Inventory Quality Control in Clinical Engineering: A Lean Six Sigma Approach

A. P. S. Silva[1], J. M. Palermo[1], A. Gibertoni[1], J. A. Ferreira[2], R. M. A. Almeida[2], L. Marroig[3]

[1] Clinical Engineering Department, Hospital Albert Einstein, São Paulo, SP, Brazil
[2] Biomedical Engineering Department, Universidade Federal de Itajubá, Itajubá, MG, Brazil
[3] Continuous Process Improvement Department, Hospital Albert Einstein, São Paulo, SP, Brazil

***Abstract* — Medical equipment inventory control is important for any hospital. Its measurement and management directly affects healthcare providers' decisions about budgets, administration and maintenance. In this paper the authors present a case study, conducted at Albert Einstein Hospital which uses both Six Sigma and LEAN methodology/tools to improve the inventory control over critical medical equipments. The Six Sigma philosophy aims to diminish the errors committed, avoiding rework while LEAN aims at reducing all form of losses and wastes in the manufacturing process. Significant results were attained, increasing the selected indicator (complete forms) from 62,6% to 99,4%, which benefit both the hospital's management as well as the patient's level of care.**

***Keywords* — Clinical engineering, Lean Six Sigma, Inventory, Quality**

I. INTRODUCTION

The concentration of medical equipment at Albert Einstein Hospital, the focus of this study, has experienced a sizeable increase over the past years, motivated principally by the institution's overall growth. This increase has required the clinical engineering department to take action in order to guarantee the medical equipment's quality and confidence.

The clinical engineering department focuses on the internal client's level of service, paying special attention to preventive and corrective maintenance. Administrative activities, inherent to the equipment's management, demands much of the clinical engineers' time, especially those activities related to inventory registration and management. The significant increase observed over the past years could have a negative impact on inventory quality, thus increasing the number of unfinished installations and incomplete registrations.

In order to investigate the greatest generators of defects in medical equipment inventory, one must be familiar with the process, starting from the point of equipment acquisition all the way up until its availability for use. In the process of this study, one of the objectives was to bring to surface wastes and eliminate rework. In order to do such, this project was elaborated based on the Lean Six Sigma philosophy.

A. *Lean Manufacturing*

An operational philosophy whose main objective is to eliminate losses over all dimensions, mainly activities that do not aggregate value to the business, unnecessary levels of inventory, rework, stoppage time, among others [1]. Lean concept characteristics are [2]:

- Focus on maximizing the process's speed;
- Utilization of process flow and process delay analysis tools for each activity;
- Separation of work into tasks which aggregate and those that do not, with tools which eliminate the root-causes of activities that don't aggregate value;
- Means to quantify and eliminate the cost of complexity.

B. *Six Sigma*

A disciplined and highly quantitative managerial strategy which aims to drastically increase a business's profitability. This is achieved via product quality and process improvement, and increasing customer satisfaction [3]. This methodology starts off with a problem to be solved and values the people involved in the process and their knowledge.

Six Sigma has three main pillars: adoption as a management philosophy, business strategy and an operation based on statistical applications [1]. It can be applied under an approach focused on business process improvement, as the fundamental question resides in process improvement via analysis of the individuals in each process stage [4]. Some characteristics are listed below [2]:

- Emphasize the necessity to recognize opportunities and eliminate defects defined by the clients;
- Recognize that variation damages the business's capacity to deliver high quality services;
- Require decisions based on data and incorporate a broad set of quality tools in order to effectively solve problems.

Adopting solely Six Sigma or Lean Manufacturing can bring about many benefits in an organization [4]. However, when used together, the two systems become even more effective, as their strong points are able to cover the other's gaps or deficiencies. This union may create a synergy,

ISBN: 978-1-4673-1134-2
IEEE CATALOG NUMBER: CFP1218G-ART

which exercises a great influence over the general performance of the business's processes.

This research's proposal is to apply Lean Six Sigma tools in order to analyze the previously mentioned process, point out bottlenecks, wastes and implement improvements and optimizations in order to guarantee process quality.

This article aims to present the Lean Six Sigma methodology applied in the improvement of inventory registration of critical medical equipment. The largest hurdle for this work was to restructure the equipment registration inventory and installation processes in the Clinical Engineering department. In order to achieve this objective, it was necessary to become familiar with the clients' necessities, the interfaces with other areas and equipment makers, the system flow already in place and its limitations and defects.

