Recommendations for the prevention of recurrence of medical accidents
Number 20

Analysis of Deaths Related to the Critical (Panic) Values in Blood Tests

December 2024

Medical Accident Investigation and Support Center
(Japan Medical Safety Research Organization)

The Purpose of “Recommendations for the Prevention of Recurrence”

These recommendations are provided as information based on the medical accident investigation reports from the concerned medical institutions. Among those reports, the Medical Accident Investigation and Support Center accumulates similar cases, investigates and analyzes their common or similar points, and provides them as recommendations.

These recommendations should be regarded as recurrence prevention measures focusing on the importance of avoiding accidents that may result in death, and should be distinguished from the “Guidelines” issued by the government and academic societies. Thus, this leads to the fact that the recommendations do not set any limit to the discretion of healthcare professionals, nor impose any new obligations or responsibilities.

Based on these considerations, we hope these recommendations will be widely used, taking into account comprehensively various situations such as the user’s medical decision-making, each patient’s condition and age, the wishes of the patient and family, as well as the medical institution’s practice systems and size.

In addition, these recommendations are to provide information to avoid similar deaths, to prevent recurrence, and to ensure patient safety. It is based on the provisions of Medical Care Act, and is not intended to be used as a means for resolving disputes.

In Publishing the Recommendations for the Prevention of Recurrence of Medical Accidents (Number 20)

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Chair of the Board of Directors
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Based on the Medical Accident Investigation System launched in October 2015, the Medical Accident Investigation and Support Center (ISC) of the Japan Medical Safety Research Organization (Medsafe Japan) has been working with every effort to promote patient safety, to prevent recurrence of medical accidents, and to improve medical quality.

Along with the increasing advancement and diversification of the medical environment in recent years, medical institutions strive every day to prevent serious medical accidents from occurring. However, serious events do in fact occur in medical settings, at times resulting in the unexpected death of patients. Such cases have been reported to the ISC. Since the system's launch nine years ago, more than 2,700 in-hospital investigation reports have been sent to the ISC. Based on these reports, to date we have published 19 recommendations as "Recommendations for the Prevention of Recurrence of Medical Accidents."

We, ISC, have published our twentieth report compiled to prevent recurrence of medical accidents. As the theme of analysis, we decided to take up the cases of deaths related to laboratory panic values. Blood tests are performed at medical institutions of various scales across the country. It is common for "test values" to reveal changes in the body that are not detectable by physical examination alone. A laboratory panic value, defined as "an abnormal value suggesting a critical condition that may be potentially life-threatening," indicates that any delay in treatment could result in fatality. In consideration of its significance, the present recommendations have been issued. We have derived five recommendations through analysis of 12 target cases related to the reporting system and presentation of panic values, and the response to panic values.

The purpose of the Medical Accident Investigation System is to promote safety in medical settings, and providing safe medical care requires widespread initiatives and efforts. "Recommendations for the Prevention of Recurrence of Medical Accidents" have been compiled after examining the cases of death reported to the ISC based on the expertise of that time and in terms of patient safety. The purpose is to "avoid unexpected deaths." These recommendations should be distinguished from guidelines published by academic societies and other organizations, which are examined based on broad knowledge, and do not limit the discretion of health-care professionals or impose any obligations on them. While each medical institution differs in environment and circumstances, including size and system, we hope that these recommendations will be widely utilized in medical institutions to avoid accidents associated with laboratory panic values. Additionally, we will continue to review our recommendations to ensure that they aid clinical practice, and will remain committed to providing information that reflects actual medical settings, based on reported cases.

Finally, we would like to express our sincere gratitude to the medical institutions and bereaved families who cooperated in providing in-hospital investigation reports and offering additional information, as well as to the experts of the analysis subcommittee who analyzed the cases in detail and explored the measures to prevent recurrence, for their understanding and cooperation.

Recommendations for the Prevention of Recurrence of Medical Accidents (Number 20)

Analysis of Deaths Related to the Critical (Panic) Values in Blood Tests

<Professions relevant to the recommendations>
Healthcare professionals and medical safety controllers involved in blood testing, such as physicians, clinical laboratory technicians, and nurses.

Panic values are "abnormal values suggesting a critical condition that may be potentially life-threatening."[1] The following recommendations are provided concerning panic values, as they require timely reporting to the physician who ordered the test and necessitate an urgent response.

[Setting panic value parameters and thresholds]

Recommendation 1

Medical institutions should investigate and specify the parameters (e.g., Glu, K, Hb, Plt, and PT-INR) and thresholds for panic values based on the medical treatment they provide.

[Reporting panic values]

Recommendation 2

Panic values should be reported by the clinical laboratory technician directly to the physician who ordered the laboratory test, in principle. The clinical laboratory department should keep a record of panic values reported to prevent missed reports.

[Responding to panic values]

Recommendation 3

Physicians who receive a report of a panic value should take actions in response to the panic value and document them accordingly. It is advisable to discuss the process through which the organization can confirm that actions have been taken by the physician in response to the panic value.

[Presenting panic values]

Recommendation 4

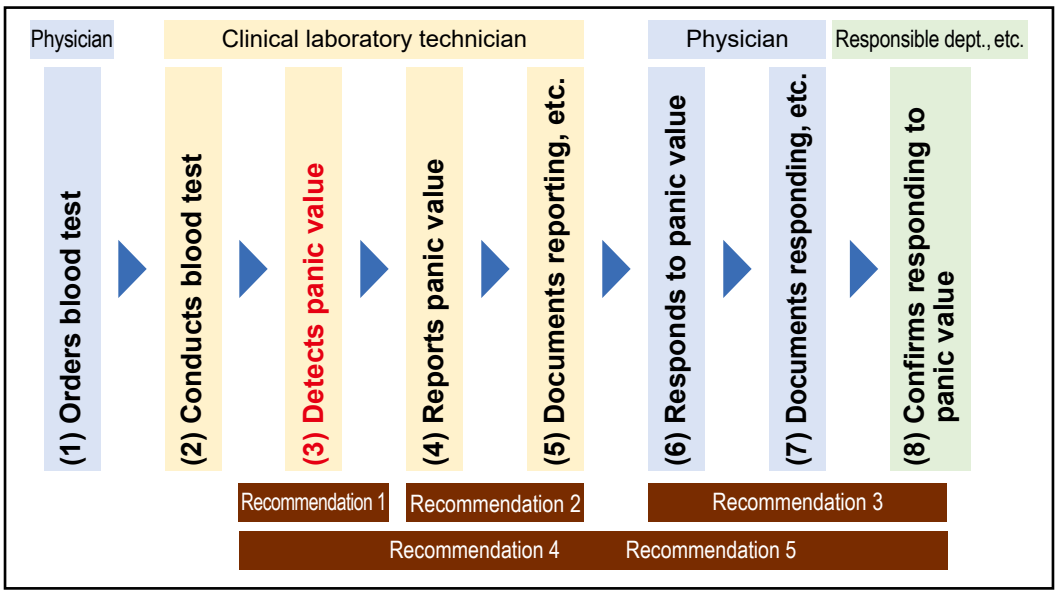
To avoid overlooking panic values, a presentation format should be devised to allow for recognition of panic values at a glance in the clinical laboratory information system, electronic medical record, and laboratory test report.

[Establishing the internal system for handling panic values]

Recommendation 5

Medical institutions should clearly define the roles of the persons and/or sections responsible for managing the internal handling of panic values, establish a system for regularly reviewing the handling rules, and ensure that the established handling rules are communicated within the institution.

Flow for responding to the detection of a laboratory panic value (example) and the scopes of our recommendations



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1. Introduction

1) Laboratory panic values

A panic value, defined as “an abnormal value suggesting a critical condition that may be potentially life-threatening,” requires immediate initiation of treatment to save the patient’s life. Such conditions are not readily detectable by clinical examination alone and require laboratory testing to be detected.[1)]

Panic values refer to laboratory results that deviate significantly from the reference interval of laboratory test values and require prompt and reliable reporting by the clinical laboratory technician to the ordering physician, because such values can have a profoundly negative impact on the patient’s prognosis if not addressed.

While various terms are used to refer to panic values, including “urgent abnormal values” and “urgent report test values,” “critical values” is typically used in articles and conference presentations in English.[1)] In this document, the term “panic values” is used because it is widely used in medical practice in Japan.

Caution has been advised to ensure thorough reporting of panic values in light of the cases where delays in urgent contact regarding panic values resulted in delayed treatment for patients, as reported in Medical Safety Information No. 111 in February 2016 as part of the Project to Collect Medical Near-Miss/Adverse Event Information by Japan Council for Quality Health Care. The questionnaire survey conducted by the Japanese Society of Laboratory Medicine in 2017 regarding handling of panic values revealed that clinical laboratory parameters with predetermined panic values and their threshold levels were not consistent across medical institutions. It was also found that, while panic values were immediately reported as provisional results by the clinical laboratory department to clinical units through various methods, there was no standardized approach among medical institutions regarding urgent communication systems, documentation in medical records, clinical responses, and review procedures.[1)2)]

In response to this situation, the Japanese Society of Laboratory Medicine published the “Recommendations on Handling of Laboratory ‘Panic Values’” in December 2021 (revised in June 2024),[1)] and initiatives to address panic values have begun. The document provides a list of panic values as examples, and among them, glucose, potassium, hemoglobin, platelet count, and prothrombin time are highlighted as “examples of parameters requiring immediate reporting” to the physician who ordered the test because panic values of these parameters require particularly urgent action.

