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IMPROVEMENT IN THE TURNAROUND TIME OF LABORATORY REPORTS USING SIX SIGMA IN A DIAGNOSTIC CENTRE

Pathology

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ABSTRACT

Background: An efficient testing process is a key to a timely diagnosis of critically ill patients. Prolonged TAT in the critical patients indicated a need to streamline the whole process from registration to sample collection till validation of the results using existing resources to decrease turnaround time of reports of critical patients. **Method:** A project to streamline the testing process within clinical biochemistry department was started using the DMAIC (define, measure, analyze, improve, control) method. Acceptable time limit for TAT of critical patients was decided 240 minutes by the team members. **Results:** During the study, the TAT from arrival of patient to laboratory till report validation by concerned doctor decreased from 45.83% to 23.72% after implementing solutions by the concerned staff. **Conclusions:** Streamlining workflows in laboratory in pre-analytical, analytical and post analytical area improved TAT for critical patients. Timely reporting and informing the critical results entrusted the patient and doctor's faith on laboratory report.

KEYWORDS

Critical value, DMAIC, Fishbone diagram, FMEA, SIPOC, TAT

INTRODUCTION

Laboratories have more than 70% of impact in patient reports in critical medical decisions but make up <5% of all health costs.[1] Quality is the most important factor in clinical laboratory which affects the individual patient care and thus the whole health system.[2] Laboratory reports are very crucial in medical treatment of patient [3] and clinicians are interested in service quality, which comprehend total test error (imprecision and inaccuracy), availability, cost, relevance and timeliness. Clinicians desire a reliable and efficient service delivered at rapid rate with low cost. So timeliness is the most important factor in this regard to the clinicians, [4] however analytical quality cannot be compromised for faster turnaround time (TAT). Turnaround time (TAT), commonly defined as the time from receiving the specimen at the laboratory to availability of a validated result.[5] Lundberg described nine steps namely, ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation and action in total testing process in a laboratory.[6]

Timelines in laboratory service is required for the practice of real-time evidence-based medicine; rapid diagnosis and treatment for good patient outcomes, especially in critical care patients. In the field of clinical laboratory services accuracy, precision and punctuality have their own value, [7] among which TAT is one of the most important parameter which is used by many clinicians to judge the quality of the laboratory. Unsatisfactory TAT is a major source of complaints in a clinical laboratory regarding poor service and consumes much time and effort from laboratory staff in complaint resolution and service improvement, so it is better for each laboratory to develop its own turnaround time according to its patients outcome.[8] TAT can differ for each laboratory and individual test, and can be different for OPD, IPD and for critical patients.

Laboratory reports which indicate a life-threatening condition requiring urgent medical treatment for the patient are called critical results and because of their critical nature, urgent notification of a critical value to the appropriate healthcare professional on time is necessary. Lundberg in a Medical Laboratory Observer article described critical laboratory values as values which reflect path physiological derangements at such variance with normal as to be life threatening if therapy is not instituted immediately.[9]

Despite advances in pre-analytical, analytical and post analytical technologies many laboratories have difficulties in improving their TAT. Improving TAT is a complex task which requires staff education, equipment acquisition, and adequate TAT monitoring. As Industry has greatly improved its efficiencies through effective use of Six Sigma approaches which focuses mainly on optimization of processes and workflows and causes the elimination of steps in a process that add no value in the process.[10] Six Sigma endeavours to eliminate defects in services or products as perceived by the customer. A defect is considered to be anything that causes dissatisfaction including unnecessary processes and services. It was observed in our lab that TAT for critical patients was high as same to the routine samples which may cause delay in the treatment of critical patients and thus patients dissatisfaction.

To address this, a multidisciplinary team was formed to focus performance improvement efforts on improving the turnaround time. In order to accomplish this project we used a structured methodology of problem describing by an acronym DMAIC (define-measure-analyze-improve-control). The purpose of this study was to streamline processes using existing resources to decrease turnaround time of critical patients and increase the patient satisfaction.

METHODS:

Our Goal was to examine processes from the arrival of specimens in the laboratory to the final reporting step in an effort to remove delays in reporting of critically ill patients.

Study design:

This was a cross-sectional study based on the data obtained from the department of clinical biochemistry at Saral Diagnostic Centre, Delhi. Obtained data was closely analyzed to observe current TAT and factors affecting prolonged TAT. A team of qualified doctors, technicians (lab staff), phlebotomist (involved in sample collection), and reception staff (involved in registration of the patient) was made, which focused on performance improvement efforts to reduce TAT of critical patients.