II. Methodology

The medical equipment administration system, in the hospital under study, is directly related to the preventive maintenance system. When new equipment arrives, before it is installed and liberated for use, it must be registered. After an initial registration, a series of procedures take place, including: an acceptance test, calibration, hospital patrimony registration (with a Clinical Engineering tag and hospital patrimony plate), creation of preventative maintenance procedures, and finally, the periodic maintenance programming plan.

For the registration, a large amount of information is necessary. One of the most commonly faced problems is the lack of information, such as the installation site, purchase request number, acquisition date, etc.

Another difficulty is gathering all the necessary information to create preventive maintenance procedures and generate system plans. For each new piece of equipment, a procedure must be created which follows the equipment maker's instructions. When there is a similar piece of equipment, the maintenance or operating procedure may be the same, which can speed up the registration and liberation process. Unfortunately this does not guarantee that this procedure covers all the necessary points for that particular piece of equipment.

In some of the cases under study, equipment was liberated without a maintenance plan. This compromises the reliability of the use of this equipment in the long term, as preventive plans were not generated adequately, and consequently, maintenance may not be performed in the correct period.

Aside from compromising the clinical engineering department's level of service, the hospital overall level of service is also affected due delays in the liberation and installation process of the equipment. In certain cases, even the safety of the patient in the mid- to long-term can be affected due to the lack of preventive maintenance.

The lack of reliable information causes rework, losses and deficiency in the management of the equipment, based on its service life registration and budget values.

TABLE 1
TOOLS FOR LEAN SIX SIGMA

Phase	Activities [3]	Tools presented in the literature[1] (*) Tools used in this project
D - Define	Identification of best Six Sigma projects based on strategic objectives. Determination of what is Critical To Quality (CTQ) for the clients.	* VOC = Voice of Client * Definition of Scope (what to include, exclude) * Macro mapping of current process * Definition of main indicators * Definition of project goals * ARMI Matrix
M - Measure	Definition of the processes linked to CTQ and measurement of the current performance of the selected processes.	* Detailed process map * Ishikawa diagram * Cause and effect diagram Effort X Impact Matrix * Pareto Graph Data collection plan
A - Analyze	Identification of the main causes for process variation and generation of non-conformities via performance analysis using statistical methods. Confirmation of the variable to be improved.	* Pareto, dispersion and Box Plot graphs Regression analysis Tendency and dispersion graphs Test of hypotheses FMEA Benchmarking
I - Improve	Experiment conduction in order to establish the best level of the identified variables in the previous phase. Establishment of an implementation plan.	* Action plan * 5S Value flow analysis Kanban JIT * Training
C - Control	Application of techniques and statistical and quality methods in order to guarantee the statistical stability of the process within its acceptable levels	* Norms and procedures * Control plan Auditing Statistical Process Control

In this research, the methodology DMAIC was adopted as a guide for the development of a Six Sigma project for inventory quality control for medical equipment. As this covers a broad reach, we focused only on highly critical equipment acquired by the hospital which was under the responsibility of the Clinical Engineering department.

The methodology DMAIC is divided into 5 phases: D (Define); M (Measure); A (Analyze); I (Improve) and C (Control), which are explained further in Table 1. Also in it, some of the tools utilized in this research are presented.

III. Results

The results obtained were compiled and are presented below. They were separated into each phase of the DMAIC

methodology in order to respect the didactic structure of this article.

A. *Define*

The first result obtained by the methodology was the formal definition, from the clients' point of view, for the project scope, the main indicator and the objective.

Project Scope: Optimize and implement medical equipment registration process improvements in order to meet the goal stipulated for critical equipment registration.

The principal indicator: The total number of complete critical equipment registrations over the total number of new pieces of critical equipment registered.

Objective: 100% completed registrations.

Another important point was to clearly define what would included and excluded from the project's scope, what would be considered critical equipment, as well as the necessary information to define the registration as "complete". In this phase, critical points and criteria were brought up which could influence overall quality, such as rework, unavailability of information, arrival rate of equipment, creation and availability of preventive procedures, etc. After understanding the particularities of each kind of the equipment, such as hospital-owned, commodatum, demonstration, on loan, it was decided that the study should focus only on the equipment purchased by the institution, entitled "owned equipment".

It was discovered through hospital records that "owned equipment" corresponds to 91% of its inventory. With this information, a process map of the current process was elaborated, with all of its bottlenecks and rework points therein contained. Figure 1 presents this initial flow in comparison to Figure 2, which presents the process flow after the improvement phase.

