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A study of critical value analysis and notification at hematology section of Central laboratory in a tertiary care hospital.

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Abstract

Background: Critical values refer laboratory results that indicate potentially serious or life-threatening conditions requiring prompt communication to the treating clinician. Accreditation bodies like NABL and NABH require laboratories to establish critical values. Critical value identification and notification have become an essential part of the medical laboratories including the Universally accepted ISO 15189:2022. A survey was done at the hematology section of the laboratory to determine current practice for analysis of critical value and notification in hematology. ***Aim and Objective:*** 1. To analyze the critical value data in hematology section of the laboratory. 2. To compare the frequency of different hematological parameters 3. To implement various ways of communication to improve the operational efficiency of critical value identification and notification procedure as a part of continual improvement plan of the lab. ***Materials and Methods:*** This is a retrospective observational study done among all the blood samples presenting to our Central diagnostic lab, The Oxford medical college hospital and research center, Bangalore. The data was collected from the critical value log sheet which is maintained in laboratory as a part of NABL/ NABH quality indicator for Continual improvement of the Laboratory. A 6 months data was collected from October 2024 to March 2025. The analysis was done after following the NABL/ NABH guidelines of sample acceptance and sample rejection criteria. The parameters chosen for CVN included platelets, hemoglobin, WBC, and International Normalized Ratio (INR). A test result which was significantly outside the normal value range was considered "critical value" (CV). Verbal telephonic and nonverbal short messages (SMS) were used as mode of communication process in our lab. Notification read back policy were also followed and included in the critical value log sheet by the person who was informed over the phone. ***Results:*** A total of 259 critical values were reported out of 51286 tests done over a period of 6 months (October2024 to March 2025). Maximum was recorded from emergency department (160, 61.7%) followed by ward in patient and ICU (82, 31.6%) and OPD (17,6.5%). Maximum critical value notification was noted during general shift hours in the morning (162, 62.5%). ***Conclusions:*** Enhanced documentation and implementation of critical value identification and notification for the tests helped reduce the anxiety and turnaround time in reporting. Monthly and organized periodic training for technical personnels working in the lab regarding the concept of critical values helped in improvement of the quality of patient care and also as quality indicator in NABL/NABH standard for continual improvement.

Keywords: Critical value (CV), Laboratory management, Patient safety, Accreditation.

INTRODUCTION

For good laboratory practice, timely identification and communication are essential elements and has gained importance in the recent years for the patient safety and timely treatment. Accreditation bodies require standardized laboratories to establish critical values [1]. Dr. George Lundberg first described the critical value in the year 1972 [2]. CVs are reported both for high and low values for selected analytical test. Recent studies and guidelines for CV have provided best contribution to the timely management, monitoring and safety of the patient care. Lack of clarity in communication and delays can cause frustration, anxiety and may threaten the life of the patient. According to The Joint Commission, a critical test result is one that must be communicated without delay because it falls far outside the expected range and could indicate a life-threatening situation. Similarly, the College of American Pathologists requires laboratories to document not only the identification of such results but also the process of notifying the appropriate caregivers.[3]

The College of American Pathologists (CAP) checklist requires the percentage of CV results with

documentation that the results have been reported to caregivers.

A summary of the CAP and TJC guidelines on CV notification is seen in Table 1.

Selection of critical value limit ranges in small to medium size laboratories and preparation of a standard list or target turn around time (TAT) for reporting of critical results is difficult due to the absence of consensus in laboratory community. Therefore, an agreement on the list of parameters and the critical value limits of each of them should be made, established and followed by each laboratory section which will help in eliminating the problem of diluting the urgency of the critical value call due to expansion of critical call out lists [4].

There is a pressing need to report these values accurately and rapidly because of its importance. Although there are no regulatory requirements to verify critical values by repeat analysis, the practice of repeating all critical values is longstanding and common in laboratories. Multiple studies have called into question the necessity of this practice, with most studies concluding it is unnecessary for accurate result reporting. Some reports have shown limited utility of repeat testing in specific instances, such as when the results fall outside the analytic measurement range [5]. But the laboratories must confirm the receipt of CV result by the intended recipient and read back is required and noted.

Aims and Objective:

1. To analyze the critical value (CV) data in hematology section of the laboratory.
2. To compare the monthly frequencies of critical values for different parameters.
3. To suggest measures for improving the effectiveness and operational efficiency of the critical value notification (CVN) process as a part of quality improvement of the lab.

