Short Communication

Effects of Assigning a Risk Manager in the Clinical Laboratory on the Management of Critical Values at Tohoku Medical and Pharmaceutical University Hospital

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Received May 20, 2025; accepted August 19, 2025
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ABSTRACT

Objective: Effective management of medical treatment information, particularly critical values, is essential in every clinical laboratory. A proposal for the management of critical values was issued by the Japanese Society of Laboratory Medicine in 2021. Our laboratory began implementing the revised proposal in December 2024, which recommends appointing a medical technologist as a risk manager. The risk manager is responsible for monitoring the occurrence of critical values, and acting as a liaison between the Clinical Laboratory and the Medical Safety Department.

Methods: We evaluated the impact of sharing and reviewing critical values, by a risk manager, with the Medical Safety Department by analyzing the number and content of critical value reports and tracking telephone communications from laboratory physician to attending physicians. Data from the fiscal year 2018 through June 2025 were included in the analysis.

Results: In our hospital, the total number of tests increased from 2,301,813 in 2018 to 3,235,049 in 2024. Between April 2018 and November 2024, there were 10 telephone calls from laboratory physician to attending physicians regarding 28,980 critical values. In contrast, from December 2024 onward, there were 13 such calls for just 2,495 critical values—a statistically significant increase ($z = -8.65$, $p < 0.0001$) following the appointment of a risk manager.

Conclusions: The introduction of a risk manager to facilitate the sharing and review of critical values with the Medical Safety Department led to a significant increase in follow-up telephone communication from laboratory physician. This may reflect improved professional oversight and laboratory management.

〔Lab Med Int 2025; 4(4): 125-131〕

Key Words
critical value, risk management, medical safety

I. Introduction

In clinical laboratories, the frequency of errors is considered to be lower than in other hospital departments. However, even a low error rate can still result in a considerable number of incidents due to the large volume of tests performed daily [1]. Therefore, ensuring medical safety is essential not only in high-risk areas but also

in all departments, including clinical laboratories. The 2007 medical service law required medical institutions to prepare guidelines for various aspects of hospital operation, including maintenance plans for medical equipment, procedures for pharmaceutical use, infection control, and importantly, medical safety [2]. As a result, medical safety guidelines are now seen as necessary tools to support the delivery of accurate and reliable clinical laboratory data to physicians, and efforts to enhance medical safety have attracted growing attention [3][4].

Our laboratory, the Department of Clinical Laboratory at Tohoku Medical and Pharmaceutical Hospital, obtained ISO 15189 accreditation in January 2019 [5]. Thereafter, we experienced, and reported in this journal, that the implementation of ISO 15189 led to a significant improvement in risk management, contributing to enhanced medical safety and a reduction in the number of incidents [6][7].

In 2021, the Japanese Society of Laboratory Medicine issued a proposal for managing critical values, which was revised in 2024 [8]. Our laboratory, started following the proposal for critical values from December 2024, which recommends to appoint a medical technologist as a risk manager to monitor the number of critical values occurred, review and act as a conduit between Clinical Laboratory, and Medical Safety Department. We report here, the significant increment of checking telephone call from laboratory physician, which may reflect more professional laboratory management.

II. Methods

A. Participants and statistics

We analyzed the number of critical values that occurred in the Department of Clinical Laboratory at Tohoku Medical and Pharmaceutical University Hospital. The definition of critical values used in this hospital followed the criteria described previously [9]. The number of critical values observed during the study period was 28,980 from April 1, 2018 to November 30, 2024, and 2,495 from December 2024 to June 30, 2025. For statistical analysis, a z-test was performed to evaluate the significance of differences, and statistical significance was determined accordingly.

B. Ethics

We carefully considered the protection of personal information. This study focused exclusively on the number of tests and critical values, and did not involve any patient-identifiable data. We strictly adhered to the Policy on the Handling of Case Reports issued by the Ethics Committee of Tohoku Medical and Pharmaceutical University Hospital.

