Identifying the Main Causes of Medical Devices Failures While Surgery at High Specialization Hospital Implementing Lean Six Sigma

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Abstract. This project leads through the implementation of Lean Six Sigma (LSS) at two Surgical Units (SU) of the National Rehabilitation Institute (INR), a public high specialty Mexican hospital, to analyze and identify the main causes that produce failures in Medical Devices (MDs) during surgery. We applied the first three stages DMAIC methodology and LSS tools to achieve it. In the Define stage, the problematic was described. In the following stage, Measure, waste was identified on the work routine of the Biomedical Engineer (BE), who is part of the Biomedical Engineering Department (BED), with a Value Stream Map (VSM). In the final stage, Analyze, the causes of the principal ideas provided in the previous steps were determined. We identified the strongest factors that affect the processes involved in the elimination of mistakes or failures with MDs and waste. We studied these factors to understand their principal causes, to analyze them. Finally, we identified the main causes that produce MD failures during routine surgeries in the two SUs.

Keywords: Lean Six Sigma · Healthcare system · Quality improvement · Surgical unit · Biomedical engineering · Medical devices

1 Introduction

Mexican healthcare system is established by two sectors: public and private. The private sector provides services to the population with the ability to pay. The public sector includes social security institutions that provide services to workers, and institutions that protect or provide services to the population without social security [1]. The public sector has three levels of hospitals in health services.

The first level carries out actions to promote and protect the health, disease prevention, early diagnosis of damage, and outpatient care for the most frequent morbidity provided by general practitioners and nursing personnel. The second level provides basic

J. A. Marmolejo-Saucedo et al. (Eds.): COMPSE 2020, LNICST 359, pp. 143–154, 2021.
https://doi.org/10.1007/978-3-030-69839-3_10

specialties in general or specialty hospitals and has diagnostic imaging and laboratory support services. The third level provides specialized attention to greater complexity and combined with clinical and basic research activities. Teaching and research studies are also carried out here [2].

National Rehabilitation Institute Luis Guillermo Ibarra Ibarra (INR) is a third public hospital, whose scope of action includes the entire national territory and its main objective is scientific research in the field of health, the education and training of qualified human resources, and the provision of medical care services for a high specialty. The INR has three Surgical Unit (SU): Human Communication: Ophthalmology with three Operating Room (OR), Otolaryngology with three OR, Orthopedics with ten OR and CENIAQ (Center for National Specialization and Intervention for Attention to Burns) with two OR.

1.1 Literature Review

Quality in healthcare is a direct correlation between the level of improved health services and the desired health outcomes of individuals and populations. Quality improvement (QI) consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups [3]. Tolga Taner and others have mentioned the criticism to a healthcare organization of patient satisfaction in long-term, to improve it, healthcare providers must focus on six attributes for a QI: security, efficiency, efficacy, focus on the person, equity and accessibility, opportunity, and affordability [4]. Professionals who work in healthcare must demonstrate these attributes with organizational culture and monitor these attributes as a crucial element of organization philosophy.

Lean. Looks for a way to improve and optimize the production system, trying to eliminate or reduce all activities that do not add value to the production process (waste or Muda). The waste is everything that consumes resources but does not create value [5]. Categories of waste include: Transportation, Inventory, Motion, Underrated skills, Waiting, Overproduction, Over-processing, and Defects. Lean framework means: Use the necessary resources and the minimum time to do just what needs to be done and when it needs to be done [5].

Six Sigma. Aims to improve by finding and eliminating the causes of mistakes and defects in business processes [6]. "Six Sigma quality" is a term generally used to indicate that a process is well controlled [7]. A five-step define-measure- analyze-improve-control (DMAIC) methodology is used where each step outlines distinct and key activities.

