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RESEARCH ARTICLE

# CRITICAL VALUE NOTIFICATION PROCESS IN THE HEMATOLOGY LABORATORY OF A TRAUMA CARE SET UP

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**ABSTRACT**: **Introduction:** In order to improve the critical value notification (CVN) in our hematology laboratory of a busy trauma care set up, the study was planned with an aim of evaluating and improving the critical value notification process using the principles of Quality Improvement. **Settings and Design:** The pre-test/post-test intervention study was conducted in the hematology laboratory of a trauma care set up over three months by undertaking three Plan-Do-Check-Act (PDCA) cycles. **Materials and Methods:** In the pre-intervention phase, process mapping and fish bone analysis were done to identify barriers for CVN. Barrier specific solutions were proposed, discussed and implemented. CVN rate was calculated in all phases and process improvement was measured. For the perspective of the medical technologists, a feedback form was circulated. SQUIRE guidelines were followed to write the manuscript. **Statistical analysis:** Descriptive data in frequency and percentages. **Results:** QI team achieved the goal within the time frame successfully. Rate of critical value notification improved from 2.8% in the pre-intervention phase to 68.1% in the post-intervention phase. CVN rates were highest for ICU and emergency area. Abnormal platelet count was the most commonly (42%) notified parameter. Busy telephone line was the most prominent barrier for CVN in our set up. All the medical technologists unanimously believed that CVN is a good laboratory practice, and they and their colleagues give due importance to it. **Conclusions:** The principles of quality improvement proved effective to improve critical value notification in a highly demanding trauma care set up. It can be further boosted with administrative and clinician support.

**KEYWORD**: Decision limit, Laboratory management, Panic value, Patient safety, Process evaluation

## INTRODUCTION:

A critical value is defined as one that is so extremely abnormal that it represents a life threatening condition for which some corrective actions should be taken promptly.[1] Multiple international bodies like Joint commission, Royal College of Pathologists, Clinical and Laboratory Standards Institute (CLSI) have clearly defined and documented the importance of the same.[2] Critical values generally comprise less than 2% of all laboratory results.[3] A study comprising 623 health institutions reported that 95% physicians considered critical value

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notification to be helpful in management. As per their study, two-thirds of the critical values influenced a change in therapy. [4] Thus, critical laboratory results mandate urgent notification to the healthcare provider.

There can be an issue of suboptimal compliance to critical value notification (CVN) process in both high and low volume laboratories. However, its significance in the context of trauma care setup is colossal. The ever-changing clinical profile of patients admitted after trauma due to transfusion of blood products and pathophysiology of trauma itself, necessitates urgent medical decisions based on laboratory reports.

A mere displaying of critical value lists in the laboratory doesn't ensure a robust process of notifying the critical laboratory results to the fellow healthcare worker. It is of paramount importance that the variables affecting CVN process are identified, understood and addressed by the laboratory professionals so as to make the process effective.

In order to improve the compliance for critical value notification (CVN) in our hematology laboratory, the study was planned with an aim of evaluating the critical value notification process in the laboratory using the principles of Quality Improvement (QI) with the following objectives: (i) To determine the rate of critical value notification in the hematology laboratory (ii) To improve the compliance rate over a period of one month by the application of the principles of QI (iii) To demonstrate the perspective of the medical technologists on critical value notification process in the laboratory.

## MATERIALS AND METHODS:

The pre-test/post-test intervention study was conducted over 3 months in the hematology section of the Department of Laboratory Medicine, in a tertiary trauma care set up using the principles of QI. The laboratory performs routine and POCT/STAT tests providing round the clock services. The laboratory incorporates critical value notification as a part of good laboratory practice.

***Pre intervention Phase/ Preparing Period:***

This phase was spread over a month. A QI team was formed that constituted the Laboratory Director, two senior residents and two senior medical technologists for assessment of the problem and analysis of its causes. The laboratory record was audited by the QI team to establish the baseline notification rate. Internal quality control samples, samples without barcode, or ones with incomplete information were rejected in the study.

