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A study of critical value analysis at hematology and biochemistry sections of laboratory in a multispeciality hospital

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ABSTRACT

Background: The issue of laboratory critical value (CV) reporting has gained importance in the recent times due to the national focus on patient safety. Critical value notification (CVN) has become an essential part of accreditation procedures for medical laboratories, including the universally accepted International Organization for Standardization (ISO) 15189: 2012.

Aims and Objectives: Our study aimed to analyze the critical value data in hematology and biochemistry sections of the laboratory, to compare the frequencies of critical values for different parameters and to suggest measures for improving the effectiveness and operational efficiency of the critical value notification process.

Materials and Methods: Our study was a retrospective, cross-sectional, descriptive study done over a period of one year six months (January 2020 to June 2021). The parameters chosen for CVN included platelets, hemoglobin and International Normalized Ratio (INR) from hematology section and creatinine, glucose, sodium, potassium and calcium from the biochemistry section. A test result that was significantly outside the normal range and that required immediate communication was considered as a "critical value (CV)". Both verbal (through telephone) and non-verbal [through short message service (SMS)] communication processes for CVN were implemented in our lab. We also followed the practice of CV "read-back" by the person who was informed over the phone.

Results: A total of 2199 critical values were reported. A maximum of 1224 (55.7%) critical values were recorded from the emergency department. CVs were highest from biochemistry (1898, 86.3%) section. Analyte most commonly notified was creatinine (1151, 52.3%). CVNs were maximum in the morning shifts (1378, 62.7%).

Conclusions: Implementation of the critical alert short message service (SMS) send outs has greatly helped us in reducing the CV turn around time (TAT). Our study has successfully demonstrated the importance of both verbal and non-verbal communication processes for notification of CVs.

1. Introduction

The identification and timely communication of critical values are still considered as essential elements of good laboratory performance. The issue of laboratory critical value (CV) reporting has gained importance in the recent times due to the increasing focus on patient safety worldwide. Critical value notification (CVN) has become an integral part of accreditation procedures for medical laboratories, including the universally agreed International Organization for Standardization (ISO) 15189: 2012.[1] CVN is of utmost importance to instantly communicate the CVs to clinicians for faster diagnostic approach and quick changes in the patient management decisions. The Joint Commission

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(JC) defines a critical test as "a test that requires immediate communication of result irrespective of whether it is normal, significantly abnormal or critical".[2] This definition is also shared by many other organizations such as the Clinical and Laboratory Standards Institute (CLSI) and the Royal College of Pathologists (RCP).[3,4] Critical value is instead defined by the JC as "a test result that is significantly outside the normal range and may represent life-threatening values".[2] In small laboratories, the selection of critical value limit ranges, preparation of a standard list or target turn around time (TAT) for reporting of critical results is very difficult due to the absence of consensus in laboratory community.[5] It is, therefore, important that the laboratories must make an agreement on the list of parameters and the critical value limits of each of them, which should be established and followed by each laboratory. This helps in eliminating the problem of diluting the urgency of the critical value call due to expansion of critical call out lists.[5,6] The College of American Pathologists (CAP) checklist states about the importance of documentation that the CV results have been notified to caregivers. Moreover, the CAP COM.30100 states that electronic transmission of CVs is acceptable. The laboratories must confirm the receipt of CV result by the intended recipient and no read back is required.[7]

2. Aims and Objectives

1. To analyze the critical value (CV) data in hematology and biochemistry sections of the laboratory.
2. To compare the 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.

3. Materials and Methods

The present study was of a retrospective, cross-sectional, descriptive design spanning over a period of one year six months (January 2020 to June 2021). In the present study we aimed to analyze the critical value data in the hematology and biochemistry sections of our laboratory and compare the frequencies of critical values for different parameters. A total of 75,156 tests were performed during the study period. The test requests were received from out-patient departments (OPD) which included master health checkups, in-patient departments [Intensive care units (ICUs), wards and operation theatres] and emergencies. Out of 75,156 tests, 16530 and 20638 tests were from hematology and biochemistry sections respectively. A total of 2199 critical values were reported from these two sections.

