Applying Lean Six Sigma to Enhance the Medical devices Repair Process in Public Healthcare Sector in Egypt

Lina El-Sherif Ismail
Assistant Professor, Department of Industrial and Management Engineering
Arab Academy for Science Technology & Maritime Transport (AASTMT)
Alexandria, Egypt
lina.elsherif@gmail.com

Heba Elhaddad
Assistant Professor, Department of Industrial Engineering
Alexandria Higher Institute of Engineering and Technology (AIET)
Alexandria, Egypt
heba.elhaddad@aiet.edu

Mohamed S. Saleh
Military Technical College,
Egyptian Armed Forces,
Cairo, Egypt
Mohsal731@gmail.com

Ayman A. Nassar
Medical Services Administration
Egyptian Armed Forces,
Cairo, Egypt
Ayman_nassar@Knights.ucf.edu

Ahmed A Mohamed
Director, Solutions Engineering
Healthcare System
aamohamed@knights.ucf.edu

Abstract

Due to the worldwide epidemiological crisis, the biomedical engineering sector, as part of the Egyptian Public Health Administration, has become under intense pressure to play a vital role in delivering appropriate healthcare services in the country and improving its performance. Most medical equipment maintenance centers in the country have struggled to provide functional medical equipment in the public healthcare sector while keeping up with huge repair orders to meet the growing needs of medical devices to provide quality services at affordable cost. Hence, there is a great need to deploy continuous improvement and waste elimination methodologies such as lean six sigma (LSS) in the biomedical engineering sectors to promptly enhance the process capability to return repaired equipment to the field. This article aims to present a case study on the application of Lean Six Sigma methodology at a medical devices repair center in Egypt. A comprehensive analysis of the entire process has been carried out to reduce the lead time of the repair by improving the entire process. The results indicate that lean six sigma can be applied effectively to improve the availability of functional medical devices in public hospitals in Egypt.

Keywords
Lean Six Sigma (LSS), continuous improvement, DMAIC, Healthcare, maintenance, and Egypt.

1. Introduction

The COVID-19 pandemic has shown how the possibility of being attacked or harmed in health systems can have a deep impact on health, economic progress, trust in governments, and social consistency (Mofijur, Fattah, Alam, I slam, Ong, & Rahman, et al., 2021). It is still critical to reduce the virus's propagation and infection rate. Strengthening the ability of health systems to respond quickly and effectively is also important. COVID-19 has produced an unthinkable humanitarian crisis involving death and disease and economic consequences that the world has never seen before (Queen, D., 2021). Yes, the world has faced disease pandemics and worldwide economic crises in the past, but nothing like COVID-19. For society and economies throughout the world, the speed and intensity of change created huge problems. On the front lines of healthcare, this is especially difficult.

Egypt's hospitals and healthcare systems have stepped up in heroic and unprecedented ways to meet the challenges of COVID-19. On February 14, 2020, the first case of COVID-19 was reported in Egypt. Confirmed cases increased to more than 100,000 in the first week of September 2020, and about 515,000 by April 2022 with total death cases of 24,600 cases. The effect of the virus on daily life was swift and catastrophic with the advent of strict social distancing practices and stay-at-home orders. Consequently, as attacks have occurred across the country, hospitals have ramped up testing efforts and are treating thousands of Egyptians to save lives and minimize the virus' spread. This includes establishing testing tents, adding general and intensive care unit (ICU) bed capacity, and developing COVID-19 isolating units to isolate and treat patients while safeguarding the health of other patients and hospital staff. These challenges have created historic pressures for Egypt's hospitals and health systems as a result of surging hospitalization in inpatient wards and ICUs, and a lack of medical supplies and equipment. Treatment for COVID-19 has created an incredible demand for certain medical equipment and supplies as the virus has disrupted supply chains, increasing the pressure that hospitals face treating COVID-19 patients. The World Health Organization (WHO) defined a medical device as any machine, instrument, or other similar article intended to be used by the manufacturer for human beings for specific purposes of monitoring, diagnosis, treatment, or another similar article. Medical devices' conditions and performance directly affect the human being's health, to preserve adequate conditions for medical devices, maintenance and repair are the processes needed to achieve adequate performance.