Lean Six Sigma. The basic strategy of Lean Six Sigma (LSS) is to use the Lean strategy first to eliminate waste and make processes profitable. The DMAIC strategy is used to reduce errors/defects in Lean optimized processes, either by improving or replacing them [8]. LSS is a fact-based improvement philosophy that values defect/error prevention over defect/error detection [7]. The integration of the LSS as a methodology of improving the process performance provides several benefits to the organizations [9]. Six Sigma has the power to save millions of dollars in healthcare by combining its key components with the major principles of Lean [8]. Programs like LSS provide healthcare organizations with a viable approach to not only reduce costs but also improve quality [10].

Barberato Henrique and Godinho Filho, analyzed three databases where they filtered search criteria related to the terms: Lean, Six Sigma, LSS and medical care, hospital, research. The researchers eliminated redundancies keeping 118 and obtaining important conclusions: LSS represents the 22.0% of the studies analyzed; The most widely area explored in healthcare is Emergency Department with 13.6%, Operating Theatre have just a 6.8%; Only 21 countries published 100% of the researchers analyzed in this paper [11], where Mexico was not found.

Healthcare system is not modeled as an industry system that analyzes and studies the processes for the creation of a product, it does not plan the inventories of parts in a factory, it does not create transportation networks for pieces supply. Health care service is a human task where a client/patient flows by a process where quality service is provided and is expected to be the best possible quality, and if it's possible, upgrade to a quality improvement above time. For this reason, it must be modeled in a systemic and detailed way, analyzing, and studying every detail. There are many studies about LSS in healthcare systems in different departments for QI but Black explored LSS and showed that these studies do not fully consider the complex social interactions that make processes to form in organizations like hospitals [12].

Medical Devices (MD) are used in the daily work of physicians, they use these technologies to generate a better diagnosis, give the greatest treatment, help successfully with patient's recovery, etc. Shah and Robinson mentioned that medical device technology has become a touchstone of enlightened practice [13], and the World Health Organization explained that is an important issue because users are the ultimate beneficiaries of developments [14]. A Biomedical Engineering team in a hospital oversees the safety and maintenance of MD in all its areas. But what happens if the MD fails? In the industry, when a machine does not work in the right way in a process where a product flow to a client, we have consequences as loss of client satisfaction, defects, delay time, waiting time, money loss, etc. Any failure could be solved and avoiding this represents a good point to inquire. But we must remember that healthcare systems are complex, that means we are taking care of people, so we work with the flow of a patient, a human living being, through his recovery or health keeping process. So, let us reflect which is one of the areas where would be more important or of extreme emergency to prevent failures in MD? In surgical Units, at OR physicians do procedures of extreme care and eliminate MD failures would be a great opportunity to help the satisfactory result of surgical procedures. So, we decided to look for the causes that produce MD failures at the different OR while surgery implementing LSS tools and methodologies looking forward to quality improvement.

Research done in developing countries is significantly small and the lack of evidence about LSS initiatives in Latin American countries is two important points exposed by Henrique and Filho. A group of Mexican researchers looked for the state of LSS practices and their implementation at Mexican hospitals even if they are not published in the literature. They applied a survey to 30 Mexican hospitals across six states, using 258 participants, from top managers down to front-line staff, selected by a random process. They found the penetration of LSS in the Mexican health system is represented by 16% of respondent's participation, being equally used in public versus private hospitals [15].

With the above, we are allowed to highlight the importance of research and development of research the implementation of LSS in quality improvement in healthcare systems and I quote Barberato Henrique and Godinho Filho: "There is an immediate need for research in this field that not only describes what tools were applied and what were the results obtained … there are still some dark and unexplored issues" [11].

The implementation of LSS in SU in Mexico is an area of study opportunity that will generate an important contribution to quality research in the complex Mexican healthcare system, leading us to innovative and improved studies and this research field in our country. Additionally, the academic impact of these investigation projects, in a country where is not developed yet and there is practically no existence of literature, is the fact that it is being developed and at the time it is published. Start to create Mexican LSS implementation bibliography, where the actual state is shown, barriers are explained, methodologies are exposed and conclusions are shared, we begin to open a way to grow not just in the number of articles, also in the quality improvement in our country. So, this type of research will start to be considered in Mexico, and all of Latin America, leading to new findings, and concrete conclusions, that would help us improving and encouraging these investigations. The objective of this research project is to implement LSS to identify and analyze the causes which produce failures in MD while surgery procedure in OR using the optimum tools, looking for quality improvement and applying three quality approaches: efficiency, efficacy, and security; and generate concrete conclusions about the analyzed and observed while the investigation project.

