Quality Tools and Strategy for Critical Alerts Process Improvements to Ensure Patient Safety

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Abstract

Objectives A number of regulatory and accrediting bodies require the reporting of critical results on a timely basis (immediately or within the time frame established by the laboratory) to "the responsible, licensed caregiver" as timely notification of critical laboratory results can pivotally affect patient outcome. The aim of the study was to decrease the turnaround time (TAT) of critical result notification along with assurance of notification to the concerned caregiver or clinicians. The objectives was 30% reduction in the critical value notification TAT and identify factors associated with delayed reporting and root cause analysis for these factors by application of quality tools.

Materials and Methods The study was conducted at the Institute of Human Behavior and Allied Sciences, Delhi, a tertiary center teaching Hospital, from April 2019 to June 2021. A value streamed Process Map of critical alert was prepared. The incidents related to failure were presented through Pareto chart. The possible causes were analyzed through the fishbone model. The failure mode prioritization was executed with Failure Mode and Effect Analysis (FMEA). Through extensive brainstorming, appropriate and feasible corrective actions were implemented. The effectiveness of the implemented plan was analyzed by reassessing the TAT of critical alert and feedback received by clinical caregivers.

Results After implementation of corrective action plan using quality tools for 3 months, the average critical alert TAT was reduced to 21 minutes from 30 minutes (30% reduction). The median critical alert TAT for ICU, emergency, and IPD were reduced to 3 minutes (IQR: 1–7). During the pilot project, 156 critical value data were sent for feedback with treatment plan but was received only for 88 patients (56%).

Conclusion Comprehensive utilization of quality tools has a potential role in patient safety by reducing the critical alert TAT as well as establishing an effective communication between laboratory personnel and clinicians.

Keywords
- critical value
- quality tools
- FMEA
- process map
- Pareto chart
- fishbone model

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Introduction

Critical values are life-threatening laboratory results that require urgent notification to the concerned clinicians or the healthcare provider.[1] The delivery of accurate laboratory results to the concerned clinician within a suitable timeframe that ensures patient safety without overburdening the laboratory workers and clinical staff is a quality indicator for the laboratory.[2] Although timeliness in critical value notification can be helpful in saving lives and reducing morbidity, failure to communicate may lead to diagnostic errors, delayed or no treatment resulting in adverse outcomes along with big liability claims.[3] Therefore, implementation of a proper protocol for critical value notification by clinical laboratories is both a right of patients for their safety and an obligation for the laboratory to save lives, increase reliability, and reduce cost.[4]

The Joint Commission has recommended the safe and timely notification of critical values of tests and diagnostic procedures to the concerned healthcare providers on priority basis as per the second goal (subclause 02.03.01) of the National Patient Safety Goals (NPSGs) and (The Joint Commission. National Patient Safety Goals: 2021).[5] Medical laboratories are required to frame a strategy and establish a protocol for critical value notification and its periodic evaluation for NABL accreditation as per the technical requirement of ISO 15189:2012 (clause 5.8 of 15).[6] Therefore, critical value notification protocol should be subjected to continuous process improvement and further upgradation.[7]

Quality tools application to study the variables affecting the critical alert notification are helpful in improving the notification process.[8] Quality tools can analyze and identify the potential errors, risk associated with it as well the corrective and preventive plans. The College of American Pathologist has elaborated the quality monitoring among laboratories by applying the Q-Probes program that helps revisions of critical values.[9] Since then, multiple quality-enhancing strategies have been enlisted for improvement in the quality of medical laboratory projects that include Lean Process (Toyota, Aichi, Japan), Six Sigma (Motorwala, Schaumburg, Illinois), and Failure Mode and Effect Analysis (FMEA).

In our laboratory, we have a protocol for the notification of critical value to the concerned healthcare provider by making telephonic calls and read back policy within 30 minutes of the sample arrival in the laboratory. Early intimation reduces the time needed for diagnosis and initiation of intervention and patient safety. But still, there were occurrences of ineffective communication for some of the critical values results. Ineffective communication means delayed call backs, abandoned call backs, or notifications not available to concerned persons. Therefore, the present study was focused on further 30% reduction in the critical value notification time and elimination of failed notifications, if any. The process improvement for critical value notification protocol in the laboratory was designed using different quality tools, namely DMAIC model (Define, Measure, Analyze, Improve, and Control), fishbone analysis, Process Mapping, Pareto chart, and the FMEA model.

