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Application of the DMAIC approach of Lean Six Sigma in the optimization of response time to urgent requests in a medical analysis laboratory: Case study

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ABSTRACT

Similar to large companies, entrepreneurs would exploit modern management methods to improve their processes, performance and competitiveness.
Lean Six Sigma is a management approach dedicated to production organizations. It takes into account their specificity and seems to be appropriate to achieve the assigned objectives.
Medical laboratories have complex production processes, and Lean Six Sigma could improve them by using the DMAIC approach. The DMAIC approach is divided into five steps: define measure, analyze, innovate, and control; besides it is used to organize the sample handling production processes in medical laboratories.
The application of the DMAIC of Lean Six Sigma in our case has allowed us to identify problems, define the actions to eliminate failures and to monitor the effectiveness of these actions to measure the performance of our action plan.
We have improved the management of samples in the laboratory by prioritizing urgent samples in order to reduce their turnaround time, by directing them into the emergency track. This action has brought a significant reduction in the time between receiving simple to validation step of the results, with a clear improvement in turnover and the number of requests and analyses in the laboratory over the last two years.

Introduction

Medical analysis laboratories (MALs) play a major role in the healthcare field, by operating in the public and private sectors. They are obliged to develop themselves by optimizing the quality of their services, increasing their revenues, developing their activities and improving their competitiveness to survive in a changing environment.

To achieve this goal, MALs need to reorganize their strategy, in order to be ready to fulfill the customers' requirements. For this reason, it is recommended to establish an agile and efficient management, able to deal with the current context by being "Lean" and flexible.

A Lean method is based on the concept of Lean production and economical management of processes and consequently of the entire organization, with the aim of satisfying its customers.

Since the application of the Six Sigma management method in medicine in 2000, more and more laboratories in China have started to use it in the evaluation of quality systems (Peng et al. 2021). It is a very robust and validated methodology for improving quality, reducing costs, and increasing efficiency (Kuwaiti and Subbarayalu 2017).

Several approaches can be used, including the DMAIC (Define, Measure, Analyze, Improve, Control) approach of Lean Six Sigma. The latter is a management tool that helps improve process quality and focuses on identifying and eliminating defects (Inal et al. 2018).

In this paper, we seek to respond to the following problematic: What is the contribution of the use of the DMAIC of Lean Six sigma to the analysis production processes in a medical analysis laboratory?

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The purpose of this article is to enhance the management of patient samples in the laboratory, by adopting the DMAIC tool of Lean Six Sigma, which we have applied in our case study.

In fact, the application of this approach allowed us to analyze the laboratory's production processes and to identify their failures in order to improve them and to define the actions to be undertaken. We improved the management of samples in the laboratory, by prioritizing urgent samples, in order to reduce their execution time and this by directing them in the emergency circuit. This action has brought a significant reduction in the time taken to analyze samples, with a clear improvement in the turnover and the number of requests and analyses in the laboratory, over the last two years.

I. Literature review

We are going to clarify the compound concept "Lean Six sigma" by detailing separately Lean management, six sigma and Lean six sigma.

1. Concept of Lean Management

The concept of Lean, which aims to increase profit by satisfying customers, includes the basic definitions of "value added" and "waste" (ZAJKOWSKA 2012). The goal of this Lean is to increase the proportion of value added in the selling price of products, thus reducing waste. The Lean philosophy aims to meet the demands of customers, rationalizing investments in production, maximizing the use of resources, reducing inventory and shortening production cycles (ZAJKOWSKA 2012).

The flexible approach to production organization in Lean methods allows for rapid response to fluctuations in customer orders (Zahra and George 2002).

"Lean" means defatted, and "fat" means operations that do not add value in the eyes of customers. A lean organization relies on the continuous improvement of all value-added tasks and the reduction of waste in all production processes.

Lean is a management philosophy that seeks to optimize processes and resources to properly execute orders. At the same time, it ensures that manufactured products meet customer expectations, and are produced on time and at lower cost (Jeyaraman and Kee Teo 2010).

In order to minimize production costs, it is recommended to reduce waste in all activities through continuous streamlining of the entire organization and its relationships with stakeholders. This reduces waste, while maintaining a balance between customer needs and organizational capacity. As a result, organizations can improve their performance in terms of productivity and flexibility, while accelerating its flows and decreasing resource investments (Christopher 1998).