*Critical value notification was defined as notifying the critical value (laboratory-defined) to a healthcare provider in the respective ward telephonically by the laboratory technician, after checking for its analytical reliability followed by documenting the details* including name of the patient, patient's hospital identification number UHID, location of the patient, parameter and value, and the name of the receiver. Rate of CVN was calculated using the following formula:

$$\text{Rate of CVN} = \frac{\text{Number of notified and documented critical values}}{\text{Total reportable critical values observed}}$$

Process mapping (Fig 1) and fish bone analysis (Fig 2) were done for identifying the barriers to the CVN process. Thereafter, the SMART aim was generated. SQUIRE guidelines were followed to write the manuscript.

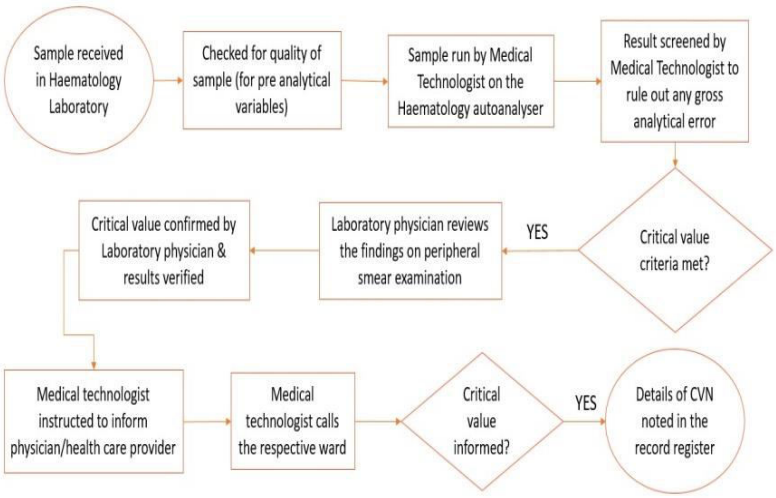


**Fig 1. Process mapping of the critical value notification process in the laboratory**

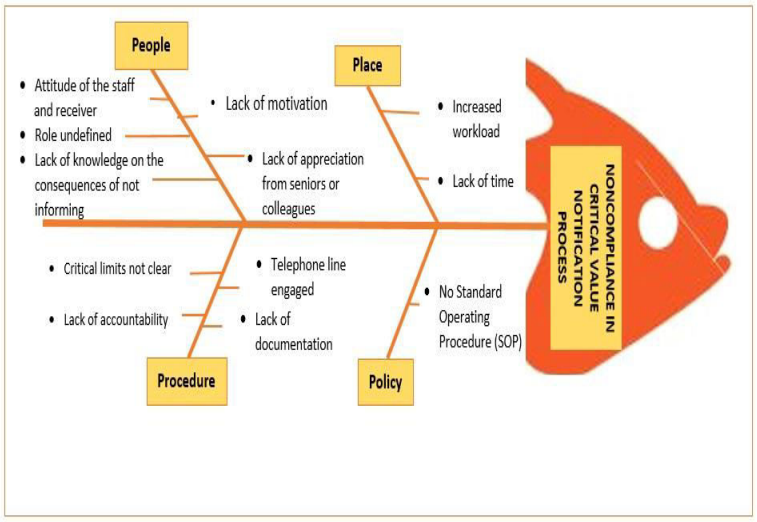


**Fig 2. Fish bone analysis for low compliance of critical value notification process**

***Intervention Phase:***

This phase was one month long consisting of the following three PDCA cycles:

**PDCA 1**

Initially, QI team carried out one-to-one discussions with the staff to describe and reiterate the CVN process. Suggestions were welcomed to improve the process. A fresh list of critical values to be reported was pasted in the vicinity of the automated hematology analyzer and in the reporting area of the laboratory. The list was created after considering the specificities of management of trauma patients in concurrence with the treating physicians, literature review and the experience of the laboratory director in the institute. The staff was told to memories the new cut-off values in the list to avoid any confusion.

