-binding effect.

Regulatory governance theory illustrates the changing nature of regulation from a hierarchical command-and-control type of regulation to a governance model that incorporates multiple stakeholders who participate in regulating their industries. In the blood transfusion industry, different actors engaged in the regulatory process include Ministries of Health, National Regulatory Authority, Professional Associations, International Organizations (e.g., WHO/ISBT), and Donor Communities. Within this networked governance model, the WHO is recognized as a standard-setter rather than as a regulator.

An additional way to understand how this process occurs is through an epistemic community. According to Haas (1992), epistemic communities are networks of professionals that have been collectively recognized as having the same level of expertise and who share common normative beliefs (e.g., transfusion medicine specialists, laboratory scientists, and public health experts). Consequently, when the WHO issues guidance on blood transfusion practices, it typically reflects the consensus of this expert network. Because the guidance from WHO is epistemically legitimate based on the agreement of the experts who form the epistemic community from which it draws, this has significant implications for compliance with soft law.

There is therefore a conceptual basis on which to attribute influence to soft law, even though it is non-binding in nature; that is, compliance with soft law is attributable to: 1) professional consensus, 2) reputational incentives, 3) peer comparison; 4) conditionalities applied to donor funding; and 5) capacity building partnerships.

The article's analytical model is based on the proposition that WHO soft law influences national blood transfusion systems through six connected mechanisms. First, WHO exercises technical authority by producing evidence-based guidance on blood donation, screening, quality management, and centralization. Second, it exercises epistemic authority because its standards are grounded in expert consensus and global public health knowledge. Third, it uses institutional templates by providing models for national blood services, regulatory authorities, hemovigilance systems, and quality management structures. Fourth, it uses benchmarking through the Global Database on Blood Safety (GDBS) and global fact sheets, which allow states to compare their performance with other jurisdictions. Fifth, WHO operates as a norm

entrepreneur by framing VNRBD and quality-assured screening as ethical and public health obligations. Sixth, these norms become effective when they are internalized into domestic law, administrative rules, professional standards, and institutional practice.

This model allows the article to evaluate not only whether states formally accept WHO standards, but also how deeply those standards are incorporated into national governance. The depth of internalization may be assessed through five indicators: formal policy endorsement, legal codification, institutional restructuring, technological modernization, and accountability mechanisms such as hemovigilance or liability rules.

WHO's Soft Law Architecture for Safe Blood Transfusion

In terms of global health governance, the WHO has created one of the most comprehensive and the longest-lasting examples of a "soft law" framework in relation to blood transfusion. Although blood safety is not governed by a universal legal instrument such as an international treaty, the WHO has built a layered set of legal norms through its constitutional base, WHO Assembly (WHA) resolutions, global strategic plans, technical guidance and benchmarks to create an overall governance structure for shaping national safe blood transfusion policies, regardless of the legal or institutional framework

In this section, it will be explored that the constitutional basis for WHO's authority, the main soft law instruments used by WHO, the normative content of WHO's blood safety agenda, and the regulatory mechanisms through which WHO has attempted to encourage compliance with this agenda.

WHO Constitutional Mandate

The authority of WHO to establish global blood governance stems from its Constitution, especially Article 2, whereby it has the role as the "directing and coordinating" agency for all international health issues. Some of these roles include proposing conventions and regulations, making recommendations to its Member States, establishing and updating international standards, providing technical assistance and responding to requests for assistance from governments. (WHO, 2009).

While WHO does not often utilize its treaty-making power as defined by Articles 19 and 21, it does regularly utilize its recommendation authority as set forth in Articles 23 and 62. Although non-binding, all WHO recommendations have a large amount of both political and technical authority because WHO is the UN's specialized agency for health. (WHO, 2009)..

An example of WHO's normative leadership function is in regard to the governance of blood transfusions. Starting with such regional publications as Blood transfusion: A basic text (WHO EMRO, 1994) and culminating with global strategies, WHO has always framed the responsibility for the safety of blood transfusions as being part of the public health system requiring a national strategy, quality control, and the ethical recruitment of donors.

This early regional WHO text is important because it already framed blood transfusion as a system-wide public health responsibility involving organization, quality assurance, donor recruitment, regulatory control, and culturally legitimate public education rather than merely a clinical or laboratory activity (WHO EMRO, 1994)

WHO's leadership function is supported by their ability to collect data. WHO uses the GDDBS to collate standardized data on donation rates, screening coverage, hemovigilance

systems and legislative systems (WHO, 2025). This function of surveillance improves WHO's epistemic authority and places WHO as the primary knowledge broker in the governance of blood at a global level.

Thus, the constitutional mandate of WHO serves as the foundation of WHO's soft law architecture; thus, directing and coordinating not through coercion, but rather through normative standards, technical advisory assistance and political endorsement.

Core Soft Law Instruments

The World Health Organization's (WHO) approach to promoting safe blood transfusions includes various interlinked legal and policy documents that work at many levels of regulation.

WHA resolutions offer Member States political agreement and support for blood safety priorities. WHA Resolution 58.13 (WHO,2005) states that VNRBD is the most important way of ensuring that there are safe and adequate supplies of blood in all countries and therefore calls for the removal of donated blood systems where donors receive payment (WHO,2005). Although these resolutions are politically binding on WHO and the Member States, they show a consensus on political commitment and the agreement on international principles.

There were also earlier WHA resolutions to establish a blood service in each country with WHA Resolution 28.72 (WHO,1975) laying the foundation for developing the national blood services. Since then, WHA has continued to make resolutions and has created a framework for developing global blood governance based on voluntary blood donations, quality screening and rational use of blood.

The 2008 WHO report on Universal Access to Safe Blood Transfusion describes a detailed plan for providing all countries with sufficient and safe supplies of blood (WHO 2008), consisting of five components: i) Coordinated blood transfusion services at the national level; ii) Blood collected from voluntary non-remunerated donors only; iii) All donated blood is screened to ensure its quality; iv) Clinical use is rational; v) A quality system exists for the complete blood transfusion system. Thus, the report provides the framework for implementing the global commitment to blood safety by identifying ways to reduce maternal mortality and the incidence of HIV as well as contributing to achieving the Millennium Development Goals (MDGs). The report also includes indicators that can be used to evaluate progress towards the goals, providing a basis for performance-based governance.

The 2008 report is therefore not merely a descriptive policy document; it functions as a strategic soft law instrument by consolidating WHO's core principles into an operational framework for national blood systems.

WHO has produced specific action frameworks to further implement their strategic objectives related to providing universal access to safe, effective, quality blood products, including timelines, performance indicators, and priority activities that aid in ensuring accuracy—a primary dimension of legalization theories (Abbott & Snidal, 2000). Strategic documents emphasize capacity building, integration of national policies, and strengthening of regulatory frameworks to convert aspirational norms into formal, structured pathways for implementation.

