The Influence of Quality Control in Clinical Laboratory: Lean and Six-sigma Approaches

Eng. Flowra Al-rawashdeh, Eng. Dena M. Aldalabeeh, Eng. Manal A. Alsharaya

Royal Medical Services – Amman, Jordan

DOI: 10.29322/IJSRP.9.03.2019.p8787
http://dx.doi.org/10.29322/IJSRP.9.03.2019.p8787

Abstract*—Recently, the quality of healthcare is a significant concern worldwide. Clinical laboratories are an essential part of healthcare services where more than 65% of medical cases are diagnosed by laboratory tests. Therefore, clinical laboratory results are playing a significant role in diagnosis, treatment and decision making. Excellent practice of quality management is an emerging issue to ensure quality control, reliable and accurate test results. The modern quality tools such as Lean and Six-sigma offer realistic and sustain approaches to increase efficiency, reduce cost, minimis errors, remove waste from working process in clinical laboratories.

Keywords: Quality control, Lean, Six-sigma, Clinical laboratory.

1. INTRODUCTION

Quality control in the medical laboratory is defined as a statistical procedure utilized to monitor and estimate the analytical process that interested in producing patient results. In fact, results of quality control are used to distinguish whether the equipment is working within pre-defined specifications, inferring that patient test results are reliable [1]. Researchers considered quality control to be a significant impact on the results of devices involved in a laboratory. Indeed, it maintains precision as well as the accuracy of results that were gathered from patients [2]. Laboratory testing result are a significant phase of decision-making process in healthcare services which influence diagnosis and medical treatment. More than 65% of healthcare cases are diagnosed by clinical laboratory tests. Besides that, the running cost of clinical laboratory is around 5% of the total cost of healthcare services. Therefore, good management of clinical laboratories can considerably reduce the cost of health expenditures. The balance between cost reduction and quality management was the key point in clinical laboratories that producing a pressure to operate efficiently under specific regulations and requirements for clinical laboratories standards. In parallel to that, the main tasks of laboratory including; collect and analyze patient specimens, perform testing and result interpretation. Indeed, the top five reasons influencing the changes in clinical laboratories are; reengineer workflow, reduce turnaround times, reduce or eliminate errors in testing or reporting, availability of qualified staff and increase outreach [3]. Therefore, according to the previous experience in industrial sector, medical researches and managers were able to customize lean and six sigma principles to be applicable in healthcare sector.

Lean approaches in clinical laboratories management are based on pillars of lean thinking which aims to transform and reduce of waste among the overall process. Where the waste is defined as anything or part of the process that doesn't add a value to the medical services, result, diagnosis, or in general to the final product. While the value can be defined as lean thinking as the capability to deliver certain produce, service or results to patient or to other operator within right time. Therefore, lean principle can be applied to clinical laboratories to eliminate or reduce the waste among total process, increase quality and reduce the running cost of clinical laboratory to significant ratio between 30% to 50%.

On the other side, the six-sigma methodology was found primarily in industrial sector, but it is applicable in healthcare system. The main aim of six-sigma is to obtain sustained strategic improvement based on reduction of variation over the total process and derive precise decision data of results. Six-sigma describes the variability over the total process of testing as a unit defect regarding the total produced units. The value of sigma (σ) represents frequency of defected units in the process. The lower value of sigma shows higher value of defects, while the higher value of sigma represents lower defects [4].

2. METHODOLGY AND PURPOSES

Six sigma and lean management tools are used to maintain quality control management of clinical laboratories according to the global requirement and specification. Providing full overview of implementation of charting and designing work flow in clinical laboratories

system. Besides that, understanding the interaction between each phase of process, workflow, medical equipment, operator, results interpreting and delivering data.

Basically, lean approaches are linked to DMAIC tool including; design, measure, analysis, improve and control. Leading to enhance quality. While six-sigma tool is associated with improving the process and reduce the cost by reducing time, variation and waste.