Constraints:

In some patients when it was known that they are critically ill and need early report in our system and they marked as urgent and run early than other samples but as most of the patients at the time of registration are not known that they are critical, so they are processed as normal routine patients. So to reduce the TAT of critical patients all patients sample processing time needs to be reduced.

The process followed in our laboratory:

All samples in our laboratory are run at the same place and validated by concerned doctor after checking the results. If a result is found to be critical it is informed to the patient or to the concerned doctor immediately to start the urgent treatment if required. All system is automated, bar codes are placed on blood vials and run automatically in machines and generated results are transferred automatically in LIS System.

In keeping with the define phase goals, a SIPOC diagram was developed. SIPOC is an acronym stands for supplier, Inputs, Process, Outputs, and customer .This six sigma tool is used to produce a diagram that documents a process and visually present the process. Figure 1 shows the SIPOC diagram for the blood draw and specimen collection process which helped the team members to develop a high-level of understanding of the process.

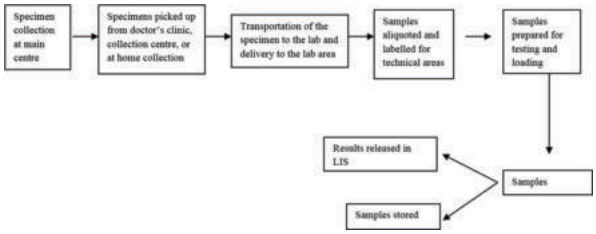

Figure 1: SIPOC and project scope:

Process Map:

During the define stage, the team developed a high level process map to help in understanding the larger process and to gain consensus for the overall scope of the project. Process Mapping can be described as visualization and description of workflow that we are working on to improve so that the connections and feedback loops are shown very clearly to team members to have a solid grasp on the steps involved in the process.[11] The entire process from registration of the patients till the validation of the report was mapped and formed (figure 2) to provide a visual representation of a sequence of activities and tasks consisting of people, work duties and transactions that occurred at the time of result release.

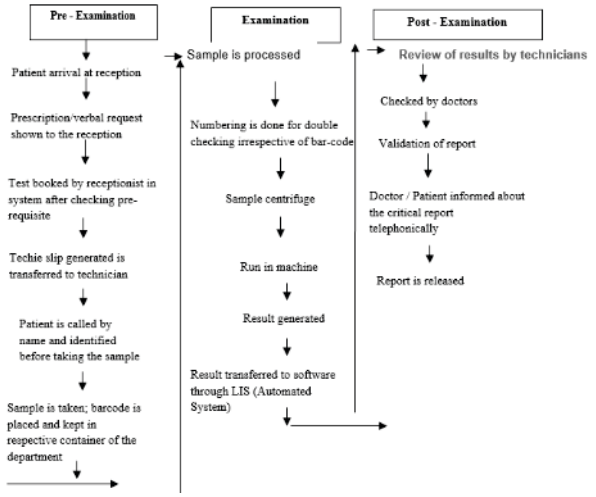

Figure 2: Six sigma initiative process flow map depicting steps in receiving and processing sample

Measuring phase:

For laboratory turnaround time, we used the time from when patient was registered in the system or sample received in the laboratory to the time when results were verified. As shown in process flow the process is broken down in three phases

- Pre – Analytical: From registration of the patient till the receiving of sample in the lab.
- Analytical: Sample processing and result generation and transfer of result in LIS software.
- Post – Analytical: Validation of result and inform the patient/doctor about the critical report.

A baseline data of critical patient TAT was collected for month of January 2019 before improvement (Table 1):

No. Of critical patients	Average TAT (Minutes)	Average time taken from registration to sample run in machine (Minutes)	Average time taken from sample run in machine to validation of results (Minutes)
48	222.83 ± 79.60	125.36 ± 42.62	106.54 ± 81.69

As it is shown in table 1 that 48 patients were reported critical in month of January having average TAT of 222.83 minutes. It was also observed that time take from registration to sample run in machine took average 125.36 minutes and average time taken from sample run in machine to validation of result was observed 106.54 minutes .

As shown in table data was categorized into different parts to analyse the time used between these three phases, which will help to analyse that at which step more time is taken and whether it can be reduced or not. Data was analyzed in these three steps:

1) **Total time taken from registration of the patient in lab till validation of critical report in system**.
2) **Time taken from registration of the patient in the system to run the sample in machine**: It involves all these steps:

- Time taken in registration
- Waiting time for sample collection, time taken in blood collection and bar code placement.
- Transportation of the sample to respective departments to analyse.
- Time taken in clot formation.
- Checking the bar-code and cross check the patient identity by checking the serial no.
- Centrifugation of sample to separate the serum / plasma.
- Run the sample according to the tests in different machines.