2 Methodology

QI process in the health field involves very important aspects: consider the healthcare organization as a system within a system of processes related to the guarantee of the quality of healthcare, understand and respect the expectations and quality requirements of the clinical efficacy of the patient/client, ensure that all staff in the healthcare organization work as a team to QI and collection and analysis of qualitative and quantitative data to monitor the quality of clinical effectiveness throughout the healthcare organization.

The regulatory framework of the NRI dictates that when an MD requires a service must be channeled through Biomedical Engineering Department (BED) and every action carried out on a medical device is recorded in a Biomedical Equipment Service Order (BESO), signed by the Department and the user area. The BESO must be registered in the SIAEM (Medical Equipment Administration Computer System). The BED has a calendar for preventive maintenance which is renovated every year. The activities of the Biomedical Engineer (BE) refer to any of the following activities, depending on the schedules or needs presented: Corrective maintenance, preventive maintenance, electrical safety tests, carry out service orders, training, and work with External Providers (EP).

We implemented the first three steps of the LSS using different tools to reach the elimination of waste and mistakes in the processes of preparation of MD in the Orthopedic and Human Communication SU. The tools used through the project development are shown in Table 1.

Table 1. LSS tools used in the project.

Step	Tool	Purpose
Define	5 s diagnosis	Measure quality performance and control with 5 s: Sort, Set in order, Shine, Standardize, Sustain
	Thread diagram	Identify waste in the engineer's work routine
	Interviews	Obtain information to generate a brainstorm. (surgeons, nursery team, BED team, and EP)
	Brainstorm	Identify the most commons problems with the MD
	Problem selection	Group the ideas of the brainstorm in the main ideas and obtained their frequency
	Pareto Chart I: *Brainstorm*	Calculate the cumulative frequency to build a Pareto Chart, identify the 20% vitals, and 80% trivial
	Pareto Chart II: *SIAEM*	Collect data from 2018 to March 2020 services done to the MD to build a Pareto Chart and identify the 20% vitals and 80% trivial
Measure	Value Stream Map (VSM)	Identify the flow of the patient through the process and to determine the Kaizen Outburst (KO), which shows waste
Analyze	Why? – Why?	Determine the causes of a problem, at each level of the diagram, the question why? is answered, until we reach the root of the problem

3 Analysis Proposal

3.1 Orthopedic Surgical Unit

Define
With all the tools before mentioned implemented, we selected the most significant data due to get closer to a real diagnosis, these ideas are exposed as follows.

5 s Diagnosis. The SU obtained "Formal Achievement" with a score of 63/120 which means 76%, like the point are not close to 90, the SU has not implemented yet the first 4 s.

Pareto Chart I: Brainstorm. In the Fig. 1 we can see that in the vital 20 are "Mistakes using MD" and with the same percentage "Damages to the MD while using it". The first one refers to the failures due to not knowing how does the MD works, therefore, not knowing how to use it properly, and the second refers to the existing carelessness when using it such as: dragging, hitting, throw cables, or parts, mistreating.

Pareto Chart II: SIAEM. The vital few reside in the "Steam Sterilizers", these are sheltered in the Sterilization Center and this does not affect directly while surgery, so we move on to the following percentage "Vital Sign Monitor", which has been replaced by new ones. So, the 20% range is discarded to decrease bias. Let's remember, the best tool is which provides us with the required information.

