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Evaluation of Quality Indicators with Lean Six Sigma in Pre- and Post-Analytical Laboratories

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ABSTRACT

Background & Objective: Medical laboratories play an important role of 60-70% in diagnosis, patient monitoring, and prevention and treatment of diseases. Therefore, the laboratory must maintain and ensure the quality of the service process. This study aims to determine the sigma value and identify waste in pre- and post analytical in the laboratory, as well as determine Improvement proposals in order to reduce errors pre and post analytical laboratory.
Method: This research design is a descriptive study that analyzes the process and quality indicators at pre- and post-analytical stages with the Lean Six Sigma approach, which is a combination of Lean methods that focus on eliminating waste and Six Sigma that focuses on eliminating defects. This research was conducted as a process Improvement effort with five Six Sigma work steps (DMAIC) and identified eight types of waste (DOWNTIME).
Result: The results showed that the sigma value at pre and post analytical was 4.6 and 3.5 Sigma, and the total sigma value for pre-post analytical was 4.3 Sigma, so that both had not met the minimum target achievement of 5 Sigma (Excellent). Two quality indicators require improvement and enhancement, including the suitability of the sample and TAT. The results also show that there are 4 wastes, consisting of 1 Defects, 1 Waiting, and 2 Not Utilizing Employees' Knowledge.
Conclusion: Proposed Improvements are then given so that all waste identified in this study can be minimized, so that the achievement of sigma quality indicators can increase.

Keywords: Lean Six Sigma; Pre-analytic; Post-analytic; Quality Indicator; Waste

INTRODUCTION

A medical laboratory is a laboratory that examines clinical specimens to obtain information about a patient's health related to diagnosis, management, disease monitoring, prognosis, and disease prevention (Kementerian Kesehatan, 2021). Medical laboratories play an important role of 60-70% in the establishment of diagnosis, monitoring of patients during hospitalization, and prevention and treatment of diseases. Therefore, the laboratory must maintain and ensure the quality of the service process (Sonmez et al., 2020). The process in the laboratory is divided into three stages, namely pre-analytical, analytical, and post-analytical (Fleming et al., 2017). Every stage in the laboratory can go wrong. According to Sawalakhe 2016, the source of laboratory process errors usually occurs in the pre-analytical stage of 62%, analytical 15%, and post-analytical 23% (Sawalakhe et al., 2016). Therefore, every stage of laboratory examination must be controlled. Control each of these stages to reduce or minimize errors that occur in the laboratory (Siregar et al., 2018).

Quality is getting the right results directly at all times and on time, using effective and efficient resources. This is important in all stages of the laboratory examination process, from sample receipt examination to test result reporting. The quality of a laboratory's output depends on several factors, one of which is the implementation and maintenance of a quality management system in a laboratory. The implementation of the quality management system on an ongoing basis will improve the quality of laboratory services and increase the competitiveness of the laboratory.

The laboratory quality management system is implemented with the Total Quality Management (TQM) Five-Q model strategy (Quality Planning, Quality Laboratory Practice, Quality Control, Quality Assurance, Quality Improvement) (Siregar et al., 2018). Because laboratory results have a large impact on patient diagnosis and management, it is necessary to prioritize focusing on quality improvement and corrective/preventive actions that can be taken to reduce errors that occur. Although there are few errors in the analytical stage due to quality control, standardization of reagent quality, policy regulations governing instrumentation, advances in information technology in the aspect of analytics, and the availability of more qualified and trained staff, quality cannot be guaranteed by focusing only on analytical procedures (Rahmania et al., 2019).

Quality indicators can be a reference for laboratory errors and error risks and highlight important processes/activities, including in the pre-analytical, analytical, and post-analytical stages in the laboratory. The implementation of quality indicators is proof of laboratory compliance with the requirements of the International Standard ISO 15189, as well as ensuring the quality and accreditation of laboratory services. The implementation and monitoring of quality indicators should be considered an important component of a continuous and reliable quality improvement program (Plebani et al., 2014).

