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Critical Value Matters: A Study of Critical Value Identification and Notification to Clinicians in the Hematology Section of the Pathology Laboratory at a Tertiary Care Hospital

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Abstract

Objective: To analyze the critical value (CV) data in the hematology section of the laboratory
Methodology: A retrospective analysis of 5 months (June-October 2024). All consecutive samples (169,667) received for investigations were included. We aim to analyze the critical value data in the hematology section and compare the frequencies of critical values for various parameters, including Hemoglobin, White cell count, Platelet count, Malaria parasite infestation, Prothrombin time (PT), International normalized ratio (INR), and Activated partial thromboplastin time (APTT). The test requests were received from outpatient departments (OPDs), inpatient departments (IPD), and the emergency department (ER).
Results: Out 402 of the total critical values, 250 (62.1%) coagulation abnormalities, including prolonged prothrombin time (PT) & Activated partial thromboplastin (APTT) followed by 61(15.1%) were decreased platelet count, 52 (12.9%) were the malarial parasites on peripheral smears, 33(8.2%) reduced hemoglobin levels, 05(1.2%) deranged leucocyte count, 01(0.2%) leukemia. Critical values constituted 0.2% of the total test results reported. The mean total turnaround time (TAT) for all tests ranged from 1.3 to 2.1 hours. The success rate of critical result reporting within 1 hour was 25.3%
Conclusion: This study suggests that the mean TAT in this teaching hospital is slightly longer than the benchmark. Further research is needed to determine the causes of delays and develop interventions to solve this problem
Keywords: Critical value, Turnaround time (TAT), Quality indicators, Pre analytical errors

Introduction

A critical value is defined as "a laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken." The Joint Commission (JC) defines a critical test as "a test that requires immediate communication of result irrespective of whether it is normal, significantly abnormal or critical".[1] Timely notification of critical alert value is now a mandatory component of medical laboratory accreditation processes [1,2]

The immediate notification of critical values from laboratory staff will be effective for the safety and management of patients and patient satisfaction towards laboratory services. Critical value management, including reporting, identification, notification & documentation and quality indicator data are the essential requirement for accreditation bodies such as ISO 15189, College of American Pathologists (CAP), and Joint Commission International (JCI) [3]

The effective communication of critical laboratory values depends on establishing defined thresholds, prompt and verified notification, and maintaining proper documentation of the whole communication process. Clear assignment of responsibility for both sending and receiving information, along with the use of optimal communication methods, is also essential to ensure patient safety[4]

The current recommended practices/guidelines related to the reporting of laboratory critical values are varied. Among professional organizations publishing standardized guidelines for the communication of laboratory critical values according to ISO 15189:2022 [5], the College of American Pathologists, CAP [6], and the Clinical and Laboratory Standards Institute, CLSI 5. These standardized guidelines outline the critical elements of the notification process in order to ensure reporting is accurate and efficient

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The Turnaround time (TAT) of different labs can vary according to the availability of resources and can be shortened to help patients and clinicians and for the continuous quality improvement of the laboratory.[7]

Laboratory results are fundamental to optimal patient care. Timely release and transmission of critical test results significantly influences healthcare decisions and patient outcomes. From the literature published, some areas of significant differences in reporting practices of CVs include the policy framework for the notification of critical values, selection of critical values, the source(s) for establishing critical limits, acceptable time frame for releasing critical values, re-testing for critical values, and which results to report.[8,9] Other issues related to the communication of critical values include means of reporting, to whom to report, and how to handle cases of unreachable primary physician

Proper identification of critical results in a timely manner is important to assure patient safety and forms an integral part of the medical validation process of laboratory results. In order not to miss a critical result, most laboratories apply an alert list, a list with a variety of parameters with their low and high critical limits. When such a limit is exceeded, there is a substantial risk for the patient, and the physician in charge should be notified as soon as possible [10]

Methodology

The present study was of a retrospective, cross-sectional, descriptive design spanning over a period of five months (June to October 2024). 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 169,667 consecutive tests were performed during the study period. The test requests were received from out-patient departments (OPD), in-patient departments including Intensive care units (ICUs), wards and emergency. All consecutive samples received for investigations in the hematology department were included. A total of 402 critical values were reported from the hematology section

A total of 169,667 samples were analyzed during the study period. The parameters measured for the critical values, included hemoglobin value, platelet count, leucocyte count, absolute neutrophil count (ANC), blast cells or malaria parasite in blood smear.

