Received: 9 August 2019 | Revised: 21 August 2019 | Accepted: 23 August 2019

DOI: 10.1002/jcla.23038

RESEARCH ARTICLE

WILEY

Enhance the effectiveness of clinical laboratory critical values initiative notification by implementing a closed-loop system: A five-year retrospective observational study

Runqing Li | **Tengjiao Wang** | **Lijun Gong** | **Jingxiao Dong** | **Nan Xiao** | **Xiaohuan Yang** | **Dong Zhu** | **Zhipeng Zhao**

Laboratory Medicine Department, Beijing Tsinghua Changgung Hospital, School of Clinical Medicine, Tsinghua University, Beijing, China

Correspondence
Runqing Li, Laboratory Medicine Department, Beijing Tsinghua Changgung Hospital, School of Clinical Medicine, Tsinghua University, No. 168 Litang Road, Changping District, Beijing 102218, China.
Email: lrqa00335@btch.edu.cn

Funding information
the Incubation Program Project of Beijing Municipal Administration of Hospitals of China, Grant/Award Number: PG2018013

Abstract

Background: Accurate and timely clinical laboratory critical values notification are crucial steps in supporting effective clinical decision making, thereby improving patient safety.

Methods: A closed-loop laboratory critical value notification system was developed by a multidisciplinary team of clinicians, laboratorians, administrators, and information technology experts. All the laboratory critical values that occurred at Beijing Tsinghua Changgung Hospital (BTCH, Beijing, China) from 2015 to 2019 were analyzed and studied retrospectively.

Results: The total number (ratio) of institutional laboratory critical values to all reported items at BTCH from 2015 to 2019 was 38 020/7 706 962 (0.49%). Percentage distribution points of critical value boundaries based on patients' test reports are 0.007% ~ 6.04% for low boundaries and 71.70% ~ 99.99% for high boundaries. After the intervention, the timely notification ratio, notification receipt ratio, and timely notification receipt ratio of critical values of ED, IPD, and total patients had increased, with a significant difference ($P < .001$). Five quality indicators, such as notification ratio, timely notification ratio, notification receipt ratio, timely notification receipt ratio, and clinician response ratio over a 5-year period, were 100%, 94%, 97%, 92%, and 99%, respectively.

Conclusions: We enhanced the effectiveness of clinical laboratory critical values initiative notification by implementing a closed-loop system and intervening. Clinical critical values and quality indicators should be analyzed and monitored to avoid adversely affecting patient care.

KEYWORDS

hospital information system, laboratory critical values, patient safety, quality indicators

1 | INTRODUCTION

There has been increased concern about issues involved with enhancing the effectiveness of clinical laboratory critical values notification since the publication of a report entitled "When to panic over abnormal values" by George Lundberg in the 1970s.[1] Laboratory critical values present a pathophysiological state at such variance with normal as to be life-threatening if an action is not taken quickly and for which an effective action is possible.[2] Critical values are needed to be proactively identified and reported timely and accurately so as to support effective clinical decision-making based on the test results.[3,4] The effectiveness of clinical laboratory critical values notification will directly be related with the safety of patients and affect the satisfaction of customers to laboratory service.[2] Meanwhile, accreditation institutions, such as ISO 15189, College of American Pathologists (CAP), and Joint Commission International (JCI), established the mandatory requirement for laboratory critical values management, including the identification, notification, handling, documentation, auditing, and quality indicators monitoring of laboratory critical values.[5,6]

A growing number of publications have addressed the reporting of critical values.[3,7-12] A CAP-sponsored study of 121 institutions determined that it takes a total of 7 minutes for technician to notify clinicians about a critical result once testing was complete.[13] It took up a lot of time reporting thousands of critical values by laboratories each year. On the other hand, a CAP Q-Probes study in 623 institutions showed that about 5% of critical value telephone calls were abandoned, with the largest percentage abandoned for outpatients.[14] There were some problems with the effectiveness of critical value notifications.

The typical processes of laboratory critical value notification are as follows. A laboratory critical value is (a) first perceived by a technician in the laboratory, (b) then reported by the technician to clinicians or nurses in time, (c) then the notification transferred and received by the clinician, (d) then clinician response is made for the patient, and (e) documentation of the response is recorded in the patient's electronic medical record (EMR). A closed-loop laboratory critical value notification system was developed based on the above five steps, and quality indicators were designed to monitor the notification process of laboratory critical values. A 5-year retrospective observational study about laboratory critical values was introduced.

2 | MATERIALS AND METHODS

2.1 | Setting

All clinical laboratory critical values that occurred in the emergency department (ED), inpatient department (IPD), and outpatient department (OPD) of a 1000-bed tertiary hospital at Beijing Tsinghua Changgung Hospital (BTCH, Beijing, China) were documented and analyzed retrospectively from January 2015 through June 2019. These included all critical values for hematology, coagulation, clinical chemistry, and microbiology testing. A closed-loop laboratory critical value notification system combined with mobile phone short message and phone call was developed by a multidisciplinary team of clinicians, laboratorians, administrators, and information technology experts. As we previously reported, the system was applied to the clinic since 2015 throughout the entire hospital.[15,16]

2.2 | Establishing a critical value list

Laboratory items to be notified with critical values were selected by laboratory director in discussion with the clinicians who use laboratory services, referring to relevant literature.[13,14,17-21] Considering the needs of special patients, such as cardiac surgery patients, critical test (high-sensitivity troponin T), and its thresholds were also added into the critical value list.[22] Critical value thresholds were set by consideration of relevant patient characteristics, clinical conditions, and the needs of clinicians to meet the special requirements of different patients for critical value boundaries.[3,18] And critical value boundaries were evaluated by calculating the percentage distribution points of the critical value boundaries based on the patients' data distribution. All the critical items and thresholds were implemented in hospital since January 2015 and modified through the annual discussion meeting with clinicians (as shown in Table 1).

