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Simulation of Clinical Laboratory Process Improvement based on ISO 15189 Standard

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Abstract

The clinical analysis laboratory plays a crucial role in the diagnosis and prevention of diseases, consequently, the results of the examinations must be issued under optimal conditions of quality and precision that allow safe medical decisions to be supported. Accreditations such as ISO 15189 are instruments that allow laboratories to ensure, through their criteria and characteristics, results that meet quality standards, ensure traceability, and have high reliability, furthermore, the analysis and application of this Standard contribute to the continuous improvement and optimization of resources in clinical laboratories, which generates greater productivity in the processes. In the present investigation, a simulation model of the laboratory service process in a medical center was designed to which proposed improvements were applied considering the evaluated criteria of the ISO 15189 Standard. The simulation model was developed in the Arena software and executed the initial system model and the one proposed for comparison, where the processing time of patient care capacity in the laboratory was increased by 33%, achieving an increase from 12 to 16 clinical analyses performed per day. Likewise, the improvement in laboratory efficiency is directly related to the 32.3% increase in the medical center's monthly income from the tests performed in its laboratory. This demonstrates that implementing the ISO 15189 Standard can generate positive impacts that only translate into the quality of the service but also the profitability of the laboratories.

Keywords
Clinic laboratory, ISO 15189, simulation, process improvement, time optimization

1. Introduction

The clinical analysis laboratory is a medical support area and serves as a diagnostic assistant, these confirm a diagnosis or provide valuable information about patients' status and responses to treatments (Rodríguez et al., 2019). According to Galván-Cervantes et al. (2016), the objective of a clinical laboratory is to establish prognoses, classify diseases, monitor them, and, in some cases, present diagnoses. Rodríguez (2019) mentions that laboratory tests have improved at an accelerated pace thanks to technological advances, and this has managed to improve people's quality of life through innovative and convenient treatment proposals. Vega et al. (2015) point out that quality is essential for managing results in a laboratory as it ensures the minimization of errors. As expressed by Ug et al. (2014), quality is not only related to the means, technology, equipment, knowledge, and skill but is mainly linked to the aptitude and attitude of those in charge of providing the service, aware that the most important thing is the people to whom the services are directed. Figueroa-Montes (2017) points out that each clinical laboratory manager, whether private or public, must commit to implementing mandatory regulations or standards, through a quality management system that allows consolidating the appropriate process so that its results are positive and reliable, for the benefit of doctors and patients.

According to Nasser et al. (2018), ISO 15189 accreditation combines the provisions of the quality system of ISO 9001, a standard that accredits the quality of laboratories before the creation of ISO 15189, with management and technical requirements of a laboratory, in which considers the general analysis that includes the preanalytical, analytical and

postanalytical phases. Schneider et al. (2017) state that the objective of this standard is continuous improvement and that personnel know exactly what to do, how to do it, and where to find the necessary information to do their work. Buchta et al. (2018) refer that the ISO 9001 and ISO 15189 standards have been established as continuous models for quality systems beyond national policies, to be used by mandatory standards. On the other hand, Tzankov and Tornillo (2017) indicate that the accreditation of these standards, such as ISO 15189, benefits patients by ensuring the commitment of a laboratory to diagnostic excellence by having trained professionals and performing analyses under conditions. Furthermore, Lavado (2019) considers that the accreditation of a laboratory is not only beneficial for tt, but also for those who provide the service, since they save resources, standardize continuous improvement processes, and have competent personnel and efficient environments. According to Pradhan (2023), the ISO promotes the well-being and satisfaction of patients and all laboratory users, through quality assurance and competence, which are guaranteed through its technical guidelines for planning and implementation. of actions to manage risks and opportunities for improvement. Likewise, López et al. (2021) describe the ISO 15189 standard as a series of requirements regarding the management of clinical samples, process quality assurance, and laboratory information management, being the most recognized standard to demonstrate the technical competence of each laboratory, which is why knowledge and understanding of its requirements are essential for its proper implementation. However, despite the benefits of ISO 15189 accreditation, Carboni-Huerta and Sáenz-Flor (2019) reveal that the level of adherence to it in laboratories still shows a very low rate.