To note, the Lean concept is composed of the term "Lean Thinking" (Womack and Jones 1996), the techniques of "Lean Management" (lean management) and the methods of "Lean Manufacturing" or "Lean Production" (lean manufacturing, lean production or lean production) (ZAJKOWSKA 2012).

The effective functioning of all these components depends on the correct implementation of the Lean concept.

2. Concept of Six Sigma

Like the concept of Lean, the main target of the Six Sigma methodology is customer satisfaction. In the case of Six Sigma, this objective is achieved simultaneously by reducing costs and significantly increasing the level of quality. The Six Sigma methodology should be able to reduce the variability of the most important processes from the customer's point of view (Bañuelas and Antony 2003; Gowen and Tallon 2005); the standardization of these processes is achieved through a statistical approach (Schroeder et al. 2008).

In the Six Sigma methodology, a quality level of 3.4 defects (or errors) per million opportunities is pursued according to one of the two main continuous improvement models associated with Six Sigma: either DMAIC or DFSS.

DMAIC is an acronym that describes a standard approach to process improvement by eliminating problems, which is achieved through the following steps: define measure, analyze, improve, and control (Montgomery et al. 2005).

- Design For Six Sigma - DFSS allows organizations to design products and processes that both meet customer expectations and can be produced at a quality level close to Six sigma standards (ZAJKOWSKA 2012).

There are other models based on the Six Sigma concept that are similar to DMAIC and DFSS. However they are somewhat rare, for example, DMADV (D - define, M - measure, A - analyze, D - designate, V - verify), and DMEDI (D - define, M - measure, E - explore, D - develop, I -

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implement) for designing new products or processes. DCOV (D -define, C - characterize, O - optimize, V - verify) for improving and reducing existing or potential problems in products or processes (Ekleş and Ay Türkmen 2022).

The concept of Six Sigma is based on the Normal distribution using the Gaussian curve. In the classical approach, the organization aims for a quality level that corresponds to ±3 standard deviations, or 99.73% of conforming items and 2700 defective units per million (Defective Parts Per Million PPM). On the other hand, the objective of the "Six Sigma process" is to obtain, for the same tolerance interval (in the specifications), a quality level of ±6 standard deviations, which corresponds to 0.002 defective parts per million.

In the statistical approach, we can evaluate the quality of the process by calculating the capability indicators that have to access the values Cp=2 and Cpk=1.5 in the Six Sigma process (ZAJKOWSKA 2012).

3. Concept of Lean Six Sigma

The concepts of Lean Manufacturing and Six Sigma are appreciated by large companies because of their positive impact on performance, which strengthens their position in the market. Following the evolution of these two methods, we have noted the development of the hybrid Lean Six Sigma "LSS", which was formed to act in an integrated way on the entire system of the organization, achieving simultaneously the objectives of these two concepts. This according to one of the two models of continuous improvement: DMAIC or DFSS.

Therefore, the combined application of Lean and Six Sigma allows each of these methods to complement each other and increase their effectiveness in enhancing the functioning of the organization (Corbett 2011). In fact, the Lean Six Sigma hybrid concept is more effective in reducing waste and improving organizational performance than using Lean and Six Sigma separately (Gremyr and Fouquet 2012).

Thus, Lean Six Sigma has become an effective method in the eyes of managers because it meets their expectations. This approach is based on the "win-win" scenario for the organization and the customers.

However, for both concepts, the separate implementation is different. Lean focuses on the rapid preparation of customer orders, providing affordability for different customer classes, and continuously improving product quality (Antony, Snee, and Hoerl 2017). Six Sigma is designed to reduce process variability to improve the quality of critical processes from the customer's perspective, and measures and then controls variability, whereas in Lean, variability is only understood qualitatively (ZAJKOWSKA 2012).

4. Conceptual framework of the study

The Lean Six Sigma methodology includes a large variety of methods, techniques, tools and metrics to better solve problems and perform statistical control.

In the Lean Six Sigma methodology, the pursuit of the quality level takes place according to one of the two main continuous improvement models associated with Six Sigma: either DMAIC or DFSS (Design for Six Sigma) (ZAJKOWSKA 2012).