MATERIALS AND METHODS

The present study was of a retrospective, observational study spanning over a period of six months (October2024 to March2025). In the present study we aimed to analyze the critical value data in the hematology section of our laboratory and compare the frequencies of critical values for different parameters. A total of 51286 tests were performed during the study period. The test requests were received from out-patient departments (OPD), in-patient departments [Intensive care units (ICUs), wards and operation theatres] and emergencies. A total of 259 critical values were reported from the hematology section. The inclusion criteria were the test samples received at hematology section for automated analysis. The exclusion criteria were the samples sent to clinical pathology, Peripheral smears, cytology, histopathology, biochemistry, and microbiology sections of the laboratory.

Critical value notification processes in our lab:

The list of parameters from hematology section which were selected for the critical value notification (CVN) and also their critical value limit ranges were developed after discussing with the treating physicians, surgeons, ICU and emergency doctors as per their requirements for management of patients. Accordingly, the parameters which were selected by the laboratory for CVN included platelets, hemoglobin and WBC and INR. The analytical reliability of CVs was checked and then after ruling out the pre-analytical errors, the laboratory technician ensure the validation of the result by repetition of test or by recalibration of the parameter if necessary and/or by checking the quality control (QC) results. A critical value chart is pasted in the Hematology section of the lab and any test value which is falling in the critical value listed in the chart is notified to the concerned caregiver (treating physicians, surgeons, ICU/ emergency doctors, nursing staff or the consultants). Notification is done through telephone or short messages in a closed group and at the same time the result is also entered in the critical value call out log sheet. Details such as the patient unique id, test parameter, department, person's name who informs the critical value, person's name to whom the critical value is notified, contact number, date and time of call out, the examination result conveyed with the measuring unit and reference range, examination result confirmed by "notification read back" are entered. The critical value call out log is then signed by the laboratory head/ pathologist in-charge.

RESULTS

The present study was a retrospective observational study conducted in the hematology section of laboratory at The Oxford Medical College Hospital and Research Centre, Bangalore. The lab received blood samples from out-patient departments (OPDs), in-patient departments [Intensive care units (ICUs), wards and operation theatres (OTs)] and emergencies. A total of 259 critical values were reported by the lab. A maximum of 160(61.7%) critical values were recorded from the emergency department followed by IPD 82 (31.5%) and OPD 17(6.5%) departments.

A total of 51286 tests were performed in the lab over a period of six months (October 2024 to March 2025). The parameters which were selected by the laboratory for CVN were platelets, hemoglobin, WBC and INR from hematology section.

Total critical values reported was 259 out of total 51286 tests done.

Rate = Total critical values reported / Total number of tests
259/51286 x100 = 0.5
The critical value limit ranges of different parameters are shown in Table 2.

A maximum of 160(61.7%) critical values were recorded from the emergency department followed by IPD [Intensive care units (ICUs), wards and operation theatres (OTs)] 82 (31.6%) and OPD 17(6.5%) departments (Table 3).

Critical values in these parameters constituted 259 (0.51%) of the total test of 51286 reported by the lab. Monthly data collected showed the most commonly notified for critical value were Platelet110(42.4%) followed by Hemoglobin 108(40.9%), WBC 28 (10.8%) and INR 15 (5.7%) as shown in Table 4. Critical value notifications were maximum in the morning shifts (162, 62.5%) and minimum in the night shifts (15, 5.7%), Fig 1.

We implemented the following measures in our laboratory for improving the effectiveness and operational efficiency of the critical value notification process: Telephonic communication and short messages with the run data were sent to the concerned clinical caregiver as and when any abnormally critically high or low value was noted in the test. We also checked the difficulties faced by Laboratory staff in the procedure of call back and found that most of the delays were due to busy phone lines of wards & ICU. Most of the time patients or their attendants were not aware of correct patient's diagnosis, requested investigations details and registration identification. Despite all these hurdles our Laboratory staffs were successful in maintaining notification time to patient or treating physician/ clinical care provider ranging from 10 to 30 minute. (Table 5)

