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Application of statistical processes control for the performance improvement of a clinical engineering department

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ABSTRACT

This article addresses the fundamental role of Statistical Process Control (SPC) as a quality tool in the field of clinical engineering, to improve and optimize internal processes. This study describes the methodology used to apply the SPC in a reference hospital's clinical engineering department. Data was collected over an extensive period, involving multiple medical equipment and verification procedures. These data were analyzed using various statistical tools, such as control charts, Pareto charts, and descriptive statistics.

The results showed stability in the department's processes, which made it possible to identify areas for potential improvement. Statistical analyses revealed behavior patterns and trends that were not previously apparent. Based on these conclusions, specific modifications were proposed in the department's processes to optimize efficiency, reduce costs, and improve service quality.

The implementation of these modifications based on evidence suggests that they would positively impact the general performance of the clinical engineering department if applied. Key indicators could improve significantly, reflecting increased medical equipment reliability and availability, decreased unscheduled downtime, and increased satisfaction for department staff and equipment users.

In summary, this study highlights the importance of using SPC as a powerful improvement tool in clinical engineering. By adopting an approach based on data and scientific evidence, clinical engineering departments can achieve more efficient and effective management of their processes, contributing to higher-quality medical care and patient safety.

Keywords – *Control chart, Equipment maintenance, SPC.*

INTRODUCTION

The performance and efficiency of clinical engineering departments can be influenced by various factors involving human, material, and financial resources. In the same way, the intellectual capital of "know how" to carry out critical activities i.e., to have a sound and effective standardized methodology to realize procedures within the department's operation, serves as an asset of great value in organizations.

Within these activities, equipment maintenance and continuous verification to ensure its correct operation emerge as critical activities. Although a series of classic activities are carried out in most clinical engineering departments, each department establishes its processes based on its conditions and scope. The standardization of methodologies that ensure the quality of the processes takes on significance in the impact these activities can have on the general operation of the department.[1,2]

The measurement of data on these processes and their statistical use represents a tool of great value in the search for improvement in their performance.[3] Statistical process control (SPC) represents a series of tools among which control charts stand out. This has traditionally been used within different industries to improve processes based on evidence generated by their own data.[4]

Within the healthcare field, it has been considered a tool for research and improvement issues,[5] as a tool for improving the culture of data measurement,[6] and even for improvements in clinical issues.[7–9]

There are many statistical tools with endless applications within the field of biomedical/clinical engineering to be used in the search for improvement of the efficacy, effectiveness, and efficiency of its activities.[10]

In the same way, there are studies in which tools used within the statistical control of processes, such as the Pareto diagram, are deployed to improve the activities of a clinical engineering department, as Cecchini, Masselli, et al. described.[11] Or the evidence-based maintenance method proposed by Wang[12] in which using data generated by a medical equipment maintenance program could modify the entire program itself. However, the use of control charts as a complement to traditional statistical techniques and those associated with quality improvement may represent a valuable option in the search for effective evidence-based improvements.

This article aims to exemplify what was previously explained through the use of SPC tools for formulating improvement strategies in standardized processes of a clinical engineering department.

METHODS

The methodology followed can be divided into the five main phases shown in Figure 1. Only procedures related to routine verification of medical equipment in different hospital areas were considered.

To find opportunity areas through SPC, it is necessary to comply with specific characteristics to be evaluated in the processes. The first two activities were focused on this: the definition of criteria, evaluation of these criteria and selection of procedures to be analysed. The next two phases correspond to the deployment of the statistical analysis, first through data capture, followed by the development of control charts. Finally, based on the results obtained, improvement proposals were made to the department's management to be evaluated and, where appropriate, implemented.

Each phase is explained in more detail below.

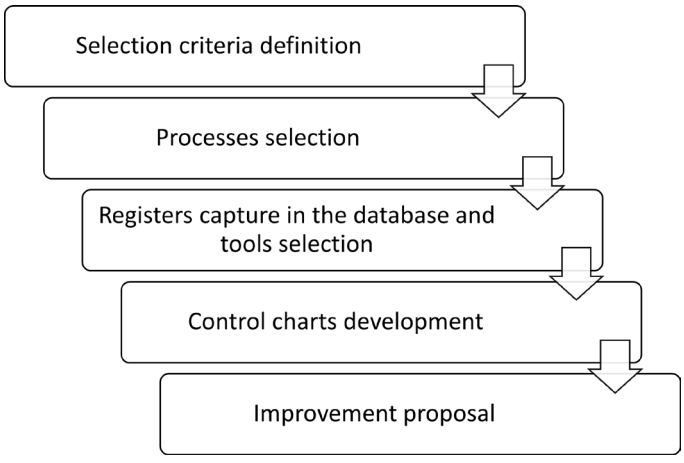

FIGURE 1. Followed methodology.

Selection criteria definition

Definition of selection criteria for the opportunity areas search was carried out considering the following factors:

- Standardized processes: The selected processes must be well standardized so that the data collection when performing them is carried out in a homogeneous way regardless of the personnel that carries it out, in addition to having written tools for capturing data generated during the routine.
- More than nine months of registers: Generated data by the processes in the lapse of the last nine months of operation were only considered to have an extended operation period, so the data reflects the closest possible reality of the department.
- Percentage compliance greater than 90% on the scheduled verification routines. The continuity and quantity of data in the measurements represent important factors in carrying out the statistical analysis of the processes since the consistency of the process with the generated data can be detected.

Processes selection based on the criteria of compliance

Once the selection criteria were defined, it determined which was compliant. Table 1 shows eight standardized procedures for carrying out verification routines in the department that met the first two selection criteria.

The routines for the vacuum and medical air systems imply verifying the work pressures for both hospital equipment. The operation theatres, intensive care units and emergency department routines demand the verification of technical aspects of the medical equipment installed in those areas, such as correct functioning, autotest, etc. This equipment ranges from vital signs monitors to stretchers.

Finally, the verification routine of the defibrillators involves physical and functional verification of all the defibrillators installed within the hospital through autotest and discharge proof.

After identifying the standardized processes, it verified the percentual compliance with carried-out routines. Figure 2 shows the results for this verification, obtaining compliance with the criteria in four of the eight processes; these correspond to:

- Emergency departments
- Defibrillators
- Medical air
- Vacuum systems

TABLE 1. Verification Routines Processes of the Clinical Engineering Department.

Verification routine	Registered time (months)	Number of routines per week	Expected done routines	Done routines
Vacuum system	9	2	78	72
Medical air system	9	2	78	72
Operation Theatre 1	9	4	156	119
Operation Theatre 2	9	4	156	119
Intensive care unit 1	9	1	39	26
Intensive care unit 2	9	1	39	23
Defibrillators	9	1	39	39
Emergency Department	9	1	39	41

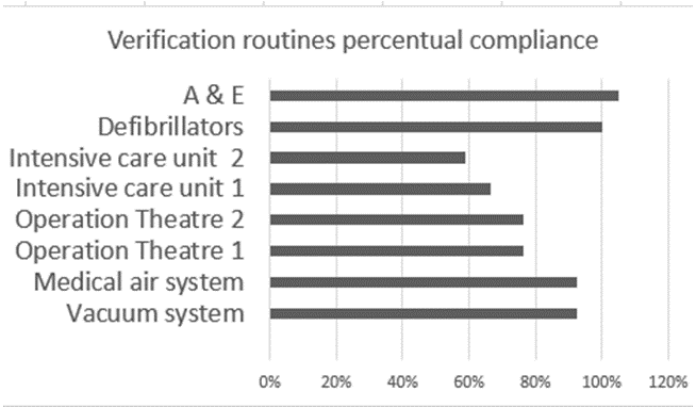

FIGURE 2. Percentual compliance of done routines.

These were the procedures on which the statistical study was studied further using SPC tools.

Record capture in the database and selection of tools

The next phase of the methodology implied the capture of the registered data in department formats in the form of

verification sheets in a digital database within statistical software. In this stage, the types of control charts to be used were selected based on the information generated by the verification routine.

Individual values and Moving range, or I-MR charts, were selected for medical air and vacuum system verification. This is due to the measured variable in each verification routine corresponding to an individual value, not a subgroup. In this way, the behaviour of the systems can be explored based on measurements made periodically to the pressure variable generated by the system itself. The moving range chart indicates the variability between each measurement caused by comparing it with the immediate previous measurement; this information makes it possible to verify the process stability statistically.

Nonconforming units, also known as NP charts, were selected regarding the verification routines of medical equipment in the emergency department and for the installed defibrillators. This chart evaluates the nonconforming portion of several measurements made. This chart was selected because there are a certain number of variables to be verified in each routine, which may be compliance or non-compliance. This number is constant in each routine. Each test variable was categorized depending on its result: "compliant" in case it was performed without problems or "non-compliant" in case it presented any detail.

Control charts development

The next phase consists of developing the control charts and the statistical analysis of the obtained results. Only I-MR charts were generated for the verification routines of the medical air and vacuum system; this is due to the results obtained that denote procedures in statistical control and it was not necessary to explore further.

Regarding the defibrillator verification routine, derived from the results obtained, the decision was made to go deeper through a Pareto diagram to make an improvement proposal that could impact the department's work.

Finally, in the case of the emergency area and derived from the results obtained, it was not necessary to carry out a significant analysis to make proposals.

Improvement proposals

After the analysis of the obtained results, proposals for improvements in the processes of the clinical engineering department were formulated. All based on evidence from the same information that this department generated.

RESULTS

Figure 3 shows the NP chart obtained for the emergency department's equipment verification routine. It can be seen that the upper control limit is located at a value of 1.008, which indicates a maximum of one non-conformity found per verification routine carried out in the period analysed. The nonconforming portion is located at the value of 0.093, which corresponds to a value of less than one non-conformity per verification routine performed. Lastly, the lower control limit is located at zero and corresponds to zero nonconformities found by the verification routine as the minimum value in the evaluated period. Within the presented values in the measurement period, only two values can be found in the upper control limit and one outside said limits. The value outside the control limits indicates two nonconformities in a verification routine. This value is considered atypical due to the stable trend of the evaluated process.

The emergency department dynamics implies an active role on the part of the equipment user in terms of continuous verifications; this is due to the high patient turnover in the service. This is reflected in the data in the control chart, and it is difficult to find technical failures related to the equipment.

Regarding the verification routines for hospital defibrillators, Figure 4 shows the obtained results. It has a value of 3.45 for the upper control limit, zero for the lower control limit, and 0.79 for the fraction nonconforming. The chart interpretation indicates that, on average, there can be a maximum of between 3 and 4 technical failures per verification routine for the 15 equipment distributed throughout the hospital, approximately one failure per routine performed, and a minimum of zero failures found. Two atypical values outside the control limits are identified, carrying out a study regarding the type of failures that led to these values; a special situation

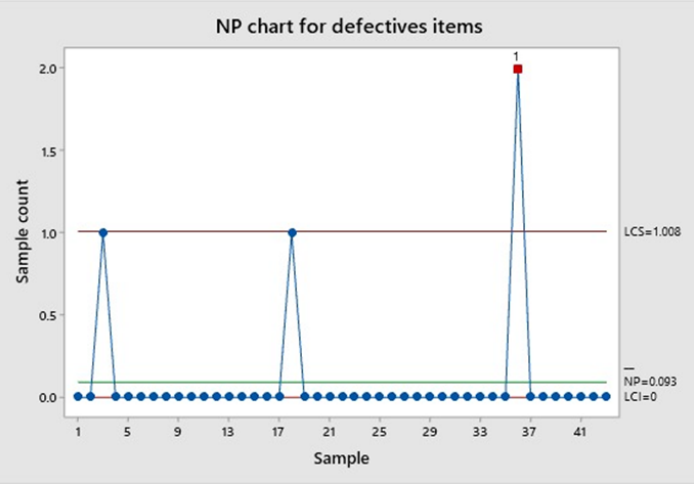

FIGURE 3. NP control chart for the emergency department.

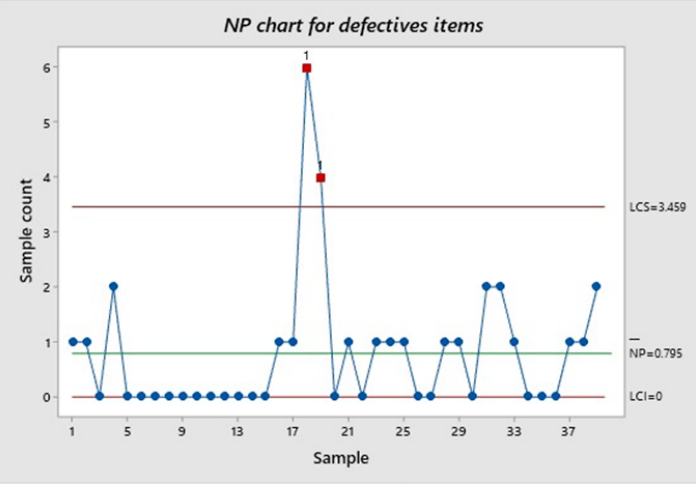

FIGURE 4. NP chart for the defibrillator verification routines.

was detected where the supply of printing paper for the equipment presented a delay in delivery by the supplier. Derived from these results, it was decided to carry out a deeper analysis that could offer a broader perspective of the behaviour of this process.

Figure 5 shows a Pareto diagram that identifies the equipment with the highest number of nonconformities in the measured period. It can be seen that 80% of the failures come from five specific defibrillators of the fifteen installed. These are installed in the areas of Nursery, Operating Theatre 1, Radiological Imaging, Emergency Department and Operating Theatre 2.

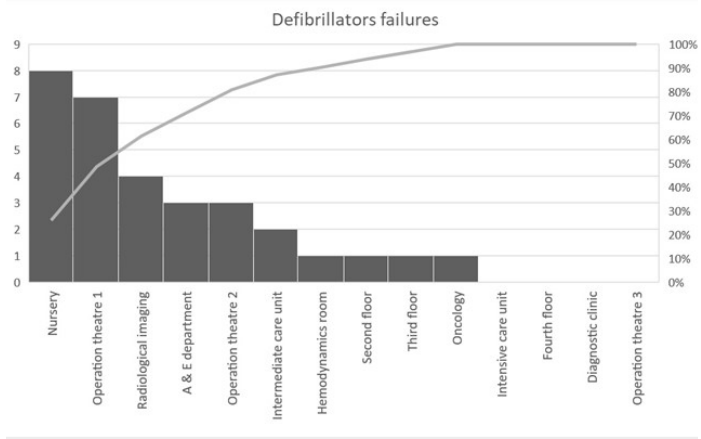

FIGURE 5. Pareto chart for defibrillator failures.

Finally, for the case of verification routines of the gas system, Figure 6 and Figure 7 show the I and MR control charts, respectively, for the case of the vacuum system. Chart I shows an upper control limit of -13.480 inHg, a lower control limit of -21.75 inHg, and an average value of -17.63 inHg. It is observed that there are no values outside the control limits; for its part, the system was programmed to operate at a value of -18 inHg, so this behavior presents reasonable statistical control.

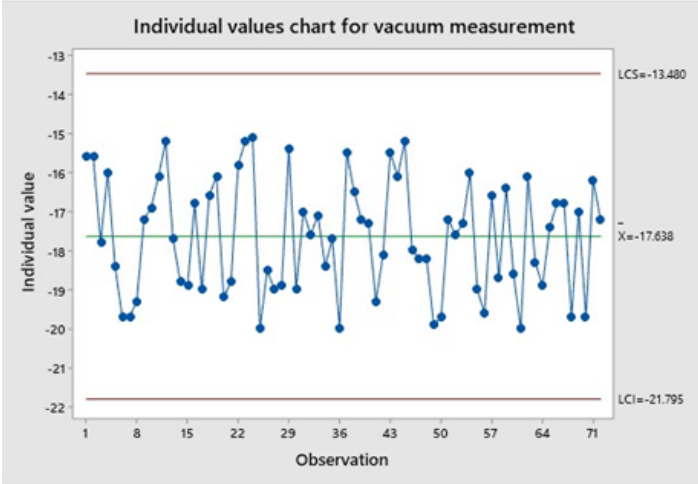

FIGURE 6. I chart for the vacuum system verification routines.

On the other hand, the chart of moving ranges in Figure. 7 also denotes an excellent statistical control of the process with only one atypical data outside the control limits. Regarding this atypical value, a significant variation

in the hospitalized patient number between one measurement and another was detected as a possible attributable cause. This issue caused variability in the range of data. However, outside of said identified cause, the data presents consistency in the statistical control denoted in the chart of Figure 6.

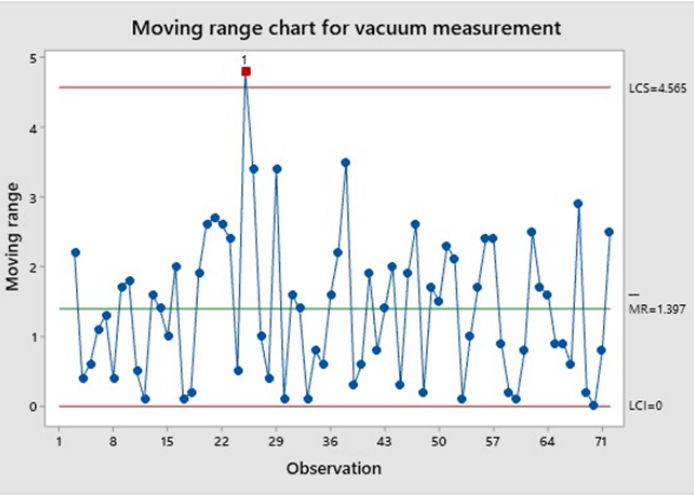

FIGURE 7. MR chart for the vacuum system verification routines.

DISCUSSION

The data obtained for the selected processes denote their stability over time. This means the data tends to behave similarly except for specific and atypical situations. However, it would be essential to conduct more extensive analysis in time. It is suggested to analyse the time of at least one year of data collection to rule out that the behaviour may be affected by temporary issues.

In the case of the verifications of the equipment in the emergency department and the gas systems, it was recommended to the clinical engineering department to extend the time between verifications so that they could focus their work on other activities that require higher priority. The stability represented in the control charts gives the certainty that no values will require monitoring as closely as it was carried out; therefore, it is possible to carry out fewer verifications with the certainty that the processes work correctly. If problems arise from implementing this strategy, it would be convenient to return to close monitoring.

Regarding the results obtained from the verification process of the hospital defibrillators, a proposal was made to the clinical engineering department to reinforce the monitoring of the equipment that represents the largest number of failures to control the nonconformities that the equipment could present. When dealing with life support equipment, a failure at the time of the operation could have serious consequences.

Once the failures have been solved or the processes regarding the nonconformities presented have been controlled, it could be considered to return to the weekly verifications or extend the time between them.

CONCLUSIONS

The results show good general statistical control for the selected processes. Based on these data, it can be assumed that the proposed strategies respond to real situations that occur in hospital operations.

However, it is important to highlight that the process selection was done to comply with the necessary characteristics mentioned for the data. The standardized collection of data and sufficient data over time encourage the behaviour description of the process to be as similar to reality as possible. In this context, it is possible to make effective suggestions for improvement strategies based on evidence, in the opposite case for the other processes whose data was insufficient to develop the tools satisfactorily.

Accomplishing all the data characteristics, statistical process control arises as an effective strategy for evidence-based efficiency improvement in the clinical engineering department.

The proposals to the clinical engineering department aim to guide its operation toward the needs detected through the statistical analysis of its generated data. If they were developed with insufficient or incorrect information, it is possible that the improvement strategies had been guided towards incorrect guidelines and were not effective.

Similarly, modifications could be considered to be done to all the department's verification processes so that while the verification times are prolonged in some of them, in others, they become more constant, focusing on priority

points and detection based on evidence. However, it would be necessary first to achieve the correct standardization of each process and capture sufficient data over time to deploy the same strategy.

Finally, it could be considered to go even deeper into the analysis of the statistics generated through individual studies of the non-conformities found. Through a categorization by type of non-conformity, improvement strategies regarding verification routines could be directed toward more specific issues.

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