In addition to this, the simulation of small systems, as referred to by Sánchez et al. (2015), has gained great importance in decision-making in small industries, as it allows them to base determinations on production, furthermore, it represents a successful way to recognize critical points in the processes. Tavakoli et al. (202considerrat the simulation models used in research to analyze medical service systems as their main objectives the optimization of patient flow and the efficient allocation of resources that translates into improvement in performance and quality of service. On the other hand, Lee et al. (2019) state that simulation allows us to imitate practical scenarios to generate reasonable recommendations in decision-making and, with this, implement them repetitively by making necessary adjustments for continuous improvement. Batllori (2020) proposes that simulation facilitates learning from reactions to clinical situations, without putting any patient at risk or interfering with the correct development of the processes involved. Van Buuren et al. (2016) consider that a simulation provides high flexibility regarding modifications to the model premises, which is valued by professionals due to its graphic and informative nature, which facilitates its understanding. According to Garza et al. (2016), the use of simulation makes it possible to analyze different improvement scenarios and determine the values of variables proposed in its development. Usuga et al. (2017) highlight that simulation studies provide value to organizations and their modeling allows the evaluation of different change scenarios.

1.1 Objectives

The objective of this research is to develop a simulation model using the Arena software to visualize the implementation of suggested improvements based on criteria established in the ISO 15189 Standard in the clinical laboratory processes of a medical center located in the city of Trujillo in Peru. These improvements are intended to raise the quality of the results obtained while optimizing efficiency and reducing procedure times in the laboratory. These changes are expected to have a positive and significant impact on the Medical Center's revenue generated by the clinical laboratory.

2. Literature Review

For the investigation, studies based on process simulation models were considered, mainly those related to health service systems, and in research on the analysis or implementation of ISO 15189 in clinical laboratories.
Guseva et al. (2018) described the methodology to develop a simulation model using the Arena software for patient service management in a clinic in Russia. With the development of process simulation, they were able to evaluate the workload of the medical and technical team to determine the number of personnel required to guarantee timely patient care and improve the efficiency of clinical service operations.

Attoh et al. (2022) carried out an analysis of the challenges present in the search for ISO 15189 accreditation in a public health laboratory in Ghana, in which they conducted surveys and interviews with the personnel who were involved throughout the transition towards obtaining certification, to measure the impact and difficulties that generated the insertion of the measures contemplated in the standard in the laboratory process. As a result, they described that the lack of knowledge in laboratory management, the establishment of security measures, and the use of obsolete

instruments were the main difficulties, in contrast, the disposition of the personnel facilitated the transformation of processes identified in the standard.

Hejazil (2021) demonstrated that the exit rate in a health center can be increased, and the average waiting time of patients can be decreased by designing an optimal system developed in a discrete event simulation to obtain ideal values without affecting quality. from service. The system was simulated in the Arena software and the OptQuest tool was used for its optimization. This increased the level of service and patient satisfaction.

In the research of Le et al. (2020), an electronic registration and notification system was implemented in a clinic using Lean and Six Sigma methodologies to reduce stay times in the establishment and avoid the accumulation of patients in waiting queues to improve the user experience; In addition, with the implementation, operational efficiency increased by being able to process 27% more patient records.

3. Methods

An applied, non-experimental explanatory research is presented, with a quantitative and qualitative approach, and an exploratory scope to design a simulation model to improve the processes that conform pre-analytical phase, where the collection, reception, and registration of samples are carried out, analytical, and post-analytical, consisting of the report and delivery of results of the examinations carried out in the clinical analysis laboratory of the Medical Center for the improvement of laboratory service processes.

Distinct techniques were applied to evaluate and improve laboratory procedures. The observation and recording of process times that conforms to the pre-analytical, analytical, and post-analytical phase were carried out, proceeding to identify and select the critical components of the system that were subsequently subjected to evaluation. In addition, an analysis of the ISO 15189 Standard was carried out, which served as a basis for developing process improvements incorporating criteria present in said standard.

All the same, information on methods, metrics, and software tools presented in BPM (Business Process Management) will be reviewed, which allows analyzing, discovering, redesigning, and improving business processes in an organization, to increase agility and operational performance by eliminating activities that do not add value (Carvalho and Teixeira 2021).

The research study is applied in the clinical analysis laboratory of the Pacifico del Norte Medical Center, which is in the city of Trujillo and has more than twelve years of activity in the field. A sample of 136 patients was taken, distributed among the nine types of analysis that conform to laboratory service, and the times of each of the flow processes were recorded to subsequently propose improvements and carry out the simulation to show the differences between the scenarios, current and proposed.