Table 1: Regulatory considerations for implementation of a CV system

Questions to Compare TJC	CAP	TJC
What to communicate?	1.) Patient Name 2.) Patient UID number 3.) Test Name 4.) Test Result 5.) Date of Result 6.) Time of Result	1.) Patient Name 2.) Patient UID number 3.) Test Name 4.) Test Result
How to Communicate?	Phone call or electronic	Telephone or verbal
Confirmation of result sent to Intended Recipient?	Yes, required confirmation of intended recipient (first and last name	Yes, required confirmation of "whom" results were reported to
Readback required?	No, not required	Yes
Electronic transmission of result is acceptable?	Acceptable	Acceptable
Evidence of Compliance?	Records demonstrating the above and documentation of responsible laboratory personnel reporting result	Records demonstrating above
Guideline	1.) CAP COM.30000 2.) CAP COM.30100	Standard International patient safety goal 2 (IPSG.2

Table 2: List of critical value limit ranges of different parameters in hematology section.

S.No.	Parameter	Lower limit	Upper limit
1.	Platelet	20,000/cumm	10,00000/cumm
2.	Hemoglobin	≤7g/dl	≥21g/dl
3.	WBC	≤2.0 x10^3/µl	≥ 40 x 10^3/ µl
4.	INR		>5

Table3: Distribution of the critical values by clinical care areas

Clinical care area	Total no. of critical values	Percentage (%)
Emergency	160	61.7
IPD (ICU, wards, OTS)	82	31.6
OPD	17	6.5

Table 4: Monthly Distribution of critical values for different parameters tested

Month	Critical value parameter				Total critical value	Total tests
	Hb	WBC	Platelet	INR		
October 2024	18	5	15	3	40	8448
November 2024	10	4	22	2	42	8893
December 2024	23	6	16	2	46	8738
January 2025	24	3	20	2	49	8944
February 2025	16	4	17	3	38	8237
March 2025	15	6	20	3	44	8026
Total (%)	106(40.9%)	28(10.8%)	110(42.4)%	15(5.7%)	259(0.51%)	51286

Fig 1: Critical value data distribution in each shift

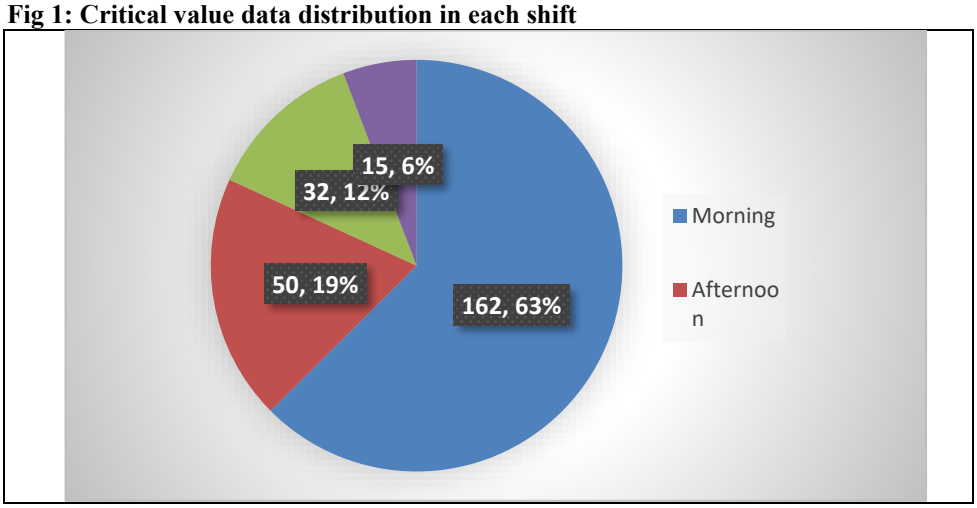

Table 5: Time taken in notification of critical alerts to respective department.

Department	Reporting time (minutes)		
	Minimum	Maximum	Mean
IPD and ICU	10	30	20
OPD	30	60	45
Emergency & Trauma Centre	10	30	20

6. Table showing comparison of our study with other studies:

Sl No	Study	Duration (months)	Total tests	Total no. of critical values	% of critical values to total tests	Sections included	Analyte with highest frequency
1.	Desai KN et al. [9]	24	90,000	19423	21.6	Hematology (H) and Clinical pathology (CP)	Hematology Hemoglobin (5212,26.8%) CP- Urine ketone bodies (3100, 16.0%)
2.	Vallalkani KN et al. [15]	6	78330	7367	9.4	Hematology and Clinical Pathology	Hematology Platelet (2082, 28.3%) , CP positive for urine ketones (48, 0.7%)
3	Shubha H. V	18	75,156	2199	2.92	Hematology (H) Biochemistry (BC)	H-Platelets (165, 7.5%) BC- Creatinine (1151, 52.3%)
4	Our Study	6	51286	259	0.51	Hematology (H)	H Platelets (110, 42.4%)

