



Quality improvement in laboratory reagent management: a Six Sigma concept

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Abstract

Background: This research is based on the findings indicating an ineffectiveness and inefficiency of the process of managing reagents. The aim of this research was to increase the effectiveness and efficiency of the reagent management process in the clinical pathology laboratory using the Six Sigma method.

Method: This was an action research study conducted at the Clinical Pathology Laboratory of X Hospital. Data analysis was done using Six Sigma's stage.

Result: The results in the define phase found that there were 4 critical to quality in the process of managing reagents. The measure phase found that the sigma value of the measurement results of the reagent management process was ≤ 2.5 sigma. The analysis stage was found in 12 root causes of the problem, with 4 root causes of the selected problem being repaired.

Conclusion: The Six Sigma can increase the effectiveness and efficiency of managing reagents.

Keywords: Six Sigma, laboratory reagents, clinical to quality

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INTRODUCTION

The implementation of a good clinical laboratory must be done to improve and strengthen the quality of laboratory examination results. Reagents are chemicals used in a reaction to detect, measure, examine and produce other substances. The laboratory commodity is very important for customer satisfaction, so its availability should be considered (USAID 2009). Excessive inventory requires a lot of space, incurs financial burdens, and increases the chance of damage and losses. Too little inventory can interfere with service (Ondari and Muturi 2016). In 2010, Indonesia Corruption Watch (ICW) conducted a survey of 989 patients in 19 public and private hospitals in Greater Jakarta area. The survey showed that 70% of patients were still dissatisfied about hospital service, especially administration service. However, health service system in hospital was not in good level and not guaranteed in delivered good service to the community. The service quality is related with patient satisfactions (Tuami, Indahwati Sidin, and Zulkifli 2018).

A hospital is an organization providing services to patients. Hospitals should pay attention to the quality of the servicers (Sriwulaningdyah and Wahyunu 2017). An

autoanalyzer at Clinical Pathology Laboratory of Hospital X belongs to the hospital and part of the supplier. The autoanalyzer at the Clinical Pathology Laboratory of Hospital X requires several materials, including reagents, consumables, controls, and calibrators. Based on the data obtained from the logistics department of Clinical Pathology Laboratory of Hospital X, it was found that several reagents were expired in storage during 2015-2017. The number of expired reagents increased from 2015 to 2017. The loss is caused by the large number of expired reagents occurring in 2017. The types of inventory contained in the Clinical Pathology Laboratory of Hospital X are reagents, compacts, controls, and calibrators. Meanwhile, the most abundant inventory is reagents, amounting to 53.5% in 2016 and 53.2% in 2017.

Mismatch between planning with consumption can cause events stockout and stagnant. Based on the previous research, drug procurement planning in a hospital inaccuracy can cause stockout events by 54% and stagnant by 39% (Fairuz and Yustiawan 2018). The

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large number of expired reagents increasing in 2017 was due to a new policy related to limiting the number of examination parameters allowed for health national insurance patients. In addition, stockout reagents were found as much as 50%, stagnant by 25%, and normal conditions by 25%. The large number of stockout and stagnant reagents illustrates the ineffective and inefficient management of reagents at the Clinical Pathology Laboratory of Hospital X. To make improvements and increase quality in management of reagents, the Six Sigma method can be used. The application of the six sigma method can improve the effectiveness and efficiency of laboratory reagent management. The Lean Management tools focus on the speed and efficiency of a process, while those of Six Sigma focus on its precision and accuracy. Lean Six Sigma is dedicated to increase quality, reduce variability, and eliminate any waste from company. The Lean Six Sigma concept is a combination of lean concepts into Six Sigma methodology (Syahputri et al. 2018).

Six Sigma is a statistical method used for reducing variations in any process, reducing costs in manufacturing and services, making savings in the bottom line, increasing customer satisfaction, measuring defects, improving quality of product, and reducing defects to 3.4 parts per million of opportunities in the organization (Siregar et al. 2019; Brahim, et al, 2018). Six Sigma is also a method focusing on removing defects by emphasizing understanding, measuring, and improving processes. In Six Sigma, there is a cycle of 5 (five) phases of DMAIC (Define, Measure, Analyze, Improve, Control). These phases are the processes of continuous improvement towards the Six Sigma target. DMAIC is done systematically based on knowledge and facts. DMAIC is a process to eliminate unproductive process steps, often focusing on new measurements and applying technology to improve quality towards the Six Sigma target (Sirajuddin, Yuri Zagloel, and Rauf 2016). The aim of this research was to increase the effectiveness and efficiency of the reagent management process in the Clinical Pathology Laboratory using the Six Sigma method.

