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RESEARCH ARTICLE

A Lean-Based Approach to Overcome Laboratory Challenges Using Process Excellence (PEx) Methods & Integrated Solutions – Experience of a Tertiary Care Laboratory from Mumbai

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ABSTRACT:

Background: The clinical laboratory's goal is to provide the right service at the right time with the best quality. It was observed that a scattered and complex workflow resulted in non-value-added activities and impacted turn around time. A shorter turnaround time was always in demand & discussion. After feedback from clinicians & the internal team, the laboratory took this project as a part of its Quality Improvement programme. A team from the laboratory & Process Excellence (PEx) Consultants from Ortho Clinical Diagnostics performed a workflow assessment to identify the root causes of delayed turnaround time. The team used the concept of 'Lean' which is a quality improvement tool that focuses on simplifying the process by removing the "waste" or "non-value added" activities.

Aim: This study aimed to use integrated solutions & Lean methodology to simplify the complex laboratory workflow.

Method: A pre and post intervention study was conducted using the DMAIC principle (Define, measure, analyze, improve & control). The intervention was an integrated platform for analysis of Biochemistry and Immunology samples. Laboratory Information System statistical analysis for turn around time, Operator tracking and Valustream mapping were used to identify the bottlenecks and eliminate non-value-added tasks. The laboratory turnaround time, number of vacutainers used, staff assigned to tasks, were compared in the pre-intervention (2019) & post-intervention (2022) period.

Results: The adoption of an integrated platform, helped reduce turnaround time for laboratory results by 26%. The integrated system also enhanced the capacity of the laboratory to handle the workload using lesser vacutainers saving US $ 2075 & US $ 30,000 per year from saving 43800 man-hours annually. The operator motion was reduced and 6 non-value-added steps were eliminated saving the laboratory 55 minutes per batch. Also, 100 sq.ft of space was saved which was utilized by the laboratory for other specialized testing.

Conclusion: Value stream mapping an important lean tool, helped the laboratory to identify bottlenecks at the pre-analytical stage due to non-value-added activities. Specific interventions like integration of the Clinical Chemistry & Immunology analyzer with central specimen receiving station the TAT compliance score improved by 41% and 6% for Biochemistry & Immunology assays respectively. The laboratory could also optimize their space, manpower and show potential savings of USD $ 32075/- per year. These measures improved the operational efficiency of the laboratory.

Introduction

Lean principles focus on minimizing waste, standardizing processes, organizing workflow, eliminating defects, and evaluating systems. The Lean approach as a quality improvement methodology, enables organizations to make quicker decisions about improving production processes by replacing complexity with simplicity, minimizing waste, and focusing on continuous improvement. It has become popular with laboratories as a pragmatic choice among many techniques offered for streamlining laboratory processes. [1]. The 5 principles of lean model include value, value stream, flow, pull (customer feedback) and perfection [2]. Lean methodology relies on three simple ideas such as deliver value, eliminate waste and continuous improvement [3].

The clinical laboratory is a complex space wherein many processes and procedures are performed involving many steps of activity along with many people [4]. Accuracy of laboratory results play a key role in improving patient outcomes. It is important to streamline clinical laboratory processes continuously as it plays a key role in supporting patient management right from making a diagnosis, to predicting severity of illness and monitoring response to therapy. Its goal therefore is to provide the right service at the right time with best quality results. There is an increased demand in the current diagnostic industry to improve Turn around time & efficiency in laboratory. Technology and process improvement methods have greatly helped labs in overcoming the common challenges like improving efficiency in the face of volume increase, manpower constraints and space optimization [5].

One of the main requirements of the clinicians who use the laboratory reports as we understood was to have consistent turn- around time (TAT) which can be regarded as one of key result area for the clinical laboratory among others. Value stream mapping and Organizing workflow are some of the aspects of Lean principles which can be considered for reducing in turn around time (TAT) and achieving consistency. But this, at times, can be a major task for the laboratory management considering the many complexities associated with the process. These complexities are inter-connected and dynamic and include the following: (1) increasing workload (2) strain on manpower (3) monitoring impact on turn around time (4) compliance and risk management (5) appropriate staff utilization (6) budgetary constraints, etc. [6,7,8]. Errors in the processes may cost a human life, create a negative impact on an organization's reputation, cause revenue loss, and open doors for expensive lawsuits. To overcome these complexities, healthcare organizations must implement Lean management approach that helps healthcare service providers to reduce waste, variation, and work imbalance in the service processes. [9,10]

Six sigma is a structured methodology of problem solving described by an acronym "DMAIC" which stands for Define, Measure, Analyze, Improve, and Control. Using this methodology, the problems can be identified, the process mapped, the causes analysed and improvements implemented. [11]

