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Evaluation of the Effectiveness of Lean Six Sigma Approach for SARS-CoV-2 RT-PCR Turnaround Time (TAT) Improvement at a Hospital-Based Tertiary Laboratory

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ABSTRACT

Objectives. This study aims to evaluate the effectiveness of the Lean Six Sigma approach in improving procedure for (TAT) of reverse transcriptase polymerase chain reaction (RT-PCR) for SARS-CoV-2 testing at The Medical City. Specific objectives of the study are to determine the following: 1) baseline sigma and average TAT (in hours); 2) post-implementation sigma and average TAT (in hours) 3) compare if there is a significant improvement between baseline and post-implementation sigma and average TAT (in hours) 4) effect on workflow efficiency.

Methodology. Lean Six Sigma method for quality improvement was applied using DMAIC: Define, Measure, Improve, and Control. The root causes identified were lack of manpower, equipment, space, and manual and complex processes. Then, process wastes were identified, and corresponding proposed solutions were sustained in the control phase, such as standardization and the use of automation. Measurement of turn-around time and six sigma of the process were performed for evaluation.

Results. Results showed a significant improvement in the TAT in RT-PCR results, with most results released within 24 hours. The pre-Lean Six Sigma data on TAT were as follows: 24.88% released within 24 hours; 65.14% released within 24-48 hours; 3.56% released within 48-72 hours, and 6.42% released in more than 72 hours. The post Lean Six Sigma TAT were as follows: 95.32% released within 24 hours; 4.29% released within 24 to 48 hours; 0.13% released within 48-72 hours, and 0.12% released more than 72 hours. The computed sigma post-implementation was increased from 3.56 to 4.82. The *p*-value was calculated using the chi-square test, and the computed chi-square statistic is 1894.1021. The *p*-value is <0.00001 and the result is significant at $p<.05$. Although there is a significant decrease in the volume of samples post implementation due to the changing COVID-19 situation, real time TAT was improved. It also resulted to increased workflow efficiency with the use of lesser manpower with more appropriate utilization.

Conclusion. Applying the Lean Six Sigma method to improve quality processes in the laboratory is shown to be practical, cost-effective, and straightforward.

Key words: Lean Six Sigma, SARS-CoV-2, turnaround time

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INTRODUCTION

Background

When the novel coronavirus (COVID-19) pandemic hit the Philippines in the year 2020, there were only a few laboratories capable of performing reverse transcriptase polymerase chain reaction (RT-PCR) testing for SARS-CoV-2. During this time, there were significant delays in the release of results, as laboratory healthcare workers were overwhelmed by the surge of specimens from all over the country. One of the biggest challenges that our laboratory faced was the tedious manual process covering the different phases of testing. All results were manually encoded, including government regulatory requirements such as line lists and certifications. There was increased utilization manpower and even misutilization because even those with different job descriptions such as pathologists, residents, medical technologists, allied medical professionals were performing encoding tasks beyond the working hours. In these situations, a management tool such as the Lean Six Sigma (LSS) approach can be useful for quality improvement.

Since the late 1990s, the application of LSS in the manufacturing industry has come a long way.[1,2] Six Sigma is a quality management strategy that makes efforts to improve the quality of processes, utilizing the DMAIC process (Define, Measure, Analyze, Improve, and Control).[3] The "Lean" concept, on the other hand, is also a powerful quality-improvement tool that focuses on providing "value" and improving performance by systematically eliminating waste or non-value-added activities, from the process.[1,3] Combined, LSS becomes even more effective, with increase in popularity In the field of healthcare, even in laboratory medicine. This might be due to the fact that quality in healthcare is hard to measure but using this approach provides metrics to be able to make better assessments. In addition, oftentimes it is also hard to justify allocation of resources for process improvement without an evidence-based or data driven approach.

We used LSS to improve the quality of SARS-COV-2 RT-PCR testing in our laboratory. We aim to evaluate the overall effectiveness of this approach in improving the TAT and workflow efficiency of RT-PCR procedure for SARS-CoV-2 testing at The Medical City.

METHODOLOGY

Population and sample

The study population included all samples submitted for SARS-CoV-2 RT PCR testing from April 2020 to May 2021. There are 73,998 tests within this period.