The 2021 Guidance Document on Centralizing Blood Testing and Processing is one of WHO's most in-depth technical documents (WHO, 2021).

It highlights the risk posed by structural fragmentation and advocates for consolidating blood testing and processing to realize economies of scale, improve QMS, and create stronger regulatory oversight.

The guidance frames centralization not just as an administrative change to operations but rather as a necessary safety measure. It provides operational steps, risk assessments, regulatory requirements, and monitoring mechanisms for the centralization process. While the document does not have the force of law, it serves as a quasi-regulatory reference material.

The 2025 WHO Fact Sheet on Blood Safety & Availability includes current global statistical data indicating continued disparity in blood donation rates; legislative systems covering blood donation; and hemovigilance worldwide (WHO, 2025). By publicizing the benchmarking data, the WHO maintains transparency and enhances peer accountability. All of these documents form a complete soft-law framework incorporating political endorsement, strategic planning, technical precision, and empirical benchmarking.

Across its resolutions, action frameworks, technical guidance, and benchmarking documents, WHO's blood safety agenda can be summarized around five core principles. First, blood systems should be based on VNRBD rather than paid or commercially driven donation. Second, all donated blood should be screened through quality-assured testing for major transfusion-transmissible infections. Third, blood services should be nationally coordinated rather than fragmented across isolated hospital-based systems. Fourth, hemovigilance and traceability should be developed to monitor adverse transfusion events and strengthen accountability. Fifth, QMS should govern the full transfusion chain, including donor selection, testing, processing, storage, distribution, clinical use, documentation, and audit. These principles form the normative core through which WHO soft law seeks to harmonize national blood transfusion governance.

Although WHO lacks enforcement authority, it employs multiple regulatory techniques to promote compliance:

- **Benchmarking:** Through the Global Database on Blood Safety, WHO publishes comparative data on donation rates, screening coverage, and legislative status (WHO, 2025). Benchmarking generates reputational incentives and peer comparison.
- **Reporting Obligations:** Member States are encouraged to report blood safety indicators. Although reporting is voluntary, participation fosters transparency and accountability.
- **Technical Assistance:** WHO provides training, assessment missions, and regulatory guidance to strengthen national capacity. Technical assistance functions as a compliance facilitation mechanism.
- **Capacity Building:** WHO organizes workshops, develops model curricula, and supports national regulatory authorities. Capacity building reduces structural barriers to implementation.
- **Peer Review and Networks:** Regional workshops and collaborative networks facilitate knowledge exchange and norm diffusion. Epistemic communities reinforce professional consensus.
- **Model Legislation Guidance:** Publications such as Smit Sibinga (2017) provide legislative templates consistent with WHO principles, encouraging domestic legal internalization.

National Implementation: Comparative Analysis

The cases of China, India, and Bangladesh are selected to examine how similar WHO blood safety norms are internalized under different domestic conditions. The selection follows a “most different systems” logic. The three countries differ in political structure, administrative capacity, economic resources, legal architecture, and enforcement conditions, but all are exposed to the same WHO normative framework on safe blood transfusion. China illustrates centralized and crisis-driven internalization; India illustrates partial internalization under federal and institutionally fragmented regulation; and Bangladesh illustrates the gap between statutory adoption and practical enforcement in a resource-constrained setting. The comparison therefore helps explain why WHO soft law produces convergence at the level of formal principles but divergence at the level of implementation.

National implementation is the clearest demonstration of WHO’s soft law framework in action. WHO recommends a common governance framework around voluntary VNRBD, centralized coordination, quality-controlled blood screening, hemovigilance, and rational clinical use of blood, but national legal systems do not uniformly adopt these WHO norms. There are some differences in national adoption of WHO norms because of differences in political will, institutional capacity, economic resources, regulatory experience, or epidemiological context.

This section undertakes an analytical comparison of national implementation patterns, focusing primarily on China and India, supplemented by observations from Bangladesh and broader regional disparities. Rather than presenting purely descriptive case studies, the section evaluates how and why WHO norms are adopted, modified, or resisted.

Case Study 1-China

China represents a case of substantial normative internalization combined with state-led regulatory consolidation. Its trajectory illustrates how crisis-driven reform can catalyze comprehensive alignment with WHO standards.

The turning point in China’s blood governance was the enactment of the *Blood Donation Law* in 1998, following severe HIV outbreaks linked to paid plasma collection in the 1980s and 1990s (Gao et al., 2020). The law formally institutionalized VNRBD and prohibited commercial blood trade.

This legislative intervention directly reflects WHO’s normative emphasis on VNRBD as the safest model of supply (WHA, 2005). It transformed a fragmented and commercially driven system into a state-regulated public welfare model.

Between 1998 and 2018, blood donors increased from 4 million to 15 million, and total blood collection rose from 5 million to 25 million units (Gao et al., 2020). These figures demonstrate measurable normative uptake.

China progressively abolished employer-organized donation (2005) and ultimately canceled family/replacement mutual blood donation (FRMBD) nationwide in 2018 (Gao et al., 2020). Although FRMBD had initially been tolerated under Article 15 of the Blood Donation Law, its expansion created risks of hidden commercialization.

The cancellation of FRMBD illustrates a shift from partial compliance to stricter alignment with WHO’s preference for pure VNRBD systems.

China's adoption of nucleic acid testing (NAT) beginning in 2010 and expanding nationwide by 2015 marked a significant upgrade in screening capacity (Gao et al., 2020). NAT reduced window periods for HIV, HBV, and HCV detection and contributed to a decline in transfusion-related litigation.

This reflects compliance with WHO's principle of 100% quality-assured screening (WHO, 2025). Importantly, NAT implementation required substantial state investment—demonstrating that normative compliance is resource-dependent.

China's 2010 Tort Law introduced no-fault liability for transfusion-related injury (Gao et al., 2020). Previously, liability depended on proof of negligence. Under the new regime, patients may obtain compensation without demonstrating fault.

This development exceeds WHO's minimum requirements and signals a shift toward patient-protective governance. It reflects domestic legal innovation rather than direct WHO mandate but is consistent with WHO's emphasis on safety and accountability.

China exemplifies strong normative convergence with WHO soft law, facilitated by centralized political authority, regulatory capacity, and post-crisis mobilization. Implementation was driven not merely by normative persuasion but by reputational damage, public health emergency, and state modernization strategy.