MATERIALS AND METHODS

Research design, population, samples, and variables

This research used action research. In action research, researcher directly involves and collaborates with the staff of Clinical Pathology Laboratory of Hospital X to examine and improve the process of managing laboratory reagents. The research subjects were Hospital X Laboratory and Pharmacy Unit. There were 20 informants, consisting of all Clinical Pathology Laboratory staff, pharmaceutical procurement and logistics staff, and Hospital X financial staff. This study

used a prospective research design. In this study, an intervention was carried out using the Six Sigma stages in the Clinical Pathology Laboratory of Hospital X. The intervention was carried out for 7 weeks. Measurement of the results of the intervention was carried out after intervention.

Instruments

The instruments in this study were in-depth interviews, observation, and group discussions. Observations made were active participation of researchers who participated in any activities at this stage. Group discussions were conducted to determine the cause of the priority settings and created solutions. Six Sigma's measurement was performed using brainstorming, flowchart, cause and effect matrix, fishbone diagram and, scoring using CARL (capability, accessibility, readiness, dan leverage).

Research procedures and analysis

The data processing in this study was adjusted to the Six Sigma steps carried out; those are: define, measure, analyze, improve, and control. The data processing was done by preparing a flowchart to describe the flow of reagent management and analysis using method of cause and effect matrix to determine the critical to quality (CTQ). At the measure stage, the numerical data obtained were calculated using the Six Sigma calculator software to calculate the DPMO value and the sigma value. In the analyze phase, a descriptive analysis was performed, using fishbone diagrams. In the improve and control phase, a descriptive analysis was performed by describing proposed improvements using the CARL method, implementing and evaluating the results of implementation.

The first stage in Six Sigma was by defining the management of reagents in Hospital X using flowcharts in order to determine the type and number of defects. In the flowchart, several stages with no SOP were found, including the stage of selection, use and supervision. In addition, there were several activities not in accordance with the existing SOP.

RESULTS

The type and number of defects found in the reagent management process were annual need planning, with 100% defects of all reagents. The planning reagent demand showed 38.2% defects. For order documents, 43.75% defects were found. Reagents storing discovered defects by 4.4%. Reagent collection according to the type of examination found defects by 16.7%. In addition, logistic card recording found 100% defects. After that, an analysis was carried out Critical to Quality (CTQ) using cause and effect matrix according to Breyfogle. The assessment was based on brainstorming results. The first step was to determine the expected output of the reagent management process. The second step was to write down the factors

Table 1. DPMO and Sigma Critical to Quality Values in the Reagent Management Process in X Clinical Pathology Laboratory in April 2018 Period

Critical to quality	Unit	Defect amount	DPMO	Sigma value
Planning need annual	68	68	1,000,000	0.0
Planning request reagent	68	35	514,706	1.5
Taking reagent corresponding examination	12	2	166,667	2.5
Recording card logistics	68	68	1,000,000	0.0

Table 2. Root Frequency Causes Problems in the Reagent Management Process

The root cause of the problem	Frequency found on Critical to Quality	
	n	%
The officer has no educational background of Pharmacy	2	66.7
The pharmacy unit lacks of human resources	3	100
BPJS payments are not on-time	1	33.3
Characteristics of reagents	1	33.3
Heterogeneous type of disease	1	33.3
Implementation of MCC as requested Customer	1	33.3
IT staff is inexperienced	2	66.7
Inaccurate reading	1	33.3
Reagents close the system	1	33.3
No funds available	2	66.7
Logistics card material is made of paper	1	33.3
FPP is not specific to Clinical Pathology Laboratories	1	33.3

Table 3. Priority Solution to Repair Problems Using CARL Method

Solution to Repair Problems	Score				Total	Rank
	C	A	R	L.		
Logistics management training	4	4	3	5	240	2
Job design	5	2	2	3	60	3
Compiling SOP related management of reagents in Laboratory (SOP planning, usage, storage and supervision)	5	5	4	5	500	1
Changing IT officers	4	2	2	3	48	4
Preparing evaluation guidelines management of reagents	5	5	4	5	500	1
Filing additional amount Pharmaceutical HR	4	2	2	3	48	4
Revising hospital budget	5	2	2	2	40	5

that are likely to be the cause or input variables on the left. In this study, the input variable was a problematic sub-stage. The third step was multiplying the input score with the output score. The fourth step was adding up the scores for each problem and calculating the average value. Score with values above average was critical to quality.

