Capstone Project

Establishment of

Blood Center Common Guidelines Committee

Project Team Members:

Mahtab Khan, VP of Finance, New York Blood Center Enterprises (Team Lead)

Grace Sese, MD, Medical Director, Inova Blood Donor Services

Bob Scanlon, CEO, Blood Bank of Alaska

Ruchika Goel, MD, Medical Director, Director of Research, Carter BloodCare

Contents

Project Proposal: Establishment of a Blood Center Common Guidelines Committee

1. Project Title

Formation of a National Common Guidelines Committee for Blood Centers and Transfusion Services.

2. Executive Summary

The blood banking industry operates within a highly regulated environment, yet significant variability persists across collection, testing, labeling, and distribution practices. These inconsistencies lead to inefficiencies, quality variability, and regulatory risk. This proposal recommends the formation of an **ABC Blood Center Common Guidelines Committee** in collaboration with other Blood industry members — a multidisciplinary body responsible for developing, implementing, and maintaining standardized procedures across donor services, testing laboratories, component manufacturing, distribution, and transfusion operations.

The committee will align its framework with **AABB, FDA, CAP, and WHO** standards, focusing on operational harmonization, data interoperability, and quality improvement across regional and national blood centers.

3. Problem Statement

Despite existing regulatory oversight, blood centers often:

- Use nonuniform donor screening and testing procedures
- Rely on variable labeling, LIS configurations, and component processing methods
- Lack standardized deviation, QC, and training documentation
- Experience barriers in data sharing and traceability between institutions

This fragmentation increases cost, risk, and inefficiency — particularly in multi-site organizations and during emergency blood sharing.

4. Project Objectives

The Common Guidelines Committee will pursue the following objectives:

- Develop and approve **standard operating procedures (SOPs)** for all critical blood center processes.
- Promote **adoption of global labeling and data standards** (e.g., ISBT 128, LIS/BIS).
- Establish **universal training and competency frameworks** for staff.

- Create a **centralized deviation and CAPA review process** to strengthen compliance and quality oversight.
- Serve as the **liaison with regulatory and accrediting bodies** to maintain industry standards.
- Set up an operating framework for a Disaster Task Force

5. Committee Structure

Membership Composition:

- **Chair:** Director of Quality / Medical Director
- **Members (max 5):**
    - Representatives from Donor Services, Laboratory Testing, Distribution, Transfusion Services
    - Quality Assurance and Regulatory Affairs leads
    - Information Systems/LIS integration specialist
    - Hospital transfusion liaison
    - External consultant (as needed)
    - Industry representative

Meeting Frequency: Monthly (initial six months), then quarterly
Governance: Reports to the ABC Board of Directors

6. Project Scope

In-Scope	**Out-of-Scope (initial phase)**
SOP harmonization	Financial contract negotiations
Standardization of QC and training	New software procurement
Regulatory compliance monitoring	M&A-level integrations
Labeling, Nomenclature and data interoperability	External manufacturing partnerships

7. Implementation Plan

Phase	Timeline	Key Deliverables
Phase 1: Committee Formation	Month 1	Charter approval, membership appointment
Phase 2: Baseline Assessment	Months 2–3	Gap analysis of current practices vs. AABB/FDA standards
Phase 3: SOP and Policy Development	Months 4–6	Draft standardized SOP library; approval workflow
Phase 4: Pilot Implementation	Months 7–9	Deploy standards at 2–3 pilot sites; collect metrics
Phase 5: Evaluation, Audit and Expansion	Months 10–12	Review KPIs; expand to full organization; publish annual report

8. Key Performance Indicators (KPIs)

- Reduction in SOP deviations by **>20%** within first year
- Decrease in product QC failures by **>15%**
- Full ISBT 128 compliances across sites
- 100% of staff certified under unified competency framework
- Improved regulatory audit scores or inspection outcomes

9. Resource Requirements

- **Personnel:** Committee members (0.1–0.2 FTE commitment each)
- **Budget:** ~$25,000 for consultant support, meeting logistics, document control tools
- **Systems:** Centralized QMS or document repository (e.g., MasterControl, Veeva, SharePoint)

10. Expected Outcomes

- Uniform operational standards and improved product quality
- Enhanced inter-facility compatibility and data sharing
- Streamlined regulatory compliance and audit preparation
- Reduced operational costs through elimination of redundant processes
- Strengthened national blood system resilience and public trust