3. Discussion

Clinical laboratories play an essential role in diagnosis of different type of human diseases, while laboratories test results influence the decision-making process and treatment plan. Therefore, it is significant to maintain and improve high level of quality control (QC) during all phases of work process among clinical laboratories. Applications of quality control (QC) in clinical laboratories were first introduced by Levey and Jennings and gained a wide acceptance worldwide. As well as, the modern quality control (QC) tools have been applied to improve laboratory work process by finding the causing of defects and related solution [5].

Firstly, six sigma (6σ) methodology aims to reduce the number of defects during the laboratory process to reach the standard operation with 6σ deviation which is equivalent to 3.4 mistakes per million opportunities. The six-sigma structure is mainly based on tools known as DMAIC. Consisting of five different stages during the implementation of road map at six-sigma methodology as shown in figure 1.

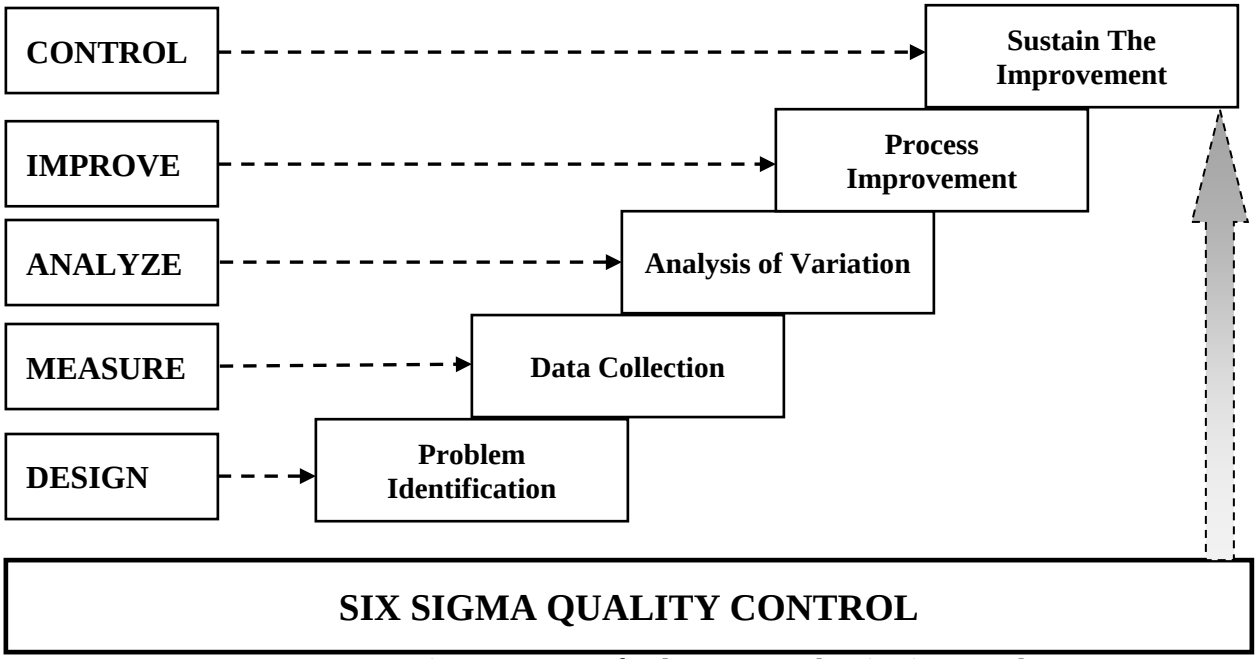

Figure 1: Stages of Laboratory QC by Six-Sigma Tool.

The above diagram describes the stages of DMAIC tool to enhance the quality of process achieving a desired target in clinical laboratory. The first stage is associated to define the problem or malfunction of the process, opportunities to produce defects or mistake and all waiting time for samples collection to result delivery. Data collection promotes the assessment of current work process and determined the required time to perform each part of laboratory testing process. While the analyze stage is related to determine the origin or the root of problems or mistakes during the operation of clinical laboratory. Improvement of clinical laboratory work process can be performed by eliminating the defects or the mistakes through the identification of causes. Finally, control the process leading to guarantee sustainable improvement and prevent reoccurred mistakes [6].