Analytically, China demonstrates a high level of WHO norm internalization. WHO norms were internalized through crisis-driven legislation, centralized administrative authority, technological modernization, and state-led institutional reform. The 1998 Blood Donation Law translated the principle of VNRBD into domestic law, while the expansion of NAT and the development of accountability mechanisms strengthened the safety and quality dimensions of the system. WHO soft law was more effective in China because the state possessed the administrative capacity, financial resources, and centralized authority necessary to convert international standards into enforceable domestic practice. China therefore illustrates how epistemic authority and technical standards become effective when they are supported by strong domestic governance capacity.

Case Study 2-India

India presents a contrasting case characterized by partial adoption, regulatory fragmentation, and persistent structural challenges.

In India, blood is regulated under the *Drugs and Cosmetics Act 1940*, which classifies blood as a “drug” (Pal et al., 2011). Licensing and oversight fall under drug control authorities rather than a specialized blood governance statute. While the National AIDS Control Organisation (2007) articulates goals aligned with WHO—100% voluntary donation, quality screening, and rational use—it lacks direct statutory force (Pal et al., 2011). This regulatory architecture reflects indirect internalization of WHO norms but without institutional coherence.

Multiple bodies operate within India's blood governance system: Drug Controller General of India, State Drug Controllers, National Blood Transfusion Council (NBTC), State Blood Transfusion Councils (SBTCs). NBTC and SBTCs hold advisory roles without enforcement authority (Pal et al., 2011). This fragmentation weakens regulatory uniformity.

Empirical data cited in the literature indicate: Significant proportions of blood banks previously unlicensed, Continued reliance on replacement donors, Limited component separation rates (Pal et al., 2011). These findings suggest incomplete implementation of WHO's

centralized and quality-assured model. Scholars have argued for a dedicated national blood law to replace the Drugs Act model (Pal et al., 2011). The absence of a specialized statute contrasts sharply with China's 1998 Blood Donation Law.

The Supreme Court of India banned paid donation in 1996, reflecting judicial reinforcement of voluntary donation norms. However, legislative consolidation remains incomplete. Although India has increased voluntary donations over time, achieving 100% VNRBD remains challenging due to demographic scale, cultural attitudes, and infrastructure limitations.

Unlike China's centralized enforcement capacity, India's federal structure diffuses authority across states, complicating uniform compliance. India demonstrates partial normative convergence with WHO standards. Core principles—voluntary donation, screening, and national policy—are formally endorsed, but institutional fragmentation and regulatory overlap impede full realization.

Analytically, India represents partial and uneven internalization of WHO blood safety norms. WHO principles are visible in national policy commitments, judicial rejection of paid donation, licensing requirements, and the promotion of voluntary donation. However, these norms have not been fully consolidated into a specialized and coherent national blood law. The classification of blood as a drug, the division of authority among central and state bodies, and the advisory rather than enforcement-based role of blood transfusion councils weaken implementation. India therefore shows that formal acceptance of WHO standards is insufficient when regulatory authority is fragmented and enforcement capacity varies across jurisdictions.

Case Study 3-Bangladesh

Bangladesh historically relied heavily on professional and replacement donors (Nurunnabi et al., 2010). The Safe Blood Transfusion Act 2002 and subsequent regulations marked progress toward WHO-aligned governance (Ministry of Law, Justice and Parliamentary Affairs (MLJPA), 2002). Screening for HIV, HBV, HCV, syphilis, and malaria became mandatory, and voluntary donation campaigns expanded. Nevertheless, replacement donation persists, reflecting socio-economic and cultural constraints.

Bangladesh's experience illustrates that legislative adoption does not automatically eliminate entrenched donor practices. Although the Safe Blood Transfusion Act 2002 establishes a formal legal basis for registration, oversight, and compulsory screening, Bangladesh still illustrates the broader implementation gap commonly found in resource-constrained blood systems, where formal legal adoption does not always ensure consistent institutional enforcement (MLJPA, 2002).

WHO regional data reveal stark disparities in legislative coverage and screening compliance (WHO, 2025). Only 39% of low-income countries report specific blood legislation, compared with 79% of high-income countries. Component separation rates reach 96% in high-income countries but only 38% in low-income settings (WHO, 2025). These regional differences confirm that normative convergence is mediated by economic capacity and regulatory infrastructure.

Analytically, Bangladesh illustrates the difference between legal adoption and practical internalization. WHO-aligned norms have been incorporated through the Safe Blood Transfusion Act and mandatory screening requirements, but implementation remains

constrained by limited resources, weak monitoring capacity, unregulated or poorly supervised blood banks, and continuing reliance on replacement donation. Bangladesh therefore shows that soft law may shape legislative reform without necessarily producing full institutional transformation. In this case, the effectiveness of WHO norms depends less on formal legal recognition and more on sustained enforcement, public trust, financial capacity, and administrative coordination.

Table 1

A Comparative Matrix.

Case	Main mechanism of WHO norm internalization	Legal/institutional transformation	Level of effectiveness	Main limiting factor
China	Crisis-driven reform, centralized authority, state technical modernization	Blood Donation Law, abolition of paid/replacement donation practices, nationwide NAT expansion, accountability reforms	High	Requires strong state capacity and financial investment
India	Policy adoption, judicial intervention, licensing on paid donation, professional regulation, advocacy	National Blood Policy, ban under Drugs and Cosmetics Act, NBTC/SBTC structures	Moderate/partial	Federal fragmentation, overlapping authority, uneven enforcement
Bangladesh	Legislative adoption and mandatory requirements	Safe Blood Transfusion Act, compulsory screening, donor campaigns	Limited/uneven	Resource constraints, weak monitoring, replacement donation, unregulated practices

Note. Created by the author.

Discussion: Why and How WHO Soft Law Works

The comparative analysis shows that WHO soft law works not through coercive enforcement but through de facto regulatory influence. WHO does not compel states to adopt blood safety standards through treaty sanctions. Instead, it shapes domestic governance through technical expertise, epistemic legitimacy, benchmarking, institutional templates, and the professional authority of transfusion medicine networks. This explains why WHO standards can become practically influential even when they are formally non-binding. The effectiveness of soft law therefore depends on the interaction between international normative authority and domestic institutional capacity.

Convergence and Uneven Domestic Internalization

WHO soft law encourages broad agreement on fundamental principles, but its practical implementation varies across national contexts. China has achieved the strongest alignment with WHO standards through legal prohibition of paid blood donation, nationwide technological modernization such as nucleic acid testing, and patient-protective accountability mechanisms. These reforms closely reflect WHO's model of coordinated, quality-assured blood

governance. High-income European systems, including the UK, show even more institutionalized forms of compliance through legally binding regulatory frameworks, licensing, inspection, traceability, and hemovigilance systems (Joint UKBTS/NIBSC), 2005). The United Kingdom provides a strong example of such institutionalization, as its national blood transfusion guidelines incorporate licensing, quality systems, traceability, component standards, and haemovigilance within a highly regulated framework.

