Redesign of a Space in the Autopsy Room Assigned for the Preparation of Biological Samples for Toxicological Analysis by Using DMADV Technique

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Abstract *— The government agency of the Institute of Forensic Sciences recently received the necessary accreditations to be able to provide the essential service it offers to the citizens of Puerto Rico. The objective of this project is to maximize the time and resources involved in the handling, preparation, and verification of biological samples for toxicological analysis. Through the master's project, it is expected to be able to implement an ideal design for the autopsy room work areas in order to reduce rework and waste in the sample preparation processes. The improvements in the autopsy room will allow case certifications to be completed within 30-90 days of receiving the case at the agency, avoiding putting at risk the accreditations granted in the past months. The analysis of the project was carried out through the Lean Six Sigma methodology with the DMADV tool.*

Key Terms *— Biological Samples, Autopsy Room, DMADV, Lean Six Sigma.*

PROBLEM STATEMENT

The toxicology laboratory of the Institute of Forensic Sciences of Puerto Rico (ICF), which receives evidence and biological samples from autopsy rooms, needs to establish some improvements to be able to carry out the required analyses in a reasonable time. The problem that will be addressed in this project is the increase in the time involved in the process of preparing and delivering biological samples to the forensic toxicology laboratory. A prolonged time in the preparation and verification of the biological samples collected in the autopsy room generates a blockage in the toxicological analyses, late results, and deficiencies in customer service. As of 2013, the pathology division of the ICF was under probation due to a high volume of cases and incomplete autopsy reports, many of these due to inadequate referrals and pending toxicological analyses [1]. Dr. Maria Conte Miller, executive director of the ICF, announced last May the accreditation of the Division of Medico-Legal and Toxicological Investigation, in which one of the parameters required to achieve accreditation is to complete autopsy reports within a period of 90 days [2]. Despite obtaining accreditation, currently, autopsy reports have been affected due to pending toxicological analysis.

Not having an enabled or equipped area available in the autopsy room for the process of preparing and verifying biological samples interrupts the daily tasks and analyses carried out in the toxicology laboratory. This is since the process of preparing and verifying biological samples is being carried out in the toxicology laboratory, in which space, time, personnel, and resources of the said laboratory are occupied to receive the samples and proceed with the requested analyses. According to the observations made in this sample preparation scenario, it has been possible to identify different types of failures and errors that contribute to the blockage of toxicological analyses due to not having an area enabled for this process. Therefore, addressing this problem in the project will allow us to design and establish an appropriate and equipped space to carry out the process of preparing and verifying biological samples collected in the autopsy room.

Research Objectives

The objectives of this investigation project are:

- To describe the process of handling, preparation and verification of biological

samples collected in the autopsy room for toxicological analysis.

- To describe what factors, affect the handling, preparation, and verification of biological samples for toxicological analysis.
- To design a fully equipped area in the autopsy room for the handling, preparation, and verification of biological samples.
- To maximize the time involved in the handling, preparation, and verification of biological samples for toxicological analysis.

Research Contributions

The main contribution of this project is the reduction of the processing time of handling, preparation, and verification of biological samples for toxicological analysis. This research will contribute to guaranteeing quality in the handling of biological samples through the organization of the evidence room and personnel, and the reduction and elimination of rework and waste. Furthermore, this project will contribute to the execution of analysis and evaluation of the results of toxicological analysis in real-time, complying with the autopsy certification within 30-90 days.

LITERATURE REVIEW

The Institute of Forensic Sciences of Puerto Rico (ICF) is a government agency created on July 24, 1985, with the purpose of having an essential resource for forensic scientific analysis within the justice system [3] Figure 1). The ICF has been characterized by the preparation of its employees and the technology it has available to carry out the pertinent analyzes within its three divisions: Medico-Legal and Toxicological, Forensic Investigation, and Criminalistics Laboratory. Due to the increase in the crime wave and type I crimes on the island, these divisions have had to make changes in operations and implement new processes in order to meet the increase in cases that are reported daily. With the shortage of personnel that the institute has suffered for some time, the division that has been most affected has been the forensic and toxicology division, which is made up of the pathology and toxicology laboratory staff. The medicolegal and toxicology division is where autopsies and pertinent analyzes are carried out in order to certify the causes of death of people affected by criminality or suspicious deaths [3].