B. *Measure:*

Important points in the equipment registration process were identified. Factors which could easily be extracted from databank software were utilized, including those for the process measurement plan. Five types of possible errors and defects within the client's requirements were identified. These defects are listed in Table 2 below. Furthermore, all of the equipment acquired by the hospital was identified in the comparative analysis period, which was registered in the equipment management system.

TABLE 2
ERROR TYPES FOUND

Error 1	Equipment without a maintenance plan in the system
Error 2	Register without equipment serial number
Error 3	Register without equipment acquisition value
Error 4	Incorrect equipment criticalness evaluation
Error 5	Incorrect equipment service life

With the defects quantified, the initial process sigma value was calculated and the analysis phase was started. Figure 3 presents the division of errors related to the registration for each of the departments under coordination of the clinical engineers in the first period of the year. For each type of error, an Ishikawa diagram was generated to study their causes. Figure 4 presents the diagram generated for Type 1 Errors: Equipment without a maintenance plan in the system.

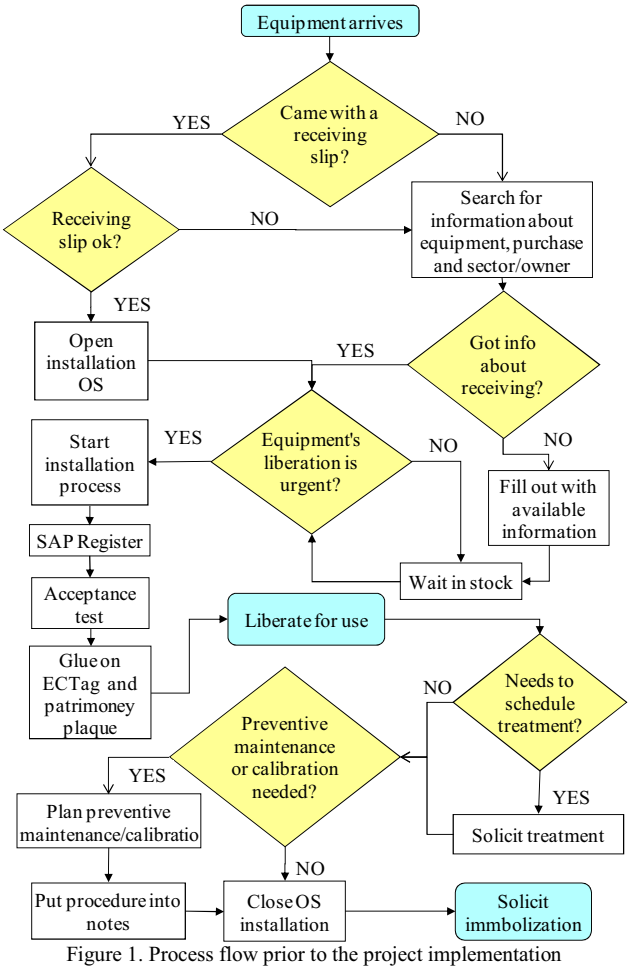

Figure 1. Process flow prior to the project implementation

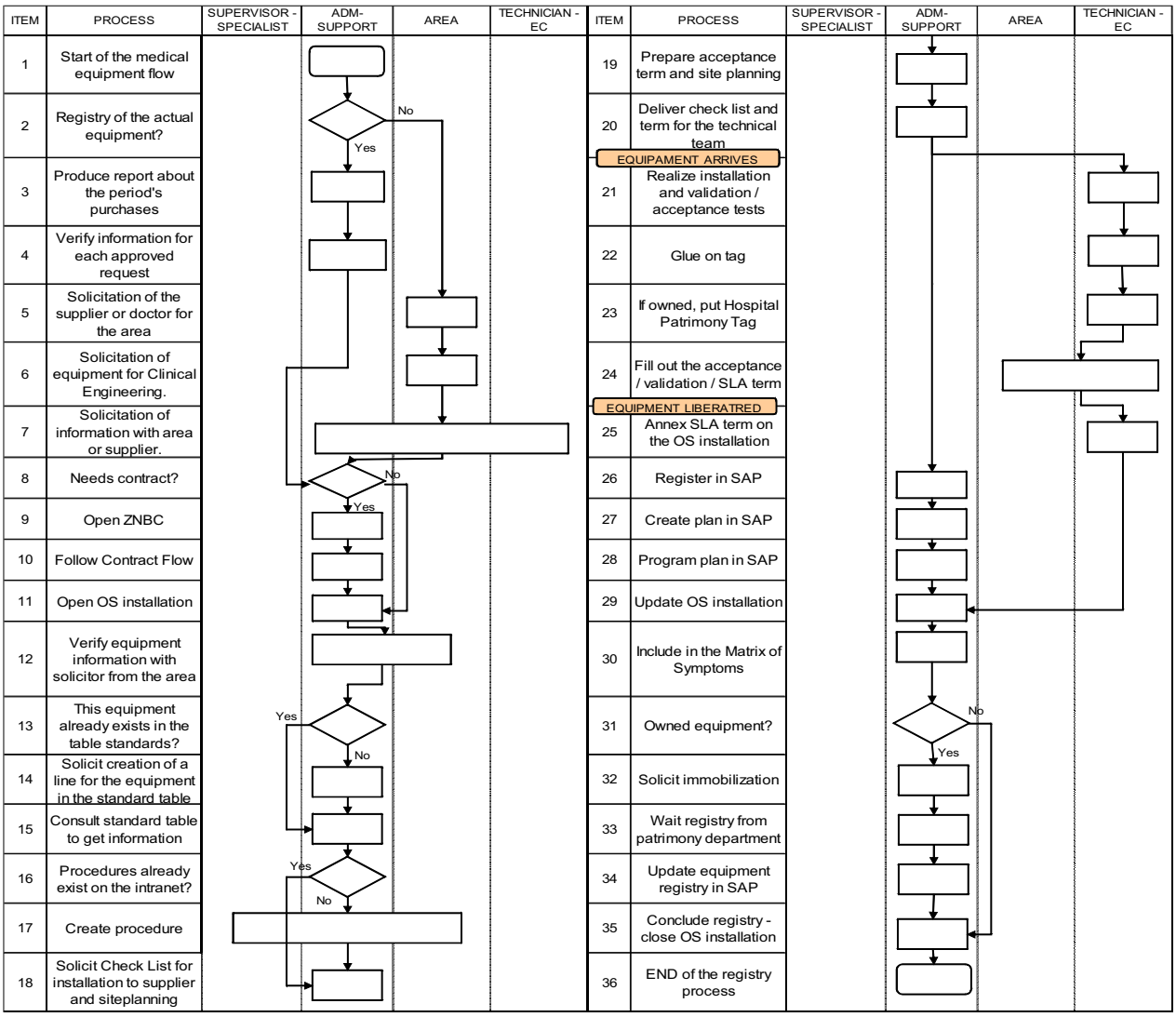

Figure 2. Process flow upon completion of the Lean Six Sigma project

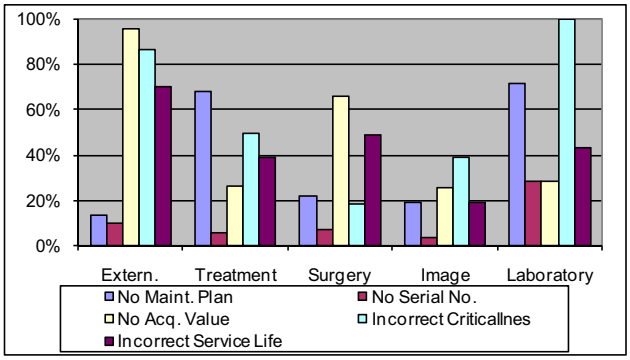

Figure 3. Percentage of errors per department of the hospital

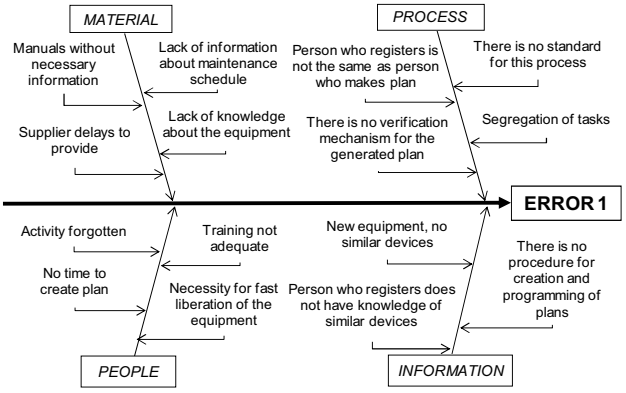

Figure 4. Ishikawa diagram for type 1 error

It was noted that, due to the number of pieces of equipment without registry, there was no guarantee that all of the new equipment passed through the Clinical Engineering department for registration and initial validation before

being put into use. This was a key point in the elaboration of the new flow and registry of equipment, seeing that it is critical to patient safety.