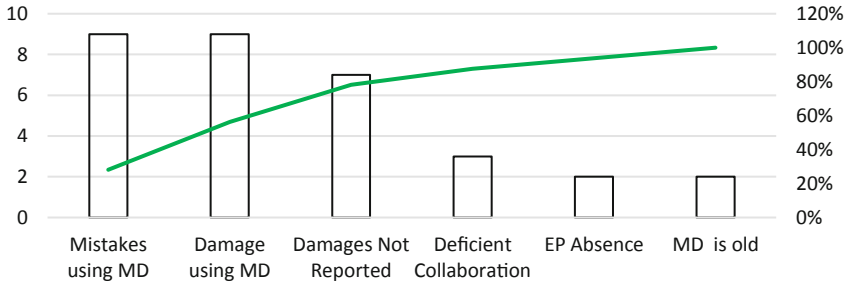

Fig. 1. The percentages obtained in the Pareto Chart I are: Mistakes using MD (28%), Damage using MD (28%), Damages nor Reported (22%), Deficient Collaboration between departments (9%), EP Absence (6%) and MD is old (6%).

Measure

From the last mains ideas, we connected them with the KO to realize a better interpretation of the problematic.

VSM. Considering the purpose of the project (identify the failures of MD in SU) we analyzed the processes carried out by the BE. There are 3 KO shown in Fig. 2: MD damages not reported to the BED, BE realizes this, it produces a delay in the preparation of the MD the next surgery, and sometimes these damages are not visible, consequently, the magnitude of the damage increases too; Frequent absence of the EP, MD is under a contract, which stipulates that an engineer from the supplier company will prepare this equipment before surgery. If EP is absent, the BE will have extra workload; Corrective Maintenance, If MD failure while surgery, Pareto Chart I show the causes of it.

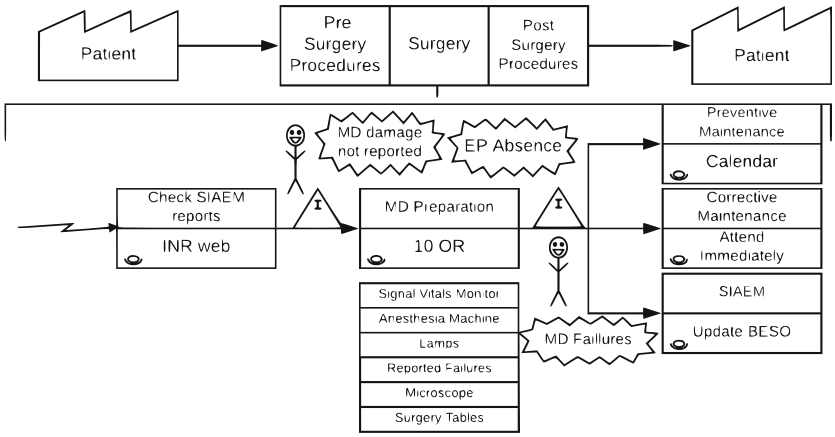

Fig. 2. At the beginning of the VSM, we can see the patient flow through the healthcare process. It is focused on the surgery process; it shows the flow of the BE through this process and the relation between the BE and MD.

Analyze

To finally define the problem and get to the exactly main causes of it, we dig into the resolutions given by the previous steps.

Why? -Why? The main cause provided by this technique is the non-attendance by the user to training and its consequences: from quality decrease to an economic point of view: expenditure in repairs. We analyzed a step behind, Lack of training, digging in this because it is important to explain the INR regulatory framework, which stipulates: Annually, a survey will be done to detect training needs, BED will establish with the Department Head the training needed and if a department of the hospital needs training, it must be solicited to the DEB, as soon as the need arises. So, the training service exists but it is not required, so the responsibility lies on the User (Fig. 3).