In the measure phase on the **Table 1**, the DPMO and sigma values showed that the best DPMO value was 166,667.

Meanwhile, the best CTQ sigma value was 2.5 sigma. The next step was to analyze and measure the root causes of reagent management problems at Hospital X. The analysis was carried out based on brainstorming results with the Head of the Clinical Pathology Laboratory, 1 Clinical Pathology Laboratory Logistics Coordinator, and 3 laboratory logistics officers. As many as 12 root causes of problems were found in the reagent management process. Furthermore, on

Table 2, the root cause of the problem with the frequency ≥ 2 on CTQ was analyzed for finding a solution to solve the problem.

Improver's step consists of two steps, the improvement planning and implementation of reagent management process improvement efforts. Based on the analysis of the search for problem solving solutions, there were 7 proposed solutions for improvement. Next, the proposed remedial solution was done by setting priorities using the CARL method by brainstorming.

Based on **Table 3**, information was obtained that the range of scores found was between 40-500 with the highest score of 500. Implementation of repairs was carried out for approximately 7 weeks by involving the laboratory logistics team as implementing the activities.

At the control stage, an evaluation of the implementation of the problem solution was carried out through observation by comparing the target. The level of effectiveness and efficiency after improvement with

Table 4. Effectiveness of Reagent Management after Six Sigma Improvements

Critical to quality	Unit	Defect amount	DPMO	Sigma value
Annual need Planning	-	-	-	-
Reagent Request planning	68	9	132,353	2.6
Taking reagent corresponding with Examination type	12	0	0	> 9
Logistics card registration	68	30	441,176	1.6

Table 5. Comparison of the Effectiveness before and after Improvements with Six Sigma

Critical to quality	Before		After		Information
	DPMO	Score Sigma	DPMO	Score Sigma	
Submission of annual needs	1,000,000	0.0	-	-	Cannot be evaluated
Planning reagent request	514,706	1.5	132,353	2.6	Effective
Taking reagent in accordance with the type of examination	166,667	2.5	0	> 9	Effective optimal
Recording card logistics	1,000,000	0.0	441,176	1.6	Effective

Table 6. Comparison of Efficiency Before and after Improvements with the Sig Sigma Method

Level stock	Amount before Repair	Percentage	Amount after improvement	Percentage	Information
Stagnant	16	23.5%	13	19.1%	Inefficient
Stockout	13	19.1%	4	5.9%	Efficient

the Six Sigma method based on critical to quality is described in **Table 4**. The highest sigma value was found in the sub-stages of reagent collection according to the type of inspection with a sigma value of >9, while the lowest was logistical card recording plan of 1.6.

Based on **Table 5**, there was an increase in the value of sigma at 3 critical to quality. An increase in sigma value is said to be effective if there is an increase in sigma value ≥ 1 sigma from the sigma value before the improvement. If an increase in sigma is <1 , it is categorized as ineffective, and if an increase in sigma value after improvement reaches ≥ 3 sigma, then it is categorized as optimal effective.

The efficiency value of the reagent management process in **Table 6** was done by calculating the stagnant and stockout values from the Clinical Pathology Laboratory of Hospital X monthly logistics report book. A stagnant reagent value decreased from 23.5% to 19.1%, and a decrease in stockout reagent value was from 19.1% to 5.9%. Conditions of stagnant and stockout are categorized as efficient when the stagnant $<10\%$ or stockout $<10\%$. Meanwhile, it is categorized as inefficient when stagnant $>10\%$ and stockout $>10\%$.