However, the results of the use of quality indicators are often measured and reported using percentage variances. Percentage error results will cause errors to appear low when the low absolute number of variants is divided by a large number of inspection volumes. For example, based on quality indicator data, one of the hospital laboratories in Bandung, regarding the suitability of samples researched by Leitifa AA (2021), found errors in 188 samples out of 5457

total samples in September and errors in 222 samples out of 6790 total samples in October. If calculated as a percentage with a target of 100% quality indicators every month, then in September the quality indicator was achieved at 96.55%, and in October it was 96.73%. The achievement of the quality indicator target in October looks better if it uses percentages, but if you look at the errors, October has more errors compared to September. Therefore, the laboratory should not allow the percentage of errors to appear low so that it can give a false picture of good laboratory performance. This is more of a concern regarding the measurement and reporting of errors because it is necessary to remember that a low percentage of a large amount is also a large amount. There needs to be a measure of the results of quality indicators that provide assessments and solutions in each process to get better performance, minimize errors that occur, and encourage a sustainable quality program (Swetha et al., 2023).

To improve quality management in the laboratory, the Six Sigma methodology is often applied. The term Six Sigma is defined as a statistical measure of a process's capability, as a process of improvement strategies to identify, assess, and improve a process. The five-stage Six Sigma model that includes Define, Measure, Analyze, Improve, and Control (DMAIC) aims to continuously reduce errors through project definition by identifying problems, clarifying scope, and defining goals.

Six Sigma involves a continuous effort to reduce process variation to a minimum, so that the process consistently meets customer expectations and requirements (Pyzdek and Keller, 2018). To achieve the highest level of quality performance, the Six Sigma methodology is often combined with Lean Management (Huang and Kenneth J, 2016). Lean Management is a holistic systems approach and focuses on identifying and eliminating non-added value activities from a process (Sproul, 2019). Lean principles improve work processes, saving time, cost, and inventory. In the long run, it can increase speed, quality, profitability, and customer satisfaction. Lean identifies and eliminates waste, which is defined as all activities or things that do not provide added value (non-value added) and increase added value (value added) (Gupta et al., 2018). Waste categories based on the Lean concept consist of Defects, Overproduction, Delays (Waiting Time), Not Utilizing Employees' Knowledge, Transportation, Inventory, Motions, Extra Processing (DOWNTIME) (Gupta et al., 2018). Lean tools can function as a self-assessment to assist clinical laboratories in creating Quality Control strategies and planning the frequency level of Quality Control.

This has a good impact on the implementation of performance measurement into the laboratory's daily analytical processes, which can minimize inspection errors and maximize error detection, resulting in accurate inspections (Mao et al., 2018). The Lean Six Sigma (LSS) combination is then used to enable laboratories to reduce inefficiencies while monitoring and improving their quality performance (Inal et al., 2018).

OBJECTIVE

This study aims to determine the sigma value and identify waste in pre- and post-analytical processes in the laboratory, as well as determine Improvement proposals to reduce errors pre and post-analytical laboratory.

METHOD

This study uses a quantitative descriptive design that analyzes processes and quality indicators at the pre-analytical and post-analytical stages with the Lean Six Sigma approach. The object of the research used is quality indicator data at the pre-analytical stage and the post-analytical stage in the Laboratory. The research was conducted in one of the West Java Regional General Hospital Laboratories from March to June 2024. The data obtained is secondary data from the results of the evaluation of quality indicators from January to December 2023. The data processing used in this study is DPO (Defects per Opportunity), DPMO (Defects per Million Opportunities), and Sigma values. Then, the data was analyzed according to a combination of Lean Six Sigma with the stages of analysis methods for the process of define, measure, analyze, and improve. This research limits the problem by carrying out the DMAIC stages without controlling due to time and authority limitations. Therefore, this study focuses more on proposing laboratory improvements in the pre-analytical and post-analytical stages.

RESULTS

The Lean Six Sigma methodology can identify the root cause of errors occurring, and process improvement strategies can be developed. These methodologies are interrelated and complementary to each other, where Six Sigma is a method that targets zero errors (3.4 errors per million events) while Lean is a method that targets waste elimination that occurs in the laboratory. The implementation of the Lean Six Sigma methodology can measure and report quality indicators so as not to give a false picture of laboratory performance, where laboratories often use percentage variants in reporting their quality indicators. The error percentage result will cause the error to appear low when the low absolute number of variants is divided by a large number of examination volumes, giving a false picture of the laboratory's performance. The implementation of Lean Six Sigma also supports a sustainable laboratory quality program so that laboratory quality is guaranteed.