2.3 | Intervention introduced (September 2015): Established quality control circle to improve the effectiveness of critical notification

Quality control circle (QCC) was established by a multidisciplinary team of laboratorians, nurses, and information technology experts to enhance the effectiveness of critical values notification. Three quality improvement strategies derived from the QCC implemented in hospital since September 2015, including (a) establish critical value notification policy and conduct employee education and assessment, (b) optimize the laboratory critical value notification system to display a pop-up window to alert the technician when the critical values are generated, and (c) set up five quality indicators to monitor the whole process of critical values notification.

2.4 | Design of laboratory critical value notification system and implementation of closed-loop management

The flowchart of laboratory critical values notification is shown in Figure 1.

The initial step involves critical values are perceived, verified, and then reported to clinical caregivers by technician within a certain time frame.[19,20] When a measured value triggers its critical value boundaries, the report will change color and a pop-up window will show up in the laboratory information system (LIS) to remind the technician of the generation of critical value. The critical value will be verified before reporting to clinicians, including rechecking the specimen, repeating test,[23] or contacting with clinicians for confirmation.

TABLE 1 Critical values by tests for all patients from 2015 to 2019

Critical value items and thresholds	Number of critical values	Constituent ratio (%)[a]	Total number of reports	Incidence ratio (%)[b]	Percentage distribution[c]
Clinical chemistry					
High-sensitivity troponin T, ≥0.053 ng/mL	8410	22.12	86 002	9.78	71.70%
Urea nitrogen, ≥25 mmol/L (70 mg/dL)	3314	8.72	366 988	0.90	98.60%
Potassium, ≤2.5 or ≥6.2 mmol/L	2649	6.97	388 633	0.68	0.28%, 99.54%
Creatinine, ≥600 umol/L (6.787 mg/dL)	2472	6.50	382 711	0.65	98.00%
Glucose, ≤2.7 or ≥27.78 mmol/L (≤48.65 or ≥ 500.54 mg/dL)	2147	5.65	380 917	0.56	0.04%, 99.97%
Sodium, ≤120 or ≥160 mmol/L	649	1.71	387 784	0.17	0.03%, 99.97%
Arterial partial pressure of carbon dioxide (blood gas), ≤20 or ≥70 mm Hg	602	1.58	20 584	2.92	1.51%, 99.99%
Calcium (serum), ≤1.5 or ≥3.5 mmol/L	583	1.53	364 368	0.16	0.03%, 99.99%
Arterial partial pressure of oxygen (blood gas), ≤50 mm Hg	580	1.53	20 584	2.82	12.97%
Cholinesterase, ≤2130 U/L	554	1.46	260 192	0.21	6.04%
Bicarbonate (blood gas), ≤10 or ≥40 mmol/L	347	0.91	20 584	1.69	1.20%, 98.22%
pH value (blood gas), ≤7.2 or ≥7.6	318	0.84	20 584	1.54	2.43%, 99.86%
Hematology					
WBC count, ≤2* or ≥30*10^9/L	3539	9.31	595 901	0.59	0.61%, 99.71%
Hemoglobin, ≤60 g/L (6 g/dL)	2177	5.73	595 901	0.37	0.60%
Platelets count, ≤20* or ≥1000*10^9/L	1580	4.16	595 901	0.27	0.43%, 99.98%
Neutrophils count, ≤0.5*10^9/L	1161	3.05	595 901	0.19	0.28%
Percentage of primitive cells (peripheral blood), ≥1%	164	0.43	1 884 084	0.01	NA
Coagulation					
Fibrinogen, ≤1.0 g/L	939	2.47	163 227	0.58	0.89%
Thrombin time, ≥150 s	793	2.09	162 755	0.49	99.99%
Activated partial thromboplastin time, ≤15 or ≥100 s	562	1.48	165 140	0.34	0.01%, 99.70%
Prothrombin time, ≤9 or ≥70 s	132	0.35	173 410	0.08	0.007%, 99.93%
Microbiology					
Blood culture, positive	2279	5.99	23 587	9.66	NA
Gram stain (sterile body fluid), positive	2069	5.44	51 224	4.04	NA
Total	38 020	100	7 706 962	0.49	NA

[a]Constituent ratio, the ratio between the number of critical values of a certain test and the total number of critical values of all twenty-three test items.
[b]Incidence ratio, the ratio between the number of critical values of a certain test and the total number of the corresponding item reported.
[c]Percentage distribution is shown as the percentage distribution points of the low and high boundaries for the critical value of a test versus the frequency distribution of patients' reports of the test.

The time frame criterion of notifying clinical caregivers of the critical values by a technician is 30 minutes for ED patients and 60 minutes for OPD and IPD patients. Two quality indicators, notification ratio (number of critical values notified by technician/total number of critical values required to notify × 100%) and timely notification ratio (number of critical values notified by technician within a certain time frame/total number of critical values required to notify × 100%), are used to monitor whether the critical value is reported and whether it was reported within the required time limits, respectively.