DMAIC is a road map for process improvement of quality improvement project consisting of Define(D), Measure (M), Analyze (A), Improve (I), and Control (C) steps.[10] Define means problem identification, clarifying the scope, and finally setting the target of achievement. Measurement means quantifying the current output and sophisticating the problem. Analyze phase methodically examines the issue, enumerates the sources with the description of individual causes, and then determines the root cause. The analyze phase can be achieved using the fishbone diagram model. Fishbone diagram is basically a first-formulated cause and effect diagram by Kaoru Ishikawa that identifies the causes of a particular situation or event.[11] It is an effective model that shows the systematic relationship between a result or a symptom or an effect and its possible causes. This tool systematically generates ideas about causes for problems and present these in a structured form. Process Mapping can be described as visualization and description of individual steps of a defined process such that the connections and feedback loops become obvious.[12]

The overall process can be improved by capturing variations at each level and identifying non-value added step (waste). Pareto charts are bar graphs and line graphs where individual factors are represented by a bar graph in the descending order of their impact and cumulative total is shown by a line graph. Pareto principle, named after Vilfredo Pareto, is based around the concept of 80/20 rule, which underlines that the large majority (80%) of problems or failures are produced by a few key causes (20%).[13] FMEA is an organized team-based method of proactively identifying potential failures so that action can be taken to prevent or minimize the effect of an error. FMEA results in the prevention of possible defects, enhanced safety, and an increase in customer satisfaction. FMEA follows the "system-based approach," where the primary aim is error prevention by not putting burden on individuals but on the designs of the system in which they work. Three factors are important to determine the relative risk of a quality failure and its effects. First and foremost is the "severity" of the consequence of failure, when it occurred. Second is the "probability" or the frequency of the failure occurrence. Third is "detection" the probability of the failure being detected before a negative impact is realized.[14]

Therefore, this study was designed to apply these widely discussed quality tools in continual quality improvement project on immediate and effective critical value notifications. The process of continual improvement with the applied quality tools was described in detail with analysis of each step. The aim of this study was to achieve at least 30% reduction in the turnaround time (TAT) of critical result notifications along with the assurance of notification to the concerned caregiver or clinicians so that diagnostic errors can be prevented and early intervention can further prevent any potential harm.

Materials and Methods

The quality improvement study was carried in the Institute of Human Behaviour and Allied Sciences, Delhi, a tertiary center teaching Hospital. The study was conducted from

April 2019 to June 2021. The study was initiated with re-evaluation of the critical value notification protocol in the biochemistry laboratory. The biochemical parameters were used to be analyzed on the PICTUS 700 & PICTUS 500 (Diatron, Hungary). Immunological assays were carried out on COBAS e 411 and COBAS e 601 (Rosche Diagnostics, North America). We had a protocol of annual review of all critical values. The established time interval between sample receipt and reporting of critical value notification was within 30 minutes. Though the last year data showed that most of the inpatient reports of critical values were notified to the caregiver within 7 minutes, the outpatients reporting was longer and there were incidences of even failed notifications. Identification of variables affecting critical result notifications in failed or delayed cases was the top tier, followed by the nomination of potential areas of failures that may hamper the patient safety. It is also important to stay informed about the evolution of patient safety. Finally, the root cause analysis for these variables by application of quality tools was executed. The biochemistry laboratory had reported 811 critical values during the last year (2018–2019) to the intensive care unit (ICU), emergencies, inpatient department (IPD), and outpatient department (OPD). These values were analyzed for timeliness, clinical area, to whom it was notified, and the patient safety achieved. The overall roadmap of quality improvement in critical value notification is represented in ►**Fig. 1**.