Inclusion and exclusion criteria

The study includes all SARS-CoV-2 RT PCR testing samples, whether oropharyngeal, nasopharyngeal, nasal/oropharyngeal swab, sputum, ETA, and other body fluids with correctly labeled samples, placed in correct containers and with filled up case investigation form (CIF). Samples with incorrect containers, mislabeled specimens, no CIF, and discrepancies in CIF were excluded in the study.

DMAIC process

The study was conducted within the Clinical Pathology section of the Department of Laboratory Medicine and Pathology, The Medical City. A Lean Six Sigma process involved the DMAIC process as follows:

1. **Define phase**, a project charter was made which includes the project objectives, importance, the scope, responsibilities of each member, budget/ resources, expectations/ assumptions, and timelines. A SIPOC diagram (suppliers, input, process, output, and customer) was performed to outline and give the appropriate scope of the process involved (Figure 1). Voice of the customer included informal feedback from the internal and external customers regarding the TAT of RT-PCR results.
2. **Measure phase**. The study included all samples submitted for SARS-CoV-2 RT PCR testing from April 2020 to May 2021 at The Medical City. Data were extracted from the laboratory database, which records information about the patient's assigned accession number, date of specimen received in the laboratory, and date result was released. Data collected were encoded and tabulated using Microsoft Excel 2019. Patients were identified only through their control numbers. TAT was categorized as to whether a sample was released within the following number of hours: within 24 hours, 24 to 48 hours, 48 to 72 hours, and more than 72 hours. Baseline sigma was calculated, as well. A detailed process map was done to lay out the entire process, which included the exact time of each step (Figure 2).
3. **Analyze phase**. The Analysis stage was conducted by brainstorming and a fishbone analysis diagram. From the detailed process map, the wastes were identified. Tools such as the fishbone diagram (cause and effect diagram) were utilized during the brainstorming to identify all the possible causes (Figure 3). All the reasons were analyzed using the effort impact diagram (Figure 4).
4. **Improvement phase**. The effort impact diagram (Figure 4) showed the best solutions to the problem, which was implemented using various tools. The 5S and the lean approach were utilized, which include auto-stop and error-proofing using automation.
5. **Control phase**. Implementation of the control and feedback system. In this stage, the corrective actions were evaluated to determine whether they led to performance improvements in the analysis process. A quality control plan was implemented to improve the TAT and the process continuously.

The project was divided into the following phases: a) process/procedure standardization; b) evaluation of corrective actions: evaluation involved data analysis, brainstorming activities, identification, and control of key performance indicators; and c) continuous improvement:

Supplier	Input	Process	Output	Customer
Messenger	CIF forms	Pre-encoding	Draft of line list Patient profile Charges	Residents
Molecular Medical Technologist	Graphs from PCR results	Interpretation	Excel with interpretation	Clerk
Molecular Medical Technologist and Consultant Pathologists	Worklist Excel results Orion Profile of patients	Typing	Typed results in Orion	Consultant Pathologist
Clerk	Worklist with results	Validation	Printed results	Residents
CIF encoders and clerk	Draft line list Worklists/reports	Line lists	Line list for Positive patients Line list for Negative patients	DOH

Figure 1. SIPOC diagram (post analysis).