4. Data Collection

Nine different types of analyses are performed in the laboratory and, to compare the number of exams for each type and know which ones generate the greatest demand, a sample was taken from a population of 300 patients who underwent analysis in the medical center laboratory, which is the approximate number of patients seen in a month. To find a representative sample of clients for the investigation, the following formula was applied:

$$n = \frac{N * Z_{\alpha}^{2} p * q}{d^{2} * (N-1) + Z_{\alpha}^{2} * p * q}$$

Where:
N = Total population (300)
Z = 95% certainly (1.96)
p = Expected proportion (20%)
q = 1 - p
d = Precision (5%)

Finally, after calculating the formula, 136 patients were obtained to be considered as a research sample. These are distributed according to the clinical analysis that has been carried out in the laboratory (Table 1).

Table 1. Distribution by type of clinical analysis

Analysis type	Amount	Percentage
Lipidic profile	27	20%
Complete urine test	12	9%
Total cholesterol	15	11%
Hemoglobin	18	13%
RH Factor	4	3%
Triglycerides	8	6%
Blood type	7	5%
Complete blood count	37	27%
Glucose	8	6%
Total	136	100%

5. Results and Discussion

5.1 Numerical Results

Times in the pre-analytical, analytical, and post-analytical phases that conform to the complete laboratory service that was provided to the 136 patients considered for the study sample was recorded. The following table 2 shows the minimum and maximum times in minutes of each process in the nine types of laboratory service analysis.

Table 2. Minimum and maximum times according to phase and laboratory process

Phase	Process	Min. (min)	Max. (min)
Preanalytical	Medical order reception	0.55	2.19
	Form filling	6.5	8.16
	Patient preparation	1.53	3.21
	Sampling	3.3	7.13
Analytical	Sample receipt	2	3
	Sample analysis	37	60
	Sending results	3	4.5
Postanalytical	Filling results in format	4.25	5.42
	Patient data verification	8.33	11.3
	Include in medical history	4.41	5
	Archive medical history	2	3
	Delivery of results	4.2	7.22

Additionally, the following table 3 shows the monthly income of the medical center for the analyses performed on the patients of the sample studied, according to the laboratory's reference prices.

Table 3. Monthly income from analyses performed in the laboratory with the current model.

Analysis type	Price ($)	Amount	Total income ($)
Lipidic profile	33.06	27	892.50
Complete urine test	10.83	12	130.00
Total cholesterol	5.28	15	79.17
Hemoglobin	3.33	18	60.00

RH Factor	20.00	4	80.00
Triglycerides	8.06	8	64.44
Blood type	5.83	7	40.83
Complete blood count	8.06	37	298.06
Glucose	5.28	8	42.22
Total		136	1,687.22

5.2 Graphical Results

A mathematical model of systems was developed by applying the Arena software through the design of a simulation. To do so, first a diagram was made of the current model of laboratory service processes carried out from the patient's admission to the medical center facilities until the receipt of the results obtained after the analysis.

The flow was planned based on the information collected in the laboratory of the medical center under study and was designed in the Bizagi tool. Through the design of the flow, it was possible to analyze the sequence of the processes to identify those that present an opportunity for improvement, considering the criteria stipulated in ISO 15189 to develop the proposed model (Figure 1).