1.1 Maintenance

The COVID-19 epidemic has emphasized the necessity for an efficient right to repair medical equipment. As healthcare systems have been stretched to their breaking point, keeping critical medical equipment (such as ventilators) operational has become a matter of life and death. The ability to keep critical equipment, such as ventilators, in good working order can mean the difference between life and death for a critically ill patient (Tur-Sinai, & Grinvald, 2021). Although many hospitals and other healthcare facilities (such as clinics) employ qualified biomedical equipment technicians, also known as "BioMed"(Malkin, 2007) who are capable of servicing, diagnosing, and even repairing such equipment, they are not always able to do so (Koebler, 2020).

Maintenance and repair activities are required to ensure that medical devices continuously function within the specific limits imposed by the calibration testing criteria and to return medical devices to the required functionality level after breakage, malfunction, or any other failure. Moreover, performance and safety tests are required to identify incorrect performance and unsafe medical devices that could cause risk to patients as well as the medical staff.

Medical device maintenance and repair should be carried out by highly qualified persons and should be audited to ensure that quality control policy is achieved. Many medical facilities tend to outsource clinical engineering services (maintenance and repair) to reduce the number of employees, cost-saving, and achieve short-term solutions. Medical facilities and repair centers are struggling to keep up with the overwhelming repair requests to fulfill hospitals' and clinics' needs for medical devices. The need to minimize equipment downtime while saving the facility money instead of purchasing new equipment is increased. The repair, spare parts, and warehouse processes in any repair center need to be revised to decrease the repair time and increase the availability of the medical device. Decreasing the repair time improves the quality goals in the repair centers and therefore increases customer satisfaction and facility revenue.

2. Methodology

2.1 Lean Six Sigma (LSS)

Lean and Six Sigma (LSS) is a powerful quality management and improvement approach that organizations use to enhance their performance (Bhamu, & Sangwan, 2014; Mohan, et al 2022). This approach integrates lean manufacturing with the five phases of the six sigma DMAIC (Singh, & Rathi, 2021) Where the DMAIC methodology provides a blueprint for the lean improvement projects (Tzadok, et al., 2022). When lean manufacturing and six sigma are combined, they become more potent and overcome the drawbacks of each methodology (Mohan, et al 2022; Zhang, & et al. 2012). The term Lean means to improve process efficiency and effectiveness by eliminating waste by minimizing non-value-added activities (Langlotz, & Aurich, 2020; Shah, & Ward, 2003). This strategy first became known in the 1990s when it was adopted by Toyota Production Systems Japan (Ganebnykh, Lezhnina, & Zhilkina, 2020). Six Sigma is a quantitative approach that aims to eliminate the root causes of defects and minimize process and product variability to produce goods or services of high quality at the lowest cost and at the last time (ben Ruben, Vinodh, & Asokan, 2017; Schroeder, Linderman, & et al., 2007; Muhammad, Upadhyay, & et al., 2022). This was first adopted by Motorola in 1986 (Chakrabarty, Tal, 2007). Like six sigma, LSS is applied through Champions, Master Black Belts, Black Belts, and Green Belts (Zhang, & et al. 2012).

LSS has lately evolved into a modern quality improvement project that has acquired traction and acceptability in a variety of industries throughout the world with the ultimate objective to improve the process efficiency and reliability to increase customer satisfaction. However, this expansion is limited to service organizations. This is owing to the belief that service processes are unquantifiable and difficult to detect and measure (Chakrabarty, Tal, 2007). However, this idea is gradually fading.

2.2 DMAIC

DMAIC is a powerful six sigma method that stands for the five phases known as D – Define, M – Measure, A – Analyze, I – Improve, and C – Control, as shown in (Figure 1). It is a data-driven method applied in a wide variety of applications including manufacturing or service sectors. DMAIC is a problem-solving technique designed to assess in identify and address any inefficiencies in the process to enhance and improve the existing products or services for better customer satisfaction.

Define: The first step in the DMAIC approach consists of defining the project framework and describing the overall process and work environment. The stage begins by selecting the project champion till deciding the responsibilities for each person in the team. Various tools are available to identify the following elements: Determining the problem, the scope of the project, defining the project teams' role, the aim of the project, mapping the process, identifying the stakeholder, project communication plan, collecting customer voice and expectations, estimating the timelines, and project charter elaboration (De Mast, & Lokkerbol, 2012).