III. Results

1. Transition of the number of the critical values and critical values commenting reports

Our hospital has undergone several transitions over the years. In 2013, it changed its name from Tohoku Welfare Pension Hospital to Tohoku Pharmaceutical University Hospital (466 beds). Following the establishment of the medical faculty in 2016, the hospital was renamed Tohoku

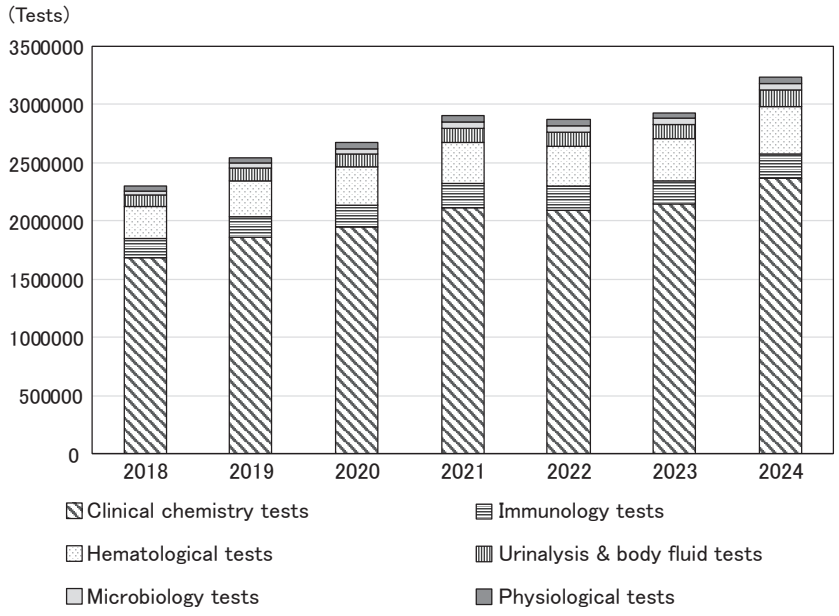

Figure 1 Annual changes of the transition of the total number of tests

Medical and Pharmaceutical University Hospital. The number of beds increased to 600 in 2020. In this way, the hospital has gradually evolved from a community hospital to a university hospital, with a unique background and changing roles and functions. Annual changes in the total number of tests (including both specimen and physiological tests) during the study period are shown in **Figure 1**. The actual numbers were as follows (by fiscal year): 2018: 2,301,813, 2019: 2,545,856, 2020: 2,670,728, 2021: 2,906,752, 2022: 2,873,229, 2023: 2,931,994, 2024: 3,235,049. Overall, the number of tests increased approximately 1.4-fold during this period.

The management of critical values in our laboratory is carried out as follows. Critical values [9] are reported through the electronic medical record system and by telephone calls from medical technologists to the physicians who ordered the test. All reports are documented in forms called "phone call record memos" (S **Figure 1**). The laboratory physician checks these memos several times a day and confirms, through the electronic medical records, whether the attending physician has taken any action regarding the critical value. If no action is observed in response to a critical value involving antibiotic-resistant bacteria, the laboratory physician issues a "critical values commenting report." For other types of critical values, if no action is taken, the laboratory physician directly calls the attending physician and issues a "critical values commenting report" if necessary (S **Figure 2**).

Until June 2020, the number of critical value items was extremely high at 64 (national average: 19.9) [9], and approximately 7,000 reports of critical values were made annually via telephone (national average: 2,472) [9]. Therefore, a review of the critical value reporting criteria was conducted to ensure appropriate operation. In June 2020, the definition of critical values was revised, reducing the number of items by 18 [10], which clearly led to a decrease in daily reported critical values.

Annual changes in the number of critical values, categorized by medical service, are shown in **Figure 2**. The number of annual critical values clearly decreased after 2020. After June 2020, most of the "critical values commenting reports" were related to antibiotic-resistant bacteria, and their numbers gradually declined (S **Figure 3**). This may indicate that documentation of pathogens in electronic medical records by the attending physicians has become standardized, thereby reducing the need for laboratory physician to issue these reports frequently.

As shown in **Figure 3**, before June 2020, roughly 30 to 40 critical values were reported daily. After the revision in June 2020, the number decreased to about 10 to 20 per day. During the period from April 2018 to November 2024, the number of checking telephone calls made by laboratory physician was 10 (out of 28,980 critical values), whereas after December 2024, when appointed a medical technologist as a risk manager to monitor the number of critical values, the number increased to 13 (out of 2,495). Notably, the proportion of such calls increased significantly, with statistical significance ($z = -8.65$, $p < 0.0001$).