By contrast, India and Bangladesh demonstrate partial internalization of WHO norms. Both countries have formally endorsed voluntary non-remunerated blood donation, mandatory screening, and national blood policies, but implementation remains constrained by fragmented regulatory authority, continuing reliance on replacement donation, uneven hemovigilance systems, and inconsistent enforcement. These differences show that compliance with WHO soft law depends not only on normative acceptance but also on domestic institutional capacity. Advanced screening technologies, quality management systems, and centralized blood infrastructure require sustained financial resources and administrative coordination (WHO, 2021).

Therefore, WHO soft law should be understood as operating along a continuum rather than through simple compliance or non-compliance. States may first endorse WHO principles, then codify them in legislation, consolidate institutions, modernize technologies, and finally develop accountability mechanisms such as hemovigilance or liability systems. The cases show that WHO norms have significantly shaped national blood governance, but full structural convergence remains limited by domestic capacity, political organization, socio-economic conditions, public trust, and sustained governmental commitment.

De Facto Regulatory Influence and Indicators of Effectiveness

WHO soft law may be considered effective not because it produces complete compliance in every country, but because it creates measurable changes in national law, institutional design, professional standards, and transfusion-safety practice. Its effectiveness can therefore be evaluated through indicators such as the expansion of voluntary donation, universal screening, technological modernization, centralization, hemovigilance, and the internalization of WHO standards into domestic governance.

VNRBD is an obvious sign of how much of an effect WHO has had with its soft laws. WHO continues to frame voluntary donation as both ethically desirable and safer from the perspective of epidemiology, referring to WHA58.13 and later documents. WHO data shows that there was a 10.7 million increase in voluntary, unpaid blood donations from 2008-2018, and there are now 79 countries that collect over 90% of their blood from voluntary donors, with 64 countries collecting 100% (WHO, 2005). While VNRBD is not universal, the increase over the last twenty years indicates that there has been significant normative convergence. The diffusion and spread of VNRBD across differing political systems demonstrate that WHO soft laws have persuasive power.

Advanced screening technology, specifically NAT, is the second indicator of WHO soft law effectiveness. WHO has emphasized that all three viruses (HIV, HBV, and HCV) must have 100% quality-assured screening as the minimum safety standard (WHO, 2025). Countries like China have progressively adopted nationwide NAT screening, reducing the window period for detecting infections and showing a measurable reduction of transfusion-transmitted infections (Gao et al., 2020). Though NAT and automated immunoassay system adoption are

not equal throughout the world, it is evident that there has been a large global expansion of these systems due in large part to WHO's technical guideline recommendations.

Another indicator, reductions in TTIs, is a reflection of improved governance through WHO statistics showing a much lower rate of prevalence for HIV, HBV and HCV in blood donors in high-income countries compared with low-income countries (WHO, 2025). While there are still disparities, the overall trend globally shows increased screening coverage. Only a small fraction of all countries that report do not test all donated blood for the major infections (WHO, 2025). It is also a strong indicator of normative compliance because the widespread introduction of screening standards is nearly universal.

A different indicator, the movement toward centralization of blood donation testing and processing (WHO Guidance on Centralization 2021), discusses fragmentation as a system risk factor and advocates consolidation to attain economies of scale and improve QMS (WHO, 2021). Several countries have initiated their reform efforts involving this model of centralization. Even in those countries where there has not yet been complete centralization, the dialogue around the issue has changed. The best practices for providing blood donations will now consist of a nationally coordinated service. Thus, this change in the institutional imagination of how to provide appropriate governance demonstrates the ideational impact of WHO's soft law instruments.

Based on the collective increase in voluntary donations, increased numbers of people being tested through blood donation, the technological modernization of laboratory processes and the consolidation of blood donation testing and processing, there is evidence that the WHO's soft law instruments have impacted national systems in measurable ways.

Soft law is more adaptable than hard law because it provides flexibility for countries to gradually adopt WHO standards without facing the same penalties for violations that they would face if they were to violate a binding treaty. This incremental approach is particularly useful in resource-limited settings that cannot meet rigid obligations rapidly. The implementation of NAT in China illustrates how states have been able to progressively align with technical standards over time (Gao et al., 2020).

The technical legitimacy that WHO provides fosters compliance. WHO's authority is based on scientific expertise and collective global epidemiological surveillance—and because the recommendations made by WHO are based on evidence-based public health needs rather than being politically imposed limits, many countries will comply with WHO's recommendations. When WHO states that countries should have 100% screening or that donations should be voluntary, WHO bases its statements on epidemiological evidence from its GDBS (WHO, 2025), providing a scientific rationale that reduces the potential for disagreements about compliance.

The use of soft law allows for less time-consuming development of normative practice than developing binding treaties. WHO has the ability to provide guidance and revise its technical recommendations within the time frames necessary to respond to new infectious disease threats. In particular, the 2021 centralization guidance is an example of adaptive governance in response to structural risks identified by WHO (WHO, 2021). The speed at which norms can be established through the mechanism of soft law is significant due to the fact that pathogens are likely to evolve quickly.

Countries may be concerned about the impact signing binding international health obligations may have on their ability to regulate at the national level. Non-binding

recommendations allow countries to maintain their formal sovereignty and facilitate the convergence of “public health law”. Resolutions of the WHA adopted jointly by Member States create a political commitment to take the action called for in the resolution, but do not compel Member States by force of law (WHO, 2005). These advantages explain why, although WHO does not have enforcement power for its blood safety architecture, the majority of countries accept it as a normative framework for blood safety.

The authority of WHO with respect to blood governance is largely epistemic in nature. As WHO has amassed global scientific data and synthesized comparative data, WHO has developed norm-creating, evidence-based standards for global blood governance. Thus, the basis for state compliance with WHO is not the threat of sanctions, but rather the perception that failure to adhere to WHO's guidance indicates deficient regulatory capacity.

The authority of WHO is further supported by its legitimacy via science. By providing recommendations for a voluntary blood donation process or a single-site blood testing process, WHO is also addressing the issue of reducing epidemiological risk; thus, the scientific basis for WHO's recommendations create a basis of policy direction that is seen as a necessity.

The experience of reputational impact compounds the normative pressure placed on states by WHO; in particular, WHO's benchmarking process provides information to states on their relative performance in blood donation rates, blood donor screening coverage, and blood donor regulatory status (WHO, 2025). States may wish to limit the negative impact on their reputation stemming from being categorized as non-compliant or being recognized as a high-risk jurisdiction. States' reputations in the global health governance arena will impact their diplomatic credibility and relationships with donors.

Finally, WHO operates through transnational professional networks; transfusion medicine professionals, the laboratory scientific community, and blood donor regulatory officials comprise epistemic communities that domestically advocate for policy changes that are consistent with WHO standards. Thus, soft law becomes embedded into the practices of those communities.