DISCUSSION

Based on the application of Six Sigma in the reagent management, there were the defects in the process of reagent management, the root cause of the problem, proposed improvements, and solutions for improvement to achieve the targets. Laboratory service activities will run smoothly if the reagents used to carry out the examination are in the right conditions of the right amount and the right type. The Six Sigma method is used to improve the process of managing reagents. The first step in defining is using flowcharts and determining the problem (defect). Flowchart making aims to find out about all the steps in the process and the role of each

officer (Sachin and Dileepal 2017). To maintain where the company is, the Six Sigma method is also used. The service industry such as hospitals has also used this method. This method is commonly used in projects with high discipline to reduce work accidents (Ishak et al. 2019). First defect caused of the planning is done based on ordering reagents in the previous period and not using certain methods that can be accounted for. The mathematical method needs to be used by considering all the variables that might arise, such as safety stock and lead time (Ruiz-Torres and Mahmoodi 2010).

The second is caused by supplier who do lock on order reagents because the hospital has not made payments on overdue bills. Delaying this examination can cause patient's dissatisfaction with the laboratory services (USAID 2009). The third defect is caused by the reagents stored not in accordance with the provisions. Fourth defect is causes by no reagent recorded on the logistics manually card. Manually recording takes longer time to be completed and allows a lot of misinformation to occur (Chan et al. 2017). Misinformation and inaccuracies in inventory data can cause inefficiencies in inventory (Liberatore 2013).

At the stage of measure, calculations of DPMO and sigma value at all CTQ were conducted. Based on the results of the study, it was found that sigma value was in uncompetitive category. The next is analyzing to find the root cause of problems in CTQ using a fishbone diagram. The four root causes of the problem are the officers who do not have a pharmaceutical background, the pharmacy unit with lack of human resources, the IT staff who is inexperienced, and no available funds. The human resource who conducts the planning of reagent needs at the Clinical Pathology Laboratory of Hospital X is an ATLM (medical laboratory technology expert) (Kagashe and Massawe 2012). Personnel only has competence in conducting reagent quality tests, not for

managing reagents. The lack of knowledge about managing logistics affects the effectiveness of managing logistics (Chan et al. 2017). Research conducted in various studies found that the low skills of logistics management officers greatly influenced the effectiveness and efficiency of inventory management (Mahidin, Yusuff, and Saad 2004). Furthermore, the financial actors who cause problems in the management of reagents are the presence of irregularities in payments or debts. This is also supported by research stating that improper allocation of funds is an inhibiting factor in inventory management. Thus, it cannot fully serve the goods needed by customers (Siregar et al. 2019).

The improvement in the Six Sigma method was done in two steps, developing alternative solutions and implementing improvement solutions. Some obstacles that might occur can be seen and prevented before implementation (O'Neal and Manley 2007). Based on the results of the study, there were 7 proposed repair solutions with 2 selected repair solutions implemented. Implementation of improvement solutions includes the preparation of SOPs and the preparation of reagent management evaluation guidelines (Paul and Lestari 2015). Research conducted shows that most of the problems identified are due to company regulations and procedures. In addition, the SOP must always be updated as a basis for implementing the inventory management operational process (Muhammad Barwa 2015).

Stage of control is carried out by comparing targets with the achievement of work achieved. Based on the research results, the implementation of Six Sigma in the Clinical Pathology Laboratory of Hospital X has been

carried out according to the specified targets. Based on the results of the study, the Six Sigma method implemented in the reagent management process at Clinical Pathology Laboratory of Hospital X has increased effectiveness characterized by increasing sigma values on CTQ and decreasing reagent stagnant and stockout events. Six Sigma implementation does not require a lot of teams and funds (Antunes, Sousa, and Nunes 2013). Effective training and communication are needed to overcome resistance to change and help employees understand the methods to be used (Zhang et al. 2016). The limitation in this study is that the implementation was still in a short period of time. In order to get optimal results, changes must be ongoing and periodically evaluated.

CONCLUSION

The application of Six Sigma in the process of managing reagents in Hospital X can have a positive impact. The impact of implementing Six Sigma in the reagent management process at Clinical Pathology Laboratory of Hospital X is seen in the increased performance of the logistics team, decreased number of defects in the reagent management process, and decreased stagnant and stockout events, indicating the reducing inventory costs and improving laboratory services.

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