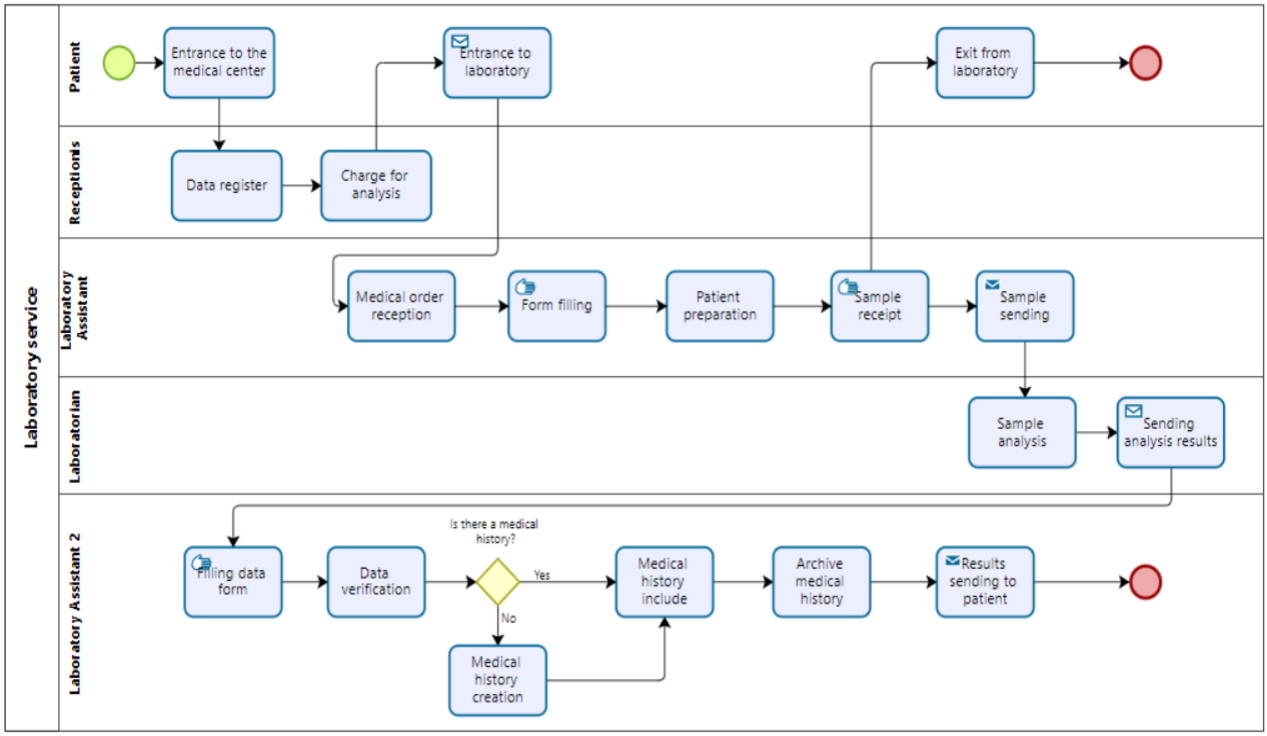

Figure 1. Process diagram of the current clinical laboratory service

5.3 Proposed Improvements

After the analysis of the process flow and its times recorded during the laboratory service, it was evident that the processes with the longest duration were filling out the form, verifying data, and including it in the medical history. In addition, procedures with opportunities for improvement were identified: patient preparation and sample collection. Requirement 5.4.4.2 of ISO 15189 refers to information for patients and laboratory users, which establishes the need to provide complete information on the types of analysis, requirements, precautions, and instructions for filling out the application form. In the current flow of the laboratory service, it was evident that the person in charge of the reception of the medical center provides information about the general requirements according to the analysis for which the patient consults during the registration of their data, and, subsequently, laboratory assistant is responsible for informing them more specifically about the procedure when preparing the patient for the subsequent sample

collection. In this case, it is proposed to give the patient a brochure before registering their data at the reception, through which they have complete and detailed information on the procedures, information on the types of analysis, laboratory services, specific categories, and biological intervals. In addition, point 5.4.3 details the information on the application form, which states that the form or an electronic equivalent must contain all the data of the patient, as well as the person providing medical care or that person. authorized to request analysis, in addition to the requested analysis. In the case of the medical center laboratory, this form is filled out manually by the laboratory assistant after receiving the medical order; this procedure has the longest duration time range: from 6 to 8.16 minutes. As mentioned in the standard, this form can be presented in an electronic version; In this case, it is proposed to send a form via email to patients at the time of registration and payment at the reception so that it is completed before entering the laboratory, thus reducing the patient's stay time, and facilitating the laboratory assistant job.

Finally, point 5.9.2 describes the selection and reporting of automated results, this is also identified as an opportunity for improvement in the post-analytical phase, specifically in the process of filling out the results and patient information form, since the establishment of criteria and reference limits (accommodated by age, sex, among other characteristics of the patient), and the use of a system or application that analyzes, validates and adjusts the results to said standards allow an automatic evaluation to be carried out and do not require filling and manual comparison of results according to a specific format such as the one currently available in the medical center's laboratory service.
The following flow corresponds to the simulation designed in Arena software of the process model proposed for the laboratory service after applying the improvements proposed based on the analysis of the ISO 15189 Standard to the processes in which opportunities for improvement could be identified to optimize time and resources and increase the quality and efficiency of laboratory service.