2. Transition of the checking telephone call from laboratory physician

As noted in the Introduction, in December 2024, we appointed a medical technologist as a risk manager to monitor the number of critical values, conduct reviews,

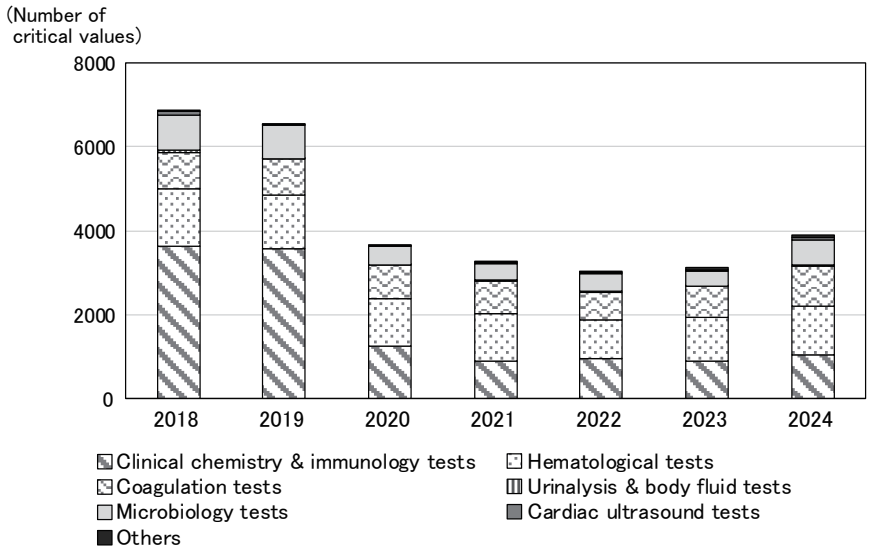

Figure 2 Transition of the number of the critical values.

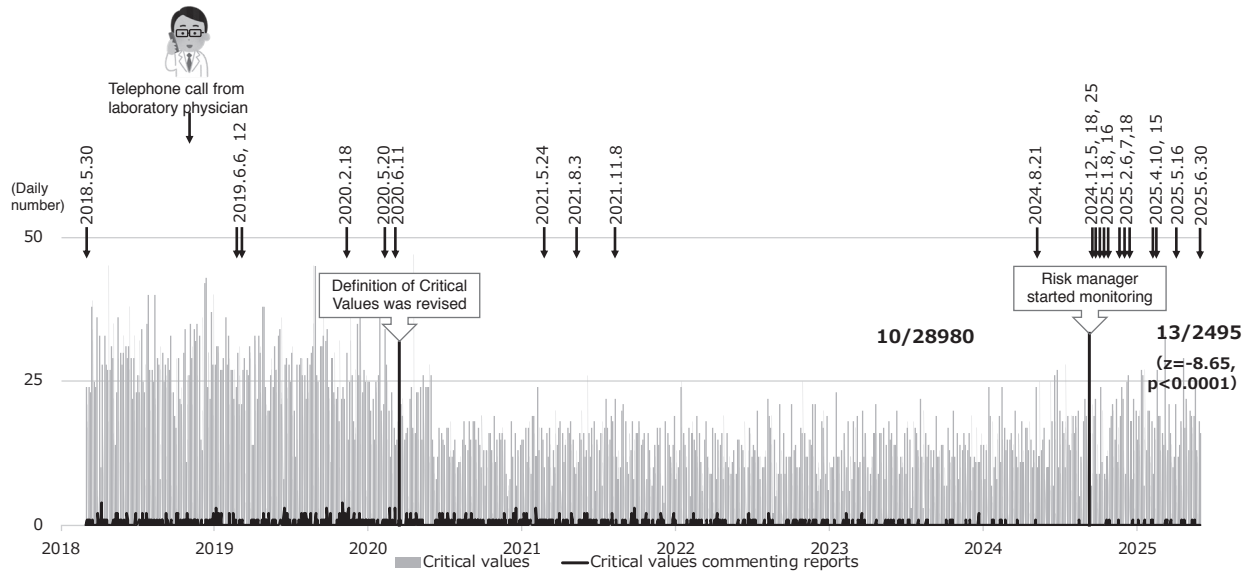

Figure 3 Transition of the number of the critical values, critical values commenting reports and checking telephone call from laboratory physician.