In the Define step, the results showed that in the suitability of the sample, clotted samples were 99.76%, hemolysed samples were 99.90%, and incorrect fill level by 99.83%, and turnaround times (TAT) of 95.54% were quality indicators with the lowest results of all quality indicators in January-December 2023. In the quality indicators of patient identification and reporting of critical values, there are very good results. This is because the process is very much paid attention to by the laboratory and has become a standard operating procedure (SOP). To be able to increase the target of achieving each quality indicator by reducing the defects that occur then becomes the goal of the implementation of Lean Six Sigma.

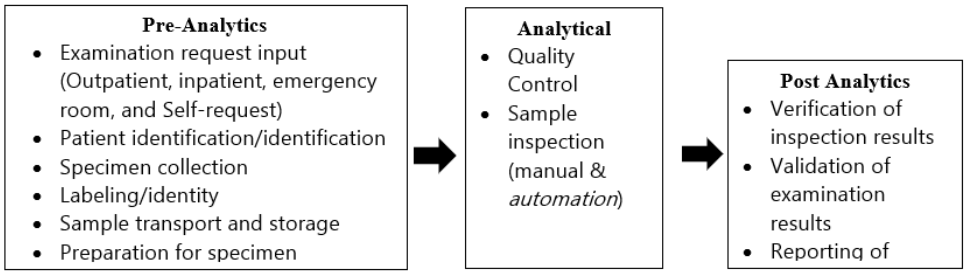

FIGURE 1. Laboratory Activity Process Map

After the activity of the process in the laboratory is known, the factors that will be Critical to Quality (CTQ) can be identified. In this study, the identified CTQ was determined based on the data of the monthly quality indicator report (Monthly Report) at the pre-analytical and post-analytical stages. The results showed that the two quality indicators in the pre-analytical stage had a total of five CTQs, while the two quality indicators of the post-analytical stage with the number of CTQs were two CTQs, so that all had a total of seven CTQs.

In the measure step, after the CTQ indicator has been determined in the Define process, it will then be selected which will be the focus of improvement and performance improvement through the sigma achievement target. The target of achieving sigma is used as a standard performance indicator of each CTQ, which has been determined by the Laboratory Installation of West Java Hospital, where this study was carried out. Each quality indicator at the pre- and post-analytical stages has a minimum target of achievement of 5 sigma. After that, the selected indicator is used as a basic measure in identifying and reducing process defects. The measurement is carried out by measuring process capabilities (Capability Measures) related to defects. The measurement results are produced on a sigma scale (Sigma Level). The results show that in both stages, both individually and combined, they have not met the minimum achievement target, where a value of 4.6 sigma was obtained in the pre-analytical stage, and 3.5 sigma in the post-analytical stage. So, there is a need for changes and improvements that need to be made.

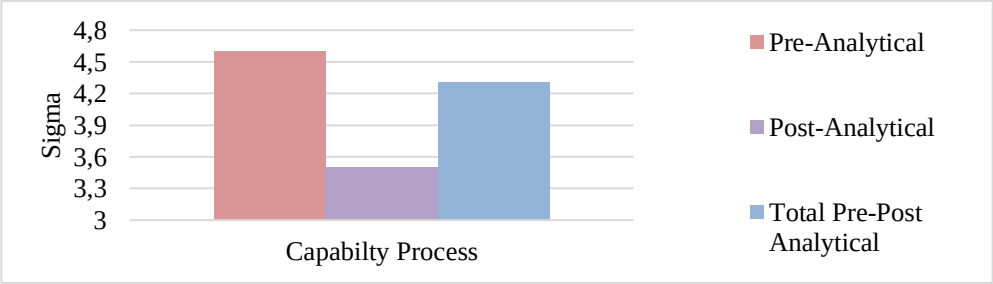

FIGURE 2. Graph of Total Pre and Post-Analytics Process Capabilities for the January-December 2023 period