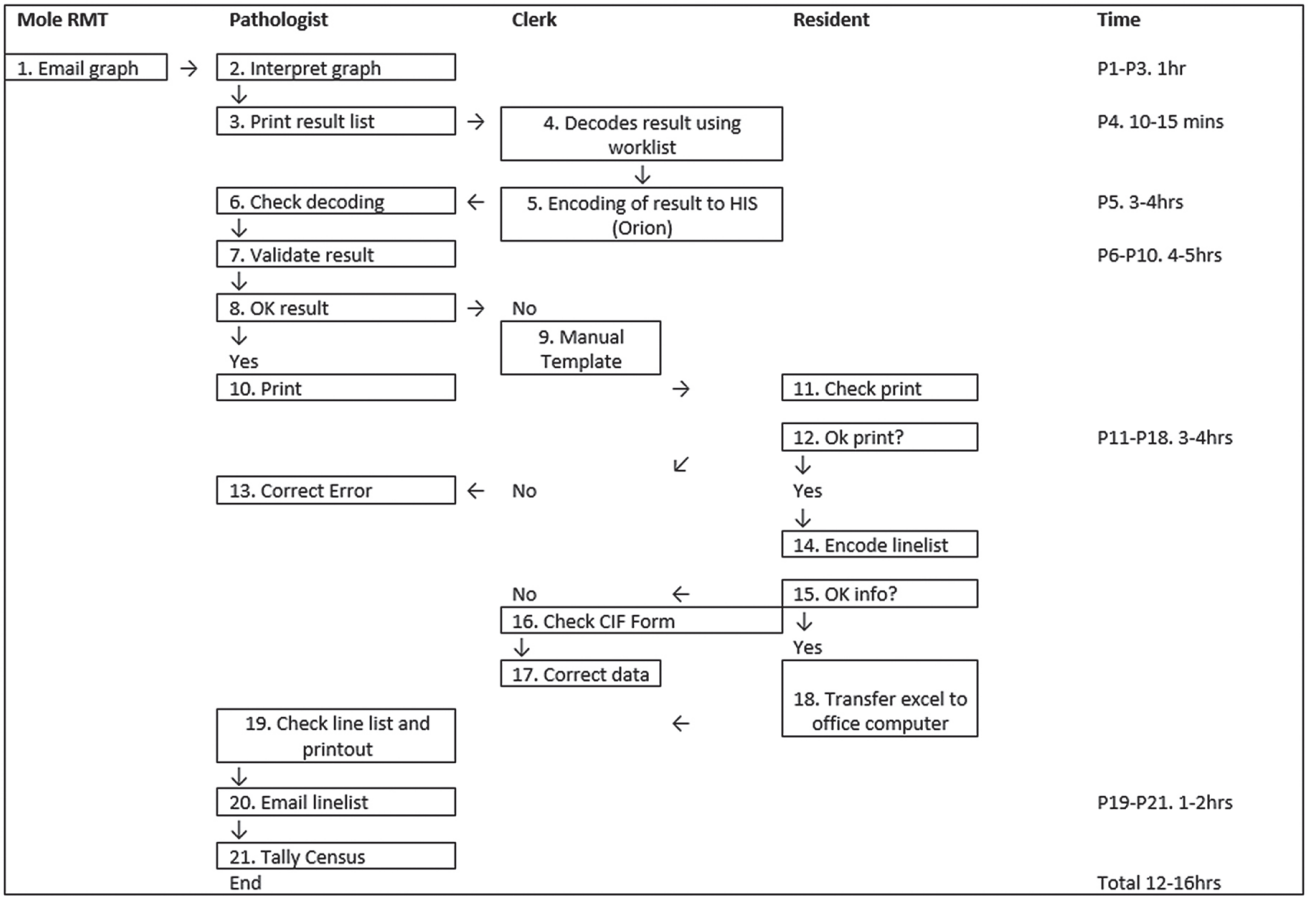

Figure 2. Detailed process map (post analysis).

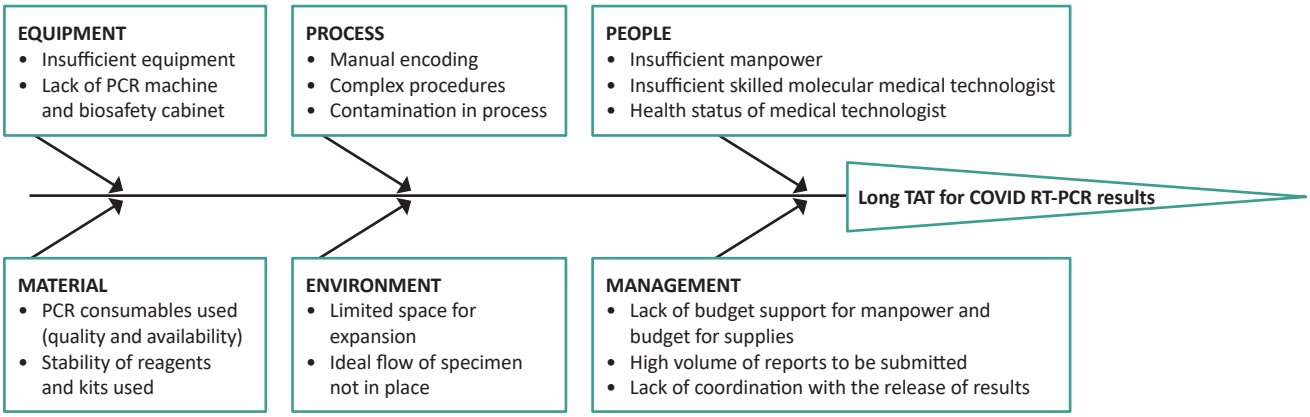

Figure 3. Fishbone analysis diagram.

staff training system, automation of the process through the Laboratory Information System (LIS).