Therefore, Lean Six Sigma (LSS) is a marriage of two different strategies or methodologies that reduce inefficiencies and increase quality. [8] In fact, Lean and Six Sigma are used as continuous process improvement frameworks in laboratory medicine successfully, in varied areas such as TAT, improving patient wait times, improving histopathology laboratory operation, etc. [9,12,13,14,15,16] In fact, there is evidence that the LSS methodology is adaptable to any process, people or place. [11] The clinical laboratory of this hospital took this study project as a part of its Quality Improvement programme (QIP). This study assumes significance because the response of clinical diagnostic laboratories has been very slow in adopting these techniques to improve the quality of a process [17]. Also, of all empirical research applying Lean and/or Six Sigma in healthcare, only 22% applied LSS. [11]

As a measuring tool, Value stream mapping (VSM) is a very important tool for process improvement for any laboratory. This tool helps the laboratory identify & eliminate bottlenecks or non-value - added steps from the process and makes way for a lean laboratory. [18] As part of applying Lean principles, value stream mapping and workflow mapping were done in this study. Since typical results of implementing lean management are operational cost reduction, cycle time reduction, and higher customer satisfaction as stated in literature [3], in addition to measuring improvement in TAT, cost reduction, customer satisfaction and any associated positive outcome were also measured.

AIM AND OBJECTIVES OF THE STUDY:

The aim & objectives of the study was (1) to achieve consistent TAT as key result area with the objective of using automation as intervention and using Lean six sigma methodologies as pre-intervention and post-intervention quality improvement strategies (2) To use Integration solutions as intervention to reduce the bottlenecks

& eliminate the non-value-added steps in the process (3) To measure cost reduction

Materials and Methods

STUDY SETTING:

This is a prospective pre & post intervention study. A quality improvement team was formed in the clinical laboratory who studied the concept of LEAN & other tools to perform this assessment at pre- intervention phase. The pre-intervention phase was between January to March 2019. The intervention was put in place in August 2020 which was the installation of an integrated system (XT7600, Ortho Clinical Diagnostics, New Jersey, USA) attached to laboratory information system. Due to the COVID -19 pandemic, this study had to be deferred for post intervention analysis until January 2022 when the laboratory functioning had returned back to pre-pandemic phase.

STUDY DESIGN USING LEAN AND DMAIC METHODOLOGY:

Definition:

This study was a longitudinal, before–after intervention analysis for process improvements in the central laboratory of a teaching university hospital. The current clinical laboratory is associated with a 220-bed tertiary care hospital of which 42 beds are assigned to adult and neonatal intensive care units. The laboratory thus caters to both inpatients and outpatients 24x7. A team with agreed & clear goals to create value by improving laboratory efficiency & TAT, was formed comprising of Biochemistry experts, Microbiology experts and the OCD Process Excellence team. The team collected data on average turnaround times from the laboratory information system (LIS) at pre-intervention and post-intervention phase. After TAT analysis at pre-intervention, study of the testing process was conducted using the DMAIC principle (Define, measure, analyze, improve & control) as applied to Lean principles of value, value stream, flow, pull and perfection [2]. TAT was again measured post-intervention to assess any improvement. The defined TAT for Biochemistry was 2 hours & for Immunology was 3 hours.

Measurements:

Measurement by application of Lean tool No1: Value stream mapping

Value-stream mapping was performed in the laboratory, which mapped all the steps from sample collection to sample processing. [18,19]. This was critical for having a good understanding of the procedure to identify the various bottlenecks and non-value-added steps in the process. VSM is an essential lean tool for an organization wanting to plan, implement, and improve while on its lean journey. A team of consultants from Ortho Clinical Diagnostics (OCD) with the support of lab team, mapped the entire process from sample collection to report dispatch and identified bottlenecks or non-value added steps in the process.

Measurement by application of Lean tool No.2: Flow:

This involves tracing the path of an operator through a process to identify redundancies in workflow & opportunities to expedite workflow. 5 operators were tracked during the process in both phases. Initial workflow assessment was planned for 3 days & data was collected.

Stakeholders' interview:

In the pre-intervention phase, seven clinicians were interviewed to get their perspective on laboratory services. Stakeholders namely the laboratory supervisors, experts & clinicians were interviewed. Feedback from the clinicians concluded that quality of laboratory results were satisfactory, but TAT was a possible area of improvement. Hence TAT improvement was taken as the prime goal or key result area for this study.