Critical values are received by clinical caregivers and documented within a certain time frame. A locked screen will show on the caregivers' computers when the message of critical values is received. The caregivers (usually primary nurses or clinicians) are required to document the acknowledgment of receipt of receiving notifications and input their employee card number and password to unlock the screen in time. Once done, the receipt message will transfer back to LIS. Meanwhile, Short Message Service (SMS) is employed to send a mobile phone short message, including

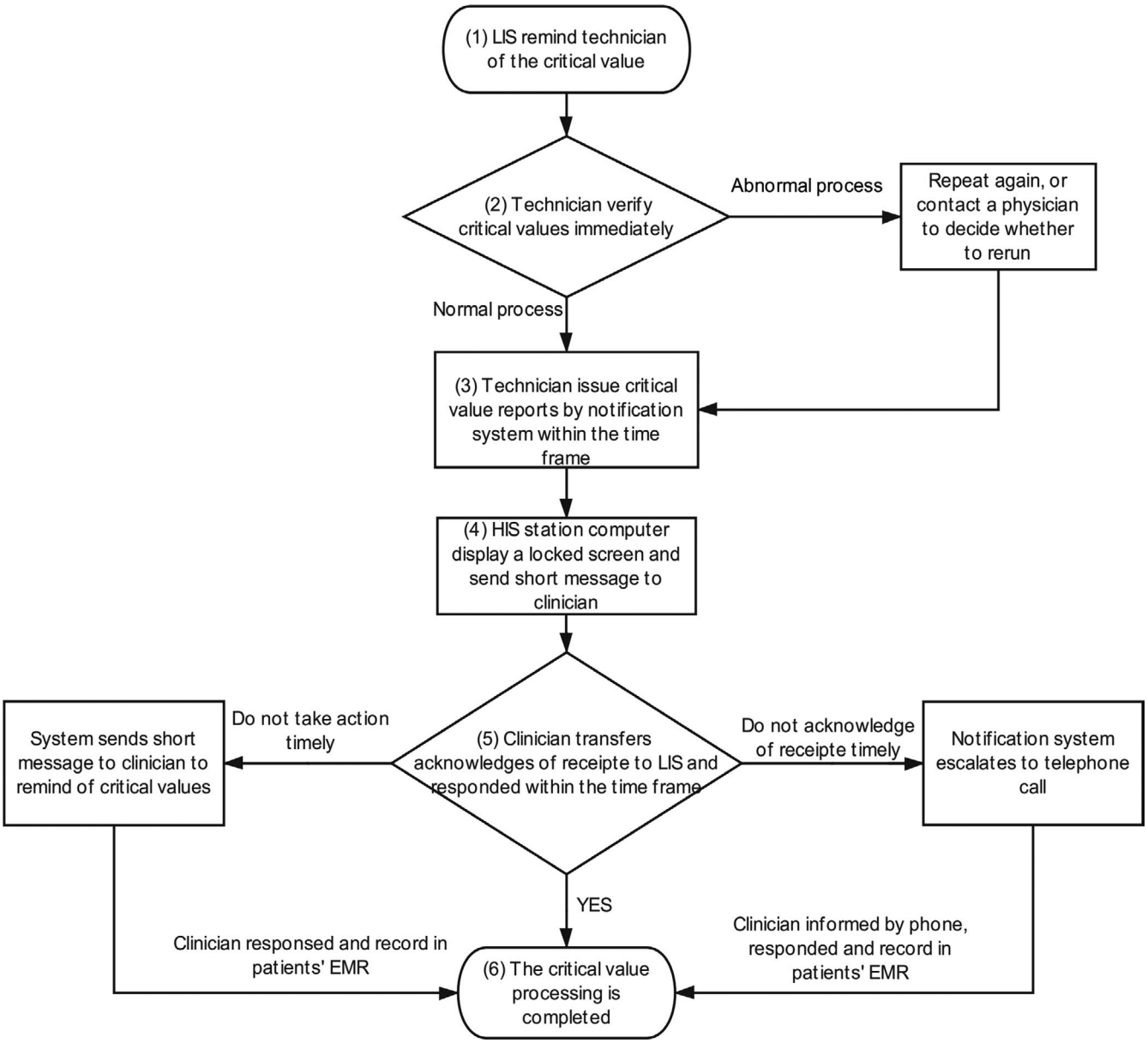

FIGURE 1 The flowchart of critical value notification process. Abbreviations: EMR, electronic medical record; HIS, hospital information system; LIS, laboratory information system

"patient identification, critical value and results, time, and technician in charge", to the patient's clinician. The documentation of critical value receipt is required within 15 minutes for ED patients, 45 minutes for IPD patients, and 480 minutes for OPD patients. The time frame criteria of documentation are set by meeting attended by relevant clinician, laboratory director, and hospital administrators. Another two quality indicators, notification receipt ratio (number of critical value receipts of caregivers acknowledgment/total number of critical values required to notify × 100%) and timely notification receipt ratio (number of critical value receipts of caregivers acknowledgment within a certain time frame/total number of critical values required to notify × 100%), are used to monitor whether the receipt of critical value is acknowledged by the caregivers and whether it was acknowledged within the required time limits, respectively. Additionally, if the caregivers do not confirm receipt in the notification information system within the above time frame criteria, then critical values are reported by technician over the telephone, and the call information is then documented in the system.

