

# ***Construction and Application of an IT-Based Full-Process Closed-Loop Management Model for Critical Values in Hospitalized Patients Using a "1+3+N" Mechanism***

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**Abstract:** This study developed an information-driven closed-loop management model for inpatient critical values based on a "1+3+N" multi-level response mechanism, significantly improving clinical workflow efficiency and patient safety. Following implementation, the average time from critical value notification to clinician receipt was reduced from 2.88 to 0.12 minutes, physician response time decreased from 5.30 to 1.86 minutes, and specialized supervision duration shortened from 3.71 to 0.51 minutes, while the critical value defect rate dropped from 5.8% to zero, with all improvements being statistically significant ( $P < 0.001$ ). The model effectively optimizes critical value handling processes, ensures accurate and timely information delivery, reduces clinical risks, enables full-process data traceability, and provides strong support for hospital refined management.

## **1. Introduction**

Critical values refer to laboratory or diagnostic test results indicating that a patient's life is in immediate danger, necessitating urgent notification to clinical physicians and prompt intervention [1]. The efficacy of critical value management has become a key metric for evaluating hospital healthcare quality [2]. Traditional management models face significant challenges, including complex transmission chains, reliance on manual registration, susceptibility to omissions, delays, or information errors, and the inability to track processing status in real-time due to weak feedback mechanisms. These limitations hinder true closed-loop management, resulting in low efficiency and direct threats to patient safety. Consequently, in March 2025, our hospital established a dedicated task force to address deficiencies in the informatization of critical value management. Aligning with relevant regulatory clauses, we collaborated with engineers from multiple departments and external vendors to re-engineer workflows. We constructed a full-process closed-loop management model for inpatient critical values, innovatively establishing a "1+3+N" multi-tiered response and assurance mechanism. This reconstruction was achieved by eliminating barriers to manual

information transfer, enabling real-time interoperability among independent systems, implementing a three-tier intelligent alert system, and optimizing workflow logic. Leveraging information technology provided robust support for optimizing critical value management [3-4], and this closed-loop model was implemented in June 2025, significantly enhancing both staff efficiency and patient safety levels.

## **2. Manuscript Preparation**

### **2.1 General Data**

This study employed a randomized pre-post control design. Data were retrospectively extracted from the Hospital Information System (HIS), Laboratory Information System (LIS), Picture Archiving and Communication System (PACS), Ultrasound System, and Electronic Medical Records (EMR):

Pre-intervention Group (October 2024 – March 2025): A random sample of 500 critical value events from hospitalized patients.

Post-intervention Group (October 2025 – March 2026): A random sample of 500 critical value events from hospitalized patients.

Exclusion Criteria: Events where missing information exceeded 10%, rendering traceability impossible. Missing information was defined as the absence of  $\geq 2$  key time points or intervention records.

### **2.2 Outcome Measures**

(1) Average Time to Notification (T1): Defined as the average interval (in minutes) from the confirmation of a critical value within the LIS/PACS/Ultrasound system to its successful delivery to the clinical department (via clinician workstation, mobile nursing terminal, or phone verification).

(2) Average Physician Response Time (T2): Defined as the average interval (in minutes) from the physician's initial confirmation of the critical value in the system to the issuance of an effective treatment order or documentation of the intervention in the progress note.

(3) Documentation Defect Rate: The proportion of sampled cases containing defects in critical value-related records. Defects included obvious errors or omissions in item names, result values, or units; missing key time points (confirmation, notification, receipt, handling); or unrecorded/inappropriate interventions.

(4) Average Supervision Time (T3): The average time (in minutes) required by hospital quality management personnel to complete a compliance review for one case of critical value management.

### **2.3 Statistical Analysis**

Data were processed using SPSS version 26.0. Continuous variables following a normal distribution are presented as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ), with inter-group comparisons performed using independent samples t-tests. Categorical variables are expressed as counts and percentages, with inter-group comparisons performed using Chi-square ( $\chi^2$ ) tests. A P-value  $< 0.05$  was considered statistically significant.

## **2.4 Intervention Strategies**

### **2.4.1 Problem Diagnosis and Model Construction**

A multidisciplinary task force was established, led by the Nursing Department and the

Department of Medical Affairs, comprising representatives from the Clinical Laboratory, Medical Technology Departments, Information Center, Equipment Department, Quality Control Department, Clinical Departments, and third-party technical developers. The task force conducted in-depth research into current practices, identifying four primary issues in traditional critical value management: (1) Reliance on manual data transmission (e.g., telephone notifications, paper-based registration), resulting in low efficiency and high risks of omission. (2) Lack of closed-loop management for specimens, leading to potential loss and untraceability. (3) Singular pathways for information retrieval by healthcare workers, increasing the risk of missed alerts. (4) Absence of intelligent quality control and monitoring tools, hindering the oversight of timeliness and completeness.