Measure: The measurement stage provides a structure to determine the metrics to pick up the parameters of the problem that need to be improved. Therefore, a data collection method is crucial to measure the project parameters/variables such as methods of a data collection plan, critical-to-quality, and SIPOC method.

Analyze: The identified variables/parameters of the process are ready to be analyzed to determine the root cause of the problem and any other causal factors. Therefore, a fishbone diagram, five whys method, and failure mode and effect analysis (FMEA) can be applied to identify all possible problem areas, inefficiencies, defects, and shortcomings (Tufail, Shakeel, Sheikh, & Anjum, 2021).

Improve: This is the process of solution identification, solution prioritization, and solution implementation. It consists of design, adjustment, and enhancement of the process to improve the process performance.

Control: The last phase in the DMAIC approach. This step takes place after implementing the improvement phase to ensure that the proposed improvement plan is well implemented and controlled. A controlled plan is created to ensure meeting the desired quality level and measuring the new process capability.

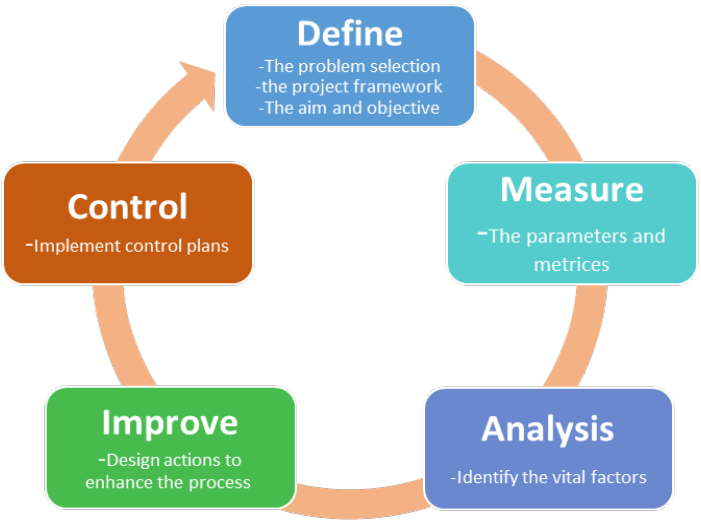

Figure 1. DMAIC Methods Five phases

3. Case study

3.1 Define phase

The medical repair center has several problems that need to be handled or improved. Problems could arise because the benchmark standards are not being met or are being met inconsistently. Some projects would be suitable to be executed by the Six Sigma approach while other projects may require a different approach to solve them. The use of an incorrect approach often leads to a sub-optimal way to solve the problem which can affect the duration of the project or even result in suboptimal results. Hence, the right methodology must be used to solve the problem. In addition, there may be multiple projects that need to be executed but due to limited resources within a company, it may be impossible to work on all of them. Hence, it becomes important that we prioritize these projects so that the most important projects are addressed first before other projects are considered.

The accuracy of Six Sigma requires that project selection be based on quantifiable metrics. Choosing a project based on quantifiable data helps the repair center identify the project that provides the greatest savings relative to the time expended and cost of deployment. A Repair process improvement project is assessed as shown in (Figure 2). The assessment indicates the importance of pursuing the project which will greatly enhance the repair process performance.

	Very Low		Moderate		Very High
	1	2	3	4	5
Must Be a Process Improvement Project					
To what degree do you believe this process can be improved (i.e. does not require complete redesign)?					5
To what degree does this project require analysis and discovery (i.e. not a ready–made solution, implementation, decision or "just do it" effort)					4
Must Be Meaningful					
What is the potential for an improved customer/client experience?					5
What is the potential for cost reduction or cost avoidance?					4
What is the potential for defect reduction?					3
What is the potential for time savings?					5
Must Be Manageable					
What is the level of leadership support for addressing this project?					5
To what degree is the scope of this project doable? (i.e. not addressing "world hunger" or "boiling the ocean")?					4
What is the level of buy-in for this project in general?					4
What is the level of expertise available to lead this project?					4
What level of resources are available to work on this project?					4
What is the potential availability of subject matter experts to offer assistance?					5
What is the availability of existing data related to this process?					3
How much clarity is there on exactly what will be measured (# of defects, cycle time, customer satisfaction) in order to show improvement?					5
What is the likelihood that this effort could be completed in 4 months or less?					4
Score	85%	If the project scores less than 75% - either consider another opportunity or address some of the low-scoring areas.			