- ANALYSIS
  - TAT was analyzed by tracking samples which meant following the sample movement from collection to sample processing. A batch of 200 samples were tracked.
  - TAT data of laboratory was extracted from the Laboratory Information System (LIS), 3 months data of 2019 (pre-COVID) & 3 months data of 2022 (post COVID).
  - TAT was calculated from sample collection till result generation.
  - Sample flow was studied and mapped during this process to confirm the bottle necks
  - In both phases the equipments were bidirectionally interfaced to automatically capture the tests requested and send results to the LIS.
  - Value stream mapping helped the team to map the entire process from patient collection to sample processing. Each step in the mapping was observed & mapped into value added & non-value-added steps. (Value added steps were the steps which were necessary & adding value to patient care, non-value-added steps were those steps which did not add any value to patient care) Fig (1).

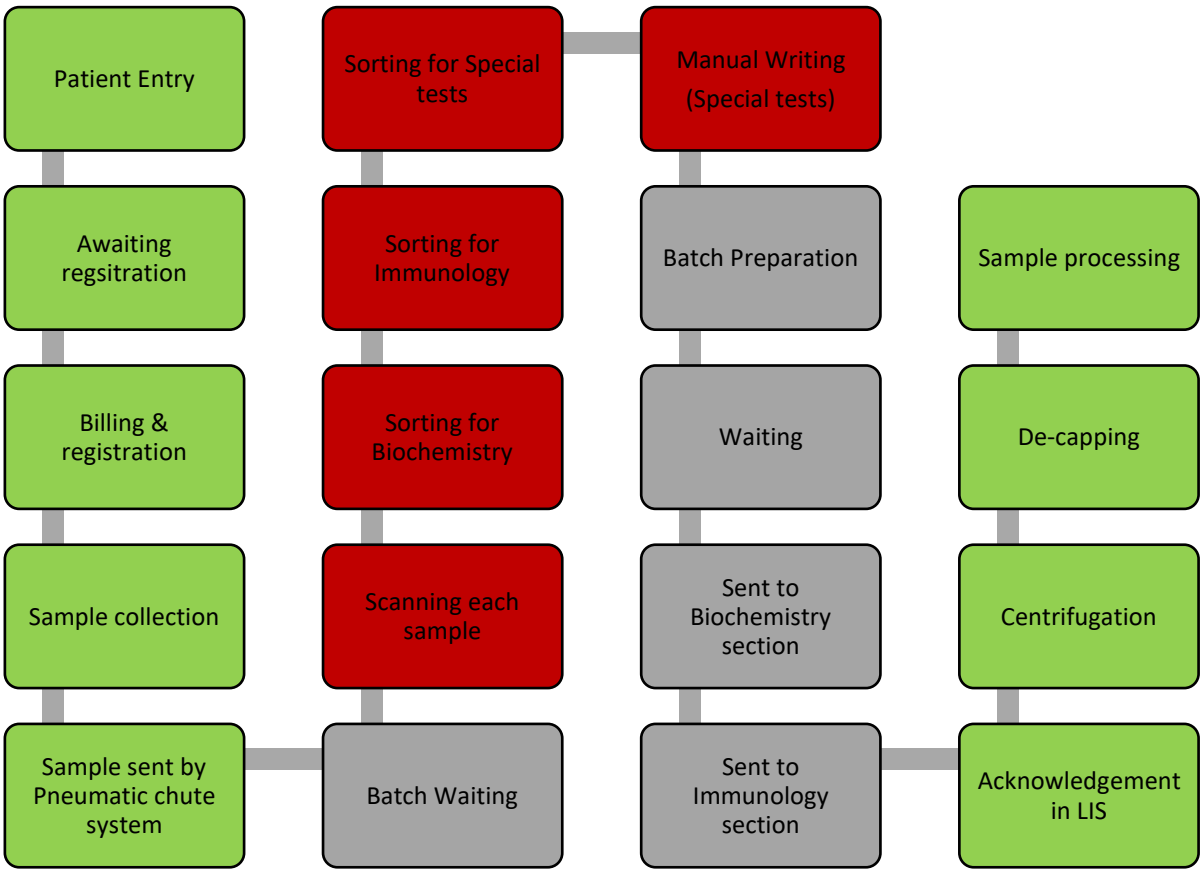

Figure 1: Pre –analytical process map of the laboratory in the pre-intervention phase

Analysis of Value stream Mapping was done for a total of 19 steps in the pre analytical phase of the preintervention period after which the value stream was divided into three categories, indicated by one of the three colours – Green, Red, Grey. Green indicated the mandatory steps adding to patient care, Grey indicated mandatory steps but could be improved using better strategies or methods & Red indicated steps which could be eliminated using a process change (Fig.1)

Sorting was essential as Biochemistry & Immunoassays were processed on two different standalone analysers. This created the need to collect one extra serum vacutainer tube in order to save on TAT. The two vacutainer tubes collected were then divided based on tests (Biochemistry or Immunoassays) & then transported to respective sections.