Despite various efforts made by medical institutions to address panic values as described above, multiple fatal cases related to panic values have been reported to the ISC. Of the deaths related to laboratory panic values that have been reported to the ISC in accordance with the Medical Accident Investigation System, 12 instructive cases have been analyzed. Based on the detailed analysis of these cases by the Expert Analysis Subcommittee, we are publishing recommendations regarding the measures to prevent accidents related to panic values.

We sincerely hope that this recommendation document will contribute to preventing the recurrence of deaths related to panic values.

2) Background of the establishment of the Expert Analysis Subcommittee

To prevent the recurrence of similar medical accidents, the Committee for Prevention of Recurrence (see page 34) at the ISC selects the subject (theme) of analysis from the cases of accidents reported to the Center. The Committee then establishes an Expert Analysis Subcommittee for each theme (see page 34) that consists of medical specialists in the theme and prepares recommendations.

The implementation of blood tests involves multiple areas within medical institutions, including outpatient clinics and inpatient wards where samples are collected, as well as clinical laboratory departments and clinical laboratories where analyses are conducted. At present, however, there is no standardized system for reporting and responding to detected panic values. These values suggest a critical condition that may pose a risk to the patient's life, necessitating an immediate response. In recognition of the importance of analyzing these cases and taking measures to prevent recurrence, we have established the Expert Analysis Subcommittee with the aim of mitigating mortalities associated with panic values.

3) Patient safety approaches that have been taken in relation to the recommendations

○ Japan Council for Quality Health Care. Project to Collect Medical Near-Miss/Adverse Event Information. Medical Safety Information No. 111 "Delays in Urgent Contact Regarding Panic Values" (February 2016)

○ Japanese Society of Laboratory Medicine
Recommendations on Handling of Laboratory 'Panic Values' (2024 Revised Edition)[1)] (in Japanese)

2. Methods of analysis

1) Extraction of target cases

Of the 2,432 in-hospital investigation reports on medical accidents sent to the ISC (October 2015-August 2023), the Expert Analysis Subcommittee analyzed a total of 17 cases in which laboratory panic values were associated with the course leading to death.

In consideration of the variations of panic value parameters and thresholds among medical institutions, the Expert Analysis Subcommittee included in the analysis a total of 12 cases, consisting of nine cases corresponding to "Examples of critical values (commonly called 'panic values')" (see 8. Materials, Material 1) presented in "Recommendations on Handling of Laboratory 'Panic Values' (2024 Revised Edition)" by the Japanese Society of Laboratory Medicine[1)] and three cases corresponding to panic values predetermined within the medical institutions.

In addition, two cases related to laboratory values obtained prior to chemotherapy and three cases related to D-dimer, of which the designation as a panic value parameter remains disputed, are also presented as reference cases.

2) Collecting and sorting information on target cases

The Expert Analysis Subcommittee analyzed the target cases based on the information submitted in the in-hospital investigation reports notified to the ISC. Regarding some ambiguous parts of the reports, additional information was collected to the extent possible with cooperation of the reporting medical institutions. Collected information was organized (see 8 Materials, Material 2).

3) Meetings of the Expert Analysis Subcommittee

◯ First meeting: July 12, 2022
◯ Second meeting: February 16, 2023
◯ Third meeting: July 5, 2023
◯ Fourth meeting: October 3, 2023
◯ Fifth meeting: March 1, 2024

• In addition, opinions were exchanged through electronic media and other means.

3. Overview of target cases

The case overview was prepared by the Expert Analysis Subcommittee by classifying the cases according to the major responsible factor as <cases related to the reporting system for panic values>, <cases related to the response to panic values>, and <cases related to the presentation of panic values> based on in-hospital investigation and additional reports. The case information was also organized according to the following (1) to (5): (1) Patient information, (2) purpose of the clinical laboratory test and other information, (3) clinical course (units for laboratory data are based on the in-hospital investigation reports), (4) time to death, and (5) cause of death and other information.

In some of the target and reference cases, laboratory panic values were involved in the process leading to death but were not directly linked to the cause of death. These cases were selected because of their cautionary nature.

<Cases related to the reporting system for panic values>

Case 1

(1) The patient was an outpatient in his/her 60s scheduled to undergo surgery for hip osteoarthritis.

(2) Preoperative blood tests.

(3) The patient experienced leg pain and was diagnosed with hip osteoarthritis, with a plan to proceed with surgery. During the preoperative laboratory tests, the patient complained of being unable to eat and having malaise. The patient returned home after infusion. The laboratory results revealed WBC 21,500/μL and CRP 34 mg/dL; however, no clinical laboratory parameters or thresholds for panic values were available and no system for reporting panic values was in place. Two days later, the patient experienced malaise and visited the emergency department, after which consciousness became impaired. Then the physician reviewed the preoperative laboratory results and transferred the patient to another hospital because of sepsis.

(4) The patient died shortly after arrival at the other hospital (two days after detection of the panic values).

(5) Cause of death: Sepsis due to iliopsoas abscess. Autopsy imaging (hereinafter, “Ai”): absent. Autopsy: absent.

Case 2

(1) The patient was an inpatient in his/her 70s after surgery for breast cancer and lung cancer. The patient was receiving chemotherapy for a metastatic brain tumor and taking warfarin for deep vein thrombosis.

(2) Routine blood collection for PT-INR.

(3) The physician was on leave and was unable to review the laboratory results showing PT-INR >5.8 (values ≥ 5.8 were not measurable) for the test he/she had ordered earlier. The clinical laboratory department did not report the panic value to the physician because laboratory results had to be confirmed by the physician as determined by the rules. The pharmacist checked the laboratory results but did not make an inquiry, resulting in continued prescription and administration of warfarin. About one week later, the patient had nausea and speech became indistinct. The emergency CT scan results led to a diagnosis of brain hemorrhage. At this time, the physician reviewed the previous laboratory results for the first time.

(4) The patient died about seven hours after the diagnosis of brain hemorrhage (about one week after detection of the panic value).

(5) Cause of death: Hydrocephalus due to brainstem compression and ventricular rupture caused by bleeding from brain metastasis. Ai: absent. Autopsy: absent.

Case 3

(1) The patient was an outpatient aged 10-19 years with multiple malformations, who exhibited symptoms of vomiting and slight fever during a routine outpatient visit.

(2) Test for cause investigation.

(3) The physician scheduled a follow-up appointment one month later during the consultation, and the patient returned home after the blood test. The clinical laboratory technician performed retesting because the CRP level was 50 mg/dL. After finalization of the results, the technician attempted to contact the physician who had ordered the test, as well as the outpatient unit, but was unable to report the results because the outpatient unit was closed. The technician sent the laboratory test results to the electronic medical record without any further attempt at contact as there was no rule for reporting during the absence of the ordering physician. The patient visited the physician's office three days later because of continued symptoms. Then the physician reviewed the previous laboratory test results, and meningitis and septic shock were diagnosed. The patient was immediately hospitalized.

(4) The patient died the day after hospitalization (four days after detection of the panic value).

(5) Cause of death: Septic shock triggered by meningitis. Ai: absent. Autopsy: absent.

Case 4

(1) The patient was an outpatient in his/her 70s who was taking warfarin for portal vein thrombosis following surgery for bile duct carcinoma.

(2) Routine blood collection for PT-INR.

(3) The physician ordered the blood test to be done on the date of imaging with no consultation, and planned to explain the test results on the day of the next scheduled outpatient visit. The laboratory results showed PT-INR of 7.71. The clinical laboratory technician reported to the physician by telephone, saying, "The PT value is abnormal. Please check the abnormal value on the electronic medical record." The physician could not remember having received a report of the panic value. The patient became unable to speak the night before the next outpatient visit and was sent to the hospital by ambulance.

(4) The patient died about 7.5 hours after arriving at the hospital (one week after detection of the panic value).

(5) Cause of death: Brain stem injury due to obstructive hydrocephalus caused by thalamus hemorrhage. Ai: absent. Autopsy: absent.

Case 5

(1) The patient was an inpatient in his/her 50s who had undergone fusion for lumbar disc herniation and lumbar spinal canal stenosis. Two days after the surgery, the patient exhibited pyrexia, a decrease in blood pressure, lowered consciousness level, and suspected hemorrhagic shock.

(2) Test for cause investigation.