Analysis

After data were collected and encoded using Microsoft Excel 2019, TAT was categorized as whether a sample was released within the following number of hours: within 24 hours, 24 to 48 hours, 48 to 72 hours, and more than 72 hours. The TAT is determined by subtracting the date the specimens were received from the date the results were released. Six sigma computation was performed by counting the defects, and opportunities and computing the process yield, using the formulas:

Formula 1: Yield = (1-DPO) x 100
Formula 2: DPO = D / N x O

Where:

O = determine the number of defect opportunities per unit.
N = determine the number of units processed.
D = determine the total number of defects made (Include defects caused and later fixed)

TAT analysis was performed for all RT-PCR tests from the start of operations defined as "pre-Lean Six Sigma" data (from April to November 2020) and compared with

Table 1. Lean Six Sigma table

Sigma level	Defects per million opportunities	Percentage yield
1	691,462	31
2	308,537	69
3	66,807	93.3
4	6,210	99.38
5	233	99.977
6	3.4	99.99966

data gathered after the Lean Six Sigma improvement phase (December 2020 to May 2021) labeled as "post-Lean Six Sigma" data. Refer to the Sigma Table (Table 1) to determine the Sigma in the process. To compare if there is a significant improvement between baseline and post-implementation sigma and average TAT (in hours), we calculated the p-value using the chi-square test with the formula below. We used <72 hours and >72 hours in computing for the chi-square test, since 72 hours was the prescribed time of release of SARS-CoV-2 RT PCR results by DOH at the start of pandemic.

$$\chi^2 = \sum_{i=1}^{c}\sum_{j=i}^{r} \frac{(\textbf{Observed value}_{ij} - \textbf{Expected value}_{ij})^2}{\textbf{Expected value}_{ij}}$$

Where different values of P indicate the different hypothesis interpretations, are given below:

$P \leq 0.05$: Hypothesis rejected.

$P > .05$: Hypothesis Accepted.

RESULTS

The pre-Lean Six Sigma data on TAT were as follows: 24.88% released within 24 hours; 65.14% released within 24-48 hours; 3.56% released within 48-72 hours, and 6.42% released in more than 72 hours (Table 2). The post Lean Six Sigma TAT were as follows: 95.32% released within 24 hours; 4.29% released within 24 to 48 hours; 0.13% released within 48-72 hours, and 0.12% released more than 72 hours. There was a significant improvement in the TAT, with most results released within 24 hours. The baseline sigma was also computed at 3.56, and after implementation of Lean Six Sigma, it increased to 4.82 (Table 3).

To compare significant improvement between baseline and post-implementation on average TAT (in hours), we calculated the p-value using the chi-square test. The computed chi-square statistic is 1894.1021 (Table 4). There was a significant difference in the (TAT) of RT-PCR for SARS-CoV-2 testing after applying the Lean Six Sigma Approach.

DISCUSSION AND CONCLUSION

The root causes of the long TAT identified during the Lean Six Sigma implementation were insufficient manpower, space, equipment, manual processes, complex procedures, and high workload volume (Figure 3). Among these, manual encoding, insufficient equipment, and lack of manpower were identified to give the highest impact on the long TAT of results, hence they were shown the highest priority for improvement (Figure 4). TAT has significantly improved due to eliminating the wastes by utilizing auto-stop and error-proofing techniques by automating manual processes using the LIS. The 5-S was also executed to organize the workplace, maximize flexibility, minimize motion, and generally eliminate workplace waste.