Synopsis

In the **blood center industry**, several processes, products, and systems can — and increasingly *should* — be standardized to improve safety, efficiency, traceability, and compliance. Here's a breakdown by category:

1. Donor Screening and Qualification

Standardize:

- **Donor medical eligibility requirement**
- **Deferral codes and reasons** across collection sites
- **Pre-donation testing panels** (HIV, HBV, HCV, syphilis, HTLV, WNV, etc.)
- **Vital sign thresholds** and hemoglobin cutoffs

Impact: Ensures uniform donor safety, reduces liability, and allows for shared donor databases across regions.

2. Testing and Quality Control

Standardize:

- **QC protocols** for reagents, calibrators, and instruments
- **Calibration frequency** and acceptance criteria
- **Validation and Audit templates for new assays and equipment**
- **Root Cause Analysis and Corrective and Preventive Action** – standardized templates

Impact: Reduces inter-lab variability and improves reliability of donor testing results.

3. Labeling and Traceability

Standardize:

- **Product codes and expiration formats**
- **Electronic traceability systems (LIS/BIS)** for full vein-to-vein tracking
- **Label placement and readability** requirements

Impact: Enables interoperability between hospitals, regional centers, and international exchanges.

4. Collection and Processing

Standardize:

- **Collection bag systems and anticoagulant ratios**
- **Component processing steps** (centrifugation speed, separation timing, leukoreduction filters)
- **Storage conditions and equipment calibration**
- **Handling times** from draw to refrigeration

Impact: Improves consistency of product yield, viability, and quality control outcomes.

5. Distribution and Inventory Management

Standardize:

- **Temperature monitoring and alarms** for transport and storage
- **Shelf-life protocols** (RBCs 42 days, platelets 5–7 days, etc.)
- **Disaster preparedness and mutual aid procedures (**raising awareness for organizations like BERC, AABB Interorganizational Task Force**)**

Impact: Minimizes waste and shortages, supports disaster response, and facilitates cross-supply.

6. Information Systems and Data Management

Standardize:

- **LIS/Blood Bank Software integration** with EMRs and national registries
- **Coding and terminology** (LOINC, SNOMED CT)
- **Audit trails and data retention** policies
- **Electronic crossmatch and transfusion documentation**

Impact: Enhances interoperability, compliance, and real-time oversight.

7. Training and Competency

Standardize:

- **Semi Annual/Annual competency checklists** for staff
- **Continuing education** requirements
- **Deviation reporting and CAPA processes**

Impact: Ensures consistent staff performance and regulatory readiness across sites.

8. Regulatory and Compliance Framework

Standardize:

- **Deviation management and documentation systems**
- **Internal and External audits** aligned with AABB/FDA/ISO 9001 standards
- **Record retention and traceability** policies

Impact: Simplifies audits and strengthens overall compliance posture.

Common Guideline Process Areas – Impact Analysis

Table outlining **Process Areas and Expected Impact with Common Guidelines** — designed for operational and quality improvement:

Process Area	Current Variability / Challenge	Proposed Common Guidelines	Key Barriers to Eliminate	Ideas for Overcoming Barriers	Expected Impact
Donor medical eligibility requirement	Eligibility criteria can be complex, frequently changing, and non-standard	Develop a centralized, FDA-backed eligibility protocol to be adopted uniformly by all U.S. blood centers	Site-specific legacy practices; fear of reduced donor pool	Central medical director approval; pilot unified criteria with donor impact analysis	Increased Donor Participation & Retention and improved Blood inventory
Donor Testing	Variable test panels and equipment brands	Adopt a standard infectious disease testing panel and harmonized NAT platforms	Variable test panels and equipment brands	Phased platform alignment; renegotiate contracts at renewal; shared validation	Ensures comparable safety data and facilitates inter-lab result sharing
Component Collection	Collection bags and anticoagulant ratios differ between centers	Use standardized bag systems, anticoagulant volumes, and collection protocols	Vendor lock-in; supply chain disruption concerns	Dual-vendor strategy; centralized procurement governance	Improves yield predictability and reduces QC failures
Component Processing	Different centrifugation and leukoreduction practices	Uniform processing SOPs and acceptance criteria	Staff resistance; retraining burden	Train-the-trainer model; standardized visual job aids	Enhances component quality and shelf-life consistency
Labeling & Identification	Multiple barcode formats and labeling templates	Full adoption of ISBT 128 global labeling standard	IT system limitations; label printer constraints	LIS configuration roadmap; temporary dual-labeling	Enables interoperability across hospitals and