Therefore, WHO's power with respect to blood transfusion governance is normative, scientific, and reputational in nature. WHO's power influences expectations, describes legitimacy, and impacts policymaking. All of these collective characteristics demonstrate that soft law does not provide a guarantee for universal compliance; however, soft law has dramatically altered the global framework for blood transfusion governance.

Structural Limits of Soft Law Governance

The most noticeable limitation is that there are no enforcement mechanisms for WHO; thus, sanctions against countries that do not comply cannot be levied. The implementation of soft law depends solely on voluntary acceptance and the political will of states to implement the legislation. The WHO has indicated that 66 per cent of the countries it has evaluated have enacted legislation specific to blood and, in low-income countries, this percentage drops to virtually non-existent (WHO, 2025). The use of soft laws, as well as the absence of binding legal obligations, leads to persistent gaps in regulatory regimes.

Another limitation is the lack of uniform application of soft law globally; high-income countries have nearly achieved universal screening, as well as advanced blood component processing and hemovigilance systems, while low-income countries often do not have a dependable replacement blood donor program, have incomplete screening processes, and do

not have adequate quality management infrastructure (WHO, 2025). The use of WHO's soft law does not ameliorate global structural inequalities, and may actually accentuate these inequalities through benchmarking.

The final structural limitation is the degree to which effective implementation of WHO's soft law approach is reliant on the political will of those states. China experienced rapid reform after a public health crisis and after implementing a predetermined governance structure with a unified central authority (Gao et al. 2020). In India, the fragmentation of the Drugs and Cosmetics Act illustrates how structural complexity associated with federalism and the coexistence of multiple governance institutions can impede progress toward achieving congruence (Pal et al., 2011). Moreover, WHO's soft law framework is unable to substitute for domestic structural political realities.

Finally, there are significant financial barriers to implementing the principles associated with WHO's soft law governance, due to the ongoing need for financial investment in implementing NAT (nucleic acid amplification techniques), quality management systems, hemovigilance networks, and centralized infrastructure. Although WHO may provide some technical assistance, it cannot provide direct funding to countries to develop their national blood centers. In low-income countries, the absence of financial support from external sources will be a major determining factor as to whether states can successfully implement soft law principles. So, the efficacy of WHO's soft law approach is predicated upon availability of resources. Collectively, the other structural limitations discussed in this article illustrate that soft law's influence is mediated by the structural capacity of the country to which it applies. Normative clarity alone cannot remedy material deficiencies.

The influence of WHO soft law is significant, but it remains limited by sovereignty, inequality, fragmented implementation, normative divergence, and the absence of binding enforcement. The global governance of blood safety reveals several of the fundamental tensions present in many soft law regimes: state sovereignty continues to exist, there is structural inequality between low- and high-income countries, potential for normative fragmentation exists, and the unresolved issue around whether binding legal instruments provide stronger guarantees than non-binding ones. This section provides a critical assessment of the aforementioned limitations of global health soft law and highlights the promise and structural fragility of global health soft law.

Soft law emphasizes state discretion. WHO guidelines, whether through WHA resolutions, guidance documents, or action frameworks, either do not create binding obligations under international law or do create legally binding obligations but with the continuing recognition by states of their sovereignty over how to organize and fund and enforce their health systems—all of which is the greatest strength and greatest weakness of this structure.

On the plus side, when states sign on to non-binding standards, they are generally more willing to support WHO resolutions—such as WHA58.13 endorsing VNRBD (WHO, 2005) —because such resolutions do not create obligations under international law. The fact that WHO resolutions do not create a treaty obligation allows for broad consensus from countries with different political ideologies.

On the flip side, sovereignty allows states to selectively implement WHO standards. According to WHO's 2025 fact sheet, two-thirds of those countries reporting to WHO have specific laws regarding blood donation, with the greatest gaps existing in low-income countries (WHO, 2025). States may endorse WHO standards but delay enacting reforms that require reallocation of financial or structural resources.

Domestic political barriers may also serve to constrain implementation of soft law. In countries like India with federal systems, regulatory fragmentation makes it difficult to implement standards uniformly (Mammen et al., 2021). More broadly, decentralized or hospital-based transfusion systems may face professional, infrastructural, and monitoring barriers that weaken quality assurance, even where national actors formally endorse WHO-aligned ethical and safety standards. Soft law is limited in its ability to overcome the deeply embedded administrative traditions and disinclination of government officials to invest in centralized infrastructure.

While soft law creates a venue for the creation of global norms, it does not limit states' discretion based on their sovereignty. The extent of authority granted by WHO is persuasive, not required.

Global inequality is one limitation of structural justice. The nature of soft law is heavily dependent on the material conditions associated with its implementation. According to WHO data, countries with high incomes have much greater access to blood donors, developing blood components, and having hemovigilance systems than countries with low incomes (WHO, 2025). New screening technologies such as NAT are also significantly more expensive than standard blood screening tests and thus create the potential for major inequities in the safe collection and processing of blood. The modernization plans for NAT in China illustrates how a national effort can significantly improve blood donation, while very few countries with low incomes have the capital to make similar upgrades (Gao et al., 2020).

Another limitation of structural justice is the significant difference in resource availability between high-income and low-income countries. For example, countries with high incomes typically rely on near-total reliance on voluntary donors and have developed comprehensive hemovigilance systems, whereas countries with low incomes may continue to depend on replacement donors and have limited laboratory capacity (Darbandi et al., 2017). In such cases, WHO normative benchmarks may be perceived as aspirational goals rather than achievable benchmarks.

In addition, soft law provides no guarantee of mobilizing the financial resources necessary to implement its provisions. In contrast to treaty-based regimes that establish funds to support compliance with the treaty, WHO recommendations are based only on financial resources available to the country using domestic funding or external donor assistance. Consequently, countries must rely on international assistance, which is subject to changing priorities of donors and may create an unstable funding situation for implementation. As a result of these two limitations, global inequality is a broader theoretical issue that structural justice does not adequately address by developing universal standards for all parties to meet but does not provide for equal capacity of those parties to meet those standards. In this regard, normative convergence does not ensure distributive justice.

One of the main concerns relating to global transfusion practices is because of the existence of the potential for normative fragmentation. While the WHO generally encourages the establishment of global harmonization for all forms of transfusion safety there are many regional and national regulatory bodies which may develop their own individual standards.

For example, blood safety in Europe is regulated not only by WHO recommendations but also by EU regulations and by the standards of the Council of Europe (one example is that the UK's blood transfusion services operate under guidelines that may provide for higher levels of regulatory compliance than required by WHO). By contrast to this, some countries or regions

may have more lenient / loose systems of regulation and may adopt their domestic legal regulations more than WHO.