C. *Analysis:*

It was perceived that the project needed a new structure, following a methodology somewhat different than DMAIC, known as DFSS (Design For Six Sigma). DFSS follows the phases of Definition, Measure, Analysis, Design, Optimization and Verification. It is based on the development of products and new processes [3].

D. *Improve:*

A new process flow was designed, aiming to meet customer requirements, eliminate rework and speed up equipment liberation and registry time. It also aimed at guarantee that all new equipment passes through the clinical engineering department with all of the necessary information for the complete registration.

The key points of the implemented flow were: the interfaces with the purchasing departments, the hospital patrimony registration, the centralization of registration activities into an administrative group and the availability and organization of information in pre-registration service orders.

An acceptance terms standard form was implemented, which establishes the equipment's delivery to the sector, its installation and all of the necessary conditions for the equipment prior to use (training, manuals, acceptance tests, accessories…). This term must be signed and annexed in the equipment service installation order. After technical approval, the administrative area does a registration of the equipment in the database software with all of the preventive programs and calibration according to the specific procedures required.

E. *Control:*

A control plan was designed and the necessary indicators were identified for verification of the newly designed process. All those involved were duly trained on the newly published procedures. With the new controls, it was possible to monitor not only the 5 defects previously identified, but 8 possible defects, thus improving the registration quality.

The sigma level was then calculated at the end of the process. Related to this indicator, the quantity of defects per million opportunities (DPMO) was calculated for situations prior to and after the implementation of these actions. These levels are presented in Table 3.

TABLE 3
CONFIDENCE INTERVALS BEFORE AND AFTER THE PROJECT IMPLEMENTATION

	Sigma Level	DPMO
Before	1.82	374472.22
After	3.99	6476.68

IV. CONCLUSIONS

The sigma level indicator translates into significant improvements in the quality of the service offered, jumping from 62.6% to 99.4% of the number of complete registrations. With the implementation of the new process flow, many benefits were aggregated, such as the diffusion of the methodology to all the members of the team; organization and creation of equipment description patterns, criticalness and service life; elimination of reworks and waste; agility in the equipment liberation process; and especially the guarantee that all of the new critical equipment had particular plans and procedures for correct preventive maintenance.

The interface with the other areas was also essential for the success of the project such as: the direct connection with the purchasing department, by evaluating what is being purchased and the predicted arrival date; contact with the hospital patrimony department, guaranteeing that all of the equipment is being tracked for depreciation, and with all of those who required the equipment in the different hospital departments, thus improving and speeding up delivery and installation.

The creation of a group focused on administrative and quality issues, inside the clinical engineering group, can greatly reduce the bureaucracy and the administrative load on the technical staff by the improving and standardizing the processes for inventory control. In the hospital under study, this leads to a better quality of the information by ensuring that almost all (99.4%) equipments with high criticalness had their files fully filled with correct maintenance plans.

ACKNOWLEDGMENT

Special acknowledgements are due to the Albert Einstein Hospital for their continued worked on process improvement. We thank all of the participants of the ARMI team, who performed their activities successfully throughout all of the DMAIC stages.

REFERENCES

[1] Galbinski J., Abraham M., *Lean seis sigma – Gestão da qualidade e produtividade com foco.* Setec Consulting Group. 2010 http://www.setecnet.com.br/artigos/o_impactoda_gestao_da_qualidade_na.pdf, accessed: 04.15.11

[2] Barreto R., Lopes C. Akabe G., *A importância da filosofia lean seis sigma e sua contribuição para redução de custos nos serviços logísticos.* Anais do XII SIMPOI – Simpósio de Administração da Produção, Logística e Operações Internacionais, 2009.

[3] Breyfogle, F. W., Cupello, J. M., Meadows, B., *Managing Six Sigma: A Practical Guide to Understanding, Assessing and Implementing the Strategy That Yields Bottom-Line Success*, 2001, ISBN: 978-0471396734 Wiley, NY.

[4] Renato E., *Six Sigma, Lean Manufacturing e Teoria das Restrições (TOC) Ferramentas, Filosofias e sua integração com a gestão de processos.* Coppe UFRJ. 2007.