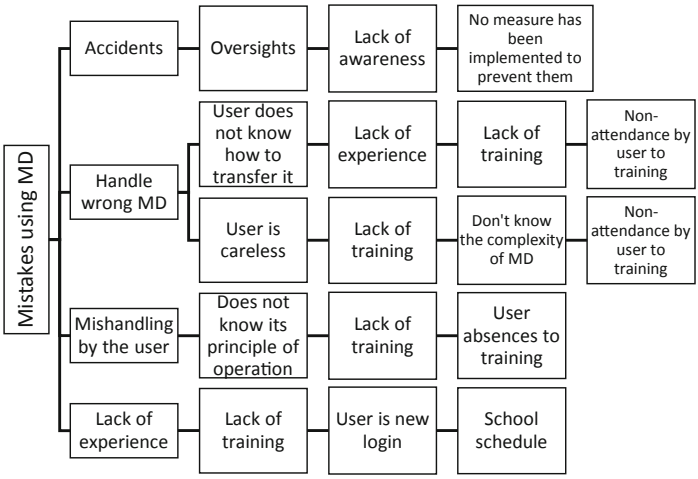

Fig. 3. Shows the main causes which are Non-attendance by the user to training.

3.2 Human Communication Surgical Unit

Define

The most significant data due to getting closer to a real diagnosis were given by the threading diagram and Pareto Charts.

5 s Diagnosis. The SU obtained "Formal Achievement" with a score of 67/120 which means 80%.

Thread Diagram. We found transportation waste because of the planning of the SU.

Pareto Chart I: Brainstorm. The vital problem is the "Area Planning", which is discarded so, the next category is the "Mistakes while using MD", this is analyzed further. We can see this result in Fig. 4.

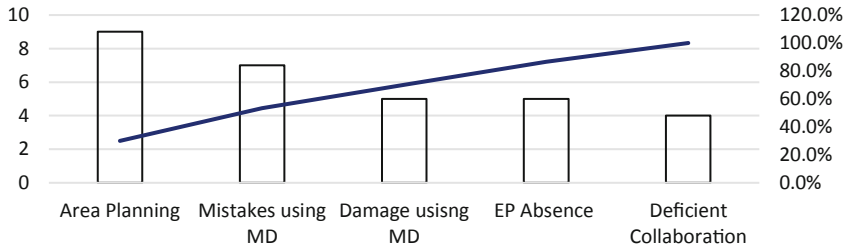

Fig. 4. The percentages obtained in the Pareto Chart I are: Area Planning (30%), Mistakes using MD (23.3%), Damages using MD (16.7%), EP Absence (16.7%), and Deficient Collaboration between departments (13.3%).

Pareto Chart II: SIAEM. The Otorhinolaryngology OR 20% vitals are represented by the "Electrosurgery Unit" and the "Vital Signs Monitor", the last ones have been replaced in December 2019, therefore, were discarded.

The Ophthalmology OR 20% of failures are caused by "Steam Sterilizers". For both areas, the MD is found in OR, so the biomedical engineer can incorporate into his routine checking it before surgery, preventing them from failing.

Measure

We connected the last main ideas with the KO to obtain a bigger interpretation of the problematic, especially transportation waste.

VSM. We find 5 KO: MD damages not reported to the BED, EP Absence and MD Failures haven been described; Delay of the EP (EP Absence) in charge of preparing the microscope and the transportation produces too a workload to BE; Transport Waste, produced by the planning of the area (Fig. 5).

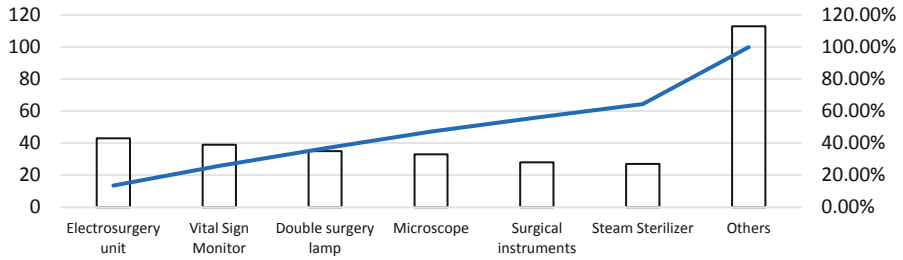

Fig. 5. The percentages obtained in the Pareto Chart II (Otorhinolaryngology SU) are Electrosurgery unit (13.5%), Vital Sign Monitor (12.6%), Double surgery lamp (11.01%), Microscope (10.38%), Surgical instruments (8.81%), Steam Sterilizer (8.49%) and Others (35.53%).