Some forms of normative fragmentation which may occur include:

- **Regionally different donor eligibility criteria:** Especially in relation to deferrals based on behavior.
- **Different threshold levels of hemovigilance reporting.**
- **Different liability models for blood transfusion practice:** For example, Blood Shield Laws exist in the US (Goldman, 1995), but in China no-fault liability laws apply (Gao et al., 2020).
- **Cultural or religious influences on the jurisprudence of refusing blood transfusion** (Molinelli et al., 2009; Martínez-Torrón, 2010).

Although not all aspects of the diversity associated with these forms of normative fragmentation will necessarily be problematic, it is the existence of fragmentation which may have the effect of undermining global consistency in the transfusion process. In a highly interconnected global marketplace where plasma products, reagents and expertise are transported from one place to another across borders, the absence of global harmonization may hinder efforts to create mutually recognized regulatory systems and integration within the global supply chain.

The flexibility of soft law in this respect may, therefore, be a two-edged sword: it provides for the adaptability of the regulatory regimes, but it also permits the divergence of the same.

The limitations identified above raise a fundamental normative question: should global blood safety governance move toward binding international law?

A treaty-based framework could theoretically establish minimum binding obligations regarding: Voluntary donation policies, Mandatory screening standards, National regulatory authority requirements, Hemovigilance systems, Reporting obligations.

Such an instrument might reduce selective implementation and strengthen accountability. The International Health Regulations (2005) (IHR) offer a comparative example of binding global health law requiring states to develop core surveillance capacities.

Nonetheless, many obstacles stand in the way of achieving this goal:

1. **Political feasibility of an international treaty:** Blood transfusion systems are deeply embedded in the national health systems and budgetary priorities of each state. States may resist entering into a treaty if they view that treaty as requiring fundamental changes to their blood systems that would be both financially taxing and administratively burdensome.
2. **Limitations of legal obligations:** Experience with the IHRs has shown that being legally binding does not guarantee compliance with the stated or agreed-upon requirements within that instrument. On multiple occasions, many states have failed to reach the Core Capacity Requirements by the required deadlines. The mere existence of a formal obligation will not resolve the existing shortage of resources.
3. **Advantages of soft law:** Because transfusion medicine is a dynamic, proactive discipline, soft law has proven advantageous as an alternative governing approach that

enables the rapid revision of blood safety and transfusion standards to accommodate the emergence of new pathogens. This flexibility does not exist in the lengthy treaty amendment processes.

4. **Cultural and ethical sensitivities:** Blood governance intersects with highly sensitive cultural and ethical issues such as commercialization of blood products, religious objections to certain procedures or therapies, and the use of reproductive technologies. The implications for sovereignty may elicit resistance from some states toward the imposition of binding uniformity.

Therefore, rather than replacing soft law, it is likely that the more realistic trajectory for international blood governance will include reinforcing and developing additional non-binding soft law mechanisms. Mechanisms such as enhanced benchmarking, peer review frameworks, regulatory capacity-building, and financing mechanisms may contribute to greater compliance without generating political opposition.

While there may not be strict necessity for hard law, the effectiveness of soft law would be dependent on the following: sustained political commitment; adequate financial resources; and institutional coherence.

The limitations of global health soft law with respect to blood transfusion governance illustrate the relationship between normative authority and structural constraints. The WHO's framework has been highly successful in creating a broad global consensus around three fundamental principles of blood transfusion safety (i.e., voluntary donation, quality screening, and centralized blood transfusion coordination), but the overall impact of that success is tempered by issues relating to sovereignty, inequities among states, and fragmentation of the global blood transfusion system. Although binding treaty law may provide states with stronger formal accountability to each other, there is strong evidence that political and practical realities will favor the continued development and strengthening of soft law as the predominant mode for enhancing blood transfusion governance.

Theoretical Contribution: WHO as Norm Entrepreneur and Hybrid Regulatory Authority

This article contributes to scholarship on global governance through the analysis of blood transfusion systems as a paradigmatic case of international soft law functioning as an effective regulatory architecture. Historically, global health law scholarship has primarily focused on binding instruments such as the International Health Regulations (2005) or the Framework Convention on Tobacco Control; however, the governance of blood safety provides an example of how non-binding standards can be the basis for significant normative convergence.

International relations theory conceptualizes “norm entrepreneurs” as actors who frame issues, mobilize expertise, and reshape expectations in international society. WHO operates as such an entrepreneur in blood governance. Through repeated WHA resolutions, technical guidance, and strategic frameworks, WHO has constructed VNRBD, quality-assured screening, centralized coordination, and hemovigilance as global standards of appropriateness (WHO, 2005; WHO, 2008; WHO, 2021).

Normative entrepreneurship can be seen in three ways:

1. **Reshaping blood governance:** WHO reshaped the view of blood and blood supply from being a technical medical activity to a public health issue and a government

responsibility. Through publications such as *Blood Transfusion: A Basic Text* (WHO EMRO, 1994), WHO articulated national coordination, quality assurance, and regulation as areas requiring normative development before being able to create a global architecture for blood supply policy.

2. **Linking blood safety to global health agendas:** WHO established the link between blood safety issues and the broader agenda of global health by connecting blood safety with HIV prevention, the reduction of maternal mortality, and Sustainable Development Goal 3 (WHO, 2025). This strategic management activity transformed the international governance of blood supply from a medical issue to a development and socio-economic issue.
3. **Establishing ethical norms:** WHO established ethical norms regarding the non-commercialization of the blood supply and introduced moral arguments as part of the regulatory framework through WHA58.13. Through this resolution, voluntary donation was determined not only to be a safety-related requirement but also an ethical obligation and thus a civic responsibility (WHO, 2005). By establishing a normative vocabulary to legitimize blood governance, WHO has created a path of influence over how states view the legitimacy of their own blood governance. This illustrates how an international organization may exert normative force without using direct coercive means.

Blood transfusion system governance adds to the growing body of literature on global or transnational administrative law, which examines how international institutions generate standards, procedures, monitoring practices, and accountability expectations outside traditional domestic administrative structures (Kingsbury et al., 2005). Global or transnational administrative law scholars investigate how internationally governed bodies create standards, procedures, and accountability mechanisms that are analogous to administrative regulations outside their domestic jurisdictions.

WHO's blood safety/development framework demonstrates several classic functions of administrative regulation: standard-setting through technical guidelines; data collection via the Global Database of Blood Safety; comparative data collection via benchmarking and reporting (WHO, 2025); capacity-building missions and regulatory assessments (WHO, 2021); and model legislative guidance for national implementation (Smit Sibinga, 2017). These functions are functionally equivalent to domestic administrative law functions of rulemaking, monitoring, inspection, and evaluation, but they take place at a transnational level.