Figure 2. Timestamp collection sheet table for ICU ventilator.

A SIPOC diagram tool is used by a process improvement team to identify all relevant elements of a process improvement project before work begins and helps to define a complex project that may not be well-scoped. SIPOC stands for a supplier, input, process, output, and customer. It's a high-level map showing a process's supplier, the inputs received from them, and the process that adds value to those inputs. That process produces an output that meets or exceeds customer requirements. The Six Sigma team applied the SIPOC model to the repair service process. Everyone takes inputs from suppliers, adds value through their processing steps, and provides an output or outputs that, at a minimum, meet the customer's needs critical to quality.

A Figure with five columns for the five words that make up the SIPOC acronym is created in (Figure 3). First, are suppliers who are tasked with delivering the malfunctioning devices to the repair center and suppliers who are tasked with delivering the spare parts. That leads to the inputs, which are the malfunctioning device, any spare parts, and any

tools needed in the repair process. Now we're getting to the process. It starts by receiving the malfunctioning medical device which must be diagnosed for the causes of the problem. Then the spare parts are identified and requested from the warehouse. The spare parts are then installed, and the device is tested to be ready to send to the client. The output of this process is the repaired medical device and all reports needed in the process. This finally leads us to the customers, who are the hospitals, clinics, or any other repair center.