Analysis of workflow study: Operator motion in the laboratory was mapped to identify non-value-added activities due to scattered workload pattern. After analysis of the workflow, the major bottlenecks identified were as follows:

1. Pre-analytical waiting time - The major bottlenecks which led to delay in turnaround time (TAT) 40 minutes was due to sorting. Sorting was essential due to scattered workload.
2. Operator motion – Causing a delay of 15 minutes.
3. No dedicated Sample Receiving Area – Leading to batch preparation & waiting.

- IMPROVEMENTS AND CONTROL:

Improving the Process for better turnaround time (TAT)- The intervention suggested was an integrated platform (VITROS XT 7600, Ortho-Clinical Diagnostics, New Jersey, USA) for analysis of Biochemistry and Immunology samples. This instrument was installed in August 2020. As an improvement after measurement and analysis, a dedicated Sample Receiving Area of 40 square feet for faster delivery of sample after sample collection was also introduced to the workflow of the laboratory.

Comparison pre and post intervention: With the intervention to restructure the laboratory workflow using a Lean-based approach and the main aim to eliminate non-value-added steps & enhance the value-added steps, the study compared January-March 2019 (Pre-covid) & January to March 2022 (Post-covid) data. Data was extracted from the laboratory information system (LIS) for both periods. This study compared 2 individual

instruments for Clinical Chemistry & Immunology with an integrated platform. TAT was calculated from sample collection till result generation and compared between January to March of 2019 and 2022. The consumption of vacutainers used for testing was also calculated as the integrated platform did not require separate tubes for Biochemistry & Immunology assays.

Results

1. OBSERVATIONS FROM VALUE STREAM MAPPING

Using the color code in mapping, it was observed that the red steps (scanning of samples for acknowledgement or lab acceptance, sorting of samples for Biochemistry & Immunology, Manual writing on samples for indication of any special tests, & transportation of samples to Biochemistry & Immunology), resulted in waiting time which led to delay in TAT.

The workflow in pre-intervention phase (2019) comprised of approximately 26% (5/19) of non-value-added steps. It was identified that sorting of tubes for Biochemistry & Immunology sections consumed about 30 to 40 minutes of the technician's time. Similarly, processes like sample acknowledgement, centrifugation and de-capping were duplicated as a result of two separate tubes for Biochemistry & Immunology. Elimination of non-value-added steps resulted in improvement of sample flow. The integrated system helped eliminate collection of one extra tube, sample sorting as per department, sample movement, separate centrifugation, separate de-capping. Sample flow was improved resulting in elimination of non-value-added steps & simplifying the workflow. (Fig 2)

