# Learnings for Best Practices of Critical Value Alert in Laboratory Quality Management System

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**ABSTRACT**

A cross-sectional study was conducted at a tertiary health care centre in India during year 2018 to 2019 to provide a standard for good laboratory practice, to increase the clinical effectiveness, patient safety and operational efficiency and designing better and more evidence-based systems for timely notification of laboratory results. The entire data was obtained from reports generated by hematology and clinical pathology laboratory recorded in critical call back log register. These laboratories reported 86727 critical values out of 394213 performed test. The majority of critical callbacks (83.8%) resulted from testing performed in the Hematology. The most common called back were Hemoglobin and Total WBCs count. We recorded maximum 52% call back from inpatient department followed by emergency department 35% and outpatient department 13%. The mean time between entering value in the critical callback register and conveying the information to the patient location or ordering clinician was 60 minutes for IPD, 120 minutes for OPD and 30 minutes for ED. The study inferred that each laboratory must have at a modus operandi to alert critical results.

**KEY WORDS:** critical alert value, hematology, patient safety

## INTRODUCTION:

The concept of critical value was introduced more than 46 years ago by Lundberg and has been widely adopted as a standard of good laboratory practice. It suggests that a result which indicates that patient is in imminent danger unless therapy is initiated immediately[1,2,3]. CAP (College of American pathology) has made critical value reporting as a part of requirement for accreditation. Health and safety in clinical laboratories is becoming increasingly important subject currently. The preparation and approval of critical alert value list should be done in consultation with the concerned hospital board/clinician's panel and it is essential to discuss the possible mode of implementation of the same with local facilities[4].

Critical value reporting parameters may be considered an important laboratory outcome measurement because they reflect clinical effectiveness, patient safety and operational efficiency. For the critical value reporting process to be effective, the organization must understand and address the variables involved in critical results reporting with opportunities for process improvement in the process. This information is not readily available in the literature. Most reports have analyzed only a few analytes for short periods or have reviewed a small number of critical values in a number of different institutions [5,6,7].

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## MATERIALS AND METHODS:

This cross-sectional study was conducted in Central Pathology Laboratory (Hematology and Clinical pathology section) of NKP Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital, Nagpur, Maharashtra, India during January 2018 to December 2019. All major medical and surgical specialties are supported by its 1000 bedded hospital inclusive of pediatric care, obstetric care, extensive primary care and specialist outpatient practices. During the study period the laboratories performed 3,94,213 reportable tests, of which 53% were for inpatients, 13% for outpatients and 35% for emergency department (ED) patients.

The critical callback list for hematology and clinical pathology laboratory used in institutional set

**Table 1**: Critical values in haematology & clinical pathology.

| Sr.No | Parameters | Critical Values |
|---|---|---|
| 1. | Hemoglobin | < 5gm/dl |
| 2. | Total WBC Count | <20,000 & <4000/cmm |
| 3. | Platelet Count | <50,000/ul |
| 4. | Presence of Blasts Cells. | Present |
| 5. | Presence of Malaria Parasite | Present |
| 6. | Positive Malarial Antigen | Positive |
| 7. | Urine Ketone bodies | Positive |
| 8. | Absolute Neutrophils Count | <1800 /cmm |
| 9. | Immature : Total Neutrophils Ratio | >0.2(Pristine PT) |
| 10. | CSF – Cell Count | >5Cells |
| 11. | INR | >5.0 |

**Table 2:** Evaluation of critical values by clinical case areas.

| Sr.No | Clinical Areas | No of Critical Call Back |
|---|---|---|
| 1. | IPD (Inpatient Department) | 45098 (52%) |
| 2. | OPD (Out Patient Department) | 11275 (13%) |
| 3. | ED (Emergency Department) | 30354 (35%) |
| 4. | TOTAL CRITICAL ALERT | 86727 (22%) |
| 5. | Gross total number of test result | 3,94,213 |

**Table 3**: Evaluation of critical callback in haematology & clinical path laboratiries.

| Laboratory | Haemat Section | Clinical Path Section | Total |
|---|---|---|---|
| Critical Call back | 72677 (83.8%) | 14050 (16.2%) | 86727 |

up with deputation of informer personnel (i.e. Resident Doctors, Lab Technicians) usually ensures validation of result by repetition of test or by recalibration of parameter, if necessary and/ or by checking quality control result (Table 1). If the result is in the critical value (upper or lower), the lab personnel would communicate with the responsible caregiver [Consultant, Registrar, Medical Officer, Nurse and Operations associate (i.e. Clerical staff who perform clinical support function)] to inform the values on phone. At the same time he/she will also inform the result to the concerned laboratory doctor (i.e. consultant, senior doctor and in charge). The outpatient critical value is informed to responsible consultant or his/her medical assistant (i.e. medical officer). The laboratory personnel records details of critical call back [parameter, critical value, informed & informer person, date, time (i.e. Result generation, information & Convey interval)] register.