The inclusion criteria were the test samples received at the hematology laboratory. The exclusion criteria were the samples sent to biochemistry and microbiology laboratories. The hematology samples include peripheral blood (complete blood count and peripheral smear examination). All relevant data including the nature of the sample, received date and time, volume and color of the samples, and appropriate test request forms, were collected and recorded in the appropriate laboratory registers.

The samples for complete blood count were analyzed using an automated analyzer (Beckmen coulter, Mindray and swe-lab) and coagulation samples were analyzed using automated analyzer (CS-1600 and STAGO). The prepared peripheral blood smears were stained using standard staining protocols with Leishman stain. The slides were examined under a light microscope to assess the morphology of different blood cell types, look for malarial parasites, and diagnose conditions like lymphoma or leukemia.

To evaluate the promptness of reporting critical values, the turnaround time (TAT) for every critical value that was taken in the laboratory was calculated. The TAT is the duration of time that passes between obtaining a sample and generating a report. The study also evaluated the TAT for critical value notification by measuring the interval between the time a critical value was identified in the laboratory and the time it was communicated to the responsible clinician.

TAT data were collected from laboratory records and cross-referenced with electronic health records for accuracy. The average TAT was calculated, along with specific metrics for each step in the process (e.g., time from sample collection to result generation, result generation to notification)

Results

The total number of tests done in our hematology laboratory was 169,667, including hematology and coagulation tests. Male female ratio is 1.3:1. In our study, around 402 critical values were reported; the highest number of critical values was from the cardiac care unit (CCU) 147 (36.5%), followed by the emergency

department 99, (24.6%), inpatient department (n=81, (20.1%), Outpatient department 43, (10.6%)) and the Intensive care unit (ICU) 32, (7.9%)) as shown in table I. During the morning shift, maximum number of critical results were reported around 167 (41.5%) and minimum critical values were reported in evening shifts around 110 (27.3%) (Fig. 1).

Table I: showing shift wise critical value data from different department.

SHIFT	CCU	ER	IPD	OPD	ICU	TOTAL (%)
Morning	62	31	44	30	01	168 (41.7%)
Evening	31	28	39	06	06	110 (27.3%)
Night	42	27	33	02	20	124 (30.8%)

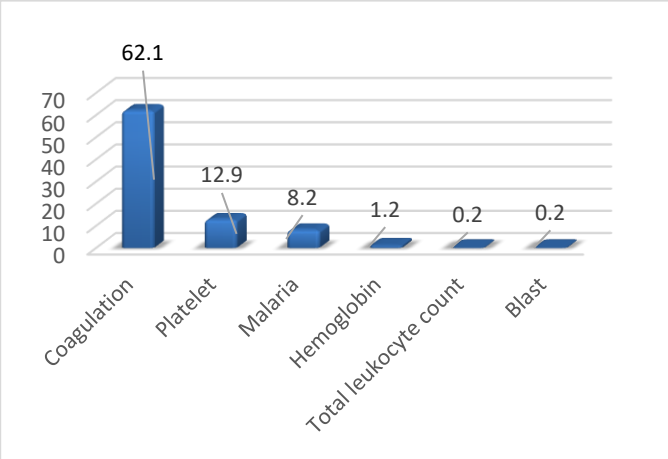

Figure 1: Critical values data of different parameters

Out 402 of the total critical values, 250 (62.1%) coagulation abnormalities, including prolonged prothrombin time (PT) & Activated partial thromboplastin followed by 61(15.1%) decreased platelet count, 52 (12.9%) malarial parasites on peripheral smears, 33(8.2%) reduced hemoglobin levels, 05(1.2%), deranged leucocyte count, 01(0.2%) leukemia as shown in figure 3. Critical values constituted 0.2% of the total test results (169,667) reported by the lab and the mean total turnaround time (TAT) for all tests ranged from 1.3 to 2.1 hours. The success rate of critical result reporting in our study within 1 hour was 25.3%