When applying six sigma methodology correctly to clinical laboratory work process, it is suggested to improve quality level, reduce cycle time, reduce waste and increase the outcomes. However, the main structures of six sigma focuse on the root or the source of errors during the laboratory operation. In general, the clinical laboratory work process consists of three main phases; Pre-analytical, Analytical and Post-analytical [7]. Any error during the three stages of work flow including acquisition, processing and analysis of a patient's samples and interpreting of a laboratory result will significantly invalidate the quality control. Investigation of defects source among clinical laboratory process were reported in many studies around the world. Approximately, 32% of total defects occurs in the

analytical stage due to wrong analysis of patient's specimens [8]. On the other hand, Plebani and Carraro et al. reported that the total defects and errors occurred in laboratory work process without quality control system may be estimated to 68% in pre-analytical stage. Compared to 18% and 13% occurred in post-analytical and analytical stage [9].

The implementation of six sigma can be achieved in all phases of clinical laboratory process. Six-sigma in preanalytical phase promotes quality of collected information, requisitions, patient's identification data, samples collection and transportation. While in the analytical phase, six sigma finds implantation for reducing error opportunity, especially in misreading of samples, misinterpretation of tests results, misjudging of obtained results and disease diagnosis. At the post-analytical phase, six-sigma can be reducing the turnaround time, reduce time needed to deliver results to diagnosis clinics. For example, Vanker et al. highlighted the clinical impact of using six-sigma. The results showed that six-sigma implementations in clinical laboratory reduce the error opportunity, in his study the total performed tests were 47543 tests, and the errors were reduced to 72. Scoring 4.446 of six-sigma [10].

In parallel to that, lean management methodology is a continuous process of improvement based on main tool known as plan-do-check-act (PDCA). Lean concepts focus to reduce waste, standardize process, prevent defects and assess systems. Enabling the clinical laboratory mangers to make quicker decision, replace complexity process by simplicity, minimize errors and improve process continuously. At first step, it is essential to develop a process map including each step of the clinical laboratory work process, each step should be evaluated by critical lean question: Does it add value to product/test? However, eliminating or reducing waste in lean methodology is generally based on a set of tools known 5's. Sustain which is associated to respect rules; exercise self-discipline; maintain a stable workplace. Shine which is mean keep clinical laboratory's work area clean. Standardize and create rules that sustain the improvement of laboratory work process. Sort work process by eliminate unneeded tools and supplies. Straighten of process by organize materials, tools, and documents. In other words, lean principle can be described as quality methodology that reduce the consumption of resources that don't add value to laboratory tests. Waste in medical laboratory may include the following; overproduction or unnecessary testing orders that slow the work process, consume resources and increase the cost. Retention of large amount of stocking leading to clutter. Transportation of patient's samples and other material can be considered as waste as well as unnecessary motion of lab operators to locate supplies, process samples and run assay on equipment. Waiting of samples to arrive as a stage of batching process is consider as waste as well as errors which are resulted from retesting.

Moving clinical laboratories to lean methodology can be achieved throught standard operating procedures (SOP). Sorting: unnecessary and non-technical work of laboratory should be shifted to secretary, while other laboratory procedure which performed outside the clinical laboratory should be shifted to other medical staff, such as blood glucose measurement at wards should be shifted to nurses. Simplify the clinical work process by splitting of specimens to minimum which offer spatial arrangement of working area and leads to clear floor plan. Also, sweep serum and plasma can be stored for further procedures and investigation. Standardize medical equipment of all section of clinical laboratory according to the manufacturer guidelines will significantly harmonize the work process, reduce the failure time, increase accuracy of results and reduce the cost.

The continuous cycle of lean improvement is significantly focusing to prevent errors to reach patients and making errors always visible as shown in figure 2. The philosophy behind that is developed by removing wastes from production to minimize the potential of defect results. In fact, defects can't be ignored during the work process of clinical laboratory. It should be corrected immediately, and continuous inspection procedures should be maintained during all parts of laboratory tests. Standardization and redundancy are an effective tool to perform inspection. Where standardization is associated with perform the same test in the same procedures every single time. While redundancy is responsible to detect errors, which were sneak previously [11].

