ORIGINAL ARTICLE

Critical Value Analysis: Insights from Haematology and Clinical Pathology Laboratories of a Tertiary Care Hospital

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ABSTRACT

Introduction: The critical value is referred to as the result that suggests the patient is in immediate danger unless appropriate therapy is started right away. Timely notification of critical alert value is now a mandatory component of medical laboratory accreditation processes. This study aims to analyse critical values and scrutinize operational efficiency to enhance the effectiveness, patient safety, and laboratory outcomes in the haematology and clinical pathology laboratory of a tertiary care hospital. **Material and methods:** This study was conducted at the Haematology and Clinical Pathology laboratory of Saveetha Medical College and Hospital, Chennai from July 2023 to December 2023 after getting proper approval from the Institutional Review Board. The study population comprised samples of patients from the emergency, inpatient, and outpatient departments. A total of 7367 samples were analysed during the study period. **Results:** The maximum critical alerts were from the inpatient department, followed by the emergency department and the outpatient department. The critical alerts were notably higher during the morning shift. Out of the total critical values, 28.3% were decreased platelet count, 26.5% were reduced haemoglobin levels, 15.1% were deranged leucocyte count, 12.6% were decreased absolute neutrophil count, 16.4% were positive for urine ketones, 0.7% were cerebrospinal fluid pleocytosis, 0.3% were leukaemia in peripheral smears, and 0.1% were the malarial parasites in peripheral smears. **Conclusion:** This study enlightened the awareness of critical value reporting among the laboratory personnel and emphasized the importance of executing novel, creative methods to enhance the critical value reporting procedure.

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INTRODUCTION

Laboratory test results reflecting pathophysiological conditions that pose a serious risk to the patient's life or that could cause irreparable injury and require prompt medical attention and action are referred to as critical values [1]. The Joint Commission describes a critical test as a test that requires immediate communication of results irrespective of whether it is normal, significantly abnormal, or critical [2]. Lundberg originally put up the idea of crucial value in 1972. He states that a result that suggests the patient is in immediate danger unless appropriate therapy is started right away is referred to be critical value [3]. Since Lundberg's original observations almost three decades ago, laboratories all around the world have embraced the practice of identifying critical values and putting in place mechanisms for reporting them [4]. Timely notification of critical alert value is now a mandatory component of medical laboratory accreditation processes, including the globally accepted International Organization for Standardization (ISO) 15189: 2012 [2]. Given that they represent clinical efficacy, patient safety, and operational efficiency, parameters associated with critical value reporting may be considered essential laboratory outcome indicators. Organizations must recognize and address the many aspects of the critical value reporting process to guarantee its effectiveness. Nevertheless, current literature does not make this information easily available. Most papers have either looked at a tiny sample of critical values from different institutions or have only looked at a limited variety of parameters over brief periods of time [5-7]. To understand the scope of critical value reporting and identify opportunities for process improvement, we examined critical value data for six months in this study, which included 7367 distinct critical alerts. Although previous research has provided valuable insights into improving the logistics of critical value reporting, there is limited evidence on the recommendations and

effectiveness of these strategies in diverse healthcare environments. This study seeks to address this gap by recommending and implementing the strategies in our hospital laboratories, thereby contributing new evidence to the discourse on optimizing patient safety practices related to critical values.

AIMS AND OBJECTIVES

The study aims to evaluate current critical value notification processes and develop actionable improvements to enhance patient safety. Specifically, it seeks to assess the timeliness and accuracy of critical value reporting to identify areas for optimization, examine factors affecting clinical response times to reduce delays, evaluate existing protocols and technologies to highlight best practices and gaps and gather healthcare professional's perspectives to ensure recommendations are practical and feasible. The findings from each objective will directly inform strategies to streamline communication, improve response times, and optimize overall critical value management.

MATERIALS AND METHODS

This study was conducted at the Haematology and Clinical Pathology laboratory of Saveetha Medical College and Hospital, Chennai from July 2023 to December 2023 after getting proper approval from the Institutional Review Board. The list of critical values used in our laboratory is shown in Table 1 which was designed based on the Clinical and Laboratory Standards Institute (CLSI) guidelines and consultation with clinicians.