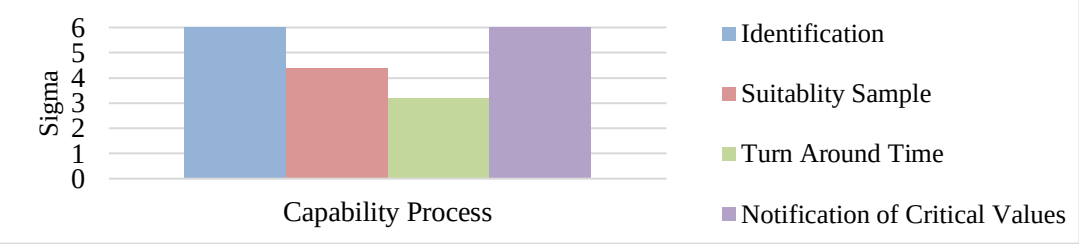

FIGURE 3. Pre and Post-Analytical Quality Indicator Process Capability Chart (January-December 2023)

The results show that several quality indicators have met the minimum target. In the pre-analysis stage, quality indicators related to sample suitability have not met the minimum achievement target. The conformity of the sample with a total of 4.4 Sigma was dominated by rejection samples (clotted sample 99.76%, hemolysed samples 99.90%, and incorrect fill level 99.83%) of the total samples examined, as the main cause, so that the quality indicators were not able to

meet the minimum achievement target. Meanwhile, in the post-analytical stage, the Turn Around Time quality indicator (TAT) has not yet met the achievement target. The TAT was obtained with a total of 3.2 Sigma, which is still far from the minimum achievement target.

In the analysis stage, it will identify several possible causes (X) of defect variations that affect the output (Y). After knowing the DPMO value and sigma level that reflect the process capability, a root cause analysis of the defect is carried out. Waste was identified by 5W+1H analysis (What, Where, Who, When, Why, How) on eight types of waste and root causes in the pre-analytical and post-analytical stages using a cause-effect fishbone diagram against quality indicators that have not met the minimum achievement target. Waste analysis with 5W+1H shows that it is determined through analysis according to the flow of work and where the error occurred and it can be seen that there are a total of 4 wastes that occurred, the most waste that occurred was Not Utilizing Employees Knowledge, found in two indicators that have not met the minimum achievement target. The next waste is in the form of Defects that occur in the quality indicator process for the suitability sample, while other waste in the form of waiting occurs in the TAT quality indicator.

In the pre-analytical stage, there is one indicator that is still below 5 Sigma, namely Sample Conformity. The discrepancy in the sample in the form of clotted, hemolysed, and incorrect fill level samples led to sample rejection during January 2023 – December 2023, so that the sigma value was obtained in the range of 4.3 - 4.6 Sigma with a total process capability during the period of 4.4 Sigma. In the post-analytical stage, there is one quality indicator that has not met the minimum target of achievement based on sigma standards during the period January – December 2023, namely the TAT. There are still inspection results with TAT > 2 hours or not by which causes the sigma value in the TAT indicator to range from 2.8 – 4.1 Sigma, with a total process capability during the period of 3.2 Sigma.

From the results of the comparison of the achievement of the quality indicator of the suitability of the percentage variant sample, it shows the achievement of the percentage variant, which is seen well (>99%), and the sigma value range is obtained between 4.3 – 4.6. The results of achieving highest percentage of variant quality indicators occurred in January and February, with an achievement of 99.66%, and the lowest in December, with an achievement of 99.29%. The results of achieving the highest sigma value quality indicators were also found in January and February, with a sigma value of 4.6, and the lowest in November and December, with a sigma value of 4.3. The achievement of the comparison of the quality indicators of the percentage variant turnaround time was obtained by the achievement of the percentage variant >90%, and the sigma value range was obtained between 2.8 – 3.5. The highest percentage of variant quality indicators occurred in March, with an achievement of 97.99%, and the lowest in September, with an achievement of 90.00%. The results of achieving the highest sigma value quality indicators are in March and October, with a sigma value of 3.5, and the lowest in August and September, with a sigma value of 2.8.

DISCUSSION

The quality indicators in this Laboratory Installation are still present and report quality indicator data using percentage variants. The percentage of variants often causes the results of the

calculation of the percentage of error to appear low when the low absolute number of variants is divided by the large number of test volumes. It is important to note that a low percentage of errors in a large number is also a large number, so laboratories should not allow a low percentage of errors in quality indicators to give a false picture of good laboratory performance. Therefore, it is necessary to have a measure of the results of quality indicators that provide assessments and solutions in each process to obtain better performance, minimize errors that occur, and encourage a sustainable quality program (Swetha et al., 2023; Westgard et al., 2018). The comparison of percentage variants and sigma values in measuring the achievement of quality indicators every month shows that a good percentage variant value does not necessarily have a good sigma value as well. The percentage variant can give a good impression in the achievement of quality indicators, not give the actual results. The observation and analysis in this study are focused on the quality that has not reached the minimum achievement target. There are quality indicators at the pre-analytical and post-analytical stages that have not met the minimum achievement target. Continuous evaluation and improvement steps are needed, especially in the post-analytical stage, so that defects and waste that have been identified can be minimized or even eliminated.