With a goal to reduce the TAT to 20 minutes from 30 minutes and the elimination of failed critical value notification, the process protocol was observed and mapped (►**Fig. 4**). The very first step of analysis of incidents related to the failed/ineffective notification was accomplished through the Pareto Chart that has been depicted in ►**Fig. 2**. The incidents reported with an ineffective or failed notification were addressed with the help of training and awareness of the staff, pilot planning, and better communication between the caregiver and laboratory personnel. Then, to further improve the TAT, the potential sources of delay were analyzed methodically using the fishbone diagram (►**Fig. 3**). The potential reasons were categorized as (1) organizational/communication system, (2) test requisition form, (3) personnel, (4) method/material, (5) instrument, and (6) irrelevant critical data. Because there were numerous causes; therefore, to define the priority areas we used the FMEA model to designate the risk priority number for all possible causes. The FMEA model included the following steps: (a) The process map for the critical value notification protocol was studied in detail by a multidisciplinary team consisting of personnel from different disciplines dealing with it (►**Fig. 4**). With specific knowledge and experience of the process, the possible failure modes were identified and assembled. The basic purpose of process map study was to eliminate all wasteful steps that can be preanalytical, analytical, or post-analytical, (b) the next step was hazard analysis that included listing of potential harmful consequences on patient safety of each failure mode and rating for the severity, probability, and detectability. The failure mode was assigned ratings to severity and occurrence based on a 10-point scale, with 1 being the lowest and 10 being the highest. A Severity Index (SI) corresponds to the seriousness of the effect of stated failure from no effect/unnoticed effect to result in patient treatment failure/mortality. Probability Index (PI) is the probability of the actual occurrence or frequency of such failure modes and were predicted based on the previous record of quality improvement data available. The Detectability Index (DI) of the failure mode looks at how likely we are to detect a failure mode or the effect of the failure. Low detectability ($<50\%$) is assigned DI between 5 and 10, (c) identification of critical failure mode is by the calculation of risk priority number (RPN) for each failure mode. The numeric rating for severity (SI), probability (PI), and detectability (DI) was multiplied to calculate the RPN. RPN can go from a minimum of 1 ($1\times1\times1$) to a maximum of 1,000 ($10\times10\times10$). The failure mode having a high RPN value is addressed first. The intervention was planned for the failure mode having RPN greater than 300 (►**Table 1**). The failure

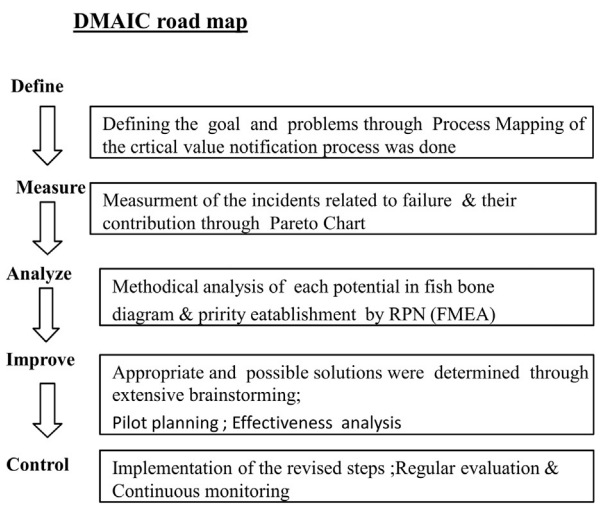

Fig. 1 DMAIC model representing the sequencial steps adopted for quality and patient safety improvement in the critical value notification process.

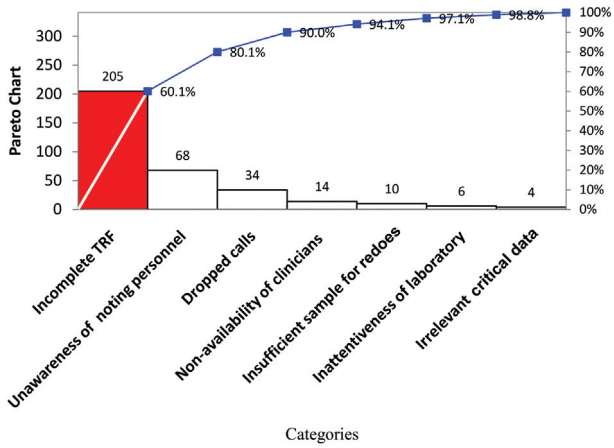

Fig. 2 Pareto chart representing the contribution of respective incidents that may lead to a delay in the TAT of the critical value notification process.