Process Area	Current Variability / Challenge	Proposed Common Guidelines	Key Barriers to Eliminate	Ideas for Overcoming Barriers	Expected Impact
				during transition	regional centers
Storage & Inventory	Variation in storage conditions and monitoring practices	Standardize equipment calibration, alarm settings, and temperature logs	Aging equipment; uneven capital investment	Risk-based equipment replacement plan; enterprise calibration contracts	Reduces product loss, ensures compliance with FDA 21 CFR 606
Distribution & Logistics	Inconsistent transport validation and temperature tracking	Implement validated transport containers with digital data loggers	Cost; staff compliance in the field	Central validation library; automated temperature exception alerts	Guarantees cold chain integrity and traceability
Information Systems (LIS/BIS)	Limited integration between donor, testing, and hospital systems	Use standardized data structures (LOINC, SNOMED CT) and system interfaces (HL7/FHIR)	Custom-built LIS workflows; integration costs	Enterprise data governance group; incremental interface builds	Enables national traceability and efficient data sharing
Transfusion Services	Variable crossmatch procedures and release criteria	Standardize electronic crossmatch rules and critical value notification protocols	Hospital preference variation; medico-legal concerns	Medical advisory committee alignment; evidence-based thresholds	Reduces transfusion errors and turnaround time
Quality Control	Different QC sample sizes and acceptance limits	Harmonize QC frequency, acceptance ranges, and documentation templates	“That’s how we’ve always done it” culture	Benchmarking data; regulatory alignment justification	Strengthens audit readiness and comparability between labs
Deviation Management	Inconsistent reporting and	Adopt a unified deviation	Competing QMS tools;	Enterprise deviation	Improves trend analysis and

Process Area	Current Variability / Challenge	Proposed Common Guidelines	Key Barriers to Eliminate	Ideas for Overcoming Barriers	Expected Impact
	CAPA documentation	tracking system (e.g., MasterControl or Veeva)	inconsistent severity grading	taxonomy; standardized CAPA templates	regulatory compliance
Training & Competency	Varied staff training programs and intervals	Standardize competency checklists and require annual recertification	Time constraints; staff fatigue	Digital competency modules; rolling recertification windows	Ensures consistent technical proficiency across staff
Regulatory Compliance	Disparate audit tools and record retention policies	Implement a uniform internal audit schedule and standardized record templates	Multiple accrediting bodies; inspection anxiety	Crosswalk mapping (FDA–AABB–CAP); mock enterprise audits	Simplifies FDA/AABB inspections and improves compliance continuity
Disaster Preparedness	Inconsistent mutual aid and supply-sharing plans	Establish a regional standard operating framework (e.g., per AABB Disaster Task Force)	Jurisdictional boundaries; unclear authority	Pre-negotiated MOUs; annual regional disaster drills	Improves response efficiency and supply chain resilience

List of References

1. **AABB.** (2023). *Standards for Blood Banks and Transfusion Services* (33rd ed.). AABB Press.
2. **U.S. Food and Drug Administration (FDA).** (2024). *Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components.* Center for Biologics Evaluation and Research (CBER).
3. **World Health Organization (WHO).** (2022). *Blood Safety and Availability: Global Status Report.* World Health Organization.
4. **International Council for Commonality in Blood Banking Automation (ICCBBA).** (2024). *ISBT 128 Standard: Terminology, Labeling, and Coding of Blood, Cellular Therapy, and Tissue Products.*
5. **College of American Pathologists (CAP).** (2023). *Transfusion Medicine Checklist.* CAP Accreditation Program.
6. **Institute of Medicine (U.S.).** (2015). *Toward a Sustainable Blood Supply in the United States.* National Academies Press.
7. **Centers for Disease Control and Prevention (CDC).** (2023). *U.S. Blood Safety Surveillance and Hemovigilance Program.*
8. **ISO.** (2015). *ISO 9001: Quality Management Systems — Requirements.* International Organization for Standardization.