(3) Clinical laboratory tests were usually outsourced, but the test for this patient was conducted using the test device in the hospital as it was an urgent case. As no rule was in place to report panic values to the physician, the clinical laboratory technician told the nurse who came to pick up the laboratory test results that there was a low value, and handed over the laboratory result paper showing "WBC 14×10^2 /μL." The in-house testing device displayed the results using a ($\times 10^2$) scale, indicating that WBC was 1,400 /μL; however, because the clinical laboratory, to which laboratory testing was usually outsourced, reported the results with ($\times 10^3$) scale, the nurse informed the physician that WBC was 14,000. The patient was subsequently transferred to another hospital by emergency transport due to suspected gastrointestinal perforation.

(4) The patient died the day after the transfer (the day after detection of the panic value).

(5) Cause of death: Necrotizing fasciitis caused by intestinal damage during surgery. Ai: absent. Autopsy: present.

<Cases related to responses to panic values>

Case 6

(1) The patient was an emergency outpatient in his/her 80s with a history of surgery for colon cancer, type 2 diabetes mellitus, and ischemic heart disease, who complained of stomach discomfort and was unable to ingest anything other than water.

(2) Test for cause investigation.

(3) Abdominal X-ray showed an air-fluid level. The physician on duty consulted the gastroenterologist by telephone before determination of blood biochemistry results and decided to have the patient revisit the clinic the following day because the symptoms were not pronounced. After the patient returned home, blood biochemistry results were finalized and reported by the clinical laboratory technician to the physician on duty, who consulted the gastroenterologist again because there were multiple panic values including K 6.5 mmol/L. However, the gastroenterologist did not change the instruction to have the patient revisit the following day.

(4) The patient died about three hours after the revisit the following day (about 16 hours after detection of the panic values).

(5) Cause of death: Arrhythmia associated with hyperkalemia. Ai: absent. Autopsy: absent.

Case 7

(1) The patient was an inpatient in his 70s after a radical operation for hydrocele. The patient was taking a synthetic mineralocorticoid and potassium chloride for mineralocorticoid-responsive hyponatremia that had developed after nephrectomy for renal tumor.

(2) Routine blood collection the day after surgery.

(3) The clinical laboratory technician contacted the ward because the K level was 2.5 mEq/L. The physician entered the direction to resume oral administration and to administer potassium chloride while changing the infusions (about 2 hours later). The nurse entered the patient's room for administration of potassium chloride and found the patient in a state of cardiopulmonary arrest.

(4) The patient died the day after surgery (about 3.5 hours after detection of the panic value).

(5) Cause of death: Arrhythmia due to electrolyte abnormality. Ai: present. Autopsy: absent.

Case 8

(1) The patient was an outpatient in his/her 70s with ischemic heart disease, atrial fibrillation, cerebral infarction, and type 2 diabetes mellitus who was scheduled to undergo an emergency above-knee amputation for lower extremity arterial occlusion.

(2) Preoperative blood test.

(3) The clinical laboratory technician reported the panic value of K 2.1 mmol/L to the physician. The physician was aware of hypokalemia, but prioritized preparation for the emergency operation and performed contrast-enhanced CT of the lower extremity without potassium compensation or fitting the monitor. One minute after injection of the contrast medium, the patient ceased to respond when called by name. A cardiac monitor was fitted and revealed development of ventricular arrhythmia.

(4) The patient died about 1.5 hours after injection of the contrast medium (on the day of detection of the panic value).

(5) Cause of death: Ventricular arrhythmia. Ai: present. Autopsy: absent.

Case 9

(1) The patient was an inpatient in his/her 60s after percutaneous coronary intervention (hereinafter, "PCI") for acute myocardial infarction.

(2) Routine blood collection the day after PCI.

(3) The physician recognized CK 1,262 IU/L and abnormal ECG, and advised the patient to remain hospitalized. However, the patient was discharged 2 days after the PCI based on the patient's wishes. The day after discharge, the patient had chest pain and was found in a state of cardiopulmonary arrest when the ambulance arrived. The patient died after being transported to the hospital.

(4) The patient died the day after discharge (2 days after detection of the panic value).

(5) Cause of death: Cardiac rupture associated with acute myocardial infarction. Ai: present. Autopsy: absent.

<Cases related to presentation of panic values>

Case 10

(1) The patient was an inpatient in his/her 90s after left hemicolectomy who had chronic renal failure.

(2) Routine blood collection during potassium compensation.

(3) The patient was undergoing potassium chloride compensation for administration of a diuretic after surgery. The laboratory test results were abnormal in 13 of 27 parameters, and the laboratory test information system displayed them in red without distinguishing them from panic values. The clinical laboratory technician did not notice K > 10.0 meq/L and Na 161 meq/L among these values. The nurse infused potassium chloride as prescribed, and about two hours after infusion, ventricular fibrillation developed. The physician reviewed the laboratory test results after the sudden change.

(4) The patient died about three hours after the sudden change (about seven hours after detection of the panic values).

(5) Cause of death: Acute renal failure. Ai: absent. Autopsy: absent.

Case 11

(1) The patient was an inpatient in his 80s after transurethral laser prostatectomy for prostatic hypertrophy.

(2) Test for cause investigation of insufficient awakening after surgery.

(3) The result of arterial blood gas analysis submitted to the laboratory office was displayed as pH 6.86, but the test results for $PaCO_2$, HCO_3^-, and BE were not displayed. The physician was aware of acidemia but was not able to estimate the cause because the values of $PaCO_2$, HCO_3^-, and BE were unknown. The clinical laboratory technician did not know that the testing device was unable to display abnormally high values.

(4) The patient died about 15.5 hours after surgery (about 11.5 hours after detection of the panic value).

(5) Cause of death: Cardiac failure due to respiratory depression and hypotension associated with postoperative CO_2 narcosis. Ai: absent. Autopsy: present.

Case 12

(1) The patient was an inpatient in her 30s who experienced stillbirth at 31 weeks of gestation and was admitted to a medical clinic with beds, with no abnormalities noted in glucose testing during pregnancy.

(2) Test to investigate the cause of vomiting and overventilation.

(3) The results of laboratory tests, including K 7.5 MEQ/L and other multiple abnormal values, were sent from the clinical laboratory by fax (glucose test was not ordered). The fax showed no indication highlighting the panic value. The maternity nurse assumed development of HELLP syndrome based on the patient's symptoms, and reported only the blood count, liver function, and inflammatory reaction, among the number of abnormal values, to the physician, who had returned home, by telephone. The physician ordered medication for alleviation of symptoms and observation. The patient was in a restless condition followed by development of cardiac arrest, and was transferred to the hospital by emergency transport.

(4) The patient died about 40 minutes after arrival at the destination hospital (about 7.5 hours after detection of the panic values).

(5) Cause of death: Ketoacidosis due to fulminant type 1 diabetes mellitus. Ai: present. Autopsy: present.

[Reference cases]

<Cases related to test values before chemotherapy>

Reference case 1

(1) The patient was an outpatient in his/her 80s with hypertension and atrial fibrillation who was receiving outpatient chemotherapy for lung cancer.

(2) Routine blood collection prior to the start of Cycle 2 of chemotherapy.

(3) Laboratory tests showed AST 482 and ALT 410, but these values were not subject to reporting by the clinical laboratory technician to the physician because the panic value threshold for AST and ALT predetermined by the medical institution was ≥1,000. The physician reviewed the laboratory test results and administered medications. Ten days later, the patient presented to the emergency department with impaired consciousness and jaundice, and was admitted for management of acute hepatic failure.

(4) The patient died two days after hospitalization (about two weeks after detection of the panic values).

(5) Cause of death: Multiple organ failure. Ai: absent. Autopsy: absent.

Reference case 2

(1) The patient was an outpatient in his/her 60s who was receiving outpatient chemotherapy for liver metastasis after colon cancer surgery.

(2) Routine blood collection prior to the start of Cycle 2 of chemotherapy.

(3) Laboratory tests showed AST 855 U/L and ALT 932 U/L, but these values were not subject to reporting by the clinical laboratory technician to the physician because the panic value threshold for AST and ALT predetermined by the medical institution was ≥1,000 U/L. The physician prescribed chemotherapy drugs without reviewing the laboratory test results. The pharmacist and nurse did not check the laboratory test results. During the routine consultation on Day 14 of oral administration, the physician reviewed the previous laboratory test results and the patient was immediately hospitalized. After hospitalization, the patient was diagnosed with drug-induced liver injury and received steroid pulse therapy.

(4) The patient died 10 days after hospitalization (about 3 weeks after detection of the panic values).

(5) Cause of death: Possible drug-induced liver injury. Ai: absent. Autopsy: absent.

<Cases related to D-dimer, of which the designation as a panic value parameter remains disputed>

→ See page 17 [Column 1]

Reference case 3

(1) The patient was an inpatient in his/her 40s after rotational acetabular osteotomy for right hip osteoarthritis.

(2) Routine blood collection after surgery. The medical institution had a predetermined panic value for D-dimer.

(3) On postoperative Day 17, D-dimer increased to 64.3 μg/mL, and the nurse reported it to the physician. Postoperative D-dimer of ≥15 μg/mL required venous ultrasound to explore the cause of deep vein thrombosis, but it was not performed. After rehabilitation, the patient developed shock followed by cardiac arrest.