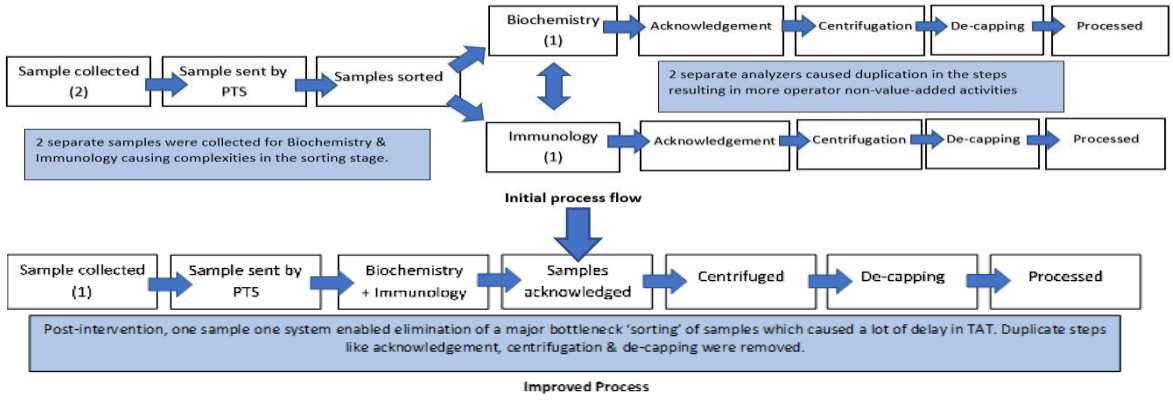

Figure 2: Improved Process

This sorting step involved a significant amount of technician's time (40 minutes). Sorting also resulted in high movement of staff between the two sections, Biochemistry & Immunology. Sorting & manual writing (for special tests) also led to batch preparation which resulted in increased waiting time thereby delaying TAT. No dedicated sample receiving area lead to pre-analytical waiting which led to delay in the sorting process. It was observed that the pre-analytical waiting due to sorting of samples for Biochemistry & Immunology was high (40minutes). Sample movement which led to technician movement also resulted in a delay of approximately 15 minutes. Laboratory team analyzed the TAT data which was extracted from LIS. The analysis concluded that the TAT achievement or compliance for Biochemistry and Immunology samples was 31% and 74% respectively for the year 2019. It was observed that additional vacutainer was collected for same sample type (Serum).

2. OBSERVATIONS FROM STUDY OF WORKFLOW:

- Scattered workload resulted in increased motion of technicians between 2 analyzers (Biochemistry VITROS 4600, Ortho Clinical Diagnostics, New Jersey, USA & Immunology VITROS 3600 Ortho Clinical Diagnostics, New Jersey, USA) (Fig 3). Duplication of steps like sample acknowledgement, centrifugation, de-capping was observed. A 30-minute tracking of operator showed 18 minutes of non-value-added activity like movement, sorting, manual writing, etc. Only 12 minutes of value-added activity was captured like sample processing, centrifugation, and result check and update the test results.

- No dedicated sample receiving area was causing lot of preanalytical waiting of the samples.
- Operator activity & motion was reduced to a great extent as one tube one machine concept removed the complexities in the workflow. (Fig 3). It also resulted in consolidated QC/Calibration practices.
- About 100 sq feet of space was saved in the Immunology section area which was subsequently utilized for Microbiology expansion
- In the pre-intervention phase, between 5 pm to 7 am (evening & night shift) both the Biochemistry & Immunology sections were handled by a single technical staff (1 Full time equivalent, FTE). This led to a lot of movement of staff between the two sections. The introduction of integration eliminated the staff movement between these areas and a lean workflow could be established.

Figure 3: Reduced operator motion post-intervention

3) TAT IMPROVEMENT

This workflow improvement resulted in minimizing the bottleneck at the sorting stage due to the scattered workload pattern affecting the TAT. The laboratory handled 1,56,193 tests between January to March (2019) & 1,57,703 tests between January to March (2022) indicating a stable workload. For TAT analysis, both reduction in TAT and TAT compliance scores were analysed. It was observed that there was a 26% (p value < 0.05) reduction in the average TAT for Biochemistry & Immunology assays Upon further analysis, it was found that the Biochemistry assay average TAT reduced by 32% (p value < 0.05) while the Immunology average TAT reduced by 11%, (p value < 0.05). (Table 1)

Table 1: TAT improvement post intervention

	Pre-intervention phase (2019)	Post - intervention phase (2022)	% reduction in TAT	P value (<0.05 = Significant)
Total tests processed	1,56,193	1,57,703		
Total average TAT in minutes	175	129	26%	< 0.05
Biochemistry average TAT in minutes	171	115	32%	< 0.05
Immunology average TAT in minutes	185	164	11%	< 0.05

A target TAT of 120 minutes was set for Biochemistry assays & target TAT of 180 minutes was set for Immunology. The compliance score for both the sections was calculated and it was observed that the TAT compliance for Biochemistry was 31% in 2019 & 72% in the year 2022. The TAT compliance for Immunology was 74% in 2019 & became 80% in the year 2022. Hence, the TAT compliance for the Biochemistry tests improved by 41% & 6% for Immunology tests.

A target TAT of 120 minutes was set for Biochemistry assays & target TAT of 180 minutes was set for Immunology. The compliance score for the both the departments was calculated and it was observed that the TAT compliance for Biochemistry was 31% in 2019 & 72% in the year 2022. The TAT compliance for Immunology was 74% in 2019 & became 80% in the year 2022. Hence, the TAT compliance for the Biochemistry tests improved by 41% & the TAT compliance for Immunology department improved by 6%.