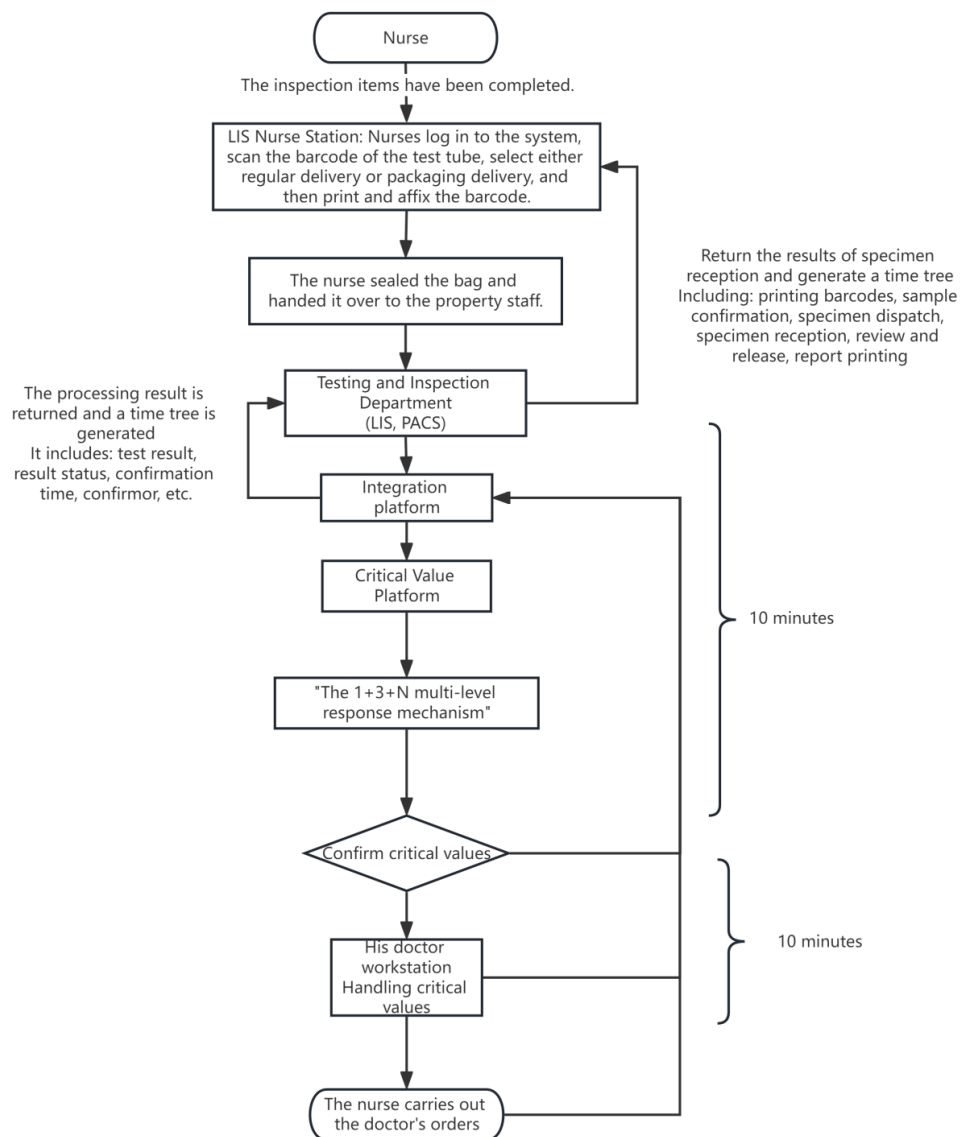


Figure 1: Flowchart of Full-Process Closed-Loop Management for Inpatient Critical Values.

These issues compromise accuracy and traceability, posing potential safety risks to patients. This study developed a closed-loop management model based on the principles of "Laboratory-Led Coordination, Multi-Tiered Response, Intelligent Interconnectivity, and Full-Process Traceability." Following a rigorous pathway of "problem diagnosis – theoretical guidance – solution design – technical implementation – validation and optimization," we established the "1+3+N" mechanism.

The workflow initiates when nurses package specimens → Medical Technology Departments receive samples → Laboratory confirms critical values → Critical Value Management Platform activates.

“1” – Laboratory-Led Core: The critical value management platform serves as the central hub, uniformly triggered and monitored by the Clinical Laboratory, acting as the "sentinel" and quality control center for the entire process.