The DMAIC approach is closely related to the Lean Six Sigma approach, which is a method that has emerged through the work done by Joseph Juran, Edward Deming or Walter Shewhart in the first half of the 20th century (ZAJKOWSKA 2012). This approach will serve as a conceptual framework in our case study.

The DMAIC approach of Lean Six Sigma is a tool that serves as a filter to move from a complex problem with many uncontrolled variables to a situation where quality is controlled. It is presented as follows:

- D for Define: This phase focuses on the processes that generate the product or service and the mapping of the processes to improve them.
- M for Measure: This is a data collection phase on the measurable parameters of the process. The purpose is to determine what is capable of delivering the process in question, namely its sigma. During this step, it is important to focus on the parameters that are critical to quality, i.e. those that have the greatest influence on the result.
- A for Analyze: The data obtained in the previous step is analyzed to calculate the performance gaps, that is, the differences between what is done each day and what can be achieved. We must then study the origins of the process variability and determine the root cause. At this stage, improvement solutions aimed at eliminating the root causes of the variability of the process concerned are proposed to achieve the objectives.
- I for Innovation: The proposed solutions to the dysfunctions are validated and the capacity of the optimized process is evaluated to ensure their impact.

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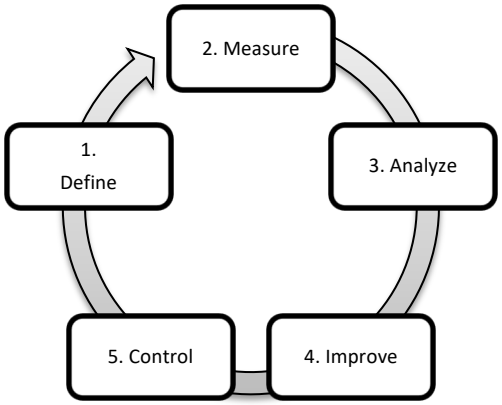
Finally, an action plan detailing the implementation of the selected solutions must be established in order to best manage the changes induced by the implemented solutions.

- C for Check: This last step consists in controlling the process to ensure that the problem is solved and the quality level is maintained. During this step, we must maintain the benefits obtained by standardizing the process.

DMAICS refers to the DMAIC approach to which is added a standardization step, intended to sustain the actions and solutions implemented in the standardization process.

Figure N° 1 is a representation of the DMAIC approach, with the order of its different steps, whitch are Define, Measure, Analyze, Control and Improve.

Figure N° 1: Illustration of the DMAIC approach



Source : (Teich and Faddoul 2013).

II. Research Methodology:

This is a qualitative approach applied in a case study, which is a medical analysis laboratory in Morocco.

The objective of this study is to test the DMAIC approach of Lean six sigmas in this laboratory, for the visualization and improvement of all the processes of its production chain.

1. Study site:

The medical analysis laboratory, according to ISO 15189, is intended to realize different types of biological examinations (biochemical, microbiological, hematological,...etc.), of substances of human origin to bring useful information for the diagnosis, the prevention or the treatment of diseases or the evaluation of the state of health of human beings. And which may offer a consultancy service covering all aspects of laboratory analysis, including interpretation of results and advice on other appropriate analyses (International Organization for Standardization 15189: 2007)

The medical analysis laboratory is a complex system, involving a production chain consisting of many steps for the realization of analyses. The management of this complex system requires that all of these processes and procedures be executed correctly.

The study is conducted in a laboratory in Morocco, whose main mission is to provide analyses for clinical wards, attached units and external patient It is a laboratory known for its remarkable production rate, serving a population of more than five million people, and it receives an average of 900 patients per day, with almost 20 to 30% of emergencies. And it is fully automated and performs more than 4000 analyses per day.

In addition, the laboratory has human resources of different profiles and counts 23 people of the technical staff (laboratory technicians and biologist engineers) directed by a chief technician and a medical staff of 25 doctors and pharmacists led by the head of laboratory who is a professor of higher education and his assistant who is an associate professor.

2. Adoption of the DMAIC approach

In 2020, we applied the DMAIC approach, which allowed us to make changes to the production processes, adding a formalized circuit for the treatment of emergencies.