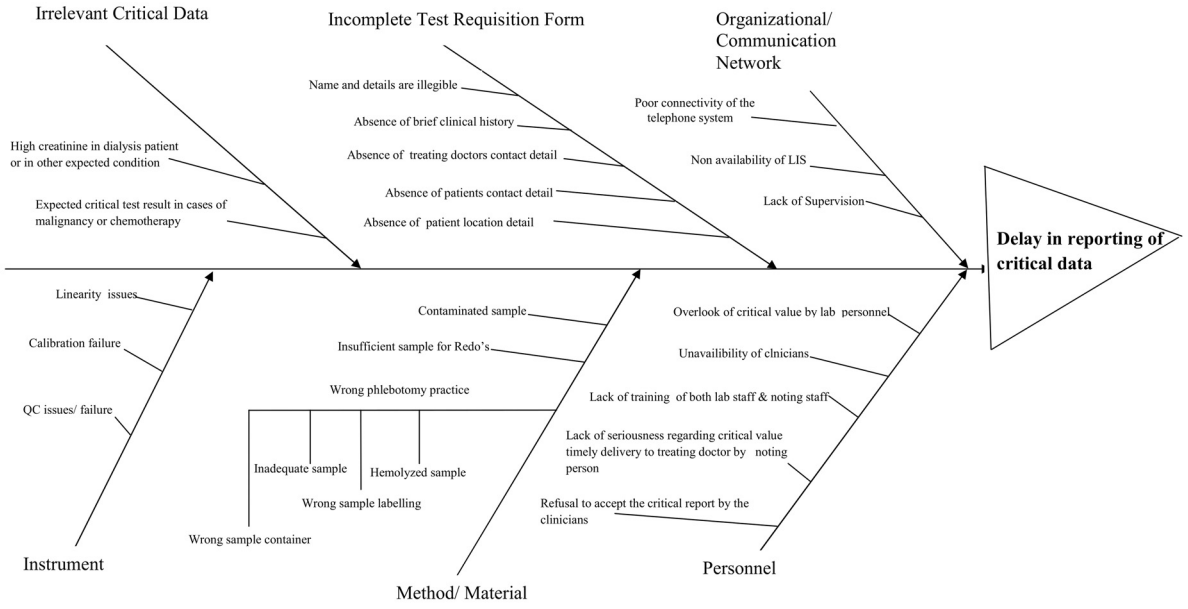

Fig. 3 Fishbone model analysis of possible souces, leading to a delay in the TAT of the critical value notification process.

modes with RPN 100–300 were less important, while failure modes with RPN below 100 was acceptable.

Extensive brainstorming and pilot planning were done to identify the solutions of critical failure. Higher ranking risk failure modes were addressed on priority through possible long-term and short-term corrective actions (►**Table 1**). The major corrective action that was implemented as follows: (A) test requisition forms (TRFs)-related issues were addressed by (1) training of the nursing staff and residents regarding filling up of TRFs, (2) use of office stamp for doctors is mandatory on TRF, (3) every patient was instructed to bring an identity proof (Aadhar or Voter) to get proper name and contact details; (B) For communication failures, (1) a WhatsApp group was made to communicate with the clinicians/on-duty resident doctors, (2) a critical value display was planned at ICU, emergency, and every ward; (C) Sample issues were solved by sensitization, induction training, and retraining of phlebotomists on phlebotomy technique with practical demonstration; (D) Laboratory system failure issues were prevented by strict scheduling of preventive maintenance at required intervals along with routine maintenance (►**Table 1**).