Discussion

The current study has been conducted for a duration of five months, that is, from June 2024 to Oct 2024. A total of 169,667 tests were carried out during study period. The critical value notification was highest for the Cardiac care unit (36.5%)

Here, we were presenting an extensive evaluation of the entire process of reporting critical values in our laboratories. We found that the critical alerts were highest in morning shifts and lowest during the evening and night shift (Fig. 2). This was statistically comparable and concordant with the studies by Shubha HV, et al.[1]

The list of critical values should be established using published national standards as a benchmark, with adjustments made by clinicians at each center as needed.[20]

In our study the second most common parameters notified were low platelet count (thrombocytopenia), which were also concordant with the studies done by Shubha HV, et al. and Desai KN, et al. [1,11] Additionally, our study had emphasized strategies of enhancing the critical alert reporting procedure as mentioned in previous studies done by Agarwal R et al. and Shubha HV, et al.[1,12]

The late notification for critical alerts include a system malfunction, technologists or staff oversight due to heavy workload, or not recognizing panic results. Critical alert parameters should be listed, and laboratories must establish the critical value limit ranges after consulting with clinicians.

Critical value reporting on time is needed for early management of patients. In case of failure to communicate on priority basis it leads to delayed management and patient's life will be compromised or threatened.[13] Many studies proved that use of information technology can lead to smooth and early delivery of critical value results. [14,15]

An effective system should incorporate an acknowledgment feature to confirm that the responsible doctor or staff has received the laboratory result. In addition, electronic systems must include a robust escalation procedure to ensure that failure to acknowledge a critical test result triggers an alternative communication pathway.

One of the major challenges in the critical value notification (CVN) process lies in the OPD area because, unlike inpatients, there is no fixed location of patients to which the critical value (CV) can be telephonically notified [16]

In a study conducted by Lynn TJ et al., in order to improve communication between clinical providers and the laboratory, secure text messaging for CVN was implemented [17]

Telephonic communication of the CV to the clinicians definitely has reduced the time needed for diagnosis and to commence treatment hence decreasing the associated morbidity and mortality. It was also observed that the CVNs were highest in the morning shifts and minimum in the evening shifts. This may be attributed to the increased test volume during the peak working hours in the morning and the active communication process due to the increased number of technical staff in the morning shifts. Similar findings were observed in a study by Desai KN et al [18]

The present study also emphasized the importance of maintaining critical values log sheets with details, consistent with the findings of Agarwal *et al.* According to Saffar *et al.*, routine repetition of hematology and biochemistry critical test results is unnecessary and may adversely affect patient safety. The critical value notification (CVN) process should therefore be implemented through a well-planned, systematic approach for patient safety.

To implement the harmonization of notification of critical values in laboratories:

- Evaluate Current Methods: Assess how well the current notification methods work, based on criteria such as reliability, speed, and susceptibility to errors
- Optimal Method: Phone calls, intercom, and other digital platforms are the methods to be selected
- Create guidelines: Determine who notifies and receives the notification, time to respond, and action plans in case of no response
- Training of staff: The standardized notification technique should be taught to all laboratory staff, ensuring that they are aware of the method for doing so
- Standardize documentation: Adhere to the same process with respect to documenting notifications, time, and parties involved
- Encourage communication: Provide feedback from the laboratory staff to the health care professionals and vice versa to iron out problems. These steps will help in achieving better consistency, efficiency, and effectiveness in critical alert notifications for quicker clinical responses and improved patient care

Based on our study's findings, we proposed and implemented a series of changes in the critical alert notification protocol at our tertiary care center. The first step of raising awareness about these changes was done for all clinical laboratory staff, duty residents, and technicians. An important link in this chain is the shift in-charge of the clinical laboratory, who has to oversee and follow up on the process until the information has been delivered. In cases where even this approach fails to trace the patient, the matter is escalated to the higher management level

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Conclusion

The study brought enlightenment to the awareness of critical value reporting among laboratory personnel and highlighted the need to implement new, innovative strategies in improving the critical value reporting process. These findings emphasize the importance of regular updating and standardization of critical limits and critical values lists to match decision thresholds.

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