The evaluation of the action undertaken was realized through the comparison of the data recovered from the laboratory information system, for the periods before and after the intervention (2020-2021-2022).

It should be noted that in the laboratory under study, the management of samples goes through different stages:

- Sorting in racks at the reception level, checking for compliance.
- Registration of samples on the information system and identification.
- Preliminary treatment (centrifugation).
- Orientation towards the different analytical stations.
- Analysis of samples.
- Validation of the examinations and delivery of the results.

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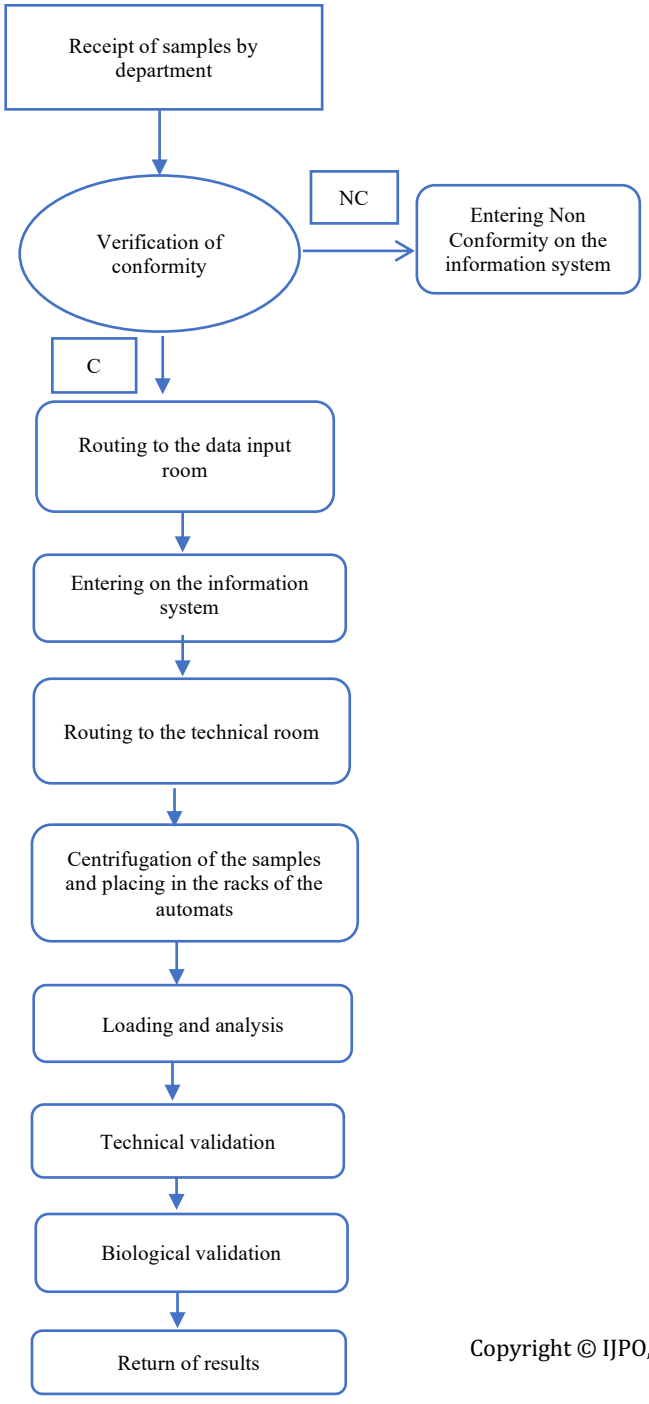
The DMAIC approach allowed us to identify areas for improvement in the laboratory's production system, through its five steps:

- **Define**

We started by visualizing the different processes of production of analyses in the laboratory. This allowed us to define and analyze the whole circuit of the analysis treatment in the laboratory and to detail the different steps from the reception of the patients' samples to the results.

This allowed us to draw the following flowchart:

Figure 2: Flowchart of analysis processing in the laboratory.
C= conforms to ; NC= not in conformity



Source : the author

- **Measure:**

In this step, we measured the indicators of patient outcomes in the laboratory in 2020 before taking any improvement action.

The indicators selected are: the time between input and validation, the number of requests, the number of analyses and also the turnover.