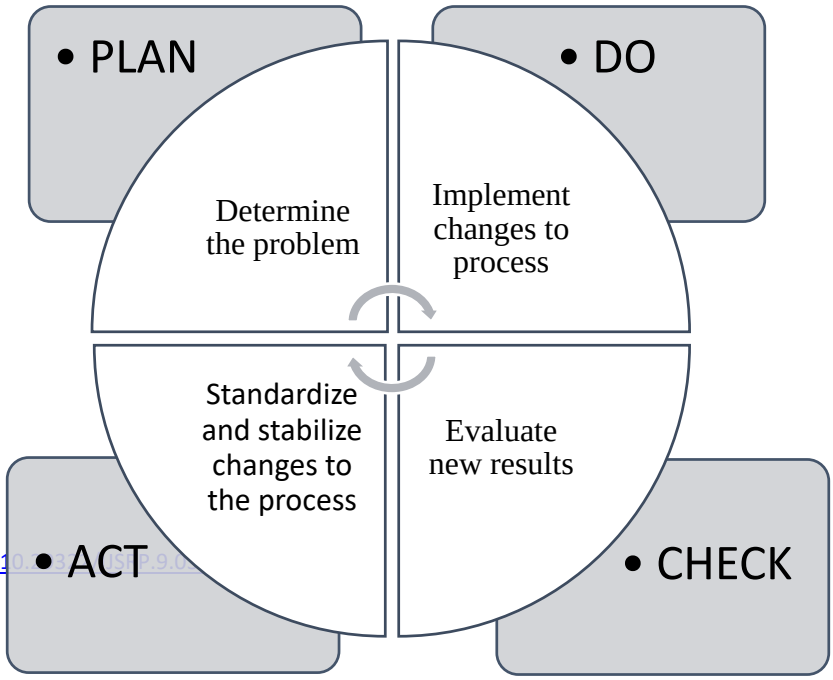

Figure 2: Continuous Improvement Cycle by Lean Methodology

4. CONCLUSION

Quality control is an important factor of a success of modern clinical laboratories to meet and exceed the expectations of performance criteria. The approaches of six-sigma and lean methodology are an evolutionary process leading to high level of quality control. The correct implementation of six-sigma and lean have proved benefits to improve the work process of clinical laboratories by increasing efficiency, reducing waste, reducing turnaround time, minimize cost and offer the best utilization of resources. As well as, combination between six-sigma strategy and lean significantly influence the outcomes of clinical laboratories.

References

1.Konieczka, P. and J. Namiesnik, *Quality assurance and quality control in the analytical chemical laboratory: a practical approach*. 2016: CRC Press.

2.Burr, I.W., *Statistical quality control methods*. 2018: Routledge.

3.Battisto DG. Hospital clinical laboratories are in a constant state of change. Clin Leadersh Manag Rev 2004; 18: 86–99.

4- D'Angelo R, Zarbo RJ. The Henry Ford Production System. Measure of process defects and waste in surgical pathology as a basis for quality improvement initiatives. Am J Clin Pathol 2007;128(3):423-9.

5- Smith TJ. Tracking the trends. Advance for the laboratory. 2006; 15: 33–40.

6- Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, Morgan T. Evaluating laboratory performance on quality indicators with the six-sigma scale. *Arch Pathol Lab Med*. 2000; 124: 516-519.

7. Goldschmidt HMJ, Lent RW. Gross Errors and Workflow Analysis in the Clinical Laboratory. *Klin Biochem Metab*. 1995; 3: 131-140.

8. Lapworth R, Teal TK. Laboratory blunders revisited. *Ann Clin Biochem*. 1994; 31: 78-84.

9. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem*. 1997; 1348-1351.

10. Vanker N, Van Wyk J, Zemlin AE, Erasmus RT. A Six Sigma approach to the rate and clinical effect of registration errors in a laboratory. *J Clin Pathol*. 2010; 63: 434-437. doi: 10.1136/jcp.2009.072058

11- Deming WE. 2000. Out of the crisis. MIT Press, Cambridge, MA