(4) The patient died about two hours after the sudden change (on the day of panic value detection).

(5) Cause of death: Acute circulatory failure due to pulmonary thromboembolism. Ai: present. Autopsy: present.

Reference case 4

(1) The patient in his/her 50s visited the emergency department with low back pain.

(2) Test for cause investigation. The medical institution had a predetermined panic value for D-dimer.

(3) The patient was hospitalized after being diagnosed with a lumbar compression fracture based on the CT scan performed in the emergency department. The physician did not check the laboratory test results of D-dimer 44 μg/mL after blood collection in the emergency department. The medical institution had a system in place for reporting panic values, but whether the value was reported to the physician is unknown. Increased CK was noted from the blood collection the following day, and the patient visited the cardiology department, but the cardiologist did not check the laboratory test result of D-dimer either. The patient was discharged from the hospital after alleviation of the symptoms, but suddenly lost consciousness in the evening of that day, and was transferred by emergency transportation.

(4) The patient died about 1.5 hours after the sudden change (two days after detection of the panic value).

(5) Cause of death: Stanford type A acute aortic dissection. Ai absent. Autopsy: present.

Reference case 5

(1) The patient was an outpatient in his/her 60s with an intellectual disability who had been institutionalized. The patient was found to have fallen in the institution and was transferred by emergency transportation.

(2) Test for cause investigation. The medical institution had no predetermined panic value for D-dimer.

(3) The physician was not aware of D-dimer of 43.6 μg/mL, and considering that the pain in the thoracolumbar junction was derived from the musculoskeletal system, allowed the patient to return home. The symptom continued after returning home, and vomiting appeared. The patient was presented to the hospital again, but the patient was unconscious and the carotid artery was not palpable upon arrival. Echocardiography revealed pericardial effusion and a large volume of bloody drainage was observed in the pericardial fenestration.

(4) The patient died on the day of presentation (about 11 hours after detection of the panic value).

(5) Cause of death: Aortic dissection that continued from the ascending aorta to both common iliac arteries and cardiac tamponade. Ai: present. Autopsy: absent.

Table 1 Overview of target cases

		Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7	Case 8	Case 9	Case 10	Case 11	Case 12
Classification by primary factor		**Cases related to the reporting system for panic values**					**Cases related to the response to panic values**				**Cases related to the presentation of panic values**		
No. of beds		≥100 - <200	≥600	≥600	≥600	<100	≥200 - <300	≥400 - <500	≥600	≥200 - <300	≥600	≥300 - <400	≤19
Unit ordering clinical laboratory tests		Outpatient	Ward	Outpatient	Outpatient	Ward	Emergency	Ward	Outpatient	Ward	Ward	Ward	Ward
Test parameter and observed panic value Figures in "( )" are the thresholds predetermined by the medical institutions		**WBC 21,500** (not specified)	**PT-INR >5.8** (≥ 5.8)	**CRP 50** (≥ 10)	**PT-INR 7.71** (≥ 3)	**WBC 1,400** (≤ 2,000)	**K 6.5** (≥ 6.0) **AST 1,526** (≥ 500) **ALT 516** (≥ 500) **LD 1,719** (≥ 1,000) **Cr 3.13** (≥ 3.00) **CK 1,056** (≥ 1,000) **UN 57.8** (≥ 50.0)	**K 2.5** (≤ 2.5)	**K 2.1** (< 2.4)	**CK 1,262** (≥ 1,000)	**K > 10.0** (≥ 6.0) **Na 161** (≥ 160)	**pH 6.86** (not specified)	**K 7.5** **FDP 20** **Fibrinogen 867** (Unknown)
Status of development of the rules concerning panic values	Panel that determined the parameter and threshold	No	Clinical laboratory department alone	Decision-making meeting for organizational operation	Decision-making meeting for organizational operation	Unknown	Decision-making meeting for organizational operation	Clinical laboratory department alone	Unknown	Clinical laboratory department alone	Decision-making meeting for organizational operation	Representative physicians from the departments	Unknown
	Rule for reporting	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes Reported only for new outpatients	Yes	Yes (urgently sent by fax)
	Reporting destination			Physician	Physician	Ward	Physician	Physician	Physician	Physician	Physician	(1) Physician (2) Nurse	From the clinical laboratory to the medical institution
	Reporting system in the case of unsuccessful contact			No	Yes	Unknown	Yes	Unknown	Yes	Yes	Yes	Yes	Unknown
	Reporting destination in the case of unsuccessful contact				Physician/nurse of the same department	Unknown	Nurse	Unknown	Nurse	Nurse	Ward, etc.	Nurse Senior physician (same team)	Unknown
Presentation in electronic medical record		Unknown	No	No	No	No	No	No	Marked with "!"	No	Shown in orange	No	Unknown

4. Recommendations and explanations to prevent recurrence

● Current situation surrounding laboratory panic values

Given the variation in disease specialization and institutional conditions among medical institutions, establishing uniform panic value parameters and thresholds across all medical institutions is challenging.

The questionnaire survey targeting medical institutions on the handling of panic values conducted by the Japanese Society of Laboratory Medicine in 2017 revealed that laboratory test parameters with predetermined panic values and their threshold levels were not consistent across medical institutions. It was also found that, while panic values were immediately reported as provisional results by the clinical laboratory department to clinical units through various methods, there was no uniform approach among medical institutions regarding urgent communication systems, documentation in medical records, clinical responses, or review procedures.[1)2)]

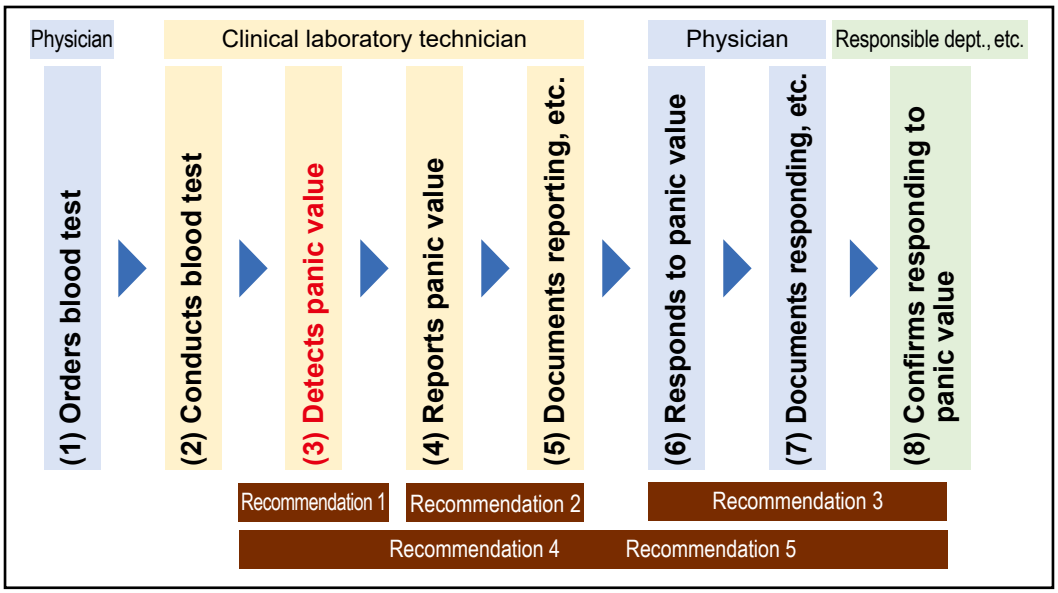
● Procedure for responding to panic values

As panic values may have a significant impact on the patient's life and require an urgent response, medical institutions are required to establish an internal system in advance to communicate panic values from the clinical laboratory department to the ordering physician to facilitate prompt provision of treatment.

Figure 1 presents an example of flow to respond to a detected panic value, covering the whole process from ordering of a blood test by the physician; conducting the blood test, reporting panic values, if detected, to the physician, and documenting reporting by the clinical laboratory technician; through to receiving the report, providing treatment and interventions, and documenting them in the medical record by the physician. Currently, it is not common for medical institutions to confirm whether the physician has responded to panic values or not; however, it is desirable to establish a system to confirm the physician's response to panic values according to the conditions of the medical institution.

In recognition of various challenges surrounding panic values as shown by the results of the 2017 questionnaire survey conducted by the Japanese Society of Laboratory Medicine, this document presents Recommendations 1 to 5 in line with the responding flow (example) shown in Figure 1. Of note, no reference test parameters or threshold values are included in the recommendations because panic values can vary depending on the diseases treated by medical institutions.

Figure 1 Flow for responding to detection of a laboratory panic value (example) and the scopes of our recommendations



[Setting panic value parameters and thresholds]

Recommendation 1

Medical institutions should investigate and specify the parameters (e.g., Glu, K, Hb, Plt, and PT-INR) and thresholds for panic values based on the medical treatment they provide.