3.1. Critical value notification process

The list of parameters from hematology and biochemistry sections 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 International Normalized Ratio (INR) from hematology section and creatinine, glucose, sodium, potassium and calcium from the biochemistry section.

The analytical reliability of CVs were checked and then after ruling out the pre-analytical errors, the laboratory technologists 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. Once the result is validated, and it is in the critical range (upper or lower), the laboratory technologists notify the value to the responsible caregiver (treating physicians, surgeons, ICU/ emergency doctors, nursing staff or the consultants) telephonically and at the same time the result is also entered in the critical value call out log sheet. Details such as the accession number, parameter, care area, 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 "read back" are entered.

Laboratory also follows the practice of CV "read-back" by the person who was informed over the phone. The critical value call out log is then signed by the laboratory head/ pathologist in-charge.

In order to facilitate and speed up the process of CVN especially of the OPD patients, we also have developed an in-house Laboratory Information System (LIS) software which automatically flags the test results requiring CVN as the critical value limit ranges of the parameters requiring CVN are tagged with the LIS. Short message service (SMS) are sent to the concerned treating doctors whose phone numbers are linked with the LIS. We also can monitor whether the SMS is forwarded or failed to the responsible caregivers. In case, if the SMS is not forwarded, then the lab technologist notifies the CV to the concerned caregiver telephonically and enters the details in the critical call out log sheet.

3.2. Statistical analysis

The obtained parameters were evaluated using the descriptive statistical analysis. The statistical analyses were done using the IBM SPSS (Statistical Package for the Social Sciences v 20.0) and Microsoft Office Excel 2007 software.

4. R esults

The present study was a retrospective study conducted in the hematology and biochemistry sections of laboratory at Fortis multispeciality hospital, Bangalore. The lab received blood samples from out-patient departments (OPDs) including master health checkups, in-patient departments [Intensive care units (ICUs), wards and operation theatres (OTs)] and emergencies. A total of 2199 critical values were reported by the lab. A maximum of 1224 (55.7%) critical values were recorded from the emergency department followed by IPD (900, 40.9%) and OPD (75, 3.4%) departments (Table 1).

A total of 75,156 tests were performed in the lab over a period of one year and six months (January 2020 to June 2021). The parameters which were selected by the laboratory for CVN were platelets, hemoglobin and International Normalized Ratio (INR) from hematology section and creatinine, glucose, sodium, potassium and calcium from the biochemistry section. The critical value limit ranges of different parameters are shown in Table 2.

Out of 75,156 tests, hematology tests constituted a total of 16,530 (21.9%) and biochemistry tests accounted for 20,638 (27.4%). Out of 16,530 hematology tests, platelets, hemoglobin and INR together accounted for 13696 tests and out of 20,638 biochemistry tests, creatinine, glucose, sodium, potassium and calcium accounted for 15,566 tests.

Critical values constituted 2.92% of the total test results (75,156) reported by the lab.

Majority of the critical values were resulted in the biochemistry (1898, 86.3%) section. Hematology accounted for only 13.7% (301 test results) of the critical alert values (Table 3). The analytes most commonly notified for critical value were creatinine (1151, 52.3%), followed by potassium (350, 16%), sodium (200, 9.1%), glucose (167, 7.6%) and platelets (165, 7.5%) (Table 3). Critical value notifications were maximum in the morning shifts (1378, 62.7%) and minimum in the night shifts (100, 4.5%) (Figure 1).

The following measures were implemented in our laboratory for improving the effectiveness and operational efficiency of the critical value notification process:

1. An in-house Laboratory Information System (LIS) software was developed which automatically flags the test results requiring CVN and sends short message service (SMS) to the concerned caregivers. We also monitored whether the SMS was forwarded or failed to the responsible caregivers. In case, if the SMS was not forwarded, then the lab technologist notified the CV to the concerned caregiver telephonically and also entered the details in the critical call out log sheet. Implementation of the critical alert short message service (SMS) send outs to deliver the CVs greatly helped us in reducing the CV turn around time (TAT) especially in the out-patient department area. Electronic communication of CVs also has avoided the possible errors in communication and has shortened the notification times.
2. Incorporating the mechanism of delta checks (i.e., to detect any change in the present test result from previous results) into LIS which serves as a second flagging layer, in addition to an electronic critical value alert.
3. Training the laboratory staff for the policy of laboratory critical value notification process and documenting the same in the log sheets.
4. Long and complex list of critical values were avoided and a concise list was prepared as increased number of calls may weaken the urgency of critical value call leading to unnecessary interference for clinicians.
5. The established list of critical values were regularly reviewed, revised and updated in consultation with the clinicians.