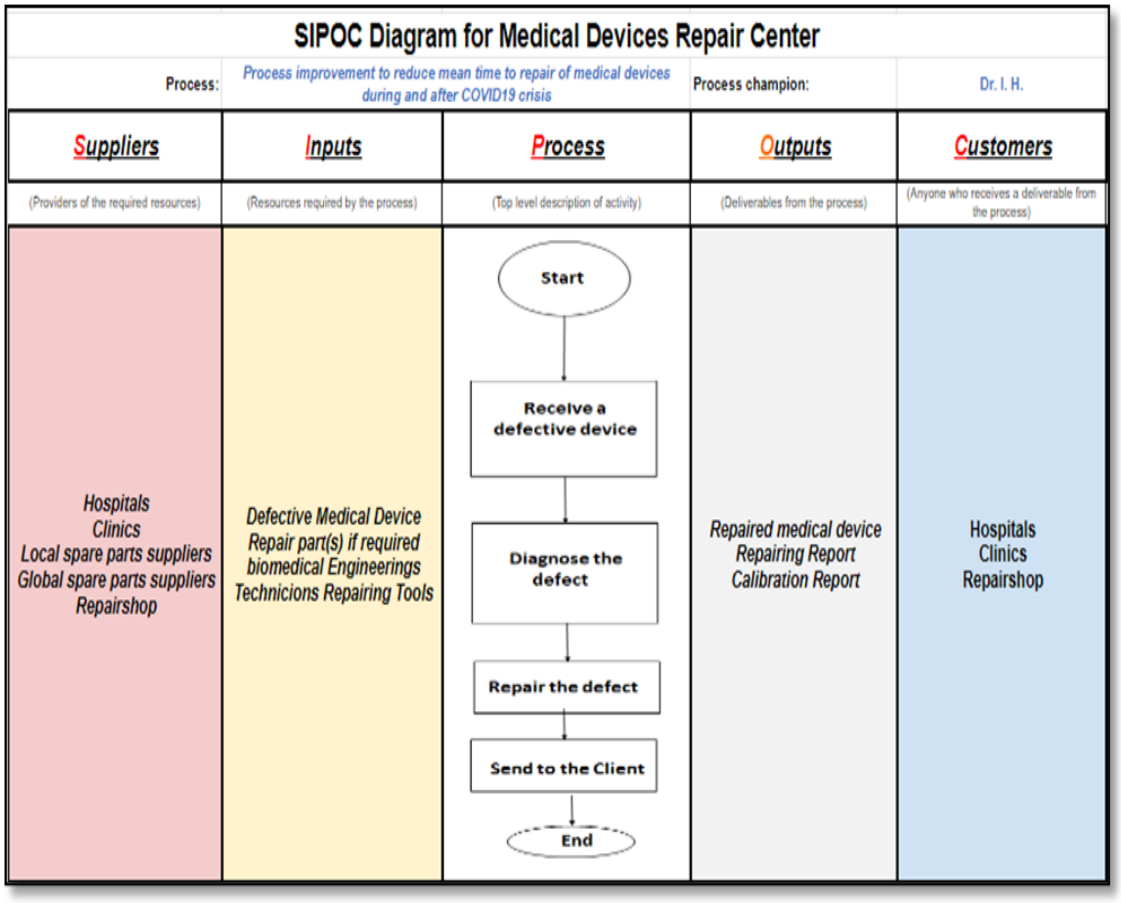

Figure 3. SIPOC Diagram for Medical Repair Center

3.2 Measure phase

This phase aims to assess and quantify the processes' data to determine their current behavior and performance and quantify and detect the problem to eliminate or reduce the wasted time. The malfunctioning medical device that enters the medical repair center underwent multiple processes which include both repairing and administrative processes. All the repairing processes were carefully studied by either the six-sigma team or the medical repair center technicians, and Thirteen points were chosen for different sub-processes to specify the time taken for each malfunctioning medical device in each of the thirteen sub-processes.

Nine of the thirteen processes are mandatory, and all the malfunctioning medical devices should undergo. However, the other processes may apply if applicable. A timestamp table was done to calculate the time taken for each sub-process as shown in Table 1.

Table 1. Timestamp collection sheet table for ICU ventilator.

No.	Process / Sub-process	Date	Time	Notes
1	Receiving the device from I/O Dept	3/10/2021	10:00 AM	
2	Finish Paperwork	3/10/2021	11:00 AM	
3	IT Registration	3/10/2021	2:00 PM	
4	Preliminary diagnosis	4/10/2021	10:00 AM	
5	Receiving the device from the Relevant Dept	4/10/2021	10:30 AM	
6	Starting the device repair	5/10/2021	10:00 AM	
7	Requesting spare parts from the warehouse	-	-	if applicable
8	Receiving spare parts from the warehouse	-	-	if applicable
9	Requesting spare part from outside	9/10/2021	10:30 AM	if applicable
10	Receiving spare parts from outside	14/10/2021	9:30 AM	if applicable
11	Finishing the device repair	16/10/2021	11:00 AM	
12	Delivering the device to I/O Dept	16/10/2021	12:00 AM	
13	Delivering the device to the Client	18/10/2021	1:30 PM	

A large data collection sheet was created to collect all the measured data from 80 medical devices. Moreover, when filling the data collection sheet, the days off were excluded, and only the operating hours were included to increase the accuracy and get accurate data for the analyzing phase. Furthermore, another customer review form was created to measure customer satisfaction with the medical repair center services, this customer review form was filled by a focused group of customers.

3.3 Analyze phase

The analysis phase is mainly aimed to identify the critical factors embedded in the current operation that are the main causal factors of the processing delay. Based on the information collected in the process of identifying all the process steps, an FMEA matrix is developed to identify potential causes and effects of delays during the repairing process and estimate their importance for the process. For the needs of the study, a scale from 1 to 10 was adopted, where 10 means most severe as shown in Table 2. The analysis conducted using the FMEA revealed that the seventh process which is the "**Finished paperwork for functional device**" has the highest Risk Priority Number (RPN).

Table 2. The Failure Mode and Effect Analysis

Process #	FAILURE MODE	A) SEVERITY Rate 1-10 10=Most Severe	B) OCCURRENCE Probability Rate 1-10 10=Highest Probability	C) DETECTION Probability Rate 1-10 10=Lowest Probability	RISK PRIORITY NUMBER RPN AxBxC
Proc_1	Receiving a non-functional device (In/Out Dept)	3	6	7	126
Proc_2	IT Registration	2	7	9	126
Proc_3	diagnosis of the device	7	6	7	294
Proc_4	withdraw spare part(s) from warehouse	10	4	6	240
Proc_5	withdraw spare part(s) from local Market / Global Market	5	5	5	125
Proc_6	Repair medical device	1	6	8	48
Proc_7	Finish paper work for functional device (In/Out Dept)	7	9	6	378
Proc_8	Giving away a functional device	7	9	3	189

Consequently, a 5-why analysis is deployed to determine the root cause of the problem. The method simply asks the question "Why" five times aiming to determine the root cause of the problem to be considered. As shown in Table 3. the problem is categorized into five main categories of causes including the environment, machines, methods, people, and measures. Then, two levels of causes were identified for each category.