Figure 1
Institute of Forensic Sciences of Puerto Rico (ICF)

As part of the autopsy process, pathologists request toxicological analyzes in order to determine if the cause and manner of death were related to intoxication. According to the literature, forensic toxicology is the toxicological study of biological samples from the autopsy room for law enforcement purposes [4] (Figure 2). Therefore, through toxicological analysis, apart from intoxication, it can be determined if the victim's behavior was the cause of death because of any substance, it being alcohol, controlled substances, or medications. It is for this reason that the importance of carrying out the process of handling, preparing, transporting, and analyzing biological samples in an orderly manner and complying with the quality and established safety and integrity protocols concerning each action taken with the samples is emphasized at all times. Failure to comply with the aforementioned, the decisions and sentences of the cases under investigation are put at stake, affecting justice [5].

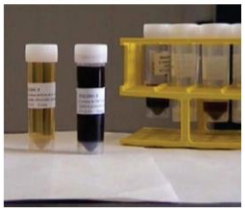

Figure 2
Biological Samples for Toxicological Analysis [4]

Currently, the institute's autopsy room does not have an assigned and equipped area for the handling, preparation, and verification of biological samples before being transported to the toxicology laboratory, affecting compliance with the required analyzes and certifications in the time established by accrediting agencies. This is why an evaluation of possible solutions was carried out to eliminate any defect that the process of handling biological samples generates, impacting the operations of the Toxicology laboratory. An alternative for the improvement of the sample management process is the application of the Lean Six Sigma methodology.

The Lean Six Sigma methodology is characterized by a series of tools and techniques that allow improvements to be made to the processes that are put into practice within an organization. This methodology is used by many companies due to its ability to eliminate defects and implement improvements to maximize resources, profits, and customer satisfaction. The focus of the Lean Six Sigma methodology is the elimination of defects throughout the organization, identification of problems, and implementation of processes, among others. Some of the tools used are DMAIC and DMADV. These tools consist of 5 steps, being DMAIC for improvements of an existing process or product, while DMADV is aimed at the implementation of a new process or product [6]. Both tools are characterized by the importance of documentation. Documentation is essential as it covers the collection of data through observations, measurements, and surveys, among other tools, which allow us to have a better overview of the processes that are carried out and what viable decisions must be made. Therefore, an example of collecting data through observation is preparing tables with specific information to be evaluated or analyzed. A common practice in the Lean Six Sigma methodology is the identification and solution to the waste generated in the processes. There are 7 types of waste, these being the following: overproduction, waiting time, motion, overprocessing, inventory, defects, and transportation [7].

In the past months, it has been possible to identify different types of waste in the process of handling, preparing, and verifying biological samples for toxicological analysis. This project provides the opportunity to apply quality methodologies that are characterized by being carried out in the manufacturing industry. This project presents the feasibility of applying the Lean Six Sigma methodology in other areas that are not related to manufacturing, such as the field of health and forensic sciences. This is why the pathology and toxicology laboratory staff of the ICF will be working hard to mitigate the effect of not having an area equipped for the process of handling, preparing, and verifying biological samples for toxicological analysis in the autopsy room. Therefore, in this project, this situation will be analyzed through the application of the DMADV tool (Figure 3).

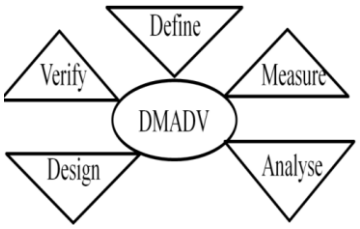

Figure 3
DMADV Process Road Map [8]

METHODOLOGY

This project explains the importance of applying the Lean Six Sigma methodology to carry out improvements in the handling, preparation, and verification process of biological samples collected in the autopsy room for toxicological analysis. In order to carry out these improvements, the Lean Six Sigma DMADV tool was selected. This tool consists of 5 steps, which will be executed by the personnel assigned to the pathology and toxicology laboratory areas. With the DMADV technique, it is expected to obtain a fully equipped area in the autopsy room, considering the requirements of the main client, this being the pathology staff. Next, a

description of the steps of the DMADV process and the tools to be used to carry out the analysis of this project is presented.