● Setting panic values based on the medical treatment provided by the medical institution

Each medical institution is required to investigate and specify the panic value parameters and thresholds as an organization. In two of the target cases, the medical institutions had no predetermined panic values. Both medical institutions had fewer than 400 beds.

Panic values should be determined in consideration of the medical treatment provided by the institution, such as "outpatient/inpatient," as well as characteristics of the diseases treated by the institution (acute/chronic conditions), and it is difficult to set up uniform panic values throughout the nation.

On the other hand, variations in panic value parameters and thresholds across departments, diseases, and treating physicians will introduce complexity. Therefore, in principle, each medical institution should discuss as an organization based on the medical treatment provided by the institution and establish uniform parameters and thresholds within the organization.

● Panic value parameters (e.g., Glu, K, Hb, Plt, and PT-INR) and thresholds to be specified with priority

When a panic value is detected, prompt reporting to the physician and immediate provision of intervention and treatment are required because the patient's life may be significantly affected. In particular, laboratory parameters such as glucose (Glu), potassium (K), hemoglobin (Hb), platelet (Plt), and prothrombin time-international normalized ratio (PT-INR) may indicate increased urgency and suggest a potentially fatal outcome. It is advisable to determine the panic values for these parameters as a priority.

Of the 12 target cases, potassium level was detected as a panic value in 5 cases, leading to fatal arrhythmia in 4 cases. PT-INR was detected as a panic value in 2 cases and resulted in cerebral hemorrhage.

In setting panic values, few panic value parameters and a narrow range of reported values may preclude early detection of abnormalities in patients. On the other hand, more panic value parameters and a wider range of reported values will result in an increased number of cases corresponding to the panic values and a higher burden on the clinical laboratory technicians and physicians in the field, possibly leading to a reduced sense of urgency and impaired performance in emergency response. Panic values should be established after examining the appropriateness of the panic value parameters and thresholds, in consideration of factors such as the number of cases corresponding to the panic values, number of reports, and manpower.

Clarification and notification of the rationale for designating panic values

Panic values suggest a critical condition that may be potentially life-threatening and requires an urgent response. Clarifying the rationale for designating panic values will enable healthcare professionals to make informed decisions, facilitating a prompt response in emergencies.

For example, the rationale should be clarified by stating, “If the serum potassium level is high, there is an increased risk of developing fatal arrhythmia, leading to cardiac arrest. Therefore, it should be addressed urgently.”

By understanding how panic values affect the body, even inexperienced healthcare professionals will be able to take action. It is therefore advisable to clearly state and notify the rationales for setting the panic values.

Column 1: Issues in handling D-dimer as a panic value parameter

Representative life-threatening diseases associated with increased D-dimer include acute aortic dissection and pulmonary thromboembolism (deep vein thrombosis) as described in [Reference case]. They are known as “killer diseases” that may not seem serious in appearance, are latent, and lead to death if left unnoticed and overlooked. These are important differential diagnoses in the emergency department. It is suggested that D-dimer with a cutoff value of 500 ng/mL (0.5 μg/mL) can be utilized in excluding these conditions.[3)]

However, increased D-dimer is also observed in conditions/diseases other than acute aortic dissection and pulmonary thromboembolism, such as malignant tumors and liver cirrhosis, as well as in postoperative settings. Thus, it should be kept in mind that these conditions are also subject to differential diagnosis when D-dimer is set as a panic value.

For determination of D-dimer, multiple analytical methods and reagents are available, including enzyme-linked immunosorbent assay (ELISA) and latex turbidimetry, with different diagnostic capabilities such as minimal detection sensitivity, limit of quantitation, and repeatability. In addition, two types of units are used for display: ng/mL and μg/mL. These factors should also be taken into consideration when handling D-dimer as a panic value.

[Reporting panic values]

Recommendation 2

Panic values should be reported by the clinical laboratory technician directly to the physician who ordered the laboratory test, in principle. The clinical laboratory department should keep a record of panic values reported to prevent missed reports.

● Panic values should be reported to the ordering physician

When a panic value is identified, it should be reported promptly by the clinical laboratory technician to the physician who ordered the test, in principle, because treatment and interventions should be provided urgently without any delay.

In 10 of the 12 target cases in which medical institutions had a rule for reporting, the report was not made to the physician in two cases.

Panic values should be reported directly to the physician face-to-face or by telephone, in principle. E-mails and the popup function of the electronic medical record are not suitable for urgent reporting because they will not be noticed unless logged in the electronic medical record.

● Determination of who to report to when the ordering physician is not available

In case the physician who ordered the test cannot be contacted after detection of a panic value, it is necessary to determine the reporting procedure during the physician's absence and outside working hours in advance.

In one of the target cases, the clinical laboratory technician tried to report the panic value to the physician who ordered the test, but the physician could not be contacted and the reporting process was discontinued because there was no rule about reporting during the physician's absence.

Given that urgent treatment and interventions are required for panic values, it is necessary to clarify who to report to when the ordering physician cannot be contacted. Specifically, it may be a physician in the same department or a physician on duty (see Table 2).

If a nurse or other personnel is asked to report to the physician, it is advisable for the organization to discuss the procedure for secure and timely communication with the physician and to inform all relevant parties in advance.

Table 2　Priority order of who to report laboratory panic values to (example)

(1) The physician who ordered the test
(2) (When (1) is not available) Physician from the same department, physician on duty, etc.

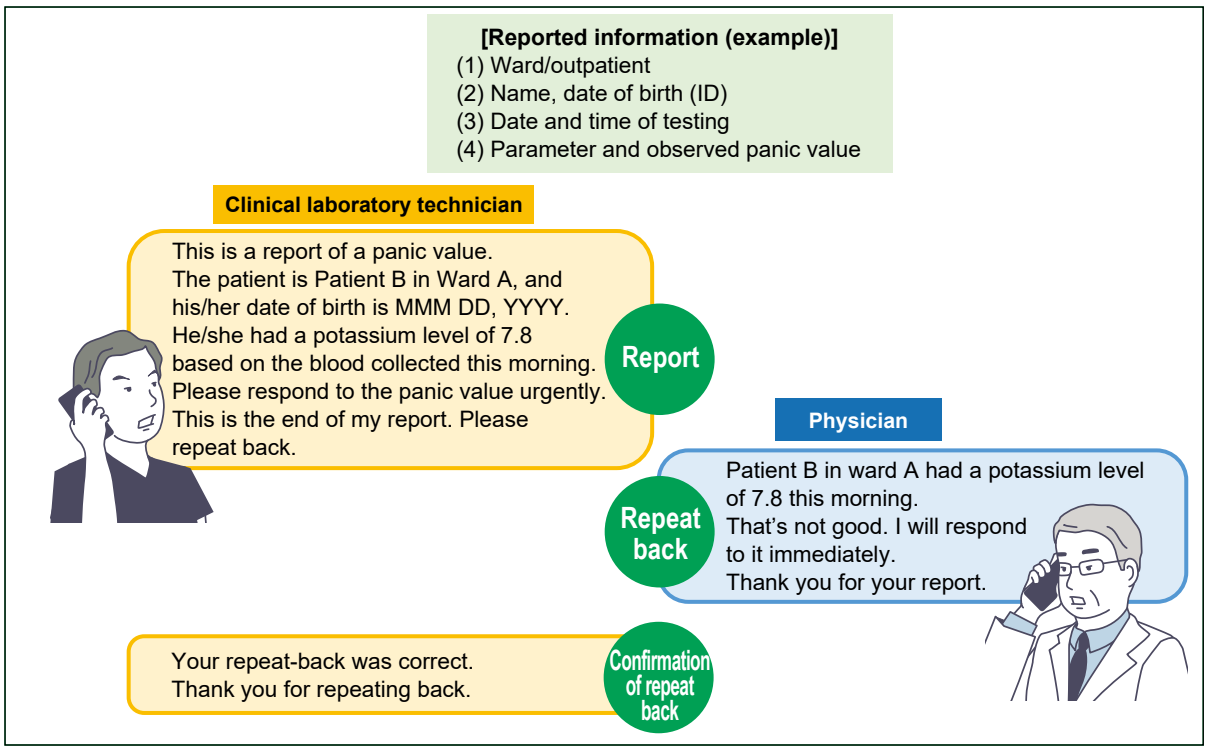
Details of panic value reporting and repeat-back

Figure 2 illustrates an example of reporting by the clinical laboratory technician to the physician who ordered the test by telephone. Firstly, it is important to inform the physician that "this is a report of a panic value." The report by the clinical laboratory technician to the ordering physician should include whether the patient is an inpatient or outpatient, patient's name, date of birth (ID number), date and time of testing, parameter and observed panic value. Standardizing the report contents can prevent omissions in reporting, and it also allows the recipient to remain focused and to accept the reported information in line with the standardized format.