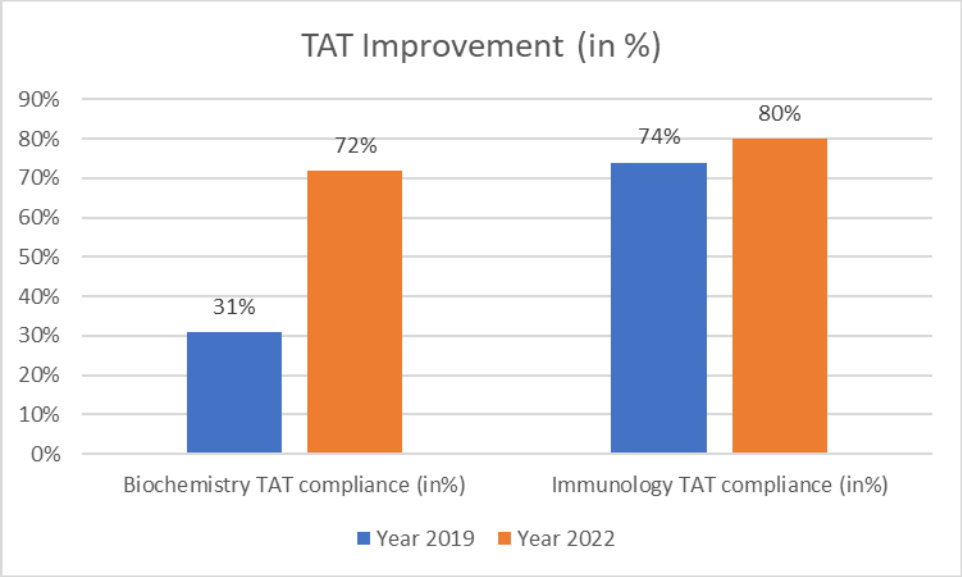

Figure 4: Average TAT Improvement

TAT analysis was also done on some high volume analytes from Biochemistry & Immunology *which* showed significant improvement. (Table 2)

Table 2: Parameter-wise TAT improvement

Sr.No.	Parameter(s)	TAT compliance in 2019 (in %)	TAT compliance in 2022 (in %)	% Improvement	p Value (if <0.05 = significant)	Average TAT in 2019 (in mins)	Average TAT in 2022 (in mins)	Improvement in Average TAT (%)
	Biochemistry							
1	C-reactive Protein	41%	63%	**22%**	<0.05	117	102	13%
2	Electrolytes	44%	77%	**33%**	<0.05	142	96	33%
3	Renal Function Test	20%	75%	**55%**	<0.05	185	122	35%
4	Lipid	22%	71%	**49%**	<0.05	180	106	42%
	Immunology							
1	Thyroid Function Test	73%	83%	**10%**	<0.05	173	145	17%
2	HIV HVC HBsAG	75%	83%	**8%**	>0.05	295	141	53%
3	Prostate-Specific antigen (PSA)	79%	84%	**5%**	<0.05	165	139	16%
4	Vitamin D	83%	85%	**2%**	<0.05	150	135	10%

Clinical Chemistry analytes like C- reactive protein (CRP) showed an improvement in TAT compliance from 41% to 63%. TAT compliance score for electrolytes increased from 44% to 78%. Renal function tests (RFT) also showed a significant improvement from 20% to 75% while TAT compliance score for Liver function tests (LFT) improved from 22% to 71%.—For Immunology analytes like Thyroid function tests (TFT) the TAT compliance improved by 10% (from 73% to 83%), Viral markers (HIV, HVC & HbsAg) showed an improvement of 8% (75% to 83%).

In addition to the improved TAT of test results, positive outcome in finance, human resources and utilization of work space were noticed.

COST REDUCTION AS AN OUTCOME

The standard practice for collection of vacutainer tubes from a patient with test requests for Biochemistry & Immunology was 2 in 2019. This was as a result of scattered workload between 2 different analysers. Post intervention an integrated analyser for Biochemistry & Immunology helped in creating a seamless consolidated workflow

pattern. The consumption data for vacutainer tubes, was extracted from the purchase department records for the pre and post intervention period (2019 vs 2022). The data showed a reduction in the number of tubes required for Biochemistry & Immunology tests to 1 from 2. This intervention thus contributed to saving of more than 2400 tubes per month which resulted in saving **US $ 2075 /year.** This resulted in decreased number of vacutainer tube inflow into laboratory.

HUMAN RESOURCE OPTIMIZATION AS AN OUTCOME

The number of manpower required in the Biochemistry & Immunology laboratory reduced to 6 FTE from 9 FTE. The manpower was then optimized in other departments like Molecular testing and Sample Receiving Area of the laboratory. The number of manhours in the pre-intervention period in Biochemistry & Immunology was 1,31,400 hours/year which could be reduced to 87,600 hours/year (43,800-man hours per year, 33% reduction) with cost savings of US $ 30,000 per year. (Table 3)

Table 3: Human resource optimization in the post intervention phase

	7 am to 5 pm	**5 pm to 7am**	**Man hours per year**
2019	7 FTE	2FTE	131400
2022	4FTE	2FTE	87600

Space Optimization

Laboratory was also struggling with space due to the scattered workload, with two different analysers for Biochemistry & Immunology. The integrated platform reduced the analyser footprint and helped the laboratory save 100 square feet of space.