All data were retrieved from reports generated by hematology and clinical pathology laboratory that has been recorded into critical call back register. The observed parameters were evaluated by using descriptive statistical analysis by Microsoft office Excel 2007 software.

## RESULTS:

During the study, hematology and clinical pathology laboratories reported 86727 critical values and 3, 9 4,2 1 3 test results reported during the period of two years. Therefore, tests with critical values represented approximately 22% of the total test results. (Table 2) The majority of critical callbacks (83.8%) resulted from testing performed in the hematology laboratory (Table 3). The clinical pathology laboratory accounted for 16.2% of critical callbacks. The analytics most commonly called back for hemoglobin were (31222 results; 36% of critical results) subsequently TLC 23850 (27.5%) of critical call back, Urine Ketone (13009 results; 15% of critical results) and platelets 11708 (13.5%) of critical callback (Table 4).

We have recorded maximum 45964 (52%) call back from inpatient department (IPD) followed by

**Table 4:** Evaluation of critical values by parameters.

| Sr.No | Parameters | Number & Percentage of Critical Call Back | |
|---|---|---|---|
| 1. | Hemoglobin | 31222 | (36%) |
| 2. | Total WBC Count | 23850 | (27.5%) |
| 3. | Platelet Count | 11708 | (13.5%) |
| 4. | Prescience of Blasts Cells | 434 | (0.5%) |
| 5. | Prescience of Malaria Parasite | 1041 | (1.2%) |
| 6. | Positive Malarial Antigen | 780 | (0.9%) |
| 7. | Urine Ketone bodies | 13009 | (15%) |
| 8. | Absolute Neutrophils Count | 2602 | (3%) |
| 9. | Immature : Total Neutrophils Ratio | 520 | (0.6%) |
| 10. | CSF – Cell Count | 1041 | (1.2%) |
| 11. | INR | 520 | (0.6%) |
| | Total | 86727 | |

**Table 5:** Frequency of call back in each shift.

| Shifts | Early Morning | Afternoon | Evening | Night | Total |
|---|---|---|---|---|---|
| Critical Call Back | 39894 (46%) | 38854 (44.8%) | 6938 (8%) | 1041 (1.2%) | 86727 |

**Table 6:** Evaluation of critical values by tat (turn around time).

| Care Areas | TAT (Turn Around Time) | | |
|---|---|---|---|
| | Minimum | Maximum | Mean |
| IPD | 30 | 90 | 60 |
| OPD | 20 | 180 | 120 |
| ED | 15 | 45 | 30 |

emergency department (ED) 30,354 (35%) and outpatient department (OPD) 11275 (13%) (Table.2). Critical value calls were maximum 39894 (46%) in morning shift and minimum 1041(1.2%) in night shift (Table 5).

The turnaround time for each critical value assessed for correctness and appropriateness of critical value reporting. Turnaround time is the time period between receiving of a sample and generation of report. The mean time between entering value in the critical callback register and conveying the information to the patient location or ordering clinician were 60 minutes (30-90 minutes) for IPD, 120minutes (60-180 minutes) for OPD and 30 minutes (15-45 minutes) for ED as analyzed for 86727 critical values (Table 6).

Gap in critical value reporting and report generation time reveals certain fallacies inclusive of following: (a) There is deficiency of modalities and directives for updating of test performed and information to outpatients (OPD) (b) Testing ordered on requisitions in the form lacking the name of the test ordering clinician and ordering location.(c) It is also found that tests performed in settings (viz. emergency test places) where technicians are continuously present. (viz. coagulation study) hence the critical alerts called back were faster than tests performed in other areas (.i.e. Routine test zone). The information was useful to put into practice all measures to improve critical value reporting in all areas of the laboratory in the form of LIS, HMIS etc.

## DISCUSSION:

Study period with existing assets, provides a comprehensive view of the critical value reporting procedure at tertiary care center in addition to the details about scope, volume, timing and operational aspects of critical value reporting. Many parameters are applicable to a variety of settings. This analysis provides a framework for comparison and process improvement required.

***Increasing workload:*** Clinical laboratory makes it important to achieve efficient use of laboratory resources to maximize clinical benefits. Spreading out of critical callback lists to include testing that does not organize the significant factor of the 'impending risk'

standard may reduce the necessity of a critical value call and direct to needless interruptions for clinicians viz. critical value calls for high INR levels will not be of clinical value for patients receiving heparin in cardiac operations. In addition, there are many clinical settings (chemotherapy, malignancy) in which the 'critical' test result is expected and reporting of this value may not contribute to improved patient care. Hence, there is felt need of modified upgraded LIS, HMIS and Server with traceable Cloud based System having confidentiality.

