

Risk Identification and Control Strategy for Blood Specimen Transportation Quality Under the Centralized Testing Model

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Abstract

Objective: To systematically identify quality risks across the entire process of blood specimen transportation under the centralized testing model in Chongqing, develop a risk evaluation index system, and propose targeted control strategies to reduce the rejection rate of transported specimens, improve the overall quality of centralized testing, and ensure the safety of clinical blood transfusion. **Methods:** The study followed a closed-loop design of "status survey—risk identification—quantitative evaluation—strategy formulation—application validation". First, a comprehensive investigation of current specimen transportation practices was conducted at Chongqing Blood Center and 10 district/county blood collection and supply facilities using questionnaires, on-site observations, and in-depth interviews, and a risk database was established. Laboratory simulation experiments were performed using a vibration table and temperature-controlled chambers, combined with on-site correlation analysis, to quantify the damaging effects of vibration and temperature on specimen quality and to construct a "temperature–vibration coupling" risk assessment model. Graded control strategies were then formulated for high-risk items and pilot-tested in selected districts/counties. The effectiveness of the strategies was evaluated by comparing outcomes before and after implementation. **Results:** Based on centralized testing records from 2023 to 2025, which included over 900,000 valid transport batch records, the average hemolysis rate was 6.55‰, the average temperature excursion rate was 8.0‰, and the average transport time exceeding 6 hours was 22.64‰. On long-distance suburban routes (>150 km), the hemolysis rate reached 10.8‰, more than doubling that on short suburban routes (3.4‰); the temperature excursion rate reached 15‰, three times that on short suburban routes (5.2‰); and the temperature excursion rate climbed to 18.0% during summer. Rejection cause analysis revealed that hemolysis accounted for 22% and temperature excursions for 28% of rejections, together representing 50%. Laboratory experiments showed that after 30 min of vibration, the hemolysis rate increased from 0.03% to 0.17% (a 5.7-fold increase); after 240 min of vibration, the hemolysis rate reached 0.96% (a 32-fold increase), with free hemoglobin rising exponentially. Temperatures above 30°C significantly accelerated hemolysis. Non-targeted metabolomics analysis demonstrated that storage at room temperature (25°C) for 4 hours significantly upregulated the erythrocyte lactate metabolism pathway ($P < 0.01$). The risk assessment identified summer cold-chain failure, mountainous bumpiness, and prolonged post-centrifugation standing as extremely high-risk items. Pilot tests showed that after implementing the graded control strategy, the hemolysis rate on the test routes decreased by 39.7%, the temperature excursion rate decreased by 60.0%, and vibration damping efficiency exceeded 75%, confirming a synergistic "temperature–vibration coupling" effect. **Conclusion:** This study established a four-dimensional "human–machine–environment–management" risk analysis framework and a "temperature–vibration coupling" risk assessment model. The resulting quantifiable risk evaluation tool and standardized operating procedures provide a transferable "Chongqing Model" for improving the quality management

of blood specimen transportation in mountain city blood stations, which is of great significance for ensuring the quality of centralized testing and enhancing blood safety.

Keywords

Centralized Blood Testing, Specimen Transportation, Risk Identification, Quality Control, Failure Mode and Effect Analysis (FMEA), Mountain City