“3” – Three-Tiered Intelligent Response Mechanism:

Tier 1: Upon confirmation, data are automatically distributed via the integration platform and pushed to clinician/nursing information systems.

Tier 2: If Tier 1 remains unacknowledged after a timeout (exceeding 8 minutes), the system triggers an AI-driven voice call via the telephony platform.

Tier 3: If Tier 2 remains unacknowledged after a further timeout (exceeding 9 minutes total), the alert escalates to the Department Head or the Hospital Duty Office via telephone for mandatory intervention.

“N” – Deep System Integration: Based on our hospital’s self-developed platform, real-time data synchronization was achieved across LIS, HIS, PACS, Ultrasound, EMR, Mobile Nursing Systems, AI Telephony, and the Integration Platform (based on ESB/HL7 standards).

The final closed-loop pathway involves: Specimen packaging → Automated identification/tagging/confirmation by Medical Technology → Push via Integration Platform → Reception/Handling by Clinicians → Quality Control by Medical Affairs → Feedback and Optimization (see Figure 1).

## 2.4.2 Technical Integration and Innovation Collaborating

With multiple technology firms, we redesigned workflows, clarified node connections, and upgraded protocols for confirmation rules, push logic, handling standards, end-to-end tracking, and intelligent feedback. We independently developed the critical value management platform, reconfigured modules, and achieved deep integration with hospital systems. Rigorous unit testing, integration testing, stress testing, and User Acceptance Testing (UAT) were conducted. Comprehensive training was provided to ensure smooth adoption. Pilot runs collected feedback for continuous optimization before hospital-wide rollout. Key innovations include:

Full-Process Audit Trail: All manual steps (result confirmation, platform push acknowledgment, order issuance, progress documentation, feedback) are automatically logged with timestamps and operator IDs, ensuring complete traceability.

Intelligent Analytics & QC Reporting: The platform features embedded modules for real-time visualization of core metrics (TI, T2) and supports customized report generation by department or timeframe.

Three-Level Alert Triggering: Automatic alarms are generated if notification latency exceeds 8 minutes (against our internal standard of  $\leq 10$  minutes), activating Tier 2 and 3 responses to ensure timely action.

Bidirectional Lab-Clinical Feedback: Clinician actions (electronic orders/notes) are instantly reflected back to the laboratory system, prompting lab staff to verify closure, thereby creating a two-way feedback loop.

## 3. Results

### 3.1 Comparison of Average Notification Time (TI)

Prior to intervention, TI represented the average time for 500 cases where laboratory staff

manually telephoned clinicians. Post-intervention, TI represented the average time for 500 cases where the platform automatically identified and notified clinicians. The mean TI decreased significantly from  $(2.88 \pm 1.71)\text{min}$  to  $(0.12 \pm 0.03)\text{ min}$  ( $P < 0.05$ ), indicating substantial improvement (Table 1).

Table 1: Comparison of Mean Notification Time Before and After Intervention ( $\bar{x} \pm s$ )

| Group             | n   | Mean Time (min) | t-value | P-value |
|-------------------|-----|-----------------|---------|---------|
| Pre-intervention  | 500 | $2.88 \pm 1.71$ | 35.895  | 0.000   |
| Post-intervention | 500 | $0.12 \pm 0.03$ |         |         |

### 3.2 Comparison of Average Physician Response Time (T2)

Pre-intervention, timing began when the lab called the nurse, who then informed the doctor, ending when the doctor manually recorded actions in a logbook. Post-intervention, timing began upon digital notification to the clinician's interface and ended with the issuance of electronic orders. Mean T2 decreased significantly from  $(5.30 \pm 2.32)\text{min}$  to  $(1.86 \pm 0.72)\text{min}$  ( $P < 0.05$ ) (Table 2).

Table 2: Comparison of Mean Physician Response Time Before and After Intervention ( $\bar{x} \pm s$ )

| Group             | n   | Mean Time (min) | t-value | P-value |
|-------------------|-----|-----------------|---------|---------|
| Pre-intervention  | 500 | $5.30 \pm 2.32$ | 30.313  | 0.000   |
| Post-intervention | 500 | $1.86 \pm 0.72$ |         |         |

### 3.3 Comparison of Documentation Defect Rates

Pre-intervention, manual audits of 500 logbooks revealed defects such as illegible handwriting, incorrect data, omissions, missing units, or missing signatures. Post-intervention, automated backend audits of 500 records showed a reduction in the defect rate from 5.8% to 0% ( $P < 0.05$ ) (Table 3).