Discussion

The clinical laboratory plays a key role in managing patients. Often laboratory results are responsible for the diagnosis of disease conditions not suspected clinically. Accuracy of laboratory results therefore is the key to all testing processes. The clinical laboratory is a complex space wherein many processes are performed involving multiple steps of activity performed by a large number of technologists and other support staff working together. [4] As the dependence on laboratory results increased, there is demand to improve TAT & efficiency of the clinical laboratory.

In the present study, the process was analysed from the start of billing to specifically highlight any pre-analytical delays or steps having a scope for improvement (duplication in steps). In the present study, only the pre- analytical phase was selected for Value stream mapping as it is known for inefficiencies and higher error rate. ([20,21])

VALUE STREAM MAPPING

Value stream mapping helped the laboratory identify the bottlenecks in the pre-analytical stage i.e. the sorting of samples for Biochemistry & Immunology parameters, which resulted in waiting or delay in the analytical process. This scattered workflow pattern also resulted in a non-lean flow in the laboratory which caused high technician movement & sample movement in the lab. Hung et al also used VSM to improve surgical specimen handling thereby reducing human errors and increasing safety and efficiency. [22] In this study by using VSM, we could identify 40 minutes of non-value added (NVA) time in the pre analytical phase. Anderson et al similarly used VSM to identify 22 minutes of NVA in their phlebotomy area which could be optimised by a series of interventions like automated phone system, additional phlebotomy station, patient wait time display, designated courier pick-up points, and task redistribution.[23] Alain et al [24] found 62% of NVA in their laboratory workflow right from patient reception, sample assemblage to result reporting which could be entirely eliminated using lean methods. TC Inal et al [8] found that the pre-analytical process in the reception area was improved by eliminating 3 h and 22.5 min of non-value-adding work. As an example of how non-value-added work can cause safety issues, in their study 25-30% of all sample were erroneously labelled due to low quality of barcode and less trained workers. Consequently, after improvement on similar aspects, steps prone to medical errors and posing potential biological hazards to receptionists were reduced from 30% to 3%.

In current study, after initial value stream mapping (VSM), the laboratory decided to consolidate the workflow by switching to an integrated analyser for Biochemistry & Immunology. Integration resulted in eliminating the collection of two tubes for Biochemistry & Immunology, and thus eliminating the sorting process as per department. We concur with Prakash et al [2] who state that Automated sample transport & acquisition system, automated laboratory analyzers, automated

reflex testing, automated acquisition of results by integrating machines and laboratory information system, automated quality control systems and automated human resource processes are few examples of process automation in a clinical laboratory. Process automation not only improves precision but also reduces cost of operation and increases safety. Integration also helped save 100 square feet of space which was utilised for Microbiology services expansion. A dedicated sample receiving area to acknowledge all samples could also be created through space optimization.

In a review by Prakash et al [2] cites study by Karine B et al found "wastes" that increased the process time lead to increased waiting time at the reception. Using lean management as an improvement plan, the authors reported reduction or elimination of waste in processes and increasing customer satisfaction, mainly by reducing the waiting time, which is extremely important when considering healthcare delivery. B Umut and PA Sarvari [23] reported that in their cathlab for creatinine test delays, after implementing Lean concepts, the sample delay which was due to batching, improved after introducing as-is basis, from 60% delay to only 23% of sample delays. The major bottlenecks which led to delay in turnaround time (TAT) of 40 minutes in this study was due to sorting, which works out to 20% delay considering total TAT of 175 mins (Table 1). Hence, this clearly highlights the importance of Value stream mapping tool for any lab to identify "waste" in processes and improve its efficiency & workflow.

TURN-AROUND TIME

Improving laboratory TAT is one of the most important opportunities for quality improvement in a clinical laboratory.[25] Thus, TAT is also the most frequent metric studied following the introduction of lean principles with clinical laboratories TAT being the most recurrent settings.[25]In our study, the overall TAT reduced by 41 minutes (175 minutes preintervention to 129 minutes post intervention), indicating the utility of VSM and integration.