Computerized test order entry was planned for implementation in near future. We also proposed to update the contact detail of duty resident doctors data to the laboratory staff weekly from ICU, emergency, and every ward as duty shuffling or tenure completion was highly expected. Departmental heads were intimated weekly about all critical values conveyed to the particular department in the entire week. The clinicians were asked to give their feedback and treatment plan on the concerned patients (►**Supplementary Table S1**). This loop was helpful in moral motivation of the laboratory staff as well as care providers as patient safety was achieved due to their responsible work. A critical value abstract form was suggested to attach with the patient file.

Statistical analysis: To study the outcomes of the intervention, SPSS-16 was used to analyze the data before and after the implementation of the pilot plan. The chi-square test was used to compare the average TAT of critical alert before and after intervention. IPD and OPD TATs were represented as the median and interquartile range (IQR). Feedback received from clinician is denoted as percentage.

Results

After the implementation of the proposed correction plans for 3 months, the critical value data were analyzed again. The biochemistry had reported 256 critical values during this time. The major area of critical alerts were ICU and emergency followed by wards (IPDs) and then OPDs. The outcome of this quality improvement project was measured in three terms: (1) the current RPN of probable failure modes after corrective action; (2) the current critical value notification time; and (3) timeliness of clinical care provided to patients in response to critical value notifications.

The RPN of the failure modes was reduced from the high risk (>400) to an acceptable level (►**Table 1**). The RPN for improper test requisition form (TRF) was reduced to 60 from 560, whereas for communication-related failures, the RPN decreased to 189 from 540. Training and sensitization improved sample-related issues fairly (►**Table 1**). The critical failures due to laboratory system issues were reduced to a great extent (RPN: 432 to 45).

The effectiveness in critical value notification TAT is shown in ►**Table 2**. The average notification time was reduced to 21 minutes from 30 minutes, that is, about 30% reduction in TAT, close to our goal of quality project. There was a significant 40% reduction (3 minutes from 5 minutes) in the median notifying time of critical reports to ICU, emergency and IPDs, whereas for

