

Editorial

Quality management system in transfusion medicine

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Introduction

Blood transfusion has been practiced for more than a century. In its early stages, blood was directly transferred from donors to recipients without systematic consideration of safety or quality. The establishment of the American Association of Blood Banks (AABB) in 1947¹ and the World Health Organization (WHO) in 1948² marked the beginning of organized quality control, initially focusing on technical procedures and later expanding to include the prevention of transfusion-transmitted infections (TTIs). The implementation of structured quality management systems (QMS) in transfusion medicine began around the 1990s. Such systems are essential due to their direct impact on donor and patient safety, as well as the efficacy of clinical treatment. A comprehensive QMS must cover the entire blood supply chain, often referred to as the “vein-to-vein” process – from donor recruitment and selection to blood collection, testing, processing, storage, distribution, and transfusion.³

Currently, transfusion medicine activities can be categorized into three major chains:³

1. Donor Chain – blood collection and processing
2. Testing Chain – laboratory testing and quality assurance
3. Recipient Chain – transfusion practices and patient management.

Each chain comprises multiple processes governed by various quality systems and regulatory frameworks. Personnel in transfusion services must understand and integrate these systems to ensure the delivery of safe and high-quality blood products.

In Thailand, quality systems are generally aligned with international standards such as ISO 15189, ISO 9001, and Good Manufacturing Practice (GMP). In the United States, standards are commonly based on AABB, College of American Pathologists (CAP), the Food and Drug Administration (FDA), the Code of Federal Regulations (CFR), and state regulations.⁴ Therefore, to facilitate understanding of quality systems appropriate for various operational functions, examples of quality frameworks applied across different chains in the United States are summarized in Tables 1-3. Table 4 presents a representative model from Australia, while Table 5 illustrates an example from organizations primarily operating under ISO 15189 standards.

Role of hemovigilance and risk-based quality systems

Hemovigilance represents the final and overarching surveillance system covering the entire blood supply chain, from donation to transfusion. Its primary objectives are to enhance donor and recipient safety, prevent adverse transfusion reactions, and promote continuous improvement through data-driven corrective and preventive actions (CAPA).⁹ Modern transfusion services have evolved toward risk-based quality management systems, emphasizing proactive identification and mitigation of potential failures. This evolution also supports emerging fields such as biobanking and advanced therapy medicinal products (ATMPs), including cell and gene therapies. Recognizing this transformation, AABB changed its name in 2002 to the Association for the Advancement of Blood & Biotherapies, reflecting its expanded scope beyond traditional transfusion services.

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Table 1 Quality systems in the donor chain (United States Model)³⁻⁶

Step	Process	Description	Key standards
1.1	Donor screening	Assessment of donor eligibility through health questionnaires and interviews to minimize risks	FDA 21 CFR 630; AABB standards (donor selection)
1.2	Blood collection	Aseptic techniques and standardized procedures for collection	FDA cGMP; AABB standards
1.3	Labeling & traceability	Unique identification labeling at collection site to ensure full traceability	FDA 21 CFR 606; AABB standards
1.4	Component processing	Preparation of blood components (RBCs, plasma, platelets) under controlled conditions	FDA 21 CFR 640; AABB standards

Table 2 Quality systems in the testing chain (United States Model)³⁻⁷

Step	Process	Description	Key standards
2.1	Blood grouping	ABO/RhD typing including weak D testing	AABB standards; FDA 21 CFR 640
2.2	Infectious disease screening	Testing for TTIs such as HIV, HBV, HCV, syphilis, West Nile virus	FDA 21 CFR 610
2.3	Antibody screening & identification	Detection of clinically significant alloantibodies	AABB standards
2.4	Quality control & EQA	Reagent/instrument QC and participation in external quality assessment	CAP; AABB QMS

Table 3 Quality systems in the recipient chain (United States Model)³⁻⁶

Step	Process	Description	Key standards
3.1	Compatibility testing	Crossmatching to ensure donor-recipient compatibility	AABB standards
3.2	Storage & distribution	Temperature-controlled storage and final verification	FDA cGMP; AABB standards
3.3	Patient blood management (PBM)	Clinical evaluation to optimize blood use	AABB PBM standards
3.4	Transfusion monitoring	Bedside verification and patient observation	AABB standards
3.5	Hemovigilance & CAPA	Reporting, investigation, corrective and preventive actions	FDA; AABB QMS

Table 4 Australian model of quality systems in transfusion medicine⁸

Chain	Main standards	Regulatory authorities
Donor & processing	Australian Red Cross Lifeblood Quality Systems	Therapeutic goods administration (TGA)
Testing	NPAAC requirements; ISO 15189	NPAAC
Recipient	NSQHS standard 7; PBM guidelines	ACSQHC, ANZSBT, NBA

Table 5 ISO 15189-based quality framework across all chains⁸

Chain	Objective	Key activities	Main standards
Donor chain	Ensure safe and quality blood supply	Donor screening, aseptic collection, component preparation	ISO 9001, ISO 15189, ISO 15190, GMP
Testing chain	Ensure product safety	Blood grouping, infectious screening, QC, controlled storage	ISO 15189, ISO 15190
Recipient chain	Safe and effective transfusion	Crossmatch, cold chain management, bedside checks, PBM, hemovigilance	ISO 15189, ISO 9001

Blood establishments are increasingly viewed as biological manufacturing facilities.⁶ Consequently, regulatory authorities such as the US FDA require compliance with Current Good Manufacturing Practices (cGMP), ensuring consistent product safety, quality, and traceability similar to biopharmaceutical production.¹⁰⁻¹⁶

Conclusion

Transfusion medicine differs significantly from conventional clinical laboratory services due to its broad operational scope encompassing three interconnected chains. This complexity necessitates the integration of multiple quality systems to safeguard donors, recipients, and biological products, including blood components, stem cells, and tissues. Quality systems are not supplementary tasks but fundamental pillars of healthcare service delivery. Even minor errors can result in serious harm and system failure. Budget constraints should never justify the elimination of quality activities. Instead, institutional leadership bears responsibility for ensuring adequate resources to maintain robust quality frameworks.

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