After applying Lean Six Sigma, there was a significant improvement in the TAT, with most results released within 24 hours compared with the pre-implementation TAT of

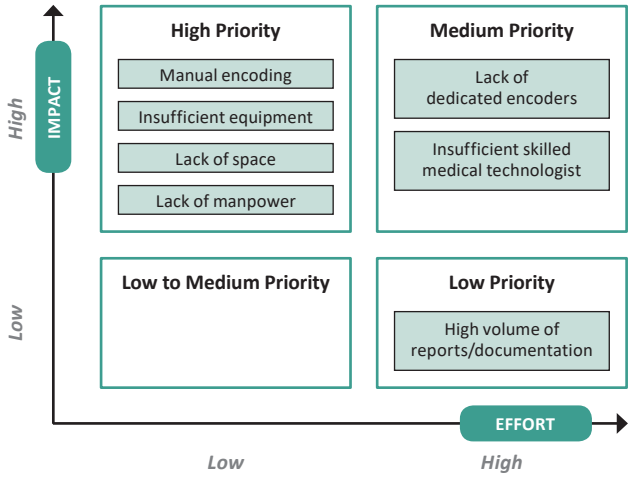

Figure 4. Effort impact diagram.

Table 2. Average TAT of RT-PCR for SARS-CoV-2, at The Medical City, pre-lean six sigma" data (from April to November 2020) and "post-lean six sigma" (December 2020 to May 2021)

TAT	Total number of cases released from April 2020 to December 2020	Percent of cases released %	Total number of cases released from January 2021 to May 2021	Percent of cases released %
Within 24 hours	10988	24.88%	28444	95.32%
24 to 48 hours	28764	65.14%	1320	4.42%
48 to 72 hours	1572	3.56%	40	0.13%
>72 hours	2834	6.42%	36	0.12%
Total	44158	100.00%	29840	100.00%

Table 3. Lean Six Sigma computation "pre" and "post" implementation

	Pre-Lean Six Sigma	Post-Lean Six Sigma
O	3	3
N	44158	29840
D	2834	36
DPO	0.02139	0.0004
Yield	97.86%	99.96%
Process Six Sigma	3.53	4.85

Table 4. TAT pre- and post-implementation of Lean Six Sigma approach

TAT of results released	Pre-LSS	Post-LSS	Total
Within 72 hours	41,324	29,804	71,128
More than 72 hours	2,834	36	2,870
Total	44,158	29,840	73,998

The computed chi-square statistic is 1894.1021. The p-value is <.00001, and the result is significant at p<.05. Degree of freedom (df) = 1.

48 hours. Six sigma of the process was also increased to 4.82 post-implementation from 3.53 pre-implementation. This can be interpreted using the sigma scale of 1 to 6. A performance that is close or higher than 6 indicates world-class performance with only 3.4 defects per million opportunities or a yield of 99.99966%. On the other hand, a low sigma level of 1 indicates 691,462 defects per million opportunities of 31% yield (Table 1). A low sigma value and a value less than three are considered unstable and unacceptable. This would likely cost a laboratory a lot of money, time, and effort to maintain the quality of test results.[4] Inclusion of six sigma allows for a quantifiable scale where quality can be measured, and improvement can be better monitored, especially when we want to see even small improvements in the process. The study results are comparable with other studies, where a significant positive change in TAT was observed after initiating and implementing the Lean process throughout their laboratory.[2,5,6] However, the impact of the Lean Six Sigma on TAT was reduced due to the significant drop in the number of samples received post implementation.

One of the limitations of this study is the unstable situation of the pandemic causing the lack of control in the volume of samples sent. The lower number samples sent may have contributed also to the improvement in TAT as well but the target TATs were achieved with more ease post implementation using lesser manpower. Previously, there were eight support staff, two residents, and two pathologists helping with the clerical work (a total of 12 people). After implementing the automated processes, this was reduced to eight administrative staff performing all the clerical work. These staff were also able to manage all the tasks other than producing results, such as answering concerns, emails, auditing, and even helping different sections in the laboratory. Typographical errors were also eliminated as most of the tasks, such as results generation, were automated through the laboratory information system. These results were similar to other studies where after implementation of Lean Six Sigma, the key performance metrics and workforce utilization has improved hence reducing staff and teams' idle time, resulting to cost reduction.[5] Although low volume sample during post implementation reduced the impact of LSS on TAT, there was notable improvement in manpower utilization and workflow which resulted in cost savings and improved customer satisfaction.[7,8] The study supports that Lean Six Sigma is an effective tool in improving processes in a workplace and can be highly adaptable in the laboratory setting.

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AUTHOR DISCLOSURE

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