We find in the table below the results of the 2020 indicators extracted from the information system.

Table N° 1: Results of the indicators for the year 2020

Indicators	Year 2020
Average time to input/validate	18h24min
Laboratory requests	155 224
Analyses	1 213 149

Source : the author

- **Analyze:**

We began by analyzing the laboratory's analysis processing circuit, which allowed us to identify a failure related to the absence of a formalized circuit for processing urgent analyses. This leads to a delay in the return of results for urgent patients, with a relatively long delay between the receipt and processing of the urgent sample.

Urgency is defined in collaboration with the prescribing physicians according to the patient's condition, clinical information and according to the laboratory's criteria for performing the analyses.

Before using the DMAIC approach, we noted several constraints behind the delay in the management of urgent specimens in the laboratory. Among the causal factors identified:

- Urgent specimen sorted with the rest of the specimens.
- Urgent specimen processed in the normal circuit.
- Absence of the mention of urgency during the routing of the samples.

We researched all the parameters influencing the management of urgent samples in the laboratory using the Ishikawa diagram (Figure 3).

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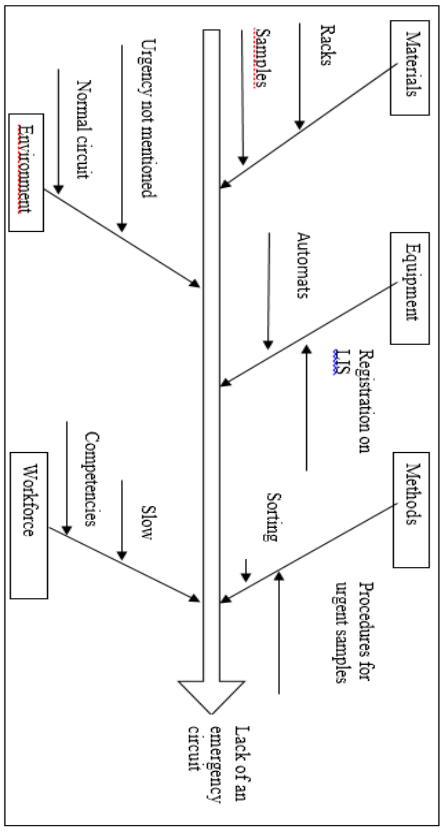
Figure 3: 5M diagram (Ishikawa)



Source : the author

- **Improve:**

In order to improve the analysis processing circuit and to remedy the problem raised, we organized a meeting with the laboratory's resource persons, with the participation of the following profiles:

- Two professors in medical biology
- Two biologist engineers
- Two medical biologists in training
- A laboratory administrator
- A chief technician
- Three laboratory technicians

This meeting recommended the creation of an emergency circuit that will allow the prioritization of urgent samples. In fact, at the reception area, we also recommended the creation of racks for urgent samples ("red racks"). After sorting and checking for compliance, the samples are recorded in the emergency register.

Urgent analyses are reported to the staff (oral information) and are given priority treatment (entry, order of passage, advancement of series, etc.).

The technician and the biologist monitor the results by checking the information system until the technical and biological validation of the results.

- **Control**

This step aims to continuously measure the improvement of the laboratory's production processes in order to verify and maintain the improvement over time, by adopting indicators to measure the performance of the production process and particularly the time required to deliver urgent results to patients.

We compared the results for 2020 with those for 2021 and 2022.

3. Results:

The DMAIC allowed us to identify the points to be improved in the production process of the laboratory and to come out with recommendations that in turn allowed us to improve this process, which gave us an improvement in the laboratory indicators.

We start with the first result related to the change of the analysis processing circuit. This change concerned the formalization of a circuit for the treatment of emergencies.