The sample suitability quality indicator is one of the quality indicators in the pre-analytical stage that has not met the minimum target of achieving 5 Sigma. Blood clot samples are the most inappropriate samples that come to the laboratory. To be able to provide the right improvement proposal, it is necessary to know why and how the blood sample is clotted. Clots/clots can form in every tube, including tubes with anticoagulants, even if they are not properly homogenized according to the procedure. Once a lump has formed in the tube, the sample should not be used for testing, as it will give an incorrect result. It is never appropriate to physically remove a blood clot from a blood tube. The tube must be discarded, and a new specimen must be retrieved (Lorenzo and SK, 2016; Sianipar, 2019).

Lysed blood samples occur due to the presence of cellular components in the serum/plasma that are released when red blood cells rupture. This can be caused by improper procedures for the collection, transportation, and processing of samples, such as incorrect techniques or difficulties during venipuncture, blood collection through an intravenous catheter, time to use a tourniquet, delayed centrifugation, and the use of pneumatic tubes. Lysed samples can give rise to significant bias results, such as falsely high yields of potassium, lactate dehydrogenase, iron, and magnesium (Sianipar, 2019). Hemolysis resulting from blood sampling can be caused by incorrect needle size, non-homogeneous tubes, incorrect tube filling, excessive suction, too long a tourniquet, and difficult collection (Azman et al., 2019). In case of sample discrepancies, it is recommended to provide a continuous phlebotomy education and training program for nurses and ATLM, and the procurement of more ergonomic tools for use.

According to ISO 15189, the turnaround time (TAT) is the time set between two points that go through the pre-analytical to post-analytical process (Susanti, 2017). TAT is the time interval from the time of submission of a process to the time of completion of the process. It can also be thought of as the sum of the period spent waiting to enter the final step of the process (Lokesh et al., 2020). The TAT covers all three stages of the process and can be a single excellent measure of laboratory performance. The laboratory should periodically evaluate whether the laboratory

service wait time is in line with the set (Lenicek Krleza et al., 2019; Susanti, 2017).

In this study, the TAT calculated is the time from specimen check-in to the result of the instrument authorized/validated. In a study in the Emergency Department, the focus on improving LSS (Lean Six Sigma) with various scenarios in the process of collecting blood and specimens resulted in a 30% reduction in the median TAT in Complete Blood Count (CBC) analysis, a 50% reduction in the variation of TAT CBC, and a 10% decrease in the variation of TAT Troponin (Sanders and Karr, 2015). The application of LSS was also able to reduce the TAT of STAT samples in a central laboratory of a teaching hospital from 68 minutes to 59 minutes by reducing incorrect sample labeling through training, replacing low-quality barcodes with new, high-quality barcodes, and eliminating handwritten forms. Furthermore, this method can improve the pre-analytical process in the sample reception area by eliminating 3 hours and 22.5 minutes of work that has no added value (Inal et al., 2018). Another study showed that the new TAT after the Improvement process was reduced by almost 49% from the original 69 minutes to 36 minutes. The improvement process is carried out using ARENA simulation software so that the numbers obtained are predicted numbers and still have to be validated with real-time data (Sunder M et al., 2019). Through a series of studies on reducing TAT time through the application of LSS, better patient satisfaction and care can be achieved.

CONCLUSION

In the pre-analytical stage, the Patient Identification indicator obtained World Class results which indicates excellent laboratory performance. However, in the Sample Conformity indicator, the results have not met the target, so there needs to be an improvement in the laboratory process. Meanwhile, in the post-analytical stage, the TAT indicator has not received results that meet the target. In contrast, the Critical Value Reporting indicator gets results that indicate excellent laboratory performance.

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CONFLICT OF INTEREST

No conflict of interest

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