3) Time taken from sample run into machine to validation of the report of critical patient:

Steps which are involved here:

- Time which is taken into machine for the test running process.
- After result generation analysis of the critical list in the software/ machine by technician / doctor.
- Rerun the sample in many cases to confirm the results.
- Dilution and rerun the sample in some tests where result is out of linearity limit.

Analysing the phase:

After compiling and collecting the data the team analyzed about the root cause of the delay in TAT of critical patients. Causes which had greater impact on the process were analysed via a fish bone diagram (figure 3).

Fishbone diagram is basically a first-formulated cause and effect diagram by Kaoru Ishikawa that identifies the causes of a particular situation or event. [12] This tool systematically generates ideas about causes for problems and present these in a structured form.

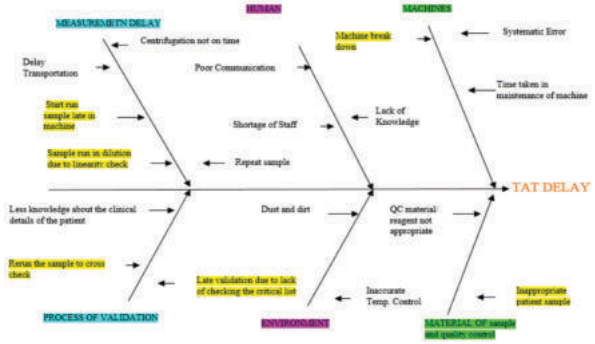

Figure 3: Causes affecting turnaround time of critical patients

The multidisciplinary team also evaluated the change failures by performing failure mode and effect analysis (FMEA) which is a step-by-step approach for identifying all possible failures in a design, a process, or a service.

Among the countless techniques for risk assessment (iso2009)[13], laboratory professionals generally apply FMEA [14] as recommended by ISO/TS 22367.[15]

Each step of the process was identified and reviewed to determine its failure potential (on a scale of 1 to 10) based on severity, frequency of occurrence and current detection methods, these values were then multiplied to obtain a risk priority number (RPN).The highest value are listed below:

Figure 4:- FMEA analysis implementing the action plan

phase	Failure Mode	Potential	Severity	Potential causes	Prevention controls	Occurrence	Defection controls	Detection	RPN
1	Delay in blood collection (in lab, at home, at clinics)	Delay in blood collection	8	Staff shortage, delay in peak hours	Little effective prevention	2	Efficient detection 75%	2	32

2	Delay in pre analytical process (Barcode placing, centrifugation)	Delay in sample run in machine	10	Poor coordination between staff/ Lack of staff in lab area	Controls are less effective	2	Detection rate not good	5	100
3	Machine breakdown	Delay in sample run in machine	10	Environmental causes/ reagent insufficient / inappropriate control out	Effective prevention	2	Partial detection	3	60
4	Delay in analysis of the critical results of the patient	Delay in validation	10	Technicians / doctors not checking the critical list and validation not on time	Controls are less effective	5	Partial detection	3	150

Multiple observation studies were conducted by the team members to see the extended duration from collection to validation. These observations indicated that under the current system and processes:

- The time from registration of the patient till the specimen collection and transport to the lab area was appropriate, even in peak hours (morning time from 8-1 0 am).
- It was observed that at peak hour's staff was involved in phlebotomy which may cause delay in sample run in machine.
- It was also observed that due to lack of coordination between staff, sample often waiting for processing in the analytical area after entering the working station which was the second largest contributing factor in TAT delay.
- Machine breakdown due to any reason; machine maintenance/qc outlier/environmental factors /reagent insufficient or poor quality could also caused delay in report of critical results.
- It also may happen due to less knowledge about the patient's health and unnecessary repeating the tests to ensure the results.
- It was also observed that sometime critical results were rerun in machine due to out of linearity limit, and this step could not be avoided.
- It was observed that due to negligence of checking critical list in software or in machine, critical results could be missed and not validated on time, which may cause increase in time of validation of critical results which was having highest RPN number in FMEA analysis.

At the end of this phase, the team had identified several factors that affected the TATs of critical patients. As results of these findings, team divided to focus improvement on these issues.