Improved flowchart of analysis processing in the laborator

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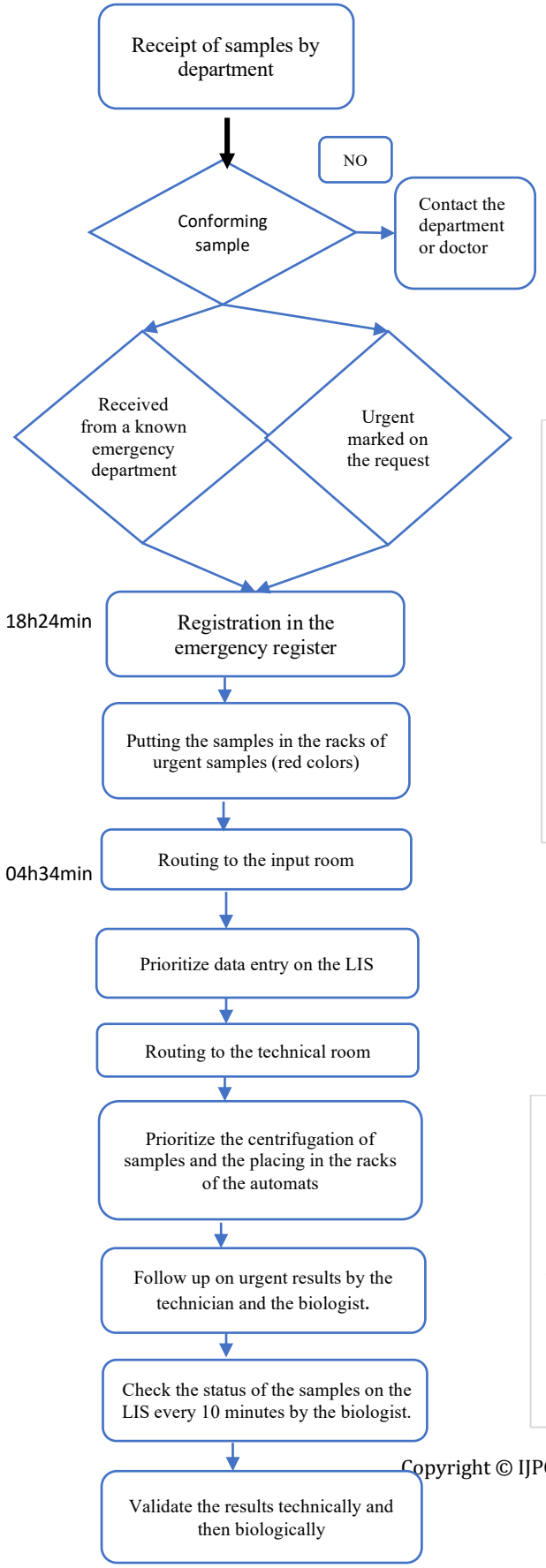
Source : the author

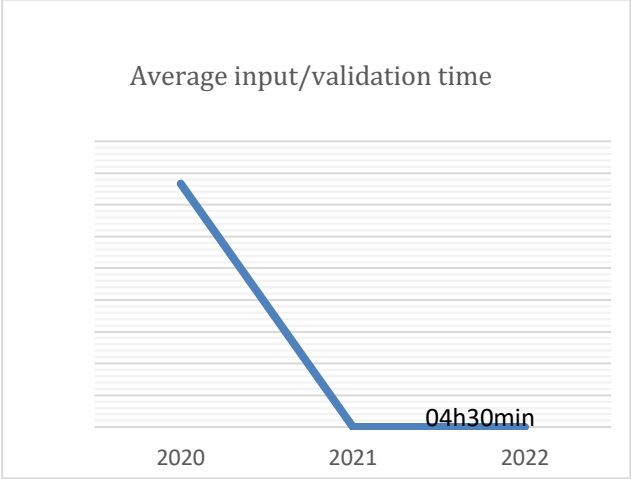
rocessing analyses in the laboratory



This new circuit of analysis processing was applied in December 2020 and this allowed the following indicators to be improved:

Indeed, after the adoption of the DMAIC approach of Lean Six sigma, we noted the reduction of the time between the receipt of the sample and the return of patient results. A clear improvement is registered in the indicator of the time between input and validation for the years 2021 and 2022 compared to 2020.