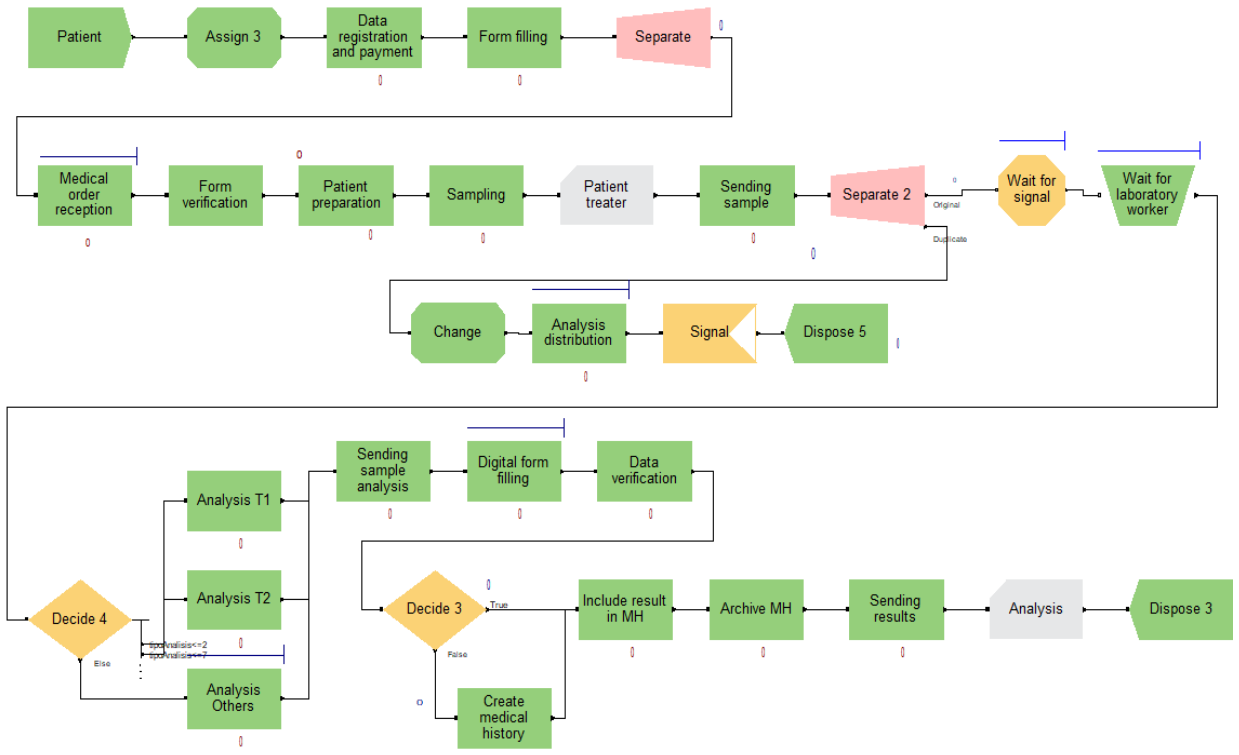

Figure 2. Simulation of the proposed process flow for the laboratory service

After the design of the simulation system of the proposed model, the number of patients treated per day and the average time spent in the laboratory were evaluated to observe the variation in the results (Table 4).

Table 4. Simulation results in Arena software of both scenarios

Model	Entity	Amount	Min. (min)	Max. (min)	Average (min)

Actual	Patient	12	17.74	21.34	19.78
	Laboratory Assistant	1	6	8.16	7.12
	Laboratorian	1	3.13	5.7	4.55
	Analysis	4	22.3	57.12	39.71
Proposed	Patient	16	13.66	17.35	15.51
	Laboratory Assistant	1	2	2.25	2.13
	Laboratorian	1	2	3	2.44
	Analysis	5	20.18	56.12	38.15

The Figure 2 displays the bar graph that presents the variation in the number of samples processed from the clinical analyses carried out in one month in the current scenario compared to the proposed model which was simulated in the Arena software. The variation in the number of patients treated in the laboratory is distributed according to the percentage by type of analysis recorded of the total study sample (Figure 3).