Improvement phase:

Team decided to hold meetings with reporting staff and phlebotomists and lab staff to generate solutions to decrease the turnaround time of critical patients. Areas in process flow were identified where improvement was much required **(Figure 5)**

Solutions were developed to improve work flow with case of implementation. Through the application of six sigma techniques, the team implemented the following changes:

- At the time of collection staff was trained to get the clinical details or any other history of patient which may help in patients tests results.
- Staff was trained to check the quality of outdoor received samples.
- Early transportation of sample from the collection area to lab area was assured.
- Staff was given directions to coordinate in peak hours to maintain the work in lab area and blood collection area so that all work can be done efficiently.
- One staff was employed to check the bar codes and centrifuge the samples on time so that time from registration to sample run in machine could be reduced.
- One staff was employed for properly maintenance of machines in the morning and running the controls on time so that tests can be start running in machine on time, which was very important step in TAT reduction.
- Early loading of samples was done so that TAT could be reduced.
- Staff was trained to analyse the critical test results in machine as well as in software and to inform the concerned authority.
- Staff was also trained to rerun the sample if it out of linearity limit timely so that time could be reduced in further checking by doctors.
- Concerned validating doctor also instructed to check the critical list and timely validate the results.

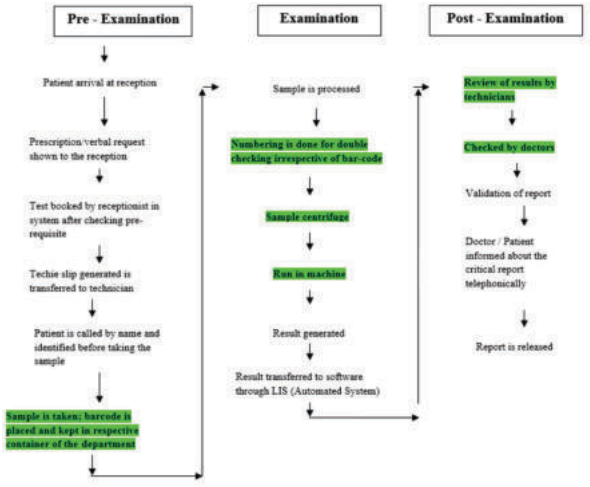

Figure 5: Process flow map depicting steps where improvement was done

RESULTS:

After implementing all these factors TAT of critical patients was observed in month of February. Findings which were obtained are shown below in Table 2:

Month	No. of critical patients observed	Average TAT (Minutes)	Average time taken from Registration to sample run in machine (Minutes)	Average time taken sample run in machine to validation of results (Minutest)
January Before improvement	48	222.83 ± 79.60	125.36 ± 42.62	106.54 ± 81.69
February After improvement	59	173.18 ± 81.04	98.94 ± 52.77	70.21 ± 52.18
		t value = 3.187 p value = 0.002	t value = 2.803 p value = 0.006	t value = 2.78 p value = 0.006

As it is shown in Table 2 that 59 patients were reported critical in month of february having average TAT of 173.18 minutes which was percent less as compared to 222.83 minutes before improvement in the month of January. It was also observed that time take from registration to sample run in machine also reduced to average of 98.94 minutes from 125.36 minutes and average time taken from sample run in machine to validation of result was observed 70.21 minutes as compared to 106.54 minutes before improvement .Statistical calculation was done using t test to compare both the results and difference were statistically significant.

DISCUSSION:

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 to improve TAT of critical patients by using

various six sigma tools as DMAIC,process mapping,fishbone diagram and FMEA model. Ibrahim et al. also used the various tools of six sigma to successfully improve the timeliness of inpatient routine CBC tests.[16] Li et al studied that for outpatient settings quality indicators were poor for critical alert values.[17] Implementation of these quality tools ensured that all relevant area of TAT improvement were considered and targeted for timeliness of report. Lokesh et al also used lean sis sigma tools like DMAIC in laboratory samples to reduce TAT in tertiary care hospital.[18]Process performance was monitored through the use of the lab reporting system (LIS) by daily monitoring. Specimens not meeting goal were reviewed and factors contributing to the failure modes were identified and action plans were put in place to eliminate or minimize impact to future processing. Critical list was monitored in LIS after each half an hour by both technicians and doctors. Staff was given regular training to take patient clinical history and analyze the critical data. The use of quality tools in an appropriate manner led to achieve significant improvement in TAT reduction in critical patients reports.

CONCLUSION:

We have successfully applied six sigma (DMAIC) methodologies to improve turnaround time for critical patients in our laboratory which has helped in Improving TAT of critical patients as well as routine patients. Improvement areas were identified in process flow and timely monitored by system.

Staff felt appreciated and motivated as their suggestions played a vital role in the success of this project.

Furthermore, this project has served as a model that launched other quality improvement programs in our laboratory.

Limitations:

Limitation of our study is that this was a single centre study and the findings might not be feasible to other clinical laboratories with different laboratory process flows. Nevertheless, given the improvement demonstrated in our findings by the implementation of tools of six sigma it can be valuable to other laboratories at some level. As the onetime expense associated with the moves were minimal so to our experience six sigma techniques can be applied in a cost-effective manner to minimize pre-analytical wastes and improve patient care.

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