and act as a conduit between the Clinical Laboratory and the Medical Safety Department. The details of a phone call from 2018 are described in **Table 1** (S **Figure 4**). Among the confirmation calls made by laboratory physician during this period, those concerning potassium concentration (n=8) were the most frequent. Other calls were related to white blood cell morphology and/or counts (n=4), platelet number (n=3), possible M-protein (n=2), flow cytometry results (n=2), coagulation and fibrinolysis (n=2), blood glucose levels (n=1), and antibiotic-resistant bacteria (n=1). Among these calls, on February 18, 2020, we encountered a case in which the laboratory physician contacted the attending physician, who was unaware of a critically low platelet count (Plt = 6,000/μL). This occurred because, laboratory technologists typically notify the physician who ordered the test. However, in this instance, the attending physician differed from the ordering physician, and the notification failed to reach the appropriate recipient. In May 2025, serum protein electrophoresis revealed a possible M-protein in a patient managed by a resident physician in a certain department. Although the resident had been informed of the result, they were uncertain about the appropriate next steps, and no follow-up action was taken. The following day, the laboratory physician contacted the resident, advising additional diagnostic orders and referral to hematology, which subsequently led to a diagnosis of multiple myeloma. A similar incident occurred again in June. These cases suggest that a certain proportion of phone calls made by laboratory physicians may indeed contribute to patient safety. Therefore, the confirmation calls made by laboratory physician serve as a final safeguard.

IV. Discussion

The definition of critical values has been debated by laboratory professionals for decades [11]. Lippi et al. summarized recommendations regarding the notification, parameters, and communication of critical laboratory values based on available guidelines from the Joint Commission, Clinical and Laboratory Standards Institute, and the Royal College of Pathologists [12]. Although there is some agreement on the definition of critical values, they remain relatively heterogeneous worldwide [12], and no universally accepted definition or list of parameters exists. They are typically defined locally in agreement with relevant stakeholders.

In this context, Doering et al. examined five years of inpatient admissions for critical or near-critical results. They found that elevated potassium thresholds effectively identified patients at risk of death. Furthermore, they clarified that the mortality risk associated with most critical values is time-dependent [13]. Murakami et al. investigated the importance of various clinical test items (glucose, BUN, sodium, potassium, AST, ALT, LDH, CK, phosphate, calcium, serum amylase, white blood cell count, hemoglobin, platelets, PT-INR) by conducting a questionnaire survey among physicians. They found that abnormal results for glucose, PT-INR, and potassium concentration were most frequently regarded as "critical values requiring immediate medical intervention" [14]. In our study, among the checking calls made by laboratory