An appropriate response is made by the doctors who were informed and the response is documented in the EMR, meanwhile, the records are transmitted from hospital information system (HIS) to LIS. Another indicator, clinician response ratio (number of critical values responsed by clinician/total number of critical values required to notify × 100%) is used to monitor whether the diagnosis or treatment for the critical value is made by doctors.

In a word, five quality indicators, notification ratio, timely notification ratio, notification receipt ratio, timely notification receipt

TABLE 2 The median (inter-quartile range) minutes of the turnaround time (TAT) of critical value notification by tests from 2015 to 2019

Critical value items and thresholds	Detection system and method	Pre-analytical TAT (from sample collection to registration)	Analytical TAT (from sample registration to critical values reporting)	Post-analytical TAT (from critical values reporting to notification of caregivers)	Post-analytical TAT (from critical values reporting to clinician's response recorded in the EMR)	Total TAT (from sample collection to clinician's response recorded in the EMR)
Clinical chemistry						
High-sensitivity troponin T, ≥0.053 ng/mL	Roche Cobas c8000, electrochemiluminescence	29 (13, 73)	32 (26, 42)	1 (0, 2)	188 (41, 2029)	327 (139, 2120)
Urea nitrogen, ≥25 mmol/L (70 mg/dL)	Siemens Advia 2400/Roche Cobas c8000, urease colorimetric	36 (12, 93)	50 (35, 99)	1 (0, 3)	544 (73, 5708)	770 (221, 5939)
Potassium, ≤2.5 or ≥6.2 mmol/L	Siemens Advia 2400/Roche Cobas c8000/Roche b 221, ion-selective electrode	18 (6, 39; routine)[a] 30 (12, 94.5; urgent)[b] 11 (5, 21; blood gas)[c]	198 (127, 316; routine) 37 (29, 51; urgent) 9 (5, 15; blood gas)	20 (1, 90; routine) 1(0, 2; urgent) 1 (0, 2; blood gas)	2581 (199, 37 926; routine) 253 (47, 2657; urgent) 224 (45, 1445; blood gas)	2919 (610, 38 090; routine) 453 (169, 2803; urgent) 290 (87, 1535; blood gas)
Creatinine, ≥600 umol/L (6.787 mg/dL)	Siemens Advia 2400/Roche Cobas c8000, enzymatic	12 (2, 60; routine) 31 (11, 83; urgent)	153 (100, 252; routine) 36 (28, 48; urgent)	10 (1, 67; routine) 1(0, 2; urgent)	3968 (328, 31 691; routine) 802 (81, 10 235; urgent)	4369 (1066, 31 942; routine) 931(194, 10 363; urgent)
Glucose, ≤2.7 or ≥27.78 mmol/L (≤48.65 or ≥500.54 mg/dL)	Siemens Advia 2400/Roche Cobas c8000, enzymatic	112 (20, 204; routine) 28 (11, 88; urgent) 13 (6, 27; blood gas)	199 (134, 295; routine) 41 (32, 54; urgent) 9 (6, 16; blood gas)	1 (0, 17; routine) 1 (0, 2; urgent) 1 (0, 2; blood gas)	1053 (117, 3148; routine) 246 (49, 2978; urgent) 305 (64, 1462; blood gas)	1443 (538, 4256; routine) 425 (166, 3112; urgent) 343 (105, 1611; blood gas)
Sodium, ≤120 or ≥160 mmol/L	Siemens Advia 2400/Roche Cobas c8000, ion-selective electrode	59 (19, 179; routine) 25 (11, 62; urgent)	219 (138, 338; routine) 35 (27, 47; urgent)	1 (0, 2; routine) 1 (0, 2; urgent)	181 (31, 1200; routine) 258 (44, 3162; urgent)	671 (408, 1637; routine) 376 (150, 3223; urgent)
Arterial partial pressure of carbon dioxide (blood gas), ≤20 or ≥70 mm Hg	Roche Cobas b211, ion-selective electrode	11 (5, 20)	7 (5, 13)	1 (0, 3)	271 (46, 2310)	328 (74, 2395)
Calcium (serum), ≤1.5 or ≥3.5 mmol/L	Siemens Advia 2400/Roche Cobas c8000, colorimetric	60 (15, 144; routine) 37 (14, 88; urgent)	255 (165, 364; routine) 41 (32, 52; urgent)	1 (0, 17; routine) 1 (0, 2; urgent)	309 (66, 2720; routine) 203 (47, 1589; urgent)	1225 (464, 3493; routine) 392 (168, 1984; urgent)
Arterial partial pressure of oxygen (blood gas), ≤50 mm Hg	Roche Cobas b211, ion-selective electrode	12 (6, 21)	8 (5, 14)	1 (0, 2)	205 (37, 2735)	269 (68, 2862)
Cholinesterase, ≤2130 U/L	Roche Cobas c8000, butyrylthiocholine (Trinder)	20 (10, 51)	32 (26, 41)	1 (0, 2)	678 (68, 8065)	741(151, 8112)
Bicarbonate (blood gas), ≤10 or ≥40 mmol/L	Roche Cobas b211, calculated	12 (5, 20)	8(5, 12)	1(0, 3)	318 (63, 2730)	348 (88, 2853)
pH value (blood gas), ≤7.2 or ≥7.6	Roche Cobas b211, ion-selective electrode	8 (4, 16)	8 (5, 13)	1 (0, 3)	190 (35, 2549)	257 (63, 2740)
Hematology						