Physicians commonly receive a panic value report by telephone, and they need to repeat back in order to inform the clinical laboratory technician that the information has been received correctly. The clinical laboratory technician reporting to the physician should say at the end of the report, "Please repeat back," to encourage the physician receiving the report to repeat back. Repeating back is effective not only to report panic values, but also for other verbal reporting and ordering. It is therefore desirable for medical institutions to make an effort to utilize this procedure within the organization. In addition, the process of reporting panic values often involves multiple functional units, and improved mental stability is important for smooth implementation. As a way to promote effective communication during reporting, some medical institutions encourage staff to conclude with expressions of gratitude, such as "Thank you for the report" or "Thank you for the repeat-back."

In order to prevent miscommunication of reported information, some medical institutions have clinical laboratory technicians report the detection of panic values to physicians without providing the "numerical values," instead encouraging the physician to review the electronic medical record. However, it should be noted that in such cases, there is a risk that the physician may be unable to check the electronic medical record immediately, potentially leading to a delayed response or oversight.

Figure 2 Reporting a laboratory panic value to the physician by telephone (example)



History of panic value reporting

It is necessary to prevent any missed reports from clinical laboratory technicians to physicians. This may be achieved by several methods, such as preparing a reporting table of panic values to keep a record of reporting to physicians.

In one of the target cases, the physician was unable to be contacted and the data were sent to the electronic medical record, and subsequent communication to the physician was overlooked.

Panic values may endanger the patient's life and need to be reported to the physician in a reliable manner. Some medical institutions have the clinical laboratory department designate a person responsible for checking the status of reporting to physicians as well as the timing of checking in order to ensure reliable reporting to physicians. If available, the reporting verification function of the Clinical Laboratory Information System may also be utilized.

In medical institutions where electronic medical records are shared by multiple functional units, information can be shared when clinical laboratory technicians enter the "record of reporting" in the electronic medical records. However, clinical laboratory technicians do not describe medical records in some medical institutions where electronic medical records have been introduced. Therefore, it is advisable to consider enabling clinical laboratory departments to describe electronic medical records as well.

Column 2: Reporting system of clinical laboratories

Clinical laboratories conduct testing of specimens entrusted by hospitals and clinics. Unlike laboratory tests performed within medical institutions, outsourced laboratory tests involve transportation of specimens to clinical laboratories outside the medical institutions and a procedure for reporting the measurement data after testing, resulting in a time lag.

According to "Results and Analysis of Questionnaire Survey on Reporting of Panic Values at Clinical Laboratories" from the Ministry of Health, Labour and Welfare's scientific research in 2023,[4] among 81 clinical laboratories that responded to the questionnaire, most of the laboratories conducting entrusted blood testing were reporting panic values to medical institutions by some communication methods. Such communication methods included fax in 97%, telephone in 83%, and email in 9% (multiple answers allowed). However, communication methods used during the night after the clinic had closed and on holidays were fax in 87%, telephone in 42%, and email in 7%, showing that the telephone was used less frequently. In addition, only 20% of the clinical laboratories were being informed by medical institutions that panic values were reviewed by some means after reporting, regardless of whether it was nighttime or a holiday.

These results from the questionnaire survey suggest that, although panic values should be reported directly to the physician who ordered the test in principle, panic values detected in laboratory tests outsourced to clinical laboratories during the night after the clinic had closed or on holidays may not be recognized by physicians in a timely manner.

Panic values need to be recognized by the physicians in a reliable and timely manner since these values indicate a critical condition that is potentially life-threatening. Therefore, clinical laboratories are advised to make arrangements with medical institutions regarding the procedure for reporting panic values on holidays and during night.

[Responding to panic values]

Recommendation 3

Physicians who receive a report of a panic value should take actions in response to the panic value and document them accordingly. It is advisable to discuss the process through which the organization can confirm that actions have been taken by the physician in response to the panic value.

● Physician's response to panic values and documentation

A prompt response is required upon detection of a panic value, which suggests a critical state with potentially life-threatening consequences. However, clinical implications of laboratory values and the necessity of an urgent response vary depending on the patient's condition, treatment strategy, and other factors, and cannot be uniformly determined. Physicians who receive a report of a panic value should evaluate the patient's condition comprehensively, for example, by comparing the value with the previous laboratory result, and assess the necessity of an urgent response on an individual basis.

Furthermore, it is important for the physician who has responded to a panic value to promptly document the details of the response. Physicians may not be able to record the action immediately since they prioritize treatment and response to patients. Neverthelss, recording should take place as promptly as possible so that information can be shared within the medical team regarding the status of treatment and response to the patient.

● Confirming whether a panic value has been responded to

Physicians are often informed of a panic value during medical care. In such cases, consultations are interrupted in order to respond to the panic value; however, if the physician is performing a surgery or similar procedure that cannot be interrupted, there may be delays or oversights in responding to the panic value.

Currently, most medical institutions have a rule in place for the clinical laboratory technician to "report a panic value" to the physician, but do not have a rule to "confirm that a panic value has been responded to by the physician." At some medical institutions, however, the clinical laboratory department confirms and documents the physician's response to panic values. Future discussions on "when," "who," and "how" to confirm the "physician's response to a panic value" are advisable on an organizational basis.

Communicating panic values after closure of the outpatient service/patient's return home

In the outpatient department, blood testing may be performed after closure of the outpatient service, with the patient to be informed of the laboratory results during the next appointment. In such cases, the patient may not be within the medical institution upon detection of a panic value. Worsening condition of an outpatient, unlike that of an inpatient, cannot be noticed by the healthcare professionals once the patient has returned home. Also, if a panic value is detected after closure of the outpatient service, the physician who ordered the clinical laboratory test may not be contacted.

Five of the 12 target cases involved outpatient services, including the emergency department. In four of these cases, the patient had gone home when the panic value was detected, and the patient's condition worsened before the next appointment.

Predetermination of the communication and other procedures upon detection of a panic value while the patient is away from the medical institution will lead to a prompt response to the panic value. The physician should check the patient's condition once the patient is contacted and, if an urgent intervention is considered necessary, instruct the patient to come to the hospital by ambulance, depending on the circumstances, instead of allowing the patient who is at home to come to the hospital alone.

For cases of panic value detection after closure of the outpatient service or while the ordering physician cannot be contacted (e.g., in the case of a part-time physician), the person to report to (e.g., a physician in the same department, physician on-duty) should be specified in advance in accordance with the procedures to be taken during the absence of the physician (see Recommendation 2).

[Presenting panic values]

Recommendation 4

To avoid overlooking panic values, a presentation format should be devised to allow for recognition of panic values at a glance in the clinical laboratory information system, electronic medical record, and laboratory test report.

● Devising a presentation to allow for recognition of panic values at a glance

Laboratory test results are presented in the clinical laboratory information system that is checked by the clinical laboratory technicians at the clinical laboratory department, as well as in the electronic medical record and laboratory test report used by multiple functional units. In general, high test values deviating from the upper limit of normal are shown "in red, with 'H' or an upward arrow (↑)" while low test values appear "in blue, with 'L' or a downward arrow (↓)." However, there are still only limited cases where panic values are distinguished and highlighted in color and/or with marking.

Of the 12 target cases, medical institutions had a presentation of panic values in the electronic medical record in two cases, but not in eight cases. In one case, panic values were overlooked because there were many abnormal values and parameters requiring retesting shown in red in the clinical laboratory information system. Since patients with detected panic values are also assumed to have multiple abnormal values, it is advisable to display panic values in a manner that ensures recognition of panic values at a glance and prevents oversight, even when presented alongside abnormal values.

Examples of panic value presentation include changing the color of the figure field to a distinguishable fluorescence color, adding "P" in front of each panic value, and showing the panic value in boldface. Of the target cases, panic values were distinguished by putting an exclamation mark "!" in one case, while such values were described in the comment section in the margin because there were no panic value indications available in another case. There was also a case in which the system was modified so that an alarm display of panic values appears once the user logs into the electronic medical record without accessing the relevant patient's medical record. While multiple approaches have been developed, it should be noted that most clinical laboratory reports are printed in black and white. It is advisable as a first step to check whether the system of each medical institution is capable of presenting panic values and to discuss how such a display can be achieved.

The purpose of presenting panic values is to allow the relevant healthcare professionals to recognize the panic values at a quick glance, to understand the condition of the patients requiring urgent intervention, and to take action. Under the current circumstances, however, there is a risk of overlooking because the presentation method is different for each clinical laboratory information system and electronic medical record system. In busy clinical settings, minimizing the risk of human error is crucial, and modification of devices and systems is very useful. Therefore, it is advisable to examine the presentation format for panic values to prevent oversight and to equip the blood test-related devices and systems with that format as a standard function to ensure recognition of panic values at a glance. It is also anticipated that compatibility between the clinical laboratory information system and electronic medical record should be established and ways to improve the framework should be discussed to facilitate information sharing (see 5. What we expect of (or what we want to propose to) academic societies and companies).

Indication of “Retesting” to show the progress of testing

In the laboratory test result screen of the electronic medical record, an indication of “Under testing” for pending parameters helps the progress of testing to be understood; however, at some medical institutions, test result fields are left blank.