Letelier at al [10] used the lean management principles to reduce the TAT for glucose and haematocrit by using redesigning their pre-analytic process. Alain et al [24] used Value stream mapping to improve the process flow within their laboratory and reduced their average TAT from 503 minutes to 191 minutes. [24] In the study by TC Inal et al [8], turnaround time improved for stat samples from 68 to 59 min after applying Lean. FH Ronny et al [15] reported 12 months mean ED CMP TATs before the lean assessment move as 44.4 minutes with 90% of results reported in 60 minutes or less; after the move this improved to a mean of 37.1 minutes with 90% of results reported in 49 minutes or less which works out to reduction in TAT mean by 16% and 90% TAT achievement improvement by 18.3%. Gupta et al [26] from India also demonstrated a reduction in average TAT of 48% in the haematology laboratory and 23% in the biochemistry laboratory using the VSM and lean management.

This compares well with our study results where there was reduction in TAT by 26% (46 mins out of total 175 mins) overall across sections in biochemistry laboratory (Fig 4). As regards compliance to target TAT, I Ibrahim et al [11] in Egypt reported compliance to timeliness to inpatient reporting was much lower at 35%, reaching 60% after improvement using DMAIC methodology, which is improvement by 25%. In our study, the compliance rate improved from 31% to 71% (Fig.5). AK Samantha et al [14] reported a reduction of mean TAT in their study using LSS approach from 164 mins to 83 mins whereas our finding of TAT reduction was from 175 mins to 129 mins (Fig.4). The higher rate of reduction observed by Ak Samantha et al could be due to the low sample size. Shilpasree et al [27] reported a 31.34-minute reduction in TAT for reporting electrolytes from the emergency services department after introduction of lean methods. In our study, we could reduce our electrolyte reporting TAT by 46minutes (33%) in the post intervention phase.

DIRECT COST REDUCTION

In 2022, Tlapa et al [25] in the systematic review to study effectiveness of lean methods noted that there was scarce data on cost savings from these interventions. [25] Amati et al [28] from Switzerland reported potential savings of 1500 CHF per room per day in the operating room set. [28]. Bhatt et al [29] from India reported annual potential savings of US $ 20,000 in the medical records department. Lee et al [30] from USA reported emergency department cost reduction and savings in penalties of US $ 29.1 million between 2008 to 2012. Based on a large survey of 31 Jordanian hospitals who undertook lean management as improvement tool, AA Abdullah [3] reported that there was 80% reduction in operational cost in addition to 60% of reduction in cycle time and many other benefits. This was result of capacity increase, less mistakes and rework, less paperwork and less material used. In 2023, Thakur et al [31] from Canada used the Lean Six Sigma approach DMAIC process to modify their quality control (QC) processes and bring in 26% reduction in their QC costs. Our study

reported US $ 2075 per year of cost savings on the number of vacutainers after the integration of analysers.

HUMAN RESOURCE OPTIMIZATION

As an outcome of LSS implementation, this hospital saved on 43, 800 man hours/year which was a 33% reduction from the pre-intervention phase. This amounted to cost savings of US $ 30,000/ year. This is the first study from India reporting on cost savings in a clinical laboratory setting with adoption of integration and lean methods. A similar outcome was stated by A Abdallah [3] in a case study of a hospital from Jordan where operational cost could be reduced by manpower resource management.

PATH FORWARD

Prakash et al [2] mentioned that the healthcare managers need to be made aware that "lean" is not with respect to staff or quality but rather pertains to wastage. As per A Abdallah et al [3], the implementation rate of the LSS approach in healthcare is low. This could be because the failure rate for implementation is high at 70% of the Lean projects failing. The author cited lack of knowledge in Lean management practices as one of the reasons for failure. Among the factors which contribute to success of Lean projects, the author cited leadership, having a clear goal in advance for lean projects, and adequate training of the workforce as key factors. We recommend clinical laboratories similar to our set up to consider Lean six sigma approaches for quality improvement in areas which are identified as immediate need.

LIMITATIONS OF THE STUDY

There were some limitations in our study. First, this study was conducted in a single hospital and the findings may not be generalized to all institutions as they have a different SOP, manpower, etc. for the laboratory process. Secondly, comprehensive analysis of direct and indirect cost reduction as an outcome could not be undertaken. However, it has to be noted that our findings and implementation of the LSS strategy may be of importance to another similar laboratory that aims at quality improvement.

Conclusion

With the help of Process Excellence methods like Value stream mapping, the laboratory identified bottlenecks at the pre-analytical stage due to non-value-added activities. Specific interventions like integration of the Clinical Chemistry & Immunology analyzer with central specimen receiving station the TAT compliance score improved by 41% and 6% for Biochemistry & Immunology assays respectively. The laboratory could also optimize their space, manpower and show potential savings of USD $ 32075/- per year.

Conflict of Interest

PJ, Dr.K KD were employed by the company Ortho Clinical Diagnostics. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationship that could be construed as a potential conflict of interest.

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