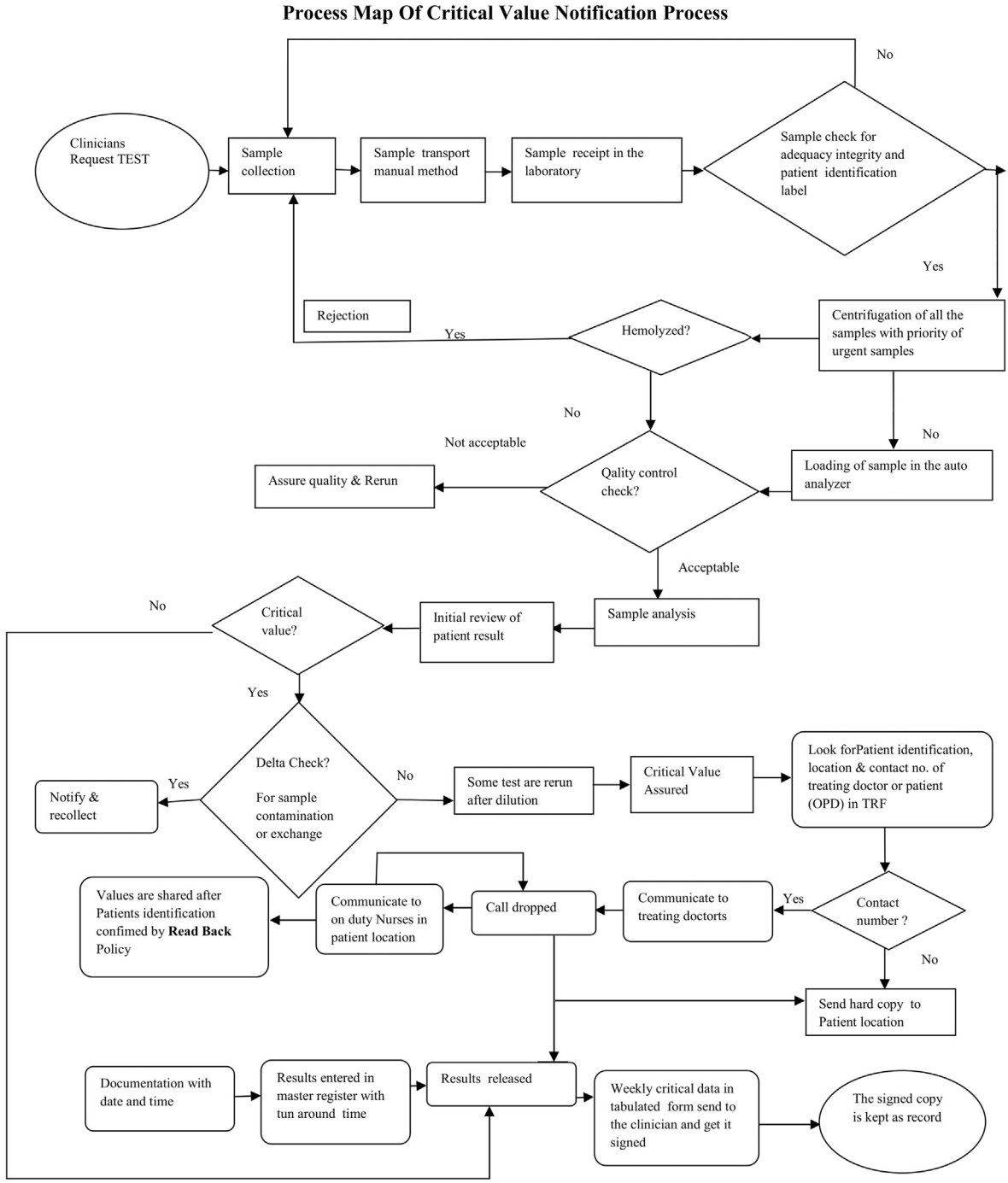

Fig. 4 Process map representing the detail of each step in the critical value notification process.

OPD notification, approximately 18% (37 min–45 min) reduction in the TAT was noted.

Weekly compiled critical value data were sent to all clinical departments and were requested to give the feedback with treatment plan after the receipt of critical alert by a specific deadline (within 15 days). In the 3-month period, we sent 156 critical value data as per the given format but the feedback and treatment plan was received only for 88 patients, that is, around 56% only. The care provider treatment action was in time in all 88 cases (►**Table 2**).

Discussion

This quality improvement project exhibits the practical application value of different quality tool in a tertiary care hospital center to enhance patient safety. Reporting of critical values of analytes to the concerned clinician is a standard protocol in every medical laboratory but at times there are problems in providing the critical alert to the responsible care provider on timely basis as multiple steps are involved in communication. This project was designed for complete

Table 1 FMEA model for risk prioritization and effect analysis with effectiveness of proposed corrective action

Potential failure Mode	Potential failure mode effects	SI	Failure checklist	PI	Current controls	DI	RPN	Proposed corrective action	Effectiveness (RPN)
Incomplete TRF	Delay in critical value reporting	7	*TRF does not have clinical presentation and probable diagnosis of the patient*	7	Take required information from wards	9	*441*	*Training of nursing staff and residents regarding the filling up of TRFs*	*324*
Incomplete TRF	Non-reporting of critical report	10	TRF does not have the name of the treating clinician/ward where patient is admitted	2	Not accept of the form at reception	2	40		
Improper TRF	Non-reporting of critical report	10	*Name and details are illegible*	7	Refusal of forms	8	*560*	*Training of relevant personnel/electronic filling of requisition form/ for doctors use of stamp in TRF/patient is asked to carry an identity proof, e.g., Aadhar or voter card*	*60*
Clinician's phone not reachable	Delay in critical value reporting	7	*Poor connectivity of phone*	6	Inform the nursing staff/residents doctors in the ward/closed user group facility started	9	*540*	*WhatsApp group was made to communicate with clinicians/on-duty resident doctors A critical value display was planned in ICU, emergency, and every ward*	*189*
Refusal to accept the critical report by the clinician	Delay in critical value reporting	7	Change in duty of resident doctors	4	Inform the nursing staff	9	252	Communicate with clinicians/on-duty resident doctors Update the resident doctors contact data weekly	
Insufficient sample	Delay in critical value reporting	9	*Wrong phlebotomy practices*	6	Delta check done with previous value to confirm present result	9	486	*Induction training and retraining of phlebotomists on phlebotomy technique with practical demonstration*	*105*
Improper sample	Delay in reporting or non-reporting of critical report	9	*Hemolyzed sample Contaminated sample Old samples*	8	Repeat sample	8	596	*Training and sensitization*	*63*
Irrelevant critical data	Not applicable	3	Expected critical test result	6	Delta check	5	90	Not applicable	
Laboratory system issues	Delay in reporting of critical report	9	*QC failure Calibration failure Linearity issues*	4	Quality assurance Recalibration Repeat with dilution	9	432	*Preventive maintenance along with routine maintenance*	*45*