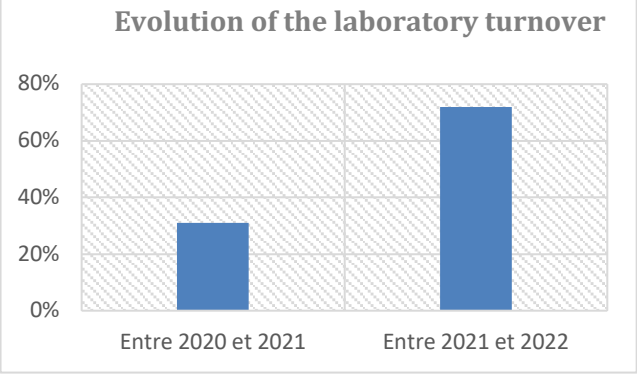
Figure 5: Evolution of the average time of input/validation 2020-2021-2022



Source : the author

A clear improvement of 72% in revenue between 2021 and 2022, compared to an increase of 31% between 2020 and 2021.

Figure 6: Evolution of the turnover in the laboratory 2020-2021 and 2021-2022



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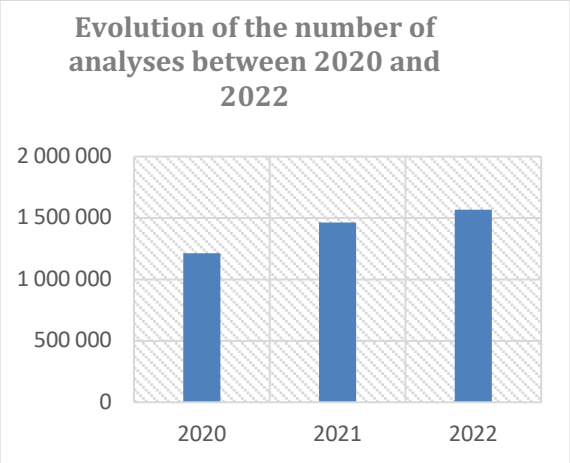
Source : the author

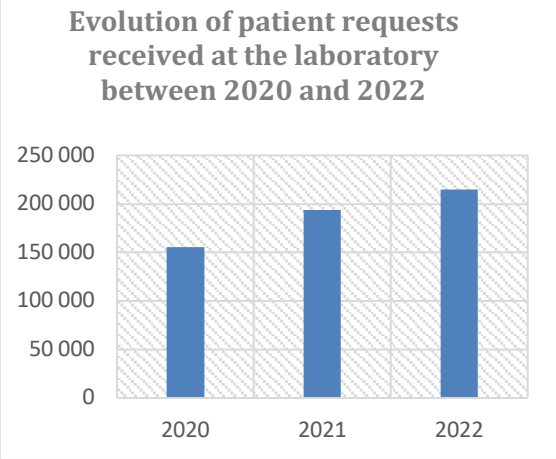
The number of patient requests to the laboratory, as well as the number of analyses, has also increased over the last three years.

Figure 7: Evolution of the number of analyses between 2020 and 2022



Source : the author

Figure 8: Evolution of patient requests received at the laboratory between 2020 and 2022



Source : the author

The adoption of the DMAIC approach of Lean Six Sigma allowed to take a beneficial action for the laboratory, taking into account the improvement of the indicators.

4. Discussion:

Historically, the concept of Lean was born at Toyota in the automotive industry, but due to its adaptability, it has been applied in various fields of activity, including the medical sector (Joosten, Bongers, and Janssen 2009; Liker 2004).

As a reminder, the concept of Lean Six Sigma aims at satisfying patients, reducing investment and maximizing resources. This reduces waste, while keeping the balance between patient needs and AML capabilities. As a result, the organization can improve its performance in terms of productivity and flexibility while accelerating its flows, reducing investment and defects.

Among the applications received at MAL, several are urgent. On the basis of their results the doctor makes the therapeutic decision. However, the management system for urgent analyses can sometimes be inefficient when the prioritization of samples is anarchic. This is why it is important to establish an adapted and efficient system to manage emergencies and thus reduce the time required to process these analyses.

In order to identify the sampling circuit within our laboratory, we chose to apply the DMAIC approach of Lean Six Sigma, to improve the performance of the production processes and meet the needs of the patients.

The exploration of several factors allowed us to conduct an in-depth analysis of the causes in order to implement an appropriate management system for the flow of analysis requests received at the AML.

Among the quality indicators used to systematically evaluate the analysis process and the laboratory's contribution to patient care, we note:

- Average time for input/validation: this is an important parameter, allowing for the best possible evaluation of the organization of work and the performance of the processes adopted, in order to ensure rapid and efficient management of samples, particularly those of an urgent nature.