***Communication Devices:*** Communication by technicians is a costly practice in terms of the resources required to complete the phone calls and document the process, in favor to this reason, it is helpful to try and reduce the number of phone calls by careful review of the critical values list. In addition to determining which tests are to be included in the critical values list, another important strategy is to examine the consequences of changing the boundaries for critical value reporting. These boundaries must be defined in consultation with clinicians. Small changes in critical value reporting parameters may result in the addition or loss of thousands of phone calls for the laboratory staffs. Its better to have link with LIS and HIMS to display the color code of abnormal biological reference values and Critical Values must be précised by joint venture of Lab & Consultant authorities to avoid gap between result generation time and information time, which will become in Critical alert as well as TAT maintenance under guideline of accreditation.

***Critical values of OPD*:** This is an exceptional task to report clinicians. The strongest correlates of delayed reporting of critical values were the samples of an outpatient (i.e. OPD). Outpatient critical values are required to communicate to the responsible clinician who is not traceable because both are having different approaches in various practices for decision of patient coverage. They are not like inpatients. There is no fixed patient location that can be called on mobile number for tracking through SMS/What sup. So OPD patients required location communication of both patients and consultant to inform /to display with color code on communication devices by upgrading APP provision of Web site based cloud system with confidentiality.

***Non accessible Authority/Scrawled/Missing:*** Another factor observed during this study causing delay for outpatients was scrawled or missing patients information. It is also found that recent improvements in the critical value communication times have coincided with increased awareness of critical value monitor working with outpatient practices to improve communication between the laboratories and the outpatient care centers by using HIMS, App, and Website based cloud system with confidentiality. It must be upgraded with accessibility and traceability via communicating devices. Next contributor to delay in outpatient critical value reporting is the heterogeneity of the outpatient population having specimen receipts from health centers (i.e. RHTC), clinics (OPD), urgent care centers (satellite center), dialysis centers, casualty and physicians offices. Each of above areas are liable to have a different call schedule, answering service and cross-coverage procedure, making reliable communication with the responsible licensed caregiver is still not easy as they may shift to emergency services provider zone i.e. IPD, MICU, NICU, PICU, ICCRU, ICCU for emergency services. The nature of outpatient specimen transport and processing often results in outpatient test results being generated in the evening when the outpatient clinic or physician's office is closed. The laboratory must have a mechanism to determine on-call coverage and work with outpatient practices to improve the communication processes.

***Up-gradation (potential solution) of critical value reporting technique:*** The use of information technology (i.e. HIMS) to automatically communicate with the responsible provider has proven to help reduce critical value reporting time in controlled settings.[8,9] For implementation of automated critical value reporting, interfaces from the LIS to technologies that facilitate bidirectional communication (such as e-mail, whatsapp or 2-way pagers) need to be developed. An important component in such a system is the ability of the automatic reporting system to reliably determine the identity of the responsible provider. At larger medical centers, this task can be challenging because there may be different coverage lists, tests ordered by consultants unknown to the primary caregiver and patient transfers to different locations. An electronic reporting system potentially could create dangerous delays in communication if not properly implemented. The system needs to have a 'recognition' function such that the laboratory can ensure that the responsible caregiver has received the result[10]. Electronic systems also requires an intensification procedure so that lack of acknowledgment of the critical result prompts an alternative approach for communication in the form of APP provision of Web site based cloud system with confidentiality to assess openly any service provider

and beneficiaries directly/ vice versa [8,910].

Up gradation of LIS: Rules-based logic can be applied to laboratory values to build alerts that take into account not only the result value, but also other related results, a change in the current test result from previous results (e.g. delta checks, Sigma check), patient demographics, ordering provider rejection follower and other parameters to customize for alerting patient's condition and the needs of clinical team for notification viz. many oncologist do not want to be notified regarding patients with neutropenia. The ability to provide a physician specific critical values list could eliminate a large number of unnecessary critical value calls. These systems, when interfaced with automated alerting systems, will have the potential to improve patient safety and provide further frameworks for susceptible critical value reporting.

## CONCLUSION:

Laboratory must have clearly defined and technically enriched procedure for informing and alerting all concerned systematically for critical results. An agreement should be made with clinicians to establish a specific list of critical limits according to the type of patients and the relevance of laboratory test. Laboratories have a system of critical call back system in laboratory with accreditation, which must be followed for ensuring patient's safety. The entire scenario can be upgraded through website based cloud system with password protected access of results by authorities and beneficiaries. This will reduce laboratory errors and progressively improve quality, efficiency and outcomes. However, extensive follow-up, monitoring with continued documentation are necessary to ensure long term success of quality management systems.

It is hence inferred that the critical value reporting is crucial for patient safety as standardization of such practice would be beneficial. It is also essential for effective use of the existing resources and it also creates professional responsibility. Regular quality assessment review meeting with technical staff and strict adherence to the set norms are thus the key to achieving the goal of quality management in laboratories.

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