(Continues)

TABLE 2 (Continued)

Critical value items and thresholds	Detection system and method	Pre-analytical TAT (from sample collection to registration)	Analytical TAT (from sample registration to critical values reporting)	Post-analytical TAT (from critical values reporting to notification of caregivers)	Post-analytical TAT (from critical values reporting to clinician's response recorded in the EMR)	Total TAT (from sample collection to clinician's response recorded in the EMR)
WBC count, ≤2* or ≥30*10^9/L	Sysmex XN-9000, electrical impedance	53 (15, 142)	43 (20, 80)	1(0, 2)	229(39, 2745)	446(206, 2861)
Hemoglobin, ≤60 g/L (6 g/dL)	Sysmex XN-9000, sodium dodecyl sulfate hemoglobin	30 (12, 107)	27 (14, 54)	1 (0, 2)	259 (41, 3002)	445 (160, 3135)
Platelets count, ≤20* or ≥1000*10^9/L	Sysmex XN-9000, electrical impedance	52 (17, 138)	44 (21, 80)	1 (0, 2)	259 (49, 2856)	465 (222, 3034)
Neutrophils count, ≤0.5*10^9/L	Sysmex XN-9000, light scattering	48 (13, 142)	50 (21, 89)	1 (0, 3)	307(50, 2824)	519 (239, 3016)
Percentage of primitive cells (peripheral blood), ≥1%	Sysmex XN-9000/ Microscope, counting	103 (29, 161)	115 (88, 164)	1 (0, 2)	253 (48, 1639)	893 (307, 1964)
Coagulation						
Fibrinogen, ≤1.0 g/L	Sysmex CS5100, coagulation	40 (16, 82)	90 (53, 150)	1 (0, 2)	270 (39, 1915)	510 (213, 2160)
Thrombin time, ≥150 s	Sysmex CS1500, coagulation	25(12, 57)	92 (55, 144)	1 (0, 2)	462 (49, 2564)	637 (232, 2740)
Activated partial thromboplastin time, ≤15 or ≥100 s	Sysmex CS1500, coagulation	21 (11, 48)	79 (49, 141)	1 (0, 2)	329 (35, 2364)	497 (188, 2629)
Prothrombin time, ≤9 or ≥70 s	Sysmex CS1500, coagulation	24 (12, 48)	115 (66, 191)	1 (0, 2)	285 (29, 3670)	549 (235, 3816)
Microbiology						
Blood culture, positive	BD blood culture	25 (14, 39)	1250 (967, 3031)	1 (0, 2)	230 (16, 1045)	3176 (1328, 5850)
Gram stain (sterile body fluid), positive	Microscope, manual	22 (12, 39)	1139 (870, 1523)	1 (0, 2)	974 (115, 3951)	2633 (1485, 5617)
Total		27 (11, 80)	41 (27, 89)	1 (0, 2)	323 (52, 3255)	648 (192, 3836)

Abbreviation: EMR, electronic medical record.

[a]Routine: the test was analyzed in the way of routine examination by a routine instrument (Siemens Advia 2400). The same below.

[b]Urgent: the test was analyzed in the way of urgent examination by an urgent instrument (Roche Cobas c8000). The same below.

[c]Blood gas: the test was analyzed by the blood gas instrument (Roche b 221). The same below.

ratio, and clinician response ratio, are applied for monitoring the whole process of laboratory critical value management.

2.5 | Statistical analysis

The TAT data of pre-analytical, analytical, post-analytical, and total analytical phase of laboratory critical values showed a skewed distribution by Kolmogorov-Smirnov normality test ($P < .01$), the median and inter-quartile range of the TAT were used for statistical analysis. Five critical value indicators were expressed as percentages. IBM SPSS Statistics for Windows, version 24 (IBM Corp.) and Microsoft Excel 2006 (Microsoft) were used for statistical analysis.

3 | RESULTS

3.1 | Critical value items, thresholds, and their percentage distribution

There were 7 706 962 test reports of 23 test items at BTCH from January 2015 through June 2019, of which 38 020 (0.49%) reports were notified as critical values, an average of about 32 critical values a day. Of the total critical values, most (24 050, 63%) were from inpatient department (IPD) patients, followed by emergency department (ED) patients (9211, 24%) and outpatient department (OPD) patients (4759, 13%). The top five items (thresholds, constituent ratio) in order of constituent ratios of critical values were high-sensitivity troponin T (≥0.053 ng/mL, 22.12%), WBC count (≤2* or ≥30*10^9/L, 9.31%), urea nitrogen [≥25 mmol/L (70 mg/dL), 8.72%], potassium (≤2.5 or ≥6.2 mmol/L, 6.97%), and creatinine [≥600 umol/L (6.787 mg/dL), 6.50%]. According to the incidence ratios of critical values, the top five items (thresholds, incidence ratio) were high- sensitivity troponin T (≥0.053 ng/mL, 9.78%), blood culture (positive, 9.66%), Gram stain (sterile body fluid; positive, 4.04%), arterial partial pressure of carbon dioxide (blood gas; ≤20 or ≥70 mm Hg, 2.92%), and arterial partial pressure of oxygen (blood gas; ≤50 mm Hg, 2.82%). The percentage distribution points of critical value boundaries based on patients' test reports are 0.007% ~ 6.04% for low boundaries and 71.70% ~ 99.99% for high boundaries, as shown in Table 1.