Table 3: Comparison of Documentation Defect Rates Before and After Intervention (n, %)

| Group             | n   | No Defects  | Defects Present | $\chi^2$ | P-value |
|-------------------|-----|-------------|-----------------|----------|---------|
| Pre-intervention  | 500 | 471 (94.2%) | 29 (5.8%)       | 29.866   | 0.000   |
| Post-intervention | 500 | 500 (100%)  | 0 (0%)          |          |         |

### 3.4 Comparison of Average Supervision Time (T3)

Pre-intervention, supervisors physically visited labs and clinics to check 500 logbooks for timeliness, accuracy, and adherence to protocols. Post-intervention, supervision involved tracing database records for 500 cases. Mean T3 decreased significantly from  $(3.71 \pm 0.32)\text{min}$  to  $(0.51 \pm 0.01)\text{ min}$  ( $P < 0.05$ ) (Table 4).

Table 4. Comparison of Mean Supervision Time Before and After Intervention ( $\bar{x} \pm s$ )

| Group             | n   | Mean Time (min) | t-value | P-value |
|-------------------|-----|-----------------|---------|---------|
| Pre-intervention  | 500 | $3.71 \pm 0.32$ | 97.032  | 0.000   |
| Post-intervention | 500 | $0.51 \pm 0.01$ |         |         |

## 4. Discussion

Full-process closed-loop management enables proactive risk mitigation at every stage,

facilitating early prevention, precise intervention, and continuous monitoring, thereby fundamentally reducing adverse events [5]. Multiple studies indicate [6-7] that IT-based management effectively prevents human error in critical value workflows. This approach significantly contributes to improving service quality, preventing adverse events, and mitigating medical risks [8-10].

#### **4.1 Enhancing Accuracy and Standardization of Reporting**

Accurate reporting and handling are prerequisites for closed-loop management [11]. The Action Plan for Comprehensively Improving Medical Quality (2023–2025) emphasizes optimizing critical value identification and strengthening reporting accuracy. While ideal accuracy is 100%, traditional manual systems often suffer from error rates between 0.1% and 10.0% due to systemic gaps, workload pressures, and fatigue [12]. Prior to this study, processes relied on manual confirmation, paper logging, and phone calls, leading to delayed/incorrect reports, illegibility, and missing data. The new model automates multi-tiered responses, eliminating human error at the source. Automated logging and intelligent analysis replaced manual recording, reducing the defect rate to 0%. This enhances data reliability while lowering labor costs and adverse event incidence.

#### **4.2 Reducing Response Times To Ensure Patient Safety**

Tertiary hospitals handle high volumes of critical values, where traditional manual methods struggle with timeliness [13]. Prompt reporting, receipt, and handling are vital for patient outcomes [8]. Guidelines from the Chinese Society of Laboratory Medicine stipulate a maximum 30-minute window for confirmation and receipt. Our internal protocol requires: Lab-to-Dept notification  $\leq 10$  mins; Dept-to-Physician notification  $\leq 10$  mins; Physician Action  $\leq 10$  mins. Previously, single-channel phone notifications often failed these constraints. The “1+3+N” mechanism ensures no blind spots in information flow, utilizing multiple pathways to notify clinical teams. Results show T1 dropped to 0.12 min and T2 to 1.86 min, well within the 10-minute limit, ensuring timely intervention and reducing medical risk.

#### **4.3 Improving Efficiency and Supporting Precision Management**

Traditional manual records lack real-time synchronization and traceability [14]. Previously, supervisors spent considerable time physically auditing logbooks. Post-intervention, the integrated platform enabled real-time interoperability across HIS, LIS, PACS, etc. Critical value information can be imported into progress notes with one click, with automatic timestamping and attribution of responsibility. This streamlined supervision, reducing T3 from 3.71 min to 0.51 min. Furthermore, the platform’s analytics module generates real-time KPIs and automated reports, providing objective data support for management decisions and enhancing overall operational efficiency.

### **5. Conclusion**

This study developed and implemented an information-driven, full-process closed-loop management model for critical values in hospitalized patients. By leveraging the “1+3+N” mechanism, integrating multiple systems, and ensuring end-to-end traceability, this model effectively mitigated the deficiencies of traditional approaches regarding the accuracy, timeliness, and standardization of critical value notification and intervention. Furthermore, it reduced labor costs and medical risks while enhancing operational efficiency. As critical value management is a continuous process requiring ongoing improvement, future efforts should harness rapid

advancements in information technology to further promote the informatization, standardization, and efficiency of hospital-based critical value management. We intend to continuously refine the closed-loop management workflow to better align with clinical demands, thereby strictly adhering to patient safety goals and safeguarding the quality of healthcare services.

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