Analyze

We dig and compare the main ideas reached to finally define the problem and to know exactly the main causes of the problem. It must be considered that the poor planning and design of the area and its resolution is not included in the project limitations (Fig. 6).

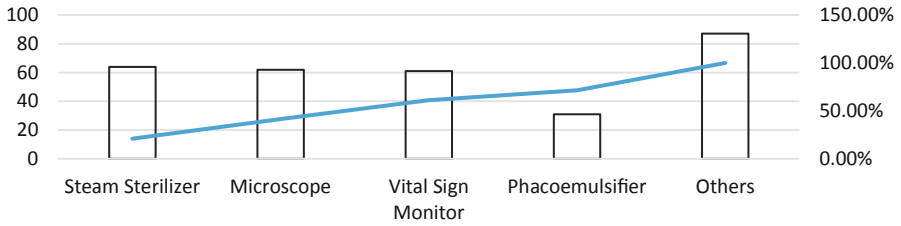

Fig. 6. The percentages obtained in the Pareto Chart II (Ophthalmology OR) are: Steam Sterilizer (20.98%), Microscope (20.33%), Vital Signal Monitor (20.00%), Phacoemulsifier (10.16%), and Others (28.52%).

Why? -Why? Considering that the problem to be analyzed is "Mistakes while using MD", the causes converge to the same root cause in the first Why? - Why? diagram.

4 Results

During the project development, we identified the mistakes and wastes that cause MD failures while surgery procedures at the INR's SU. The main cause is the lack of training by the user, and this main cause was analyzed. The analysis leads us to identify the real main cause which is the non-assistance to training and that this training are also not required by the user. The failures of the MD in Orthopedics and Human Communication SU, would be solved with the increase in the number of training provided with the complete assistance of the user (Fig. 7).

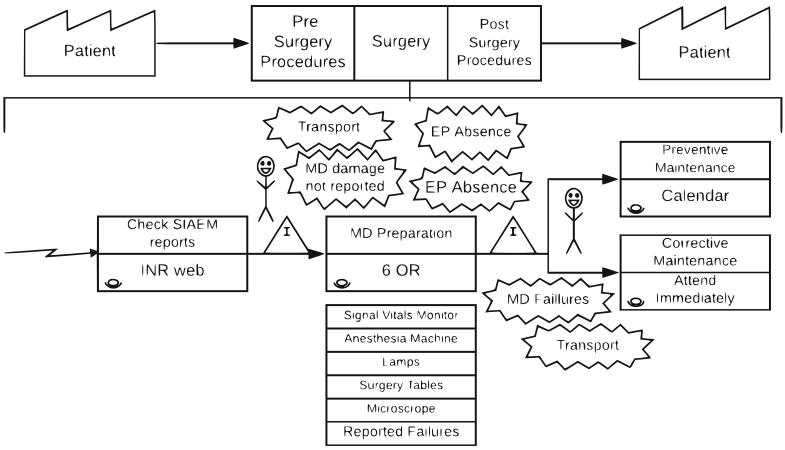

Fig. 7. At the beginning of the VSM, we can see the patient flow through the healthcare process. It is focused on the surgery process; it shows the flow of the BE through this process and the relation between the BE and MD. It shows 6 KO.

The absence of the EP should be deal with by the provider to set and re-structure the contract and avoid the work overload to the BE. Transportation waste, like it has been

already said, does not take part in the project limitations. The results obtained in Pareto Charts II at Human Communication Surgical Unit recommend including in the work routine the supervision of the MD on the 20% vitals, as Steam Sterilizer, Electrosurgery unit, and Vital Sign Monitor. The Pareto Chart of Orthopedic SU does not give a strong recommendation. The problems mentioned above do not impact as the main cause but the elimination of these will contribute to the QI in the SU at the NRI.