3.2 | Turnaround time of critical value notification

The median (inter-quartile range) of the turnaround time (TAT) of pre-analytical (from sample collection to registration), analytical (from sample registration to critical values reporting), post-analytical (from critical values reporting to notification of caregivers), post-analytical (from critical values reporting to clinician response recorded in the EMR), and total analytical (from sample collection to clinician response recorded in the EMR) phase of all laboratory critical values at BTCH over 5 years were 27 (11, 80), 41 (27, 89), 1 (0, 2), 323 (52, 3255), and 648 (192, 3836) minutes, respectively. The median (inter-quartile range) of the turnaround time of critical value notification by tests from 2015 to 2019 are listed in Table 2.

3.3 | Enhance the effectiveness of critical values notification by the intervention

Three quality improvement strategies derived from the QCC were implemented throughout the hospital in September 2015, as shown in Figure 2. To analyze the effects of interventions, baseline data were collected for a 9-month period (January 2015 through September 2015 as the pre-intervention period and October 2015 through June 2016 as the initial post-intervention comparison period). After the intervention, timely notification ratio, notification receipt ratio, and timely notification receipt ratio of critical values of ED, IPD, and total patients were all increased, with a significant difference for the two periods ($P < .001$, Table 3).

3.4 | Quality indicators of critical values

Five quality indicators, such as notification ratio, timely notification ratio, notification receipt ratio, timely notification receipt ratio, and clinician response ratio, from total patients over a 5-year period at BTCH, are 100%, 94%, 97%, 92%, and 99%, respectively. However, critical values from OPD patients show relatively poor indicators, timely notification ratio, notification receipt ratio, and timely notification receipt ratio are 92%, 72%, and 48%, respectively. Five quarterly quality indicators of critical values were shown in Figure 2 and Table 4.

4 | DISCUSSION

A complete critical value notification and response process should be established in hospitals to provide safe and high-quality medical services.[24] This study described here was a 5-year retrospective observational report of laboratory critical values notification after implementing the electronic closed-loop notification system. The main strengths of the study were as follows: data coverage for 5 years, a large number of objects (38 020 critical values of over 7 million item reports), and multiple service practice sites, including the ED, IPD, and OPD.

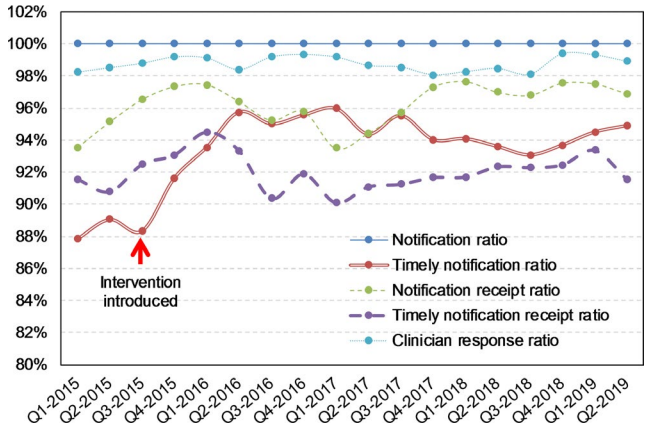

FIGURE 2 Five quarterly quality indicators at Beijing Tsinghua Changgung Hospital over a 5-y period

TABLE 3 Comparing critical value indicators between 2015 and 2016

Sites	January-September, 2015 (before intervention)					October, 2015-June, 2016 (after intervention)				
	Notification ratio (No./Total No.)	Timely notification ratio (No./Total No.)	Notification receipt ratio (No./Total No.)	Timely notification receipt ratio (No./Total No.)	Clinician response ratio (No./Total No.)	Notification ratio (No./Total No.)	Timely notification ratio (No./Total No.)	Notification receipt ratio (No./Total No.)	Timely notification receipt ratio (No./Total No.)	Clinician response ratio (No./Total No.)
ED	100% (286/286)	88% (253/286)	99% (285/286)	94% (270/286)	98% (281/286)	100% (1132/1132)	95% (1073/1132)[a]	100% (1132/1132)[a]	96% (1092/1132)	98% (1107/1132)
IPD	100% (961/961)	90% (869/961)	96% (923/961)	95% (912/961)	99% (947/961)	100% (2177/2177)	95% (2057/2177)[a]	99% (2165/2177)[a]	99% (2157/2177)[a]	99% (2160/2177)
OPD	100% (80/80)	90% (72/80)	68% (54/80)	43% (34/80)	99% (79/80)	100% (327/327)	91% (299/327)	67% (220/327)	49% (160/327)	99% (325/327)
Total	100% (1327/1327)	90% (1194/1327)	95% (1262/1327)	92% (1216/1327)	98% (1307/1327)	100% (3636/3636)	94% (3429/3636)[a]	97% (3517/3636)[a]	94% (3409/3636)[a]	99% (3592/3636)

Abbreviations: ED, emergency department; IPD, inpatient department; OPD, outpatient department.
[a]Chi-square test, $P < .001$ vs before intervention.