Table I: List of critical values in haematology and clinical pathology laboratories

S.No	Department	Laboratory parameter	Laboratory critical values
1	Haematology	Haemoglobin	<5 g/dl >20 g/dl
2	Haematology	Haematocrit	<20 % >60 %
3	Haematology	Platelet	<50000/cu.mm >10,00,000/ cu.mm
4	Haematology	Total leucocyte count	<2000/cu.mm >50,000/cu.mm
5	Haematology	Absolute Neutrophil count	<500 cells/ cu.mm
6	Haematology	Peripheral smear	Leukaemia
7	Haematology	Malarial parasite	Present
8	Clinical Pathology	Urine ketones	Positive
9	Clinical Pathology	Cerebrospinal fluid – Total count, Differential count	>5 cells

The study population comprised samples of patients from the emergency, inpatient, and outpatient departments. The details of the important call-backs such as the lab parameter, critical value, notified person, date and time when notified are recorded by the laboratory staff in a critical alert register and tabulated in the Microsoft Office Excel 2016 software. Then, the duty laboratory personnel informed the concerned clinician and pathologist on call.

A total of 7367 samples received in the haematology and clinical pathology laboratories were analysed during the study period, out of which, 2946 (40%) were inpatient samples, 2438 (33.1%) were emergency department samples, and 1983 (26.9%) were outpatient samples. The parameters measured were the critical values like haemoglobin value, platelet count, leucocyte count, absolute neutrophil count (ANC), leukaemia or malarial parasite in blood smear, urine ketones, and the total count or differential count of cerebrospinal fluid.

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

The relevant history, clinical details and investigation details regarding any case were taken from the test request forms and MIAS (Medical Information Archiving Software) database of our hospital. The samples for complete blood count were analysed using an automated analyser (Sysmex XN 1000 six-part analyser), and a dipstick method for urine analysis. The cerebrospinal fluid samples were processed to concentrate cellular material by centrifugation, then smeared and fixed. The prepared peripheral blood and fluid smears were stained using standard staining protocols with Leishman stain. The slides were examined under a light microscope to assess the morphology of different types of blood cells, look for any malarial parasites, diagnose conditions like anaemia or leukaemia and the total count or differential count of cerebrospinal fluid. The frequency of critical values distribution, the total number of critical alerts done in each department and each shift, and the time taken for notifying critical values were calculated and the results were correlated.

To evaluate the promptness of reporting critical value, the turnaround time for every critical value that was taken in the laboratory was calculated. The turnaround time (TAT) is the duration of time that passes between obtaining a sample and generating a report. The study evaluated the turnaround time (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).

To mitigate potential biases in sample selection, cases with incomplete data were excluded, and sensitivity analyses were performed to check the robustness of the findings. Furthermore, confounding variables such as case complexity and patient demographics were controlled for in the statistical analysis to ensure that the conclusions drawn were as reliable and unbiased as possible. The causes for delay in critical alerts were scrutinized to foster strategies to enhance efficient turnaround times and improve effectiveness, patient safety, and laboratory outcomes.

RESULTS

The total number of tests done in our haematology and clinical pathology laboratories was 51155 complete blood count tests, 5449 peripheral blood smears, 21648 urine examinations, and 78 cerebrospinal fluid examinations. Table I shows the list of critical values followed in our laboratories. During the study period, 7367 critical values were identified, of which maximum critical alerts were from the inpatient department (n=3212, 43.6%), followed by the emergency department (n=2482, 33.7%) and the outpatient department (n=1673, 22.7%) as shown in Fig. 1. The critical alerts were notably higher during the morning shift, totaling 4641 (63%), compared to a minimum of 295 (4%) during the night shift (Fig. 2).