DISCUSSION

Critical result and urgent sample results notification is very important for critical treatment decision. Appropriate and timely management of patients largely depends on the clinical communication. A large number of reports have proven the ability of information technology to speed up the process of critical value reporting. In our lab the in-house Laboratory Information System (LIS) software was developed but still lacks the automatic flags of the test results requiring CVN and sends short message service (SMS) to the concerned caregivers. Training the laboratory staff for the policy of laboratory critical value identification and notification process and documenting the same in the log sheets has helped in reducing the timeline for the CVN. In a study conducted by Lynn TJet al., in order to improve communication between clinical providers and the laboratory, the secure text messaging (STM) for CVN was implemented [6].

Agarwal et al reported that there is a poor awareness among nursing and lab staff regarding urgent sample and critical value reporting [7].

In the present study, other reasons for delay in CVN include shifting patients to other location in the hospital for example from in patient ward to ICU and phone call not attended by caregivers. But this was reduced by sending an SMS alert to the closed group system among the staffs and clinical caregivers. Moreover, the practice of repeating critical values has been shown to add little value in regard to hematology and coagulation and is not necessary for accurate reporting when the shifting has been done. Evaluation of the impact of the repeat practice was performed and reduced as repeating critical hematology and coagulation results was found to be an unnecessary process that leads to wasting of laboratory resources and lengthened turnaround time, delaying clinical intervention [8].

In the OPD cases, one of the major challenges faced in CVN process was that unlike inpatients, there was no fixed patient location to which the CV can be telephonically notified.

Another observation was that CVNs were highest in the morning shifts (162, 62.5%) and minimum in the night shifts (15, 5.7%). This may be attributed to the increased test volume during the peak working hours in mornings and active communication process due to increased number of technical staffs in the morning shifts. Similar findings were observed in a study by Desai KN et al. [9]

A study by Hawkins on ‘laboratory turnaround time’ also noted that training of laboratory staff to expedite handling of laboratory samples, improves services [10].

The key goal for our study was to train the technical staffs on how to identify critical values on automated instruments and how to notify within the time frame enlisted as turnaround time in the lab for critical value notification which is 30 mins to 1 hour for our lab. In a national survey, 11% of patients stated that they had experienced delays in receiving abnormal test results.[11] Poor awareness among nursing and lab staff regarding critical value reporting was the main reason for the delays in the patient management intervention. After intervention we have found an improvement in reporting and recording of critical value samples in separate register log data sheet.

Fernandes et al reported that the time taken to convey specimens to the laboratory can be shortened by using a pneumatic tube system. [12]

One of the strategies to strengthen the CVN process could be to have a robust Laboratory Information System (LIS) that could automatically detect critical value and raise alarm which automatically send out short messages or emails to the treating physician directly.13] Help from the hospital management and the IT department in this regard would really improve in communication process. Similar finding was also stated by T Mukhopadhyay et al. [14]

Unexpected system technical issues or malfunctions, and human errors due to high workload, distractions, fatigue, or failure to recognize the critical nature of certain values were some of the reasons for delays in notification which was also found in similar study done by Vallalkani KN et al. [15]

The limitation of the study is that evaluation could not be done on the morbidity and mortality of the patients who were reported of critical values. Further studies can be planned in that perspective.

CONCLUSION

Laboratory has an essential responsibility of efficient and timely communication of critical test results. Quality indicator in lab has become a mandatory policy for the improvement in Quality standard for accredited laboratories. A written policy for implementing critical value notification with a well-coordinated communication between laboratory personnel and the clinical care provider are fundamental to improve patient care. Information technology (IT) plays an essential component of medical laboratories and also for the immediate communication with the clinicians. The critical value notification was highest for platelets (118, 45.5%) and maximum notification was done in the EMD (160, 61.7%) in our study. The importance of both verbal and non-verbal communication processes for notification of CVs has been established and the significance of

employing innovative measures to improve the CVN process has been highlighted.

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