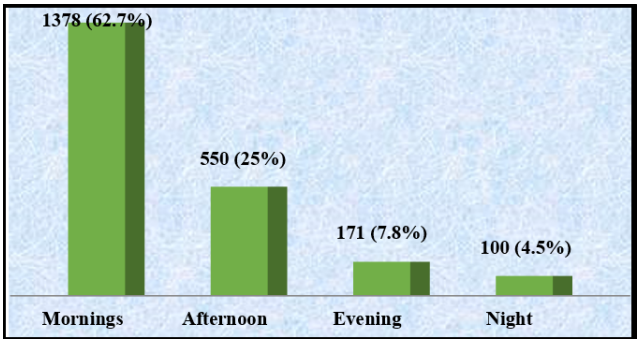

Fig. 1: Distribution of critical value data in each shift

5. Discussion

The present study was conducted over a period of one year six months (January 2020 to June 2021). A total of 75,156 tests were performed during the study period. The critical value notification was highest in the emergency area (55.7%). Majority of the critical values were resulted in the biochemistry (1898, 86.3%) section. Hematology accounted for only 13.7% (301 test results) of the critical alert values. The analytes most commonly notified for critical value were creatinine (1151, 52.3%), followed by potassium (350, 16%), sodium (200, 9.1%), glucose (167, 7.6%) and platelets (165, 7.5%).Table 4 shows the comparison of frequencies of critical values of our study with that of the others. Thus, this study focusses on the need for analysing the critical value frequencies in laboratories to identify the parameters with highest critical values. Laboratories must list out the parameters for CVN and set the CV limit ranges in consultation with the clinicians. This helps to modify clinical management of the patients and thus can be very useful for both clinicians and patients. Moreover, this will

Table 1: Distribution of the critical values byclinical care areas.

Clinical care area	Total no. of critical values	Percentage
OPD with master health check ups	75	3.4
IPD (ICU, wards, OTS)	900	40.9
Emergency	1224	55.7
Total	2199	100

Table 2: List of critical value limit ranges of different parameters in hematology and biochemistry sections.

S.No.	Parameter	Lower limit	Upper limit
	Hematology		
1.	**Platelets**	40,000/cumm	10,00,000/cumm
2.	**Hemoglobin**	6.0 g/dl	20 g/dl
3.	**INR**		>5
	Biochemistry		
1.	**Creatinine**		>3.0 mg/dl
2.	**Glucose**	50 mg/dl	400 mg/dl
3.	**Sodium**	120 mEq/L	160mEq/L
4.	**Potassium**	2.5 mmol/L	6.0 mmol/L
5.	**Calcium**	6.5 mg/dl	13.0 mg/dl

Table 3: Distribution of critical values for different parameters tested

S.No.	Parameter	Total test volume	Critical test results	Percentage of critical test results	Percentage of test volume with a critical result
Hematology					
1.	**Platelets**	5580	165	7.5	2.95
2.	**Hemoglobin**	4916	66	3.0	1.34
3.	**INR**	3200	70	3.2	2.18
Total hematology		**13696**	**301**	**13.7**	
Biochemistry					
1.	Creatinine	8428	1151	52.3	13.65
2.	Glucose	3421	167	7.6	4.88
3.	Sodium	1678	200	9.1	11.91
4.	Potassium	1704	350	16.0	20.53
5.	Calcium	335	30	1.3	8.95
Total Biochemistry		15566	1898	86.3	
Total		29262	2199	100	

serve as an important tool to initiate a healthy interaction between the clinicians and the laboratory staff and in turn, will prove beneficial in the long term.[8]

Appropriate and timely management of patients largely depends on the clinical communication. Ambiguous communication or failure to communicate on time can cause delayed treatment and also the patient's safety is threatened.[11] Numerous reports have proved the ability of information technology to speed up the process of critical value reporting.[12,13] Automatic communication with the responsible provider due to increasing use of information technology (IT) has proved to reduce the CV reporting time. In a study conducted by Lynn TJ et al., in order to improve communication between clinical providers and the laboratory, the secure text messaging (STM) for CVN was implemented.[14] In our study too, the use of SMS to deliver CVs was efficient and reliable. Our results are consistent with the study conducted by Lynn TJ et al., that employed technology to automate the CVN process.

