Establishment of an America's Blood Centers' Common Guidelines Committee

Mahtab Khan, VP Finance, NY Blood Center (Team Lead)
Grace Sese, MD, Inova Blood Donor Services
Bob Scanlon, CEO, Blood Bank of Alaska
Ruchika Goel, MD, MPH, CABP, Carter BloodCare

America's Blood Centers
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Executive Summary

Establish Common Guidelines Committee to reduce inefficiencies and regulatory risks by following standard processes across donor services, testing labs, manufacturing, distribution and transfusion operations.

Problem Statement

Despite regulations, blood centers face inconsistent donor screening, testing, labeling, and training documentation. Data sharing barriers raise cost and risk, especially during emergency blood distribution.

Project Objectives

- Standardize SOPs for all key processes
- Promote ISBT 128 & LIS/BIS adoption
- Create unified training/competency frameworks
- Centralize deviation/Corrective and Preventive Action (CAPA) processes
- Operating framework for a Disaster Task Force

Key Performance Indicators (KPIs)

- 20% reduction in Standard Operating Procedures (SOP) deviations
- 15% decrease in Quality Control (QC) failures
- 100% staff certified under new framework
- Full ISBT 128 compliance

Sample Process Areas with Proposed Common Guidelines and Expected Outcomes

Process Area	Current Variability / Challenge	Proposed Common Guideline	Expected Outcomes
Donor Medical Eligibility	Eligibility criteria - complex, frequently changing	Centralized, FDA-backed eligibility protocol	Increased Donor Participation & Retention
Component Collection	Collection bags and anticoagulant ratios differ between centers	Standardized bag systems, anticoagulant volumes and protocols	Improves yield predictability and reduces QC failures
Storage & Inventory	Variation in storage conditions and monitoring	Standardized equipment calibration, alarms, Temp logs	Reduces product loss, ensures compliance
Information Systems (LIS/BIS)	Limited integration between donor, testing, and hospitals	Standardize data structures and system interfaces	Enables national traceability and efficient data sharing
Transfusion Services	Variable crossmatch procedures and release criteria	Standardized crossmatch rules and critical value notification protocols	Reduces transfusion errors and turnaround time
Quality Control	Different QC sample sizes and acceptance limits	Harmonized QC frequency, acceptance ranges, documentation	Strengthens audit readiness and comparability
Deviation Management	Inconsistent reporting and CAPA documentation	Unified deviation tracking system	Improves trend analysis and compliance
Disaster Preparedness	Inconsistent mutual aid and supply-sharing plans	Standard operating framework for a Disaster Task Force	Improves response efficiency and supply chain resilience