Note: The Italics is used where RPNs were high and corrective action plan were implemented.

Table 2 Effectiveness measurement after implementation of corrective action plan

	Critical value notification time			RPN (risk priority number)	Clinical care provided to patients after critical alert	
	Average time	Median & IQR for ICU, Emergency & IPD	Median & IQR for OPD		Feedback received	Timeliness of treatment
Previous	30 min	5 min (1–11)	45 min (2–99)	300	Nil	Not applicable
After	21 min*	3 min (1–7)*	37 min* (28–87)	< 100*	88/156 (56%)*	56%

*p-Value < 0 .01 is considered significant. IPD: inpatient department; OPD: outpatient department.

assessment of the protocol of critical value notification and address the potential issues associated with delays. The area of improvement was properly assessed with various quality tools, namely, DMAIC, Process Mapping, Pareto chart, fishbone diagram, and the FMEA model. All quality tools were connected to each other and applied in the required manner, as shown in ►**Fig. 1**. Their sequential application was to ensure that all relevant areas of patient safety concern were identified and targeted for improvement. The average TAT for critical alert was reduced significantly by 30% (►**Table 2**), fulfilling our objective of quality project in achieving a higher patient safety. Patient safety is a continuous focus for the joint commission and thus for our laboratory also.[15] The median reporting time of notification to the ICU, emergency, and other inpatient areas was also reduced significantly (►**Table 2**) but communicating the critical value to outpatients and their timely intervention by the responsible care giver is still a major hurdle (►**Table 2**). Li et al had also reported that quality indicators for critical alerts were poor for outpatient setting.[5] Although training and sensitization regarding the process protocol of critical alert and subsequent awareness on patient safety led to an effective communication of critical alert and timely intervention by the caregiver. However, the feedback with details of treatment intervention from the clinicians is still a gray zone. There is requirement of implementation of more effective communication between the laboratory personnel and clinical caregivers. A proposed solution was implementation of the Laboratory Information System (LIS) that can detect and report critical values to the care provider. The LIS should have the provision of identifying the personnel to whom it was delivered and receipt of acknowledgment. Further, the LIS can be linked to clinicians mobile phones to give real-time critical alert to on-duty doctors. The individual failure modes have been targeted through risk prioritization and then planned corrective actions, which led to the reduction in RPN of individual root causes (►**Table 1**). Patient safety can only be enhanced by taking care of the actions such as preventing error events, detecting them when they occur, and eliminating their effects proactively. The FMEA model helped in the utilization of resources on areas where good outcomes were expected. The applications of quality tools in an appropriate way led to achieve a significant improvement in critical alert notification TAT and patient safety.

Conclusion

Quality tools implication resulted in around 30% reduction in the critical alert TAT. Identification of quality failure requires the creation of a culture that actively encourages the staff to develop a constructive and critical attitude to work and which emphasize the identification of quality failure as an opportunity to enhance patient safety.

Future Plan

Establishment of better communication establishment with the clinicians so that significant compliance from the clinical provider will help in meeting the desired outcome. Patient

safety can be more ensured by quality monitoring of integration of medical record reviews with critical alert notifications. Therefore, timeliness and appropriateness of treatment plans can be evaluated, ongoing compliance can be ensured, and variations can be seen.

Authors' Contributions

Rachna Agarwal contributed to the conception and design and revising it critically for important intellectual content.

Puja Kumari Jha contributed to the conception and design, acquisition of data, or analysis and interpretation of data and drafting the manuscript.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of Interest

None declared.

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