An electronic reporting system potentially could create dangerous delays in communication if not properly put into use. The system needs to have an "acknowledgment" function such that the laboratory can ensure that the responsible caregiver received the result. Electronic systems also require an intense procedure so that lack of acknowledgment of the critical test result elicits an alternative way for communication.[5] In the present study, we monitored whether the SMS was forwarded or failed to the responsible caregivers. In case, if the SMS was not forwarded, then the lab technologist notified the CV to the concerned caregiver telephonically and entered the details in the critical call out log sheet.

One of the major challenges in CVN process lies in the OPD area because unlike inpatients, there is no fixed patient location to which the CV can be telephonically notified.[5] Introduction of critical alert SMS send outs in OPD cases

Table 4: Table showing comparison of our study with other studies

S. No.	Study	Duration	Total tests	Total no. of critical values	Percentage of critical values to total tests	Sections included	No. of analyt-es	Analyte with highest frequency
1.	Namrata Bhutani et al.[8]	2 months	183056	11875	6.5	Emergency biochemistry	8 (in adults)	Potassium (2933,8.3%)
2.	Desai KN et al.[9]	24 months	90,000	19423	21.6	Hematology (H) and Clinical pathology (CP)	H-9 CP-2	Hematology-Hemoglobin (5212, 26.8%) CP- Urine ketone bodies (3100, 16.0%)
3.	Dighe AS et al.[5]	12 months	14000000	37503	0.25	Biochemistry (BC) and Hematology (H)	BC-14 H-6	BC-Potassium (7955, 21.2%) H-Partial thromboplastin time (PTT) (5467, 14.6%)
4.	Agarwal R et al.[10]	25 months	478,980	1187	0.25	Clinical chemistry	6	Sodium (249, 20.97%)
5.	Present study	18 months	75,156	2199	2.92	Biochemistry (BC) and Hematology (H)	BC- 5 H-3	BC- Creatinine (1151, 52.3%) H-Platelets (165, 7.5%)

has helped a lot to inform the CV to the concerned doctor in our study. 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 (1378, 62.7%) and minimum in the night shifts (100, 4.5%). 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]

This study has also emphasized on the measures to improve the CVN process. Agarwal R et al. have highlighted on the importance of CVN policy which includes list of parameters for which CV should be notified, laboratory staff responsible for notifying CV and the person to whom CV will be notified, TAT and the communication method. They have also mentioned about the maintenance of a log book for the same.[10] In the present study too we gave importance on maintaining the critical call out logsheets which had similar details as mentioned by Agarwal R et al.

In a study by Saffar H et al., it was suggested that routine repeat of hematology and biochemistry critical test result was not necessary and it may adversely affect the patient safety measure.[15] CVN process implemented through a well-planned approach, rather than a commitment for clinical laboratories, is a right for the patient in order to ensure safety. It also plays a pivotal role in healthcare systems and has proved to be both cost saving and life saving.[16]

6. Conclusion

The efficient and timely communication of critical test results is an essential responsibility of laboratories. Information technology (IT) is increasingly becoming an essential component of medical laboratories, thus unwinding interesting perspectives also for the immediate communication with the clinicians. The critical value notification was highest in the emergency area (55.7%) and in the biochemistry section (86.3%) in our study. Implementation of the critical alert short message service (SMS) send outs to deliver the CVs has greatly helped us in reducing the CV turn around time especially in the out-patient department area. Our study has successfully demonstrated the importance of both verbal and non-verbal communication processes for notification of CVs. It has also highlighted on the significance of employing innovative new measures to improve the CVN process.

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8. Conflict of Interest

The authors declare they have no conflict of interest

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