Table 3. The Five why analysis for Process 7

Problem (Cause) Statement	Categories	Level One Causes	Level Two Causes	Why 1	Why 2	Why 3	Why 4	Why 5	Improve	Order
Finished paperwork for functional device	Environment	Organizational Policy	unavaliabilty of staff / manager	Related Staff working in another tasks	No. of staff is limited	Ineffective hiring process	Owner does not want to spend the money	Limited Salary budget	Increase the salary budget in order to hire new staff	5
	Machines	Computers/	Records are not automated	Not a priority	Staff is not computer literate	Did not learn	Relatively successful without the education	job description doesn't require computer skills	Modify job description and train the current staff	3
	Process/ Methods	Accessories	Receiving Process not in control	Missing accessories	No Check list documentations	No inspection mechanism	poor quality system		Enhance current quality system	4
	People/staff	Staff knowledge/	lack of knowledge	Hire/promote wrong people	Ineffective hiring process	Owner does not want to spend the money			Modify hiring requirements	1
				Limited in-service training	Not a priority	Owner does not value formal education	Owner does not want to spend the money	Does not think it's necessary	Create training programs	2
		Human error	human error in documentation	No revision procedure	No good supervision	No Check list documentations	No inspection mechanism	poor quality system	Enhance current quality system	4
	Measures	Missing Data	No quality system	Lack of knowledge	Do not have the expertise	Management is afraid of programs like Six Sigma	No premium on raising and solving problems	Owner does not understand that to save money you need to spend some in training.	Create training programs	2

3.4 Improve Phase

During the improvement phase, the team held a series of brainstorming meetings to come up with feasible solutions to the problem's identified root causes by 5 why methods. Eventually, a future-state process map was proposed with improved process steps. Before full-scale deployment, the proposed improvement is evaluated by a pilot run to validate the solution. Also, the project plan and cost-benefit analysis were completed. Figure 4 depicts the old and improved process maps, which indicate the stages that a medical repair workshop must take to meet the current goal. The proposed improvement focuses on converting the traditional system into a fully web-based system with an electronic following-up system. Like a butterfly effect for the developed system, This modification leads to the elimination of finishing paperwork, which has the largest influence on delaying the entire repair process

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3.5 Control Phase

The purpose of the control phase is to assess and ensure that the implementation of the proposed solution is carried out efficiently and effectively. It is also essential in the control phase to guarantee that the changes will be sustained over time. To guarantee continual improvement, the team included the PDCA cycle throughout the control phase of the lean six sigma project. As shown in Figure 5, The technique was used in the book "On the New Economics" (Deming, 1993; Ben Ruben, Vinodh, & Asokan, 2010), where the Plan phase detects the proposed solution, the do phase designates the carrying out producers, the control phase focuses on evaluating the results, and the Act phase explores any further improvement by adopting or abandoning the modification and continuously improve by repeating the cycle