Proceduralizing is emphasized by WHO in its guidelines. QMS documentation requirements; hemovigilance reporting; audit structures; all reflect administrative rationality in health governance. Although WHO does not have any authority to enforce compliance with its guidelines, it creates procedural expectations from which the national regulators create binding domestic instruments. Examples include Malawi's Guidelines for Safe Blood Transfusion and China's Blood Donation Law reform (Gao et al., 2020).

Thus, Blood Governance demonstrates how global administrative norms are transferred to domestic bureaucracies. Transnational Administrative Law may be implemented through persuasion and institutional modeling and not necessarily through hierarchical command.

This article's main theory is that the soft law of the WHO acts as a de facto regulation of blood governance. As WHO instruments are technically non-binding, they also result in:

- **Adoption of VNRBD as a legal norm:** Virtually all countries have implemented voluntary non-remunerated blood donation.

- **Mandatory testing for transfusion-transmissible infections:** Near-universal testing has become standard practice.
- **Greater centralization of testing and/or processing facilities:** Centralized systems improve safety and efficiency.
- **Expansion of hemovigilance systems:** Monitoring of adverse transfusion events is increasingly implemented.
- **Integration of QMS** proven QMS frameworks are incorporated into regional regulatory structures covering blood donations and transfusions.

These outcomes suggest that soft law may achieve regulatory convergence comparable to binding instruments in certain technical domains.

Epistemic authority and reputation incentives form the foundations for effective regulation under these de facto norms. Guidance from WHO is informed by scientific consensus and epidemiological information (WHO, 2025). Thus, any departure from these prescribed guidelines may be seen as a reflection of inadequate regulation and impose reputational costs upon states or subject them to scrutiny by international donors. Moreover, when WHO standards are utilized as benchmarks by domestic courts and professional organizations to determine optimal levels of care, they convert soft law into expectational obligations.

In this manner, soft law operates via internalization rather than coercion; therefore, once incorporated into domestic law through legislation, administrative regulation or professional standards, WHO norms become practically binding.

This finding supports regulatory governance theory by showing that effective regulation can exist without a formal treaty-based obligation. As there is no clear treaty obligation for countries to adopt what are simply best practice norms established by WHO for very technical/science-based disciplines, the normative authority, combined with benchmarking and professional consensus, may be all that is necessary to promote regulatory convergence.

How countries govern their blood transfusion systems demonstrates a hybrid form of authority that incorporates:

- **Normative persuasion** via WHO resolutions and ethical codes.
- **Technical standard-setting** through guidance on blood screening, QMS, and the centralization of blood transfusion systems.
- **Data-driven benchmarking** through internationally comparative data sharing.
- **Legal internalization** of blood transfusion governance through domestic legislation and guidelines.
- **Judicial mediation** through case law and other forms of jurisprudence concerning liability and rights

This hybrid form of authority presents a challenge to traditional binary categories of hard and soft law. Blood transfusion governance demonstrates that soft law can exist alongside the enforcement of hard law at the domestic level. The WHO creates normative baselines for blood transfusion governance; in turn, domestic blood transfusion governance creates legally binding rules for compliance and enforcement of these normative baselines through: licensing

rules, rules against malpractice (tort), and rules for regulatory enforcement through site inspections.

The hybrid model of governance develops a structured governance template whereby international soft law defines expectations and templates, domestic law provides mechanisms of enforcement (i.e., sanctioning systems), and professional communities provide the epistemic legitimacy to support the legal process.

The article demonstrates how blood transfusion governance contributes to three fields or disciplines in the scholarly community by:

- **Demonstrating that procedural standards** developed in one location may travel across international borders and become institutionalized in another location within the field of global administrative law.
- **Demonstrating a regulatory transformation** of the delivery of clinical practice into structured governance within the scope of health law.
- **Demonstrating, through the lens of regulatory governance theory**, that authority can be derived from knowledge, benchmarking, and institutional design rather than from the use of power to sanction through an enforcement mechanism.

Ultimately, the governance of blood transfusion systems is representative of many global health regulations; power is exercised using expertise, legitimacy is constructed through science and compliance is achieved through institutional diffusion, rather than by coercion.

Policy Recommendations

The analysis suggests that WHO soft law should not be replaced by a binding treaty at this stage; rather, its effectiveness should be strengthened through more systematic compliance-support mechanisms. Because implementation gaps are caused largely by institutional fragmentation, limited resources, and weak enforcement capacity, future reform should focus on improving domestic legal consolidation, benchmarking, reporting, technical assistance, and equitable resource mobilization.

Despite WHO instruments' lack of binding authority, compliance can also be assured by establishing structured accountability frameworks that do not rely on treaty-based enforcement. First, the WHO could institute regular peer review assessments of national blood systems, in a manner similar to the Universal Periodic Review of human rights governance. These assessments would assess countries' implementation of core principles (i.e., voluntary non-remunerated blood donation; mandatory transfusion-transmissible infection screening; hemovigilance systems; centralized control; and quality management systems) (WHO, 2008; WHO, 2021).

Second, WHO's Global Benchmarking Tool (GBT), which is currently in use for the assessment of regulatory systems, could be adapted in a consistent manner for assessing blood regulatory authorities. By linking the results of benchmarking assessments to packages of technical assistance, the incentive for performance could be increased without the need for coercion.

Third, the use of measurable indicators (e.g., the percentage of voluntary donors; the percentage of donations that are covered by nucleic acid testing; and the completeness of hemovigilance reporting) would allow for the transformation of normative expectations into

operational compliance metrics (WHO, 2025). The effectiveness of soft law is generally increased if these same normative standards also support transparent measurements.

Inconsistent reporting is a major gap in many national systems. To obtain useful comparative information, WHO's GDBS offers many useful items of information but also provides an incomplete and inconsistent set of data in certain regions (Darbandi et al., 2017; WHO, 2025).

Thus, institutionalization of national hemovigilance reporting systems should be standard. Some suggested areas for the inclusion of mandatory national hemovigilance reporting systems through domestic legislation are as follows:

- **Systematic reporting** of all adverse events associated with blood transfusions.
- **Public reporting on blood safety**, issued at least once per year.
- **A traceability system** from the donor to the recipient of the transfusion.
- **Development of protocols for data sharing** with WHO-associated regional offices.

Malawi's Guidelines for Safe Blood Transfusion provides a good example of how national administrative mechanisms can implement vein-to-vein traceability and quality assurance mandates. Replicating these types of structured reporting mechanisms in other national jurisdictions would add to the transparency and the learning involved across jurisdictional boundaries.

Furthermore, the integration of digital health, through central blood authority information management systems, will improve blood inventories, cross-border coordination, and preparedness for emergencies (e.g., during a pandemic or other humanitarian disaster) (World Health Organization, 2021).