We propose to implement LSS tools and techniques to remedy this problem and to reach QI in the hospital. We also recommend to strength the training given: explaining the care importance; showing how does the MD work to help the user area to understand the operating principle basis, so they would manipulate it in the right way; motivate users to be part of this training. If the previous recommendations are taken, the INR will eliminate MD failures at SU and get a QI achievement.

5 Conclusions

As the first three stages of DMAIC have been implemented, and the real main cause that produces MD failures at SU of the INR has been identifying, the lack of training, and the non-participation of the user on it. Once we conclude it, we checked the regulations from the hospital, where we realized two crucial points: the capacitance that is requested has a low number of participants and the lack of more training it's because the user area does not request them. We strongly recommend starting participating in training and understanding the importance of knowing the function of MD to avoid its failures while surgery, prevent it malfunction and decreasing the number of corrective maintenances.

Above its essential to understand the economic impact, we are studying a public hospital, in avoiding MD failures attacking their main cause. If the situation continues in the same way, the hospital will continue paying for maintenance from EP and the BED will keep wasting time repairing MD. But, If the BED continues teaching the function and use of MD in capacitances and the user start to participate in these training, there is no extra expenditure cause BED is fulfilling their duty included in their work routine, so in their respective payment. So, the expenditure of this public hospital in external maintenance will plunge.

Major of studies, inf first world countries, that have implemented LSS in OR reached like major improvement was the reduction in the length of stay [16], another application focused on reducing costs [17], improvements were identified relating to reducing transportation and movement waste for hospital staff [18]. So, with this project, we can give a new perspective to analyze and improve quality methodologies on SU.

Further, we can focus in solve the problem by continuing with the following stages of DMAIC methodology: Implementation and Control. It should be considered the investigation and data reordered on this field in Mexican healthcare system is poor, so it must be registered every step and detail of the research, project, or investigation done. Then, the work registrations could be used in other research as a starting point or comparative way.

So, for a further project, we can work with Implementation by applying the solutions to the problem that has been identified. We should consider the limitations and the situations that could occur while this: opposition to change the way it has been worked

through the years, close minds, the lack of evidence (we must remember that in Mexico all the healthcare work is done basis on evidence), change resistance, etc. It would be essential to compare the situation before and after the performance of this stage, and from this comparison determined the benefits and results of implementing quality methodologies.

For the Control stage, we can perform other investigation projects. After the implementation stage, we should look for keeping the achievements that have been acquired. In the final DMAIC stage, we want to standardize the new work routines as the natural way of performing the duties. We can speculate that it would be harder this stage (Control) than the previous one (Implementation). This is predicted because it is easier to perform new routines for a given time than integrate a new way to do something like the usual routine (longer period). When you propose to someone to work in a different way than the person has always done, it will always bring resistance, and with more reason, if it is a permanent change.

The following projects of this investigation would be registered in the right way to bring new data and conclusions in this field. We expect this new research to help and promote the investigation about QI in Mexican healthcare system, and lead to concrete the fundaments of it.

The National Association of Faculties and Schools of Engineering suggested the design of a society that meets new needs in the field of health and highlighted the requirements of engineering to face it, so medical technology develops holistic and complex intervention systems, in which engineering will surely also play an important role [19]. So as Mexican quality healthcare investigations, we contribute helping with the beginning of the writing literature about LSS implementation in Mexican Healthcare Systems and Latin-American countries. The given conclusions will help another research as a pillar or argument in their new investigation projects, this continuous practice would lead to improving the number of research, implementation, literature but more important, quality in Mexican healthcare system.

Acknowledgment. This research was supported by National Autonomous University of Mexico (UNAM), PAPIIT IA105220 Optimización en la Logística Hospitalaria.

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