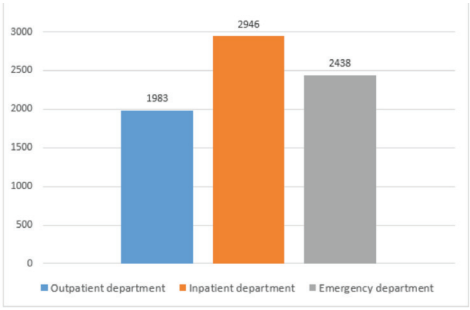

Fig. 1: Department-wise distribution of critical call alerts

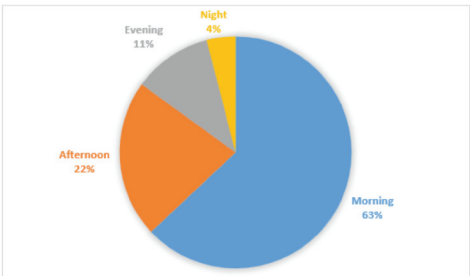

Fig. 2: Shift-wise distribution of critical call alerts

Out of the total critical values, 28.3% (n=2082) were decreased platelet count (most notified critical value), 26.5% (n=1950) were reduced haemoglobin levels, 15.1% (n=1116) were deranged leucocyte count, 12.6% (n=930) were decreased absolute neutrophil count, 16.4% (n=1209) were positive for urine ketones, 0.7% (n=48) were cerebrospinal fluid pleocytosis, 0.3% (n=24) were leukaemia in peripheral smears, and 0.1% (n=08) were the presence of malarial parasites in peripheral smears as summarized in Table II. Then, the average time between registering a value in the register maintained for critical call-backs and communicating that information to the ordering medical professional or patient location was found to be 18 minutes for the emergency department, 20 minutes for the inpatient department, and 25 minutes for the outpatient department (Table III).

Table II: Analysis of critical call alerts by parameters

Laboratory parameters	Number of critical call alerts	Percentage
Platelet count	2082	28.3%
Haemoglobin	1950	26.5%
Leucocyte count	1116	15.1%
Absolute Neutrophil count	930	12.6%
Leukaemia	24	0.3%
Malarial parasite	8	0.1%
Urine ketones	1209	16.4%
Cerebrospinal fluid – Total count, Differential count	48	0.7%
Total value	7367	100%

Table III: Distribution of critical values by average turnaround time

Departments	Turnaround time in minutes		
	Lowest	Highest	Average
Emergency	10	26	18
Inpatient	12	28	20
Outpatient	18	32	25

DISCUSSION

In this study, we presented an extensive evaluation of the entire process of reporting critical values in our laboratories. It was observed that critical alerts were highest during the morning shifts and lowest during the night shift (Fig. 2). This was statistically comparable and concordant with the studies done by Shubha HV, et al. and Desai KN, et al. [2,5]. The majority of critical alerts were recorded from the emergency department, followed by the inpatient department which was also concordant with the studies done by Shubha HV, et al. and Desai KN, et al. [2,5]. The parameters most frequently notified were platelet count and haemoglobin values which were also concordant with the studies done by Shubha HV, et al. and Desai KN, et al. [2,5].

Additionally, our study had provided due emphasis on strategies to enhance the critical alert reporting procedure. This was comparable to the studies done by Agarwal R et al. and Shubha HV, et al. [2,8]. The mean turnaround time for critical value reporting was found to be shorter for the emergency department, followed by the inpatient department which was also comparable to the work done by Desai KN, et al. [5]. The reasons for the delay in notifying critical alerts were found to be unexpected system errors (technical issues or malfunctions), and human errors when the laboratory staff overlooked the critical values due to high workload, distractions, fatigue, or failure to recognize the critical nature of certain values. The parameters for critical alerts should be listed, and laboratories must establish the critical value limit ranges after consulting with the clinicians. A brief list of crucial values should be created instead of a long and complicated one, since more calls might diminish the urgency of the call, making doctors interfere unnecessarily [2]. This can be highly beneficial for both physicians and patients as it influences the clinical care of the patients and also serves as an invaluable tool for fostering positive relationships between laboratory personnel and clinicians, which will eventually prove worthwhile in the long run [9]. To avoid failure and tardiness in reporting critical values, the most reliable and strategic measures recommended consist of further development of standardized protocols and procedures for identifying, documenting, and notifying critical values, conducting regular training sessions for laboratory staff to enhance their understanding of critical values and establishment of effective communication channels between the laboratory and clinical teams. In addition, the equipment of the Laboratory Information System (LIS) in the laboratory plays a crucial role in enhancing critical values reporting. The LIS is configured to automatically detect critical values and generates alerts through various means, including on-screen pop-up notifications or sound alarms. It also records all critical value alerts, including the date, time, nature of the critical result, and the actions taken in response to the alert. This automated process of documentation ensures traceability and accountability in the reporting process.

CONCLUSION

Therefore, one of the most important duties of laboratories is to communicate critical test results effectively. The established list of critical values should be periodically reviewed, updated, and revised in collaboration with the clinicians. This study enlightened the awareness of critical value reporting among the laboratory personnel and emphasized the importance of executing novel, creative methods to enhance the critical value reporting procedure. We started implementing this knowledge into practice to enhance the reporting of critical values across all divisions in the laboratory.

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