Table 1 Details of telephone call from laboratory physician

Date	Details of phone calls from laboratory physician	At the time laboratory physician called, the physician in charge already noticed the critical value(s)?
30-May-18	Low platelet count, Plt=23000(/μL) (Due to rapid decrease, adding coagulation tests were recommended for further evaluation).	Yes
21-Dec-18	Provision of advisory services (about reticulated platelets).	N/A
6-Jun-19	High concentration of potassium, 6.4 (mEq/L), and confirmed the response of the doctor.	Yes
12-Jun-19	Emergency report about the interpretation of READ flow cytometry result	Yes
18-Feb-20	Low platelet count, Plt=6000(/μL) and confirmed the response of the doctor.	No
20-May-20	Emergency report about the results of outsourced flow cytometry analysis, which suggests bone marrow infiltration of mantle cell lymphoma	Yes
11-Jun-20	Microbiology results after discharge, about MRSA(2+:sputum)、E.coli ESBL(4+:urine from a catheter)	Yes
17-Feb-21	Provision of advisory service (about white blood cell trends before and after dialysis)	N/A
24-May-21	Low platelet count, Plt=5000(/μL) and confirmed the response of the doctor.	Yes
15-Jul-21	Provision of advisory service (about bone marrow examination report).	N/A
26-Jun-21	Provision of advisory service (about required amount of blood for IgE measurement test).	N/A
3-Aug-21	Addition of test items [FCM, sIL2R] based on abnormalities in peripheral blood smear	Yes
6-Aug-21	Provision of advisory service (about interpretation of the result of flow cytometry issued on Aug 3)	N/A
8-Nov-21	Explain the contents of the peripheral blood smear report. Inform that chronic lymphocytic leukemia (CLL) is highly suspected.	Yes
15-Mar-22	Provision of advisory service (about pseudohyperkalemia and offered advice on differential diagnosis).	N/A
28-Apr-22	Provision of advisory service (about suspected macro-CKemia).	N/A
17-May-22	Provision of advisory service (about macro-CKemia).	N/A
21-Aug-24	Notified that degranulated neutrophils were observed and advised consideration of hematologic neoplasms with dysplasia, such as CMML.	Yes
18-Nov-24	Provision of advisory service (about peripheral blood lymphocyte morphology).	N/A
5-Dec-24	High concentration of potassium, 6.1 (mEq/L), and confirmed the response of the doctor.	Yes
18-Dec-24	High concentration of potassium, 6.2 (mEq/L), and confirmed the response of the doctor.	Yes
25-Dec-24	Low concentration of potassium, 2.6 (mEq/L), and confirmed the response of the doctor.	Yes
8-Jan-25	High concentration of potassium, 6.3 (mEq/L), and confirmed the response of the doctor.	Yes
16-Jan-25	High concentration of D-dimer 12.92 (μg/mL), and confirmed the response of the doctor.	Yes
6-Feb-25	High concentration of D-dimer 11.75 (μg/mL), and confirmed the response of the doctor.	Yes
7-Feb-25	Low concentration of potassium, 2.5 (mEq/L), and confirmed the response of the doctor.	Yes
7-Feb-25	Low concentration of potassium, 2.5 (mEq/L), and confirmed the response of the substitute doctor.	Yes
18-Feb-25	High blood glucose of 355 mg/dL and potassium level of 6.3 mmol/L and confirmed the response of the doctor.	Yes
10-Apr-25	Increased number of WBC, 24000/μL, and confirmed the response of the doctor.	Yes
15-Apr-25	Severe mitral regurgitation diagnosed by cardiac ultrasound test	Yes
16-May-25	A possible M-protein was reported. With no response from the resident, immunotyping, IgG, IgA, IgM testing, and hematology referral were recommended.	Yes (but needs guidance)
30-Jun-25	A possible M-protein was reported. Only urine protein test was ordered from the resident, immunotyping, IgG, IgA, IgM testing, and hematology referral were recommended.	Yes (but needs guidance)

physician, those related to potassium concentration were the most frequent (**Table 1**). Therefore, it may be necessary to handle results for potassium, glucose, and PT-INR with particular care, ensuring that prompt action is taken by the attending physicians. Further attention and improvement in the communication of these critical values are essential for enhancing medical safety.

It should be noted that various factors can affect serum potassium levels, including elevated white blood cell or platelet counts and pre-analytical factors such as hemolysis or delayed centrifugation during specimen processing [15]. Therefore, laboratory staff should always consider these factors and may need to provide guidance on interpreting such results.

Several studies have shown that multidisciplinary collaboration is necessary to ensure that all critical values are responded to appropriately. One report indicated that in the intensive care unit (ICU), implementation of a daily goals form—which enhanced communication among nurses and residents—reduced ICU length of stay from a mean of 2.2 days to 1.1 day [16]. Fazzini et al. also emphasized the value of regular multidisciplinary safety briefings, which improved situational awareness and nearly halved delays in critical care referrals [17].

In conclusion, sharing and reviewing critical values with the Medical Safety Department through a designated risk manager led to a significant increase in checking telephone calls from laboratory physician. This may reflect a more professional approach to laboratory management.

Funding

This work was supported in part by the Shino-Test Corporation and the Shionogi Corporation Research Fund.

Author contributions

R. Miura, played a pivotal role for this study, as a risk manager to monitor the critical value, acting as a liaison between our laboratory and medical safety department. R. Miura also analyzed the data and designed the figures. R. Kozakai contributed to manage critical value reporting system. Y. Endo analyzed the data. S. Takahashi designed the study and wrote the manuscript. All authors have accepted responsibility for the entire content of this manuscript and have approved its submission.

Disclosure of Conflicts of Interest

None

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