**PDCA 2**

All the previous day reports were screened by the QI team to list out the details of the patients with critical values and to note if they were notified or not. The staff was encouraged to perform their duties with utmost sincerity. Their role in patient care was constantly highlighted. Verbal feedback was obtained to know if they faced difficulties in learning the values in the new list and executing their task.

**PDCA 3**

An anonymous feedback form with a semi-structured questionnaire was circulated for obtaining the perspective of the medical technologists on the CVN process. It had ten statements and five options as response from 5 to 1, where 5: strongly agree, 4: agree,3: neutral, 2: disagree, 1: strongly disagree. The participants were informed about the purpose of the study and their consent to participate in the study was obtained. Critical analysis of the responses obtained was done. Potential barriers to the process were evaluated for possible changes. The staff was told about the improvement observed in the CVN documentation and applauded for their hard work.

***Post-intervention phase:***

Critical value reporting was continued and the records were reviewed for nonconformity to the laboratory guidelines. The improvement in the process was measured at the end of one month. *Quality improvement of the CVN* was defined as the improvement in the rate to more than 50% of the baseline over a period of one month.

**Ethics**

As per the institutional protocol, ethical clearance was obtained from the Institutional Ethics Committee (IEC-395/07.06.2019, RP-55/2019).

**Statistical analysis**

All data collected is descriptive and is represented in percentages.

## RESULTS:

A total of 712 critical values in the hematology section were analyzed during the study period of three months, of which 13 were rejected based on exclusion criteria. Of the total 699 critical values included, 208 were studied in the pre-intervention phase, 215 during the intervention and 276 in the post-intervention phase. The QI team achieved the goal within the time frame successfully. The rate of critical value notification improved from 2.8% (n=6) in the pre- intervention phase to 38.1% (n=82) during the intervention phase and to 68.1% (n=188) in the post-intervention phase. Maximum patients informed for any critical value belonged to general-ICU followed by the ones in the emergency department. (Fig 3) More (54.7%) critical values were notified during the night shift. Highest notification rate of 42% (n=79) was for thrombocytopenia.

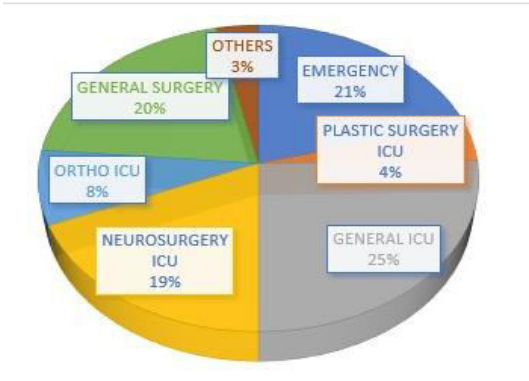


**Fig 3: Distribution of critical value notification over work area**

***Feedback of the medical technologists on the laboratory handover process***

All the medical technologists unanimously believed that CVN is a good laboratory practice and they and their colleagues give due importance to it. Most were satisfied with the way the CVN was being performed in the laboratory and believed that notifying critical values is part of their job that ensures better patient survival. (Fig 4)