DMADV Process

The tools to be used in the different phases of the DMADV process are:

- **Define**- phase where the goals are defined, and the requirements and criteria associated with the internal and external clients of the project are specified. [8]
  - *Voice of Customer (VOC)*- a tool to recognize and establish the needs, comments, expectations, and preferences of customers about the project.
  - *SIPOC*- Technique to obtain a global vision of the project represented through a diagram or process mapping. Determine the key points that come from the acronym suppliers, inputs, process, outputs, and customers, to establish a guide as a tool for the work team regarding the process of implementing the project design.
  - *Project Charter* - detailed guide in a table format that provides essential project information such as problem definition, goal statement, roles and responsibilities, project scope, preliminary project plan, and communication plan.
- **Measure**- phase of data collection and determination of measurement standards of the requirements of the project's clients [8].
  - *Critical to Quality (CTQ)*- graphical representation of the client's identified needs, the required quality controls, and the project's measurable standards.
- **Analyze**- phase of data and design alternatives evaluation that arise from the needs and requirements of the project's clients [8].
  - *Cause and Effect Diagram (Fishbone)*- a diagram that compiles the information corresponding to the root cause of the identified defects and deficiencies of the project.
  - *Failure Mode and Effects Analysis (FMEA)*- a technique for the identification and evaluation of possible failures and deficiencies of the project. It consists of two parts, the failure mode which is the part that identifies how the project can fail, and the effect analysis part, which is the study of the consequences and the impact it has.
- **Design**- phase of development and identification of possible errors and improvements of the project design [8].
  - *High-Level Design*- ideal representation of how the equipment and resources should be located to make the process of handling, preparing, and verifying biological samples in the autopsy room more efficient.
- **Verify**- Verification phase of the quality and efficiency of the proposed design according to the needs and requirements of the client [8].
  - *Plan for implementation*- development of the implementation plan and preparation of the documentation relevant to the proposed design, these being the standard operating procedure, work instructions, check sheets, and process map.

For purposes of carrying out the DMADV process in an organized manner and in a reasonable time, an itinerary by phase was prepared with the selected tools. During project execution, the itinerary may change as tasks are completed (Table 1).

Table 1

Project Schedule

Project Schedule for a Lean Six Sigma Approach by Using DMADV Technique

Phase	Description	Tools	Schedule	
			Start Date	Completion Date
DEFINE	Define the project goals and the essential information of the project.	-Voice of Customer (VOC) -SIPOC -Project Charter	July 18, 2022	July 29, 2022
MEASURE	Collection and recording of data regarding the client needs and specifications.	-Critical to Quality (CTQ)	August 01, 2022	August 12, 2022
ANALYZE	Data and design alternatives evaluation to meet the client requirements and specifications.	-Cause and Effect Diagram (Fishbone) -Failure Mode and Effects Analysis (FMEA)	August 15, 2022	September 02, 2022
DESIGN	Develop a high-level design meeting the client specifications.	-High-Level Design	September 05, 2022	September 21, 2022
VERIFY	Verification of the quality and efficiency according to the needs and requirements of the client	-Plan for Implementation	September 22, 2022	October 13, 2022

RESULTS AND DISCUSSION

This section presents the data obtained using Six Sigma tools to determine the effect of handling and preparing biological samples in the processes required for toxicological analysis. The data obtained during the execution and analysis of this project were made through observations, interviews, meetings, literature review, among others. With the data provided in each phase of the project, we proceeded with the elaboration of diagrams and tables that summarize the needs and improvements identified to guarantee a quality biological sample handling process that does not affect the processes that are carried out in the toxicology laboratory. The data collected by phase is presented below:

Define Phase

As part of the process of establishing the problem and objectives of the project, an inspection of the handling and preparation of biological samples and delivery of evidence in the toxicology laboratory was carried out. Said inspection was coordinated with the supervisors of the autopsy room and the toxicology laboratory. Once the inspection was completed and some deficiencies in the processes were identified, interviews were carried out with both the autopsy room and the toxicology laboratory staff. This was worked with the VOC tool, which allows identifying who is the customer, what are their needs and how it can be improved. Table 2 represents the voice of the customer, which presents the key questions and expectations of the customer. Through the interviews it was possible to determine that the biggest problem in the delivery process of biological samples is that it currently lasts approximately 5 hours, affecting the other operations of the toxicology laboratory.

Once the voice of the customer was determined, the project plan was organized, determining the key points and processes necessary to meet the project objectives. Figure 4 represents the SIPOC diagram, in which the clients, suppliers, tools and processes related to the project on improvements to the process of handling, preparation and delivery of evidence are established. Based on the data collected in the VOC and SIPOC tools, a meeting was held to discuss the needs and prognoses of the project. As a result of the meeting, the pertinent documentation on the objectives, itinerary, roles, and responsibilities, among other pertinent information for the execution of the project, was completed. This information is presented in table form obtaining a project charter.

Table 2

Voice of Customer (VOC)

VOICE OF CUSTOMER (VOC) A Lean Six Sigma Approach		
Customer	**Voice of Customer**	**Key Customer Issues**
Who is the customer?	**What does the customer want from us to improve?**	**What issues prevent us from satisfying and/or complying with are customer?**
Toxicology