In four of the target cases, there was no indication of the progress of retesting, and the test parameters being retested were left blank. In one of these cases, the physician thought that all test results had been obtained because some of the test results were presented on the screen, and was unaware that the PT-INR (detected as a panic value later) was being retested.

Presentation of the test progress on the screen can prevent misperception that all test results are displayed. An indication of “Retesting” may provide healthcare professionals in the clinical setting with an opportunity to be aware that “there is a problem.” It is advisable to develop approaches to facilitate information sharing among healthcare professionals, including presentation of “Under testing,” “Retesting,” etc., on the system screen (see 5. What we expect of (or what we want to propose to) academic societies and companies).

Column 3: Presentation of test values outside the measurable range of the testing equipment

Testing equipment is not capable of measuring values exceeding the upper limit of measurement or falling below the lower limit of measurement. The presentation format to show such values differs among devices - some indicate “Not measurable,” some show inequality signs (e.g., “>,” “<”), and some show no indication.

In one of the target cases, part of the blood gas analysis data ($PaCO_2$, HCO_3^-, BE) was not displayed on the testing device screen, and the test results were not displayed for some unknown reason.

It is advisable to clarify beforehand how the testing equipment used at each medical institution displays values outside the upper or lower limit and to take measures to prevent overlooking panic values, for example, by describing it in the manual.

[Establishing the internal system for handling panic values]

Recommendation 5

Medical institutions should clearly define the roles of the persons and/or sections responsible for managing the internal handling of panic values, establish a system for regularly reviewing the handling rules, and ensure that the established handling rules are communicated within the institution.

● Designation of the person responsible for managing internal handling of panic values

Handling of panic values should be discussed in advance within the medical institution. The discussion should be led by the clinical laboratory department or other units, depending on the function, size, or other conditions of the medical institution, and the roles of the responsible person and/or department should be defined within the organization.

Of the 12 target cases, panic value parameters and thresholds were determined in an organizational management meeting such as the Clinical Laboratory Management Committee in four cases, while such determination was performed by the clinical laboratory department alone in three cases.

Handling of panic values should be determined through review of the handling procedure for panic values in a series of processes, including the presentation format in the clinical laboratory information system, electronic medical record, and laboratory test report, as well as listing the person to report to (see Table 3). This process requires an organizational review with participation from the functional areas needed to be cooperated with upon detection of panic values, including physicians, nurses, and pharmacists, if feasible, and taking into account the opinions of medical safety personnel involved in incidents related to panic values.

Table 3 Parameters to be investigated when establishing a system for handling panic values (example)

- ☐ Parameters and thresholds for panic values (to be set according to the status of treatment)
- ☐ Person to report to when the ordering physician is not available
- ☐ Treatment and procedures related to panic values
- ☐ Documenting “reporting of panic values” and “responding to panic values”
- ☐ Presentation format for panic values (clinical laboratory information system, electronic medical record, and laboratory test report)
- ☐ System to confirm whether or not the physician has responded

● Periodical assessment of panic value handling system

A periodical assessment reviews operational challenges through regular checking of panic value parameters and thresholds every few months to every year. For example, panic values may be reported repeatedly for complete blood count at the hematology department and blood glucose test at the neonatal intensive care unit. Repeated detection and reporting of panic values may lead to a reduced sense of urgency, and an increase in the number of detected panic values, resulting in a constantly excessive volume of reportable cases, significantly escalating the operational workload. Therefore, opinions from the relevant departments should be collected and examined regarding the panic value parameters and thresholds.

In two of the reference cases, patients with hepatic dysfunction received outpatient chemotherapy and suddenly developed hepatic failure. There was also a case where the test values did not meet the definition of the panic values of the medical institution, and the panic value thresholds were subsequently reconsidered. Therefore, it is desirable to establish a system for periodic assessment of the appropriateness of panic value thresholds on the basis of the characteristics and treatment of the medical institution.

Panic value information, such as the “number of detections,” “number of reports to physicians,” “response by the physician and the patient’s outcome,” and “incidents” should be examined and tabulated on a regular basis, every month to every few months if possible, in order to accumulate data for periodic assessment (see Table 4). It is also advisable to collect information regarding the panic value presentation format and compatibility between the clinical laboratory information system and electronic medical record.

Table 4 Contents of periodic assessment for panic values (example)

☐ Parameters and thresholds for panic values (including cases in which the clinical laboratory was utilized)
☐ Incidents related to panic values

● Notification of handling rules for panic values

The functional units and departments involved in blood testing should be repeatedly informed of the entire workflow, including the panic value parameters and thresholds specified by the medical institution as an organization, the person to report to during the unavailability of the physician who ordered the test, and confirmation of the response after reporting the panic value. It is especially important to communicate the information to all physicians performing treatment and procedures related to panic values because panic values may be reported to a physician other than the one who ordered the test (see Table 5).

Methods of notification may include displaying in a prominent location, posting on the intranet, communicating during the orientation program for new employees and medical safety training, and distributing a pocket-sized manual.

Regarding reporting of a panic value after detection, the clinical laboratory technician in one of the target cases believed that reporting a panic value would disturb the physician giving medical care. It is advisable to provide information to healthcare professionals involved in blood testing in a manner to promote understanding of the significance of reporting panic values and confirming by repeat-back, so that panic values are reported urgently and accurately.

Table 5 Contents of notification of the handling rules for panic values (example)

☐ Handling rules for panic values (including panic value parameters and thresholds, the person to report to during unavailability of the ordering physician, confirmation of the response after reporting a panic value)
☐ Reporting panic values and verification by repeat-back

5. What we expect of (or what we want to propose to) academic societies and companies

We expect academic societies and companies to tackle the following issues and thereby make it easier to further improve patient safety.

● What we expect of academic societies

Academic societies in fields involved in blood testing, including the Japanese Society of Laboratory Medicine and the Japanese Association of Medical Technologists, are expected to discuss the presentation format that ensures recognition of panic values at a glance in the clinical laboratory information system that is checked by clinical laboratory technicians, electronic medical records used by multiple functional areas, and clinical laboratory reports in order to prevent overlooking panic values.

● What we expect of companies

Companies developing and manufacturing clinical laboratory information systems and hospital information systems are expected to do the following:

(1) Install panic value presentation as a standard function

To investigate a presentation format for panic values that ensures recognition of panic values at a glance, like that for “abnormal values” in a blood test, to be installed as a standard function.

(2) Display the progress of testing

To examine a presentation format for test parameters for which test results are pending due to retesting, etc., to indicate the progress of testing, for example, “Under testing” or “Retesting,” instead of leaving the fields blank on the media displaying the test results (e.g., electronic medical record screen, printed report paper, fax report).

(3) Expand compatibility for sharing panic value information

To discuss building a framework for easier information sharing among multiple functional areas based on compatibility between the clinical laboratory information system and the electronic medical record.

6. Conclusion

For the present Recommendations, 12 instructive cases were selected for analysis among the fatal cases related to laboratory panic values. The Expert Analysis Subcommittee consisting of 11 experts from related fields analyzed these cases in detail and compiled 5 recommendations.

Recommendation 1 is that medical institutions should investigate and specify the panic value parameters and thresholds based on the medical treatment provided by the institution. Recommendation 2 mentions that panic values should be reported by the clinical laboratory technician directly to the physician who ordered the laboratory test, in principle, and that the clinical laboratory department should keep a record of panic values reported to prevent missed reports. Recommendation 3 is that physicians who receive a report of a panic value should take actions in response to the panic value and document them accordingly. This recommendation also advised discussing the process through which the organization can confirm that actions have been taken by the physician in response to the panic value. Recommendation 4 is that, to avoid overlooking panic values, a presentation format should be devised to allow for recognition of panic values at a glance in the clinical laboratory information system, electronic medical record, and laboratory test report. Recommendation 5 is that medical institutions should clearly define the roles of the persons and/or sections responsible for managing the internal handling of panic values, establish a system for regularly reviewing the handling rules, and ensure that the established handling rules are communicated within the institution.

Medical institutions vary in size and in the medical treatment they provide, and not all medical institutions conduct laboratory tests in internal laboratories; in some cases, they are outsourced to external clinical laboratories. In compiling the present Recommendations, we made an effort to provide recommendations for handling panic values that can be implemented at every medical institution. It is essential that the entire organization works on the appropriate handling of panic values, exercising caution to avoid placing an excessive burden concerning panic value reporting solely on the clinical laboratory department that conducts many tests and is required to report accurate test results to clinical units in a timely manner.

Finally, we would like to express our sincere gratitude to the medical institutions that worked on investigating the causes of the accidents and the prevention of recurrence, and cooperated in sharing the in-hospital investigation reports. We would also like to express our deepest condolences to the patients who died due to the accidents and to the bereaved families. We hope that the Recommendations will be useful to healthcare professionals as a step toward improving patient safety.