  Through our study, we have observed a clear reduction in the time required between the input of the samples and the validation of the results, from 04h30min in 2022 to 18h24min in 2020.

  Due to the elimination of wasted time and the exploitation of resources, we have seen an improvement in the activity of the laboratory at several levels, which has had an impact on

- Turnover: which increased between the year 2020-2021 (31%) and 2021-2022 (72%).

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- Laboratory requests: which have evolved from 155,224 in 2020, 193,450 in 2021 to 214,622 requests in 2022.
- Analyses: which increased from 1,213,149 in 2020, 1,461,990 in 2021 to 1,565,307 analyses in 2022.

In a study by (Inal et al. 2018) who used the Lean Six Sigma DMAIC system to simplify the laboratory workflow and reduce turnaround time by eliminating non-value added steps. They found an improvement in the pre-analytical process at the receiving area, eliminating 3h22min of non-value-added work. After adopting Lean, sample processing time also decreased from 68 to 59 min. Steps that could lead to medical errors and pose potential biological risks to receptionists were reduced from 30% to 3%.

The successful implementation of Lean Six Sigma significantly improved all selected performance metrics (Inal et al. 2018).

(Morón-Castañeda et al. 2015) found a 17min reduction in patient handling time from arrival to departure from the laboratory and a 60% decrease in complaints for delayed results, with improved customer satisfaction and this was achieved through the application of Lean Six Sigma methodology in their laboratory.

Other studies have highlighted the importance of Lean Six Sigma in anatomy and surgical pathology laboratories to improve diagnostic and molecular testing accuracy, reduce turnaround times, and increase doctors and patient satisfaction (Inal et al. 2018; Smith 1975; Visinoni 2015).

Outside of healthcare, there has been a great deal of research implementing the DMAIC technique in various manufacturing processes and industries.

(Wang 2008) present a review of developments in the field of connecting rod forging to meet the demand for geometric accuracy and internal quality. Different technologies were discussed and explained and some new equipment was introduced to improve the production capabilities of connecting rod manufacturers.

(Kaushik et al. 2008) made an effort to justify the role of quality management techniques like DMAIC for SMEs, which are normally performed in the field of large and medium industries. Six Sigma techniques were applied to a small bicycle chain-manufacturing unit and significant improvement was recorded.

(Kumar and McKewan 2011) presented some facts and benefits of using DMAIC approach in improving the efficiency and performance level of the molding process unit with the lowest possible cost. The evaluation of optimal process parameters resulted in minimizing casting defects. In 2012, Gebremeskel and Uppsala evaluated the rejection rate of grinding steel balls for a cement industry. Due to the lack of temperature and atmosphere controls in the kiln, some deviations were observed during the heat treatment process (Chandel and Kumar 2016).

(Sambhe 2012) presented a case study conducted in a medium-sized automotive auxiliary unit with 375-400 employees that had recently implemented Six Sigma methodologies. Various defects were observed that are critical to customers. (Thottungal and Sijo 2013), identified the intensity of defects in a forging unit using Ishikawa diagram and Pareto analysis techniques. Various corrective actions such as proper use of anti-scale coating, ventilation process to prevent underfilling, simulation software to determine material flow, and proper lubricant (Espon-lss) instead of furnace oil were proposed to reduce the reject rate. In 2014, Joshi and Kadam evaluated various defects and their causes for manual metal casting operation in automotive industry using Pareto analysis and cause and effect diagrams (Chandel and Kumar 2016).

Conclusion

The application of the DMAIC methodology of Lean Six Sigma in AMLs is an effective tool to improve the performance of production processes, organize the workflow and optimize the time of taking care of patient samples, especially those of an urgent nature.

Through a case study, we succeeded in improving the results generated by the production processes of an AML, using this approach. In fact, within the framework of this research, we have noted the importance of using modern management methods to improve performance through the improvement of production processes.

The perspectives of the research in the field of medical analysis laboratories are to deepen the verification of the proposed methodology and to explore the other possibilities of its use, studying the usefulness of this proposed tool for other organizations in the health field and even outside this research field.

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