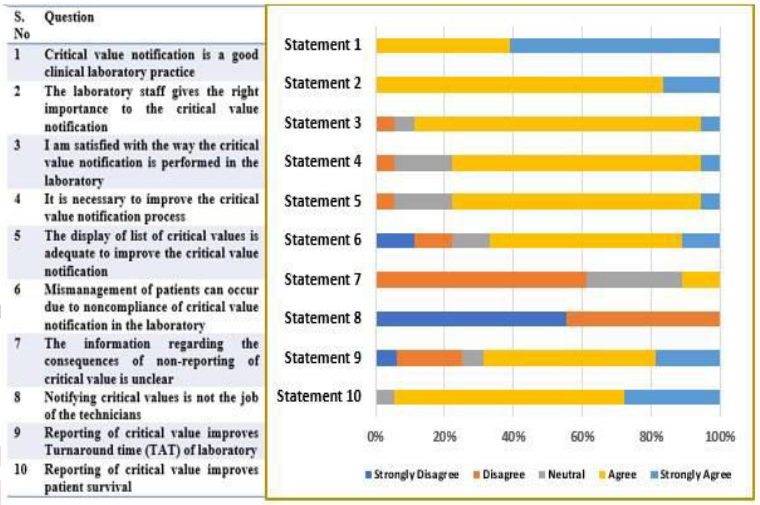


**Fig 4: Feedback response of medical technologists to statements shown in Table 2**

Busy telephone lines and lack of interest from the receivers were the top two barriers identified in our setup. (Table 1)

**Table 1: Rank order of barriers to critical value notification process (n=18)**

| S. No. | Barriers to critical value notification process | Mode of Rank Order | Percentage agreement |
|---|---|---|---|
| **1.** | Time consuming work | 4 | 38.8% |
| **2.** | Unnecessary act | 5 | 50% |
| **3.** | Critical value cut offs are unclear | 3 | 27.7% |
| **4.** | Disinterested receiver | 2 | 44.4% |
| **5.** | Busy telephone lines | 1 | 50% |

## DISCUSSION:

A critical laboratory value represents a life-threatening condition and must be communicated within a short span of time. It forms an important step in the post-analytical phase of the testing process. [5]Critical value notification is a valuable component amongst the many quality indicators, reflecting the performance of a laboratory. The clause 5.8 of ISO 15189:2012 guidelines for the laboratory accreditation program mandates reporting critical values.[6]

The purpose of our study was to improve the ability to communicate the critical test results in a timely manner to the clinicians. We had our focus on improving the process, by analysing each step involved, to ensure a better and a persistent compliance rate for critical value notification. We found QI principles to be effective to improve CVN in our clinical laboratory. Adapting and implementing principles of QI in daily practice can help in improving the existing knowledge, attitude and practice of medical technologists regarding CVN and thus can help in improving hospital outcomes. As QI is a continuous process, we expect the performance of our laboratory to improve further with time.

Critical value notification is an under-emphasized process which needs to be reinforced to improve outcomes in the hospital. Our study highlights that the approach to improve the CVN process needs a meticulous team effort. Constant motivation and encouragement provided to the staff by the QI team helped to improve the CVN rate in our set up.

Low critical value of platelet counts in patients admitted in the ICU and emergency were maximally informed corroborating with previous research article which point to abnormal value of platelet counts at admission to be life threatening in the critically injured patients in ICU. [7,8]

Establishing a laboratory-specific critical value notification written policy is a must. The list of critical values must be precise and formed after a general agreement with the clinicians to avoid diluting the sense of urgency. The list could be formed based on already published guidelines or in house reviewing the local need from time to time. [1, 9-11] However, in our study, the need to re-evaluate the list of critical values was considered only to refresh the memory of the staff and avoid any anticipated confusion. No feedback was received on the same from any clinician during the study period.

We identified multiple barriers for CVN, major being the busy telephone lines. Some of the strategies to strengthen the CVN process could be to have a dedicated telephone line for communicating critical value in the wards or having a robust Laboratory Information System (LIS) that could automatically detect critical value and raise alarm. The LIS may automatically send out short messages or emails to the treating physician directly. [12,13] Help from the hospital administration in this regard cannot be undermined.

The strength of this QI study is that the goal was achieved without any change in infrastructure, or an increase in human resources or cost. However, further improvement is expected in the post-implementation phase with continuous team effort. The limitation of the study is that the impact of the intervention in form of clinical outcome like morbidity and mortality of the trauma patients was not evaluated in regard to reporting of critical values. Further studies can be planned in that direction.

## CONCLUSION:

Quality improvement principles proved effective to improve critical value notification in the laboratory. Establishing an effective written policy for implementing critical value notification in the laboratory with a well-coordinated communication between laboratory personnel and the clinician are fundamental to improve patient care and ensure patient safety even in a highly demanding trauma care set up.

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