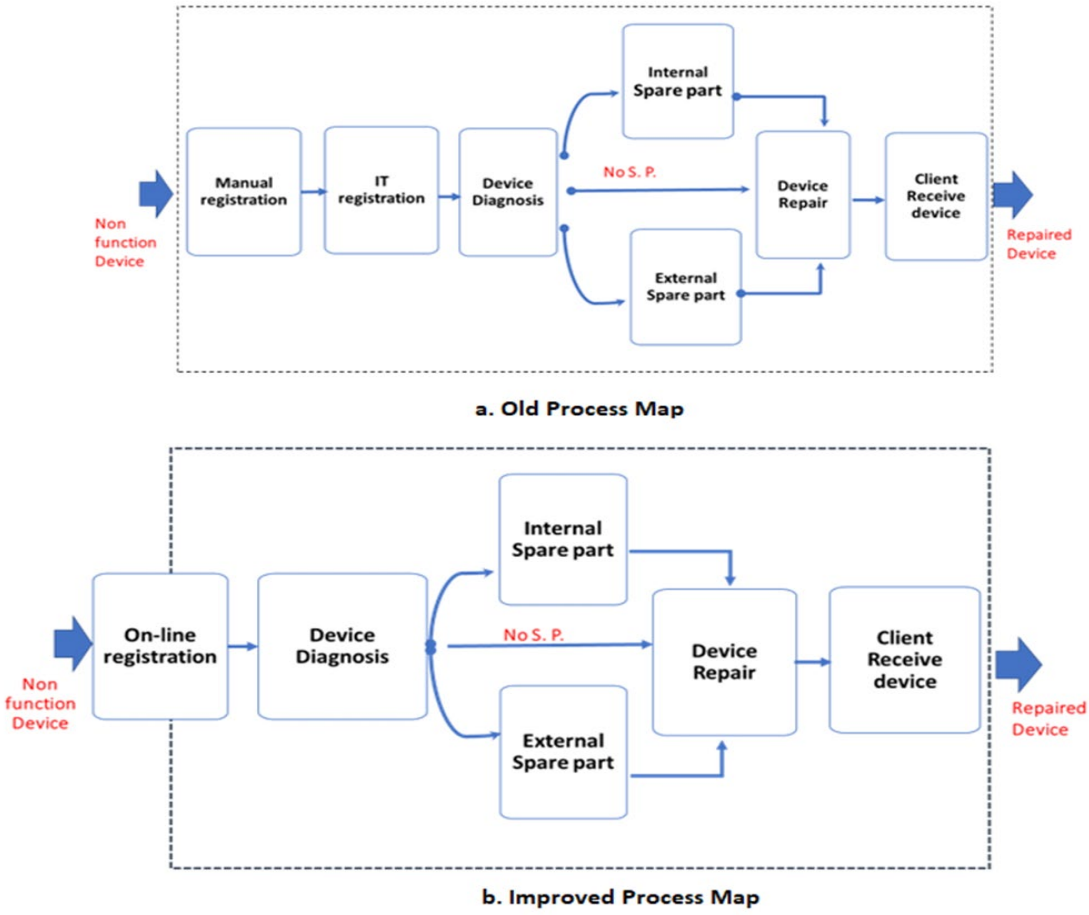

Figure 4. (a) old process map and (b) improved process map

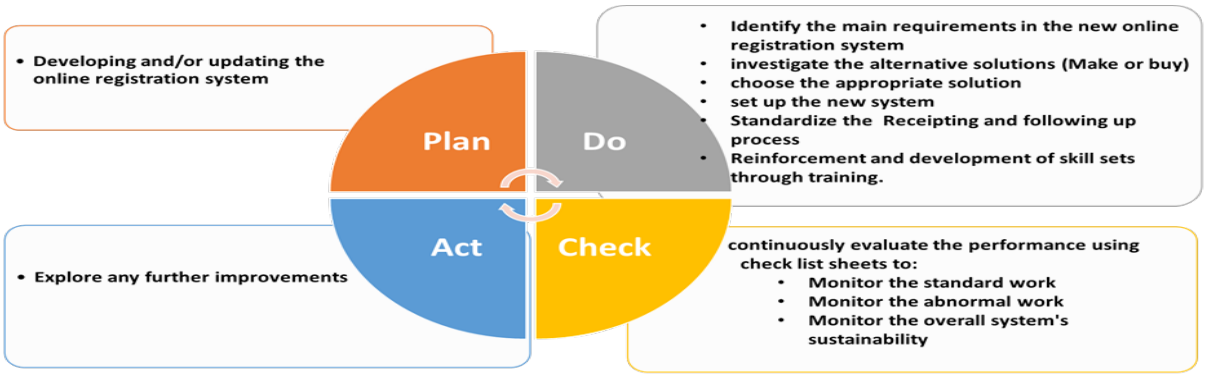

Figure 5. PDCA of control phase.

4. Conclusions

This paper demonstrated how LSS was successfully utilized in Egypt's public health system to reduce the repair time of medical devices. LSS is a long-term method and despite being time-consuming, it guarantees a proper problem-solving approach for the maintenance process. A large data collection sheet was created to collect all the measured data for 80 medical devices to assess the current state of the repair process. Results from FMEA indicated that the process of finishing paperwork for functional devices has the highest RPN. The implemented solution was transforming conventional methods related to the paperwork of all sub-processes in the repair center into a web-based system. Furthermore, the follow-up processes transformed into electronic-based methods. Consequently, the step of finishing paperwork, which has the largest influence on delaying the entire repair process was eliminated. This work showed the power of integrating the PDCA cycle with LSS throughout the control phase ensuring continuous improvement

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