To effectively monitor former UN member states with regard to blood safety, blood and transfusion programs should be explicitly incorporated as a key component of SDG monitoring. Blood safety supports multiple health initiatives, including the following:

1. **Reduction of maternal mortality.**
2. **Surgical safety.**
3. **Trauma care (emergency response).**
4. **Control of communicable diseases.**

Currently, transfusion safety and blood governance are aligned with the SDGs primarily through the indicators developed by the WHO (2025) for these health initiatives. However, blood safety is not yet incorporated as a systematic indicator within the overall SDG monitoring framework.

Thus, if measuring and reporting on transfusion safety included blood safety metrics (e.g., VNRBD, screening coverage, and availability by population—numbers per 1,000), this would elevate the importance of transfusion-related governance within national development plans. This would also:

1. **Increase the political visibility** of blood governance.

2. **Encourage budget allocation** for blood transfusion systems.
3. **Increase the attraction of donor funding.**
4. **Strengthen the linkage between blood governance and Universal Health Coverage.**

Because global normative compliance is generally assessed against soft law standards, aligning these standards with global development metrics supports and enhances the ability of the WHO to promote normative compliance through reputational and developmental incentives.

One of the clearest findings of comparative analysis is that soft law effectiveness increases when norms are codified domestically. Countries with dedicated blood legislation or structured regulatory frameworks demonstrate stronger alignment with WHO principles (Smit Sibinga, 2017; Gao et al., 2020).

National reforms should therefore prioritize: Enactment of comprehensive blood transfusion acts, Clear designation of national regulatory authorities, Mandatory licensing and inspection regimes, Statutory embedding of QMS and hemovigilance, Legal prohibition of paid donation.

India's experience illustrates both progress and fragmentation under pharmaceutical-centric legislation, while broader WHO data confirm that decentralized and weakly coordinated systems face recurring challenges in screening, haemovigilance, traceability, and enforcement. WHO could support this process by updating and disseminating model legislative templates, building upon prior guidance (Smit Sibinga, 2017) and regional policy frameworks.

Regional cooperation mechanisms provide a practical way of increasing compliance with non-binding law (soft law). The WHO regional office can establish a structured peer-review system through which member states can share best practices on donor recruitment, strategies on centralization, the design of hemovigilance systems, and experiences on strengthening regulatory structures.

Experience from the WHO Eastern Mediterranean Region has illustrated that regional networks are effective ways to address disparities in capacity within the region (Darbandi et al., 2017). Regional harmonization in the areas of plasma fractionation standards, donor eligibility, and laboratory accreditation will decrease normative fragmentation.

Collaborating with established regional organizations (such as the European Union, African Union, and Association of Southeast Asian Nations (ASEAN)) may provide hybrid governance models that combine WHO's guidelines for soft law with regionally binding regulatory structures.

These recommendations for policy development do not advocate for an immediate transition to binding treaty law but instead focus on strengthening the operationalization of existing non-binding regulatory (soft law) frameworks through benchmarking, institutionalizing reports, incorporating UN-SDGs in domestic law, codifying regional law, and peer-reviewing regions.

Such actions maintain WHO's technical legitimacy of authority as a non-binding regulatory authority while also improving accountability, transparency and convergence. Together, these actions provide further support for this article's primary thesis; that soft law

supported by political will and institutional design can serve as a suitable governing framework to promote safe blood transfusion practices around the globe.

Conclusion

This article has examined how international soft law shapes the development of national safe blood transfusion systems through the normative framework established by the WHO. Although there is no binding global treaty on blood safety, the analysis demonstrates that WHO has developed a dense regulatory ecosystem composed of WHA resolutions, strategic action frameworks, technical guidance documents, benchmarking instruments, data-reporting mechanisms, and capacity-building activities. These instruments do not create direct treaty obligations, yet they generate significant normative and practical influence over national blood governance.

The study has shown that WHO soft law has contributed to the emergence of a common global baseline for legitimate blood governance. This baseline includes voluntary non-remunerated blood donation, quality-assured screening for transfusion-transmissible infections, nationally coordinated blood services, hemovigilance, rational clinical use of blood, and comprehensive quality management systems. These principles have become widely accepted as standards of safe and responsible transfusion governance, even though their implementation differs across national contexts.

The comparative analysis of China, India, and Bangladesh confirms that WHO norms produce convergence at the level of general principles but divergence at the level of domestic implementation. China illustrates strong internalization of WHO standards through crisis-driven reform, centralized authority, legal consolidation, technological modernization, and state capacity. India demonstrates partial internalization, where WHO-aligned principles are reflected in policy commitments, judicial intervention, and regulatory practice, but implementation remains constrained by federal fragmentation, overlapping institutional mandates, and the absence of a specialized national blood law. Bangladesh shows that legislative adoption alone is insufficient where monitoring capacity, financial resources, enforcement mechanisms, and public trust remain limited.

The article therefore argues that WHO soft law operates as a form of de facto regulatory governance. Its authority does not depend on coercive enforcement but on technical expertise, epistemic legitimacy, professional consensus, benchmarking, institutional templates, and norm entrepreneurship. Through these mechanisms, WHO shapes the expectations of legislators, regulators, health professionals, donors, and national institutions. Once WHO standards are incorporated into domestic law, administrative regulation, professional standards, or institutional practice, they may become practically binding even though they remain formally non-binding at the international level.

This finding contributes to global health law and regulatory governance scholarship by showing that soft law can function as an effective regulatory instrument in highly technical fields where scientific consensus is strong but treaty-based regulation may be politically difficult. Blood transfusion governance demonstrates that international authority may operate through knowledge, legitimacy, institutional diffusion, and reputational incentives rather than through sanctions. It also challenges a strict distinction between hard law and soft law by

showing how non-binding international standards may influence binding domestic legal and administrative systems.

At the same time, the study also confirms the limits of soft law. WHO standards can define safe practice, legitimate governance, and responsible regulation, but they cannot by themselves provide blood supplies, finance laboratory infrastructure, enforce domestic laws, or monitor adverse transfusion events. Soft law provides direction, not delivery. Its effectiveness depends on political commitment, administrative capacity, financial investment, legal consolidation, professional acceptance, and sustained public trust.

The future of global blood governance therefore lies not in replacing soft law with a binding treaty, but in strengthening the institutional conditions through which soft law becomes effective. Improved benchmarking, peer-review mechanisms, domestic codification, hemovigilance systems, regulatory capacity-building, and equitable technical and financial support are necessary to reduce the gap between normative acceptance and practical implementation. In this sense, WHO soft law can contribute to saving lives, not by coercion, but by shaping the legal, institutional, and professional systems through which safe blood transfusion is delivered.

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