7. References

1) Japanese Society of Laboratory Medicine: Recommendations on Handling of Laboratory 'Panic Values' (2024 Revised Edition). https://www.jslm.org/committees/team_med/20240610-1.pdf
[Attached table] Examples of critical values (commonly called "panic values")
https://www.jslm.org/committees/team_med/20240610-2.pdf
(Accessed October 16, 2024) (in Japanese)

2) Japanese Society of Laboratory Medicine: Clinical Laboratory Tests in Team-based Medicine. Nationwide Questionnaire Survey on Laboratory Handling of Abnormal Data/Panic Values 2017.
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3) Joint guideline by The Japanese Circulation Society/The Japanese Society for Cardiovascular Surgery/The Japanese Association for Thoracic Surgery/The Japanese Society of Vascular Surgery: JCS/JSCVS/JATS/JSVS 2020 Guideline on Diagnosis and Treatment of Aortic Aneurysm and Aortic Dissection.
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4) Health and Labour Sciences Research Grants in 2023 (Regional Medical Infrastructure Development Promotion Research Project) "Research for establishment of adequate registration standards for clinical laboratories, etc.": Results and analysis of a questionnaire survey on reporting panic values at clinical laboratories.
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(Accessed October 16, 2024) (in Japanese)

8. Materials

Material 1. [Attached table] Examples of critical values (commonly called “panic values”)

Japanese Society of Laboratory Medicine: Recommendations on Handling of Laboratory ‘Panic Values’ (2024 Revised Edition) (reprinted with permission)

Parameter		Low value	High value	Examples of parameters requiring immediate reporting#
Blood biochemistry	Glucose	50 mg/dL	350 mg/dL (outpatient) 500 mg/dL (inpatient)	✓
	Sodium (Na)	115 mmol/L	165 mmol/L	
	Potassium (K)	1.5 mmol/L	7.0 mmol/L	✓
	Chloride (Cl)		120 mmol/L	
	Calcium (Ca)	6.0 mg/dL	12.0 mg/dL	
	Urea nitrogen (UN)		80 mg/dL	
	Total bilirubin		20 mg/dL (neonate)	
	Total protein	4.0 g/dL	10.0 g/dL	
	Albumin	2.0 g/dL	6.0 g/dL	
	Uric acid	1.0 mg/dL	10.0 mg/dL	
	AST		300 U/L	
	ALT		300 U/L	
	LD (LDH)		1,000 U/L	
	Amylase		1,000 U/L	
	Creatinine (Cr)		Acute renal failure: 3.0 mg/dL Chronic renal failure: 8.0 mg/dL	
	Creatine kinase (CK)		5,000 U/L	
	Cholinesterase (ChE)	20 U/L		
	Lactic acid		5.0 mmol/L	
	Osmotic pressure (serum)	255 mOsm/kg H_2O	330 mOsm/kg H_2O	
Blood gas	pH	7.20	7.60	
	$PaCO_2$	20 Torr	70 Torr	
	PaO_2	40 Torr		
	BE	-10 mmol/L	10 mmol/L	
	HCO_3^-	14 mmol/L	40 mmol/L	
Blood test	White blood cell (WBC)	1,500/μL	20,000/μL or appearance of blasts	
	Hemoglobin (Hb)	5 g/dL	20 g/dL	✓
	Platelet count (Plt)	30,000/μL	1,000,000/μL	✓
	Prothrombin time (INR)		2.0 (4.0 during warfarin treatment)	✓
	Fibrinogen	100 mg/dL	700 mg/dL	
	FDP		20 μg/mL (20 to 100 depending on facility)	
CSF test	Glucose	20 mg/dL		
	Cell count		200/μL	

Examples of laboratory parameters for critical values (commonly called “panic values”) that specifically require immediate reporting to the treating physician because an urgent response is necessary (including observation and procedures). It is advisable to select these test parameters and to set the limit values in consultation with physicians in clinical units at each medical institution.

Material 2. Laboratory panic values/Investigation parameters checklist

Parameter			Concrete parameters
Basic information	Patient information	Age/Sex	Age: Sex: ☐ Male ☐ Female
		Outpatient/Inpatient	☐ Outpatient (Department:) ☐ Emergency dept. ☐ Ward (Department:)
		Diagnosis	
		Medical history	☐ Yes ( ) ☐ No
		Oral drug	☐ Yes ( ) ☐ No
Cause of death	Autopsy/Ai	Autopsy results (including assumptions)	☐ Yes ( ) ☐ No
		Ai results (including assumptions)	☐ Yes ( ) ☐ No
Blood collection	Purpose/place	Purpose of blood collection	☐ Routine test ☐ Test for cause investigation ☐ Preoperative test ☐ Other ( )
		Location of blood collection	☐ Outpatient (Department:) ☐ Emergency dept. ☐ Ward (Department:)
Internal arrangements and actual conditions	Set parameter and detected value	Setting of panic value	☐ Yes (☐ Internal laboratory ☐ Clinical laboratory ☐ Other:) ☐ No
		Detected panic value	☐ General blood test (parameter and value:)
			☐ Biochemistry (parameter and value:)
			☐ Other (parameter and value:)
	Timing of reporting	Arrangement of timing of reporting	☐ Yes (☐ Before retesting ☐ At finalization of panic value after retesting) ☐ No
		Actual timing of reporting	☐ Before retesting ☐ At finalization of panic value after retesting ☐ No
	Person to report to/reporting means including during the absence of the physician	Arrangement of the person to report to	☐ Yes (☐ Physician who ordered the test ☐ Other:) ☐ No
		Person who actually received the report	☐ Yes (☐ Physician who ordered the test ☐ Other:) ☐ No
		Arrangement of the reporting means	☐ Yes (☐ Telephone ☐ Face-to-face ☐ Electronic medical record ☐ Other:) ☐ No
		Reporting means actually used	☐ Yes (☐ Telephone ☐ Face-to-face ☐ Electronic medical record ☐ Other:) ☐ No
	Contents of report	Contents of report	☐ Ward/Outpatient ☐ Name ☐ Date of birth (ID) ☐ Date and time of test ☐ Test parameter ☐ Panic value (Contents:)
		Repeat-back of the contents reported	☐ Yes ☐ No (Reason:)
	Document	[Clinical laboratory technician] Arrangements of “Record of reporting,” etc.	☐ Yes (Contents:) ☐ No
		[Clinical laboratory technician] “Record of reporting” actually conducted	☐ Yes (Contents:) ☐ No
		[Physician] “Record of response,” e.g., treatment/procedure	☐ Yes (Contents:) ☐ No
	Confirmation of response	Arrangement to confirm “presence/absence of response”	☐ Yes (person in charge) ☐ No
		Method of confirming “presence/absence of response”	☐ Record ☐ Other ( )
		Confirmation of “presence/absence of response” actually performed	☐ Yes ☐ No (Reason:)

Parameter			Concrete parameters
Outpatient treatment	Response to outpatient	Patient returned home	☐ Yes ☐ No
		Telephone contact with patient	☐ Yes ☐ Contact successful ☐ Contact unsuccessful (Subsequent response:) ☐ No (Reason:)
		Transportation to visit the hospital after contact with the patient	☐ Vehicle driven by someone other than the patient ☐ Taxi ☐ Ambulance ☐ Other ( )
Presentation of panic values	Presentation method	Clinical laboratory information system	☐ Yes (Presentation method:) ☐ No
		Electronic medical record	☐ Yes (Presentation method:) ☐ No
		Laboratory test report	☐ Yes (Presentation method:) ☐ No
System for handling panic values	Person-in-charge meeting	Person in charge of handling	☐ Physician ☐ Clinical laboratory technician ☐ Nurse ☐ Medical safety personnel ☐ Other ( )
		Person in charge meeting	☐ Yes (Frequency: / year) ☐ No
	Periodic assessment	Assessment of parameters and thresholds	☐ Yes (Frequency: / year) ☐ No
		Tabulation of number of reports and incidents	☐ Yes (Frequency: / year) ☐ No
	Notification of handling rules	Manual	☐ Yes (Title:) ☐ No
		Notification method	☐ Yes (☐ Intranet ☐ Workshop ☐ Pocket manual ☐ Other:) ☐ No

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Subcommittee members	Megumi Iida	The Japan Academy of Nursing Administration and Policies
	Hiroaki Ohnishi	Japanese Society of Laboratory Medicine
	Masahiro Okuda	Japanese Society of Pharmaceutical Health Care and Sciences
	Kazuya Kiyota	Japanese Association for Acute Medicine
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	Hisashi Takeura	Japanese Association of Medical Technologists
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	Seiichi Nemoto	Japanese Association of Medical Technologists
	Keisei Fujimori	Japanese Society for Quality and Safety in Healthcare

Conflicts of interest
The Medical Accident Investigation and Support Center has confirmed the status of conflicts of interest self-declared by the respective members of the Expert Analysis Subcommittee in terms of the contents of this report of recommendations.

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The list of Committee for Prevention of Recurrence members as of the time that the “Recommendations for the Prevention of Recurrence of Medical Accidents” (Number 20) was approved.

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Analysis of Deaths Related to the Critical (Panic) Values in Blood Tests

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