TABLE 4 Five quality indicators of critical value for all patients from 2015 to 2019

Sites	Total number of critical values required to notify	Number of critical values notified	Notification ratio (%)	Number of critical values notified by technician within a certain time frame[a]	Timely notification ratio (%)	Number of notifications receipt of caregivers acknowledgment	Notification receipt ratio (%)	Number of notifications receipt of caregivers acknowledgment within a certain time frame[b]	Timely notification receipt ratio (%)	Number of critical values responsed by clinician	Clinician response ratio (%)
ED	8172	8172	100	7811	96	8171	100	7898	97	8064	99
IPD	25 854	25 854	100	24 317	94	25 651	99	25 181	97	25 520	99
OPD	3994	3994	100	3684	92	2878	72	1919	48	3960	99
Total	38 020	38 020	100	35 812	94	36 700	97	34 998	92	37 544	99

Abbreviations: ED, emergency department; IPD, inpatient department; OPD, outpatient department.
[a]The time frame criterion of notifying clinical caregivers of the critical values by technician is 30 min for ED patients and 60 min for OPD and IPD patients.
[b]The time frame criterion of the documentation of critical value receipt is 15 min for ED patients, 45 min for IPD patients, and 480 min for OPD patients.

Previously, laboratory critical values notification was often made by telephone and read-back. It was more time-consuming and easy to have missing reports or even false reports.[5,14,25] The ratio of errors made by telephone contacts for critical values was 3.5% reported by Joan Barenfanger et al[25] and 5.0% reported by Peter J et al[14] Our study had clearly documented that implementing a electronic closed-loop laboratory critical value notification system combining with HIS, mobile phone short message, and phone call was an effective intervention to improve the critical values initiative notification.[5,24]

The total incidence ratio of critical values over a 5-year period was 0.49%, which was higher than that of 0.25% in Massachusetts General Hospital[26] (Medical Center Teaching Hospital, USA), and lower than that of 0.96% in Zhejiang University First Affiliated Hospital[27] (Tertiary Teaching Hospital, China) and 0.57% in Sun Yat-sen University Ophthalmic Center[7] (Special Hospital, China). The remarkable inter-laboratory differences in the critical values notification existed between different hospitals. Excessively reporting critical values may make clinicians less sensitive to true critical values. Consensus on the items and their thresholds of critical values should be established by clinical laboratorians and clinicians together, based on the characteristic of the institution itself and percentage distribution of critical value thresholds.[2,18] We previously reported that the percentage distribution points of the critical value boundaries can be evaluated on the basis of the patients' data distribution.[16] The data could provide references for the review meeting with clinicians.

We further studied the timeliness of notification, the median time from a technician notification of the critical value until the time the critical value was reported successfully to caregivers was 1 minute (Table 2), which was much shorter than the reported 6 minutes suggested by Carmen Ricos et al[28] and 7 minutes in a CAP Q-Probes study of 121 Institutions.[13] On the other hand, the median time of post-analytical TAT (from critical values reporting to clinician response and recorded in the EMR) for total critical values was 323 minutes, which was much longer than that of pre-analytical TAT (from sample collection to registration, 27 minutes) and analytical TAT (from sample registration to critical values reporting, 41 minutes). This prompted the group of critical value management of the hospital should optimize the procedures to ensure the clinicians get the information as soon as possible and treat the patients in time.[29]

The introduced quality improvement strategies from the QCC contributed to greatly improve the effectiveness of critical values notification. The study showed that poor indicators were from outpatients and that more attention should be payed to OPD critical value management.[14] The quality indicators were used to monitor the whole process of critical value notification, point-to-point communication improvements were carried out in the department with deficiencies in the indicators of critical value notification. The continuous monitoring of quality indicator data allowed identification all possible improvements, promoted the reduction of errors, and improved quality of the critical value notification, thus guaranteeing patient safety.[20,21]

This study may provide some ideas for other hospitals, including how to establish the flowchart of notification, how to set items and thresholds, and how to define related quality indicators to monitor the whole process. Further study on the personalized application of critical values for different types of patients in different departments is needed. Managers of hospitals and laboratories should attach more importance to the construction of the critical value notification system, and the closed-loop management, thus ensuring patient safety.

ACKNOWLEDGMENTS

The authors are grateful to the staff of the Department of Laboratory Medicine, Department of Nursing, and the Department of Management Information System of Beijing Tsinghua Changgung Hospital for their efforts in this study. This work was supported by the Incubation Program Project of Beijing Municipal Administration of Hospitals of China (grant number PG2018013).

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

ORCID

Runqing Li https://orcid.org/0000-0003-3139-2871

REFERENCES

1. Lundberg GD. When to panic over abnormal values. *MLO Med Lab Obs*. 1972;4:47-54.
2. Zeng R, Wang W, Wang Z. National survey on critical values notification of 599 institutions in China. *Clin Chem Lab Med*. 2013;51(11):2099-2107.
3. White GH, Campbell CA, Horvath AR. Is this a critical, panic, alarm, urgent, or markedly abnormal result. *Clin Chem*. 2014;60(12):1569-1570.
4. Hortin GL, Csako G. Critical values, panic values, or alert values. *Am J Clin Pathol*. 1998;109(4):496-498.
5. Parl FF, O'Leary MF, Kaiser AB, Paulett JM, Statnikova K, Shultz EK. Implementation of a closed-loop reporting system for critical values and clinical communication in compliance with goals of the joint commission. *Clin Chem*. 2010;56(3):417-423.
6. Piva E, Sciacovelli L, Zaninotto M, Laposata M, Plebani M. Evaluation of effectiveness of a computerized notification system for reporting critical values. *Am J Clin Pathol*. 2009;131(3):432-441.
7. Duan F, Liao J, Lin L, Liu X, Wu K. Prevalence of laboratory critical results in eye patients from an eye hospital in southern China. *Biomed Res Int*. 2017;2017:8920350.
8. Wu SW, Chen T, Xuan Y, et al. Using plan-do-check-act circulation to improve the management of panic value in the hospital. *Chin Med J (Engl)*. 2015;128(18):2535-2538.
9. Solvoll T, Hanenburg A, Giordanego A, Hartvigsen G. Communication pattern regarding alarms and patient signals between nurses, other health care actors, patients and devices. *Stud Health Technol Inform*. 2015;218:32-38.
10. Lehman CM, Howanitz PJ, Souers R, Karcher DS. Utility of repeat testing of critical values: a Q-probes analysis of 86 clinical laboratories. *Arch Pathol Lab Med*. 2014;138(6):788-793.

11. Onyenekwu CP, Hudson CL, Zemlin AE, Erasmus RT. The impact of repeat-testing of common chemistry analytes at critical concentrations. *Clin Chem Lab Med*. 2014;52(12):1739-1745.
12. Piva E, Pelloso M, Penello L, Plebani M. Laboratory critical values: automated notification supports effective clinical decision making. *Clin Biochem*. 2014;47(13–14):1163-1168.
13. Valenstein PN, Wagar EA, Stankovic AK, Walsh MK, Schneider F. Notification of critical results: a College of American Pathologists Q-Probes study of 121 institutions. *Arch Pathol Lab Med*. 2008;132(12):1862-1867.
14. Howanitz PJ, Steindel SJ, Heard NV. Laboratory critical values policies and procedures: a college of American Pathologists Q-Probes Study in 623 institutions. *Arch Pathol Lab Med*. 2002;126(6):663-669.
15. Li R, Gong L, Wang T, Zhu D, Yang S, Zhao H. The application of sigma metrics quality models in quality management of clinical biochemistry laboratory. *Chin J Lab Med*. 2017;40(9):727-732.
16. Li R, Wang T, Bi C, Peng P. Establishment and optimizing of the whole process management system of laboratory critical results in a new tertiary hospital. *Labeled Immunoassays Clin Med*. 2018;25(8):1236-1241.
17. Wagar EA, Friedberg RC, Souers R, Stankovic AK. Critical values comparison: a College of American Pathologists Q-Probes survey of 163 clinical laboratories. *Arch Pathol Lab Med*. 2007;131(12):1769-1775.
18. Emancipator K. Critical values: ASCP practice parameter. *Am J Clin Pathol*. 1997;108(3):247-253.
19. Genzen JR, Tormey CA. Education Committee of the Academy of Clinical Laboratory Physicians and Scientists. Pathology consultation on reporting of critical values. *Am J Clin Pathol*. 2011;135(4):505-513.
20. Sciacovelli L, Panteghini M, Lippi G, et al. Defining a roadmap for harmonizing quality indicators in laboratory medicine: a consensus statement on behalf of the IFCC Working Group "Laboratory Error and Patient Safety" and EFLM Task and Finish Group "Performance specifications for the extra-analytical phases". *Clin Chem Lab Med*. 2017;55(10):1478-1488.
21. Sciacovelli L, Aita A, Plebani M. Extra-analytical quality indicators and laboratory performances. *Clin Biochem*. 2017;50(10–11):632-637.
22. Roffi M, Patrono C, Collet JP, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: task force for the management of acute coronary syndromes in patients presenting without persistent st-segment elevation of the European Society of Cardiology (ESC). *Eur Heart J*. 2016;37(3):267-315.
23. Niu A, Yan X, Wang L, Min Y, Hu C. Utility and necessity of repeat testing of critical values in the clinical chemistry laboratory. *PLoS ONE*. 2013;8(11):e80663.
24. Kost GJ, Hale KN. Global trends in critical values practices and their harmonization. *Clin Chem Lab Med*. 2011;49(2):167-176.
25. Barenfanger J, Sautter RL, Lang DL, Collins SM, Hacek DM, Peterson LR. Improving patient safety by repeating (read-back) telephone reports of critical information. *Am J Clin Pathol*. 2004;121(6):801-803.
26. Dighe AS, Rao A, Coakley AB, Lewandrowski KB. Analysis of laboratory critical value reporting at a large academic medical center. *Am J Clin Pathol*. 2006;125(5):758-764.
27. Yang D, Zhou Y, Yang C. Analysis of laboratory repeat critical values at a large tertiary teaching hospital in China. *PLoS ONE*. 2013;8(3):e59518.
28. Ricós C, García-Victoria M, de la Fuente B. Quality indicators and specifications for the extra-analytical phases in clinical laboratory management. *Clin Chem Lab Med*. 2004;42(6):578-582.
29. Owens SR, Balis UG, Lucas DR, Myers JL. Application of a rules-based natural language parser to critical value reporting in anatomic pathology. *Am J Surg Pathol*. 2012;36(3):376-380.

How to cite this article: Li R, Wang T, Gong L, et al. Enhance the effectiveness of clinical laboratory critical values initiative notification by implementing a closed-loop system: A five-year retrospective observational study. *J Clin Lab Anal*. 2020;34:e23038. https://doi.org/10.1002/jcla.23038