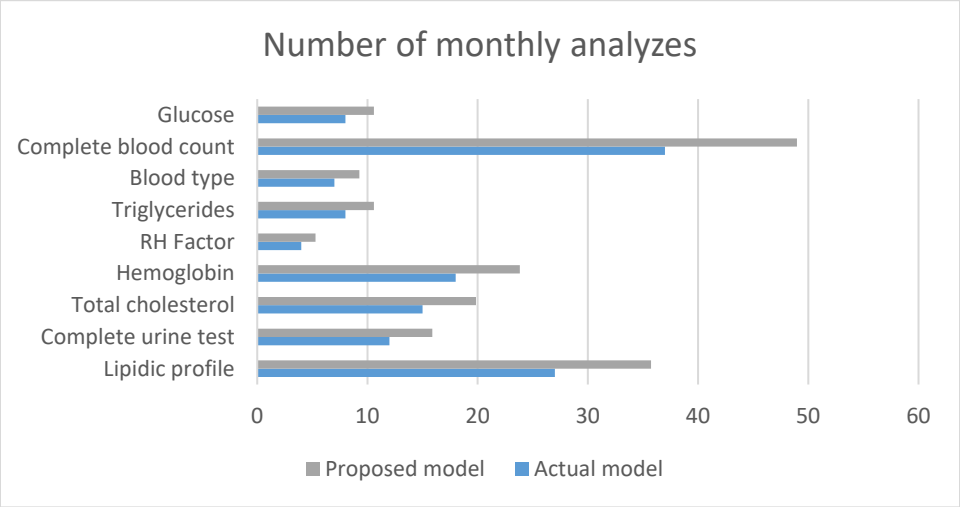

Figure 3. Number of samples taken per exam

However, the economic results obtained in the simulation of the proposed model are presented in Table 5 and 6, these are the monthly income of the laboratory for the number of samples resulting in the simulation of the proposed model of the laboratory service.

Table 5. Monthly income from analyses carried out in the laboratory with the proposed model.

Analysis type	**Price ($)**	**Amount**	**Total, income ($)**
Lipidic profile	33.06	44	1,181.25
Complete urine test	10.83	19	172.06
Total cholesterol	5.28	24	104.78
Hemoglobin	3.33	29	79.41
RH Factor	20.00	6	105.88
Triglycerides	8.06	13	85.29
Blood type	5.83	11	54.04
Complete blood count	8.06	60	394.49
Glucose	5.28	13	55.88

Total		180	2,233.09

With the increase in the patient care capacity in the laboratory service in the proposed model, an increase of 32.3% is evident in the monthly income of the medical center from the clinical analyses performed in the laboratory concerning the income obtained in the flow. of current processes.

5.4 Validation

To verify that the model simulation is valid, the Output Analyzer tool was used, which is a complement to the Arena software, it was possible to perform an analysis and compare the results of the current model against the proposed model, to demonstrate that the simulation works as expected, guarantee that the behavior of the system represents a real scenario and identify if the changes proposed to the initial flow of the process have positive effects.

Initially, 30 replicates were executed for the simulation of the initial model and the proposed model, with the result obtained from the analysis of the confidence interval on the mean and considering a mean width of a maximum of 10% of the value of the mean resulting from the interval. After the calculation, the number of 314 replicates required for the simulation.

Two indicators were evaluated in Output Analyzer: the number of patients treated (Output 1) and the number of samples analyzed by the laboratory technician (Output 2), both in one day.

Finally, in the comparison of the indicators in both scenarios, an increase of 33.1% was evident in the number of patients treated per day, as well as an increase in the number of samples analyzed by the laboratory technician by 16.3%.

Table 6. Results of the analysis of the confidence interval about the mean

Output	Sample Mean (Initial model)	Sample Mean (Propuse model)	Variation
Output 1	12.1	16.1	33.06%
Output 2	4.24	4.93	16.27%

6. Conclusion

In the research, the ISO 15189 Standard was analyzed to propose possible changes in the laboratory service of the medical center under study to achieve improvements in the process. By simulating the model in the Arena software, it was possible to visualize the procedures carried out during the laboratory service through a practical animation; Furthermore, with this, it was possible to verify that the proposed changes to the selected processes can generate positive results which provide useful information for future decisions within the laboratory.

The proposed and simulated model presented favorable results by showing a decrease in the length of stay of patients within the laboratory, which allows for a greater number of samples to be taken in one day, which is directly related to the increase in the income of the medical center; In addition, the change in processes also resulted in optimization of resources through the decrease in the utilization rate of laboratory personnel, which can have a positive impact on their work performance.

Although the process model proposed in the research can provide certain suggestions to obtain better results in the laboratory service, the study has some limitations that can be developed to complement the research, such as the performance of the laboratory staff, who have different types of experience and skills that can impact their development. Also, the wear generated during workdays can be considered, which has effects on productivity at work. In this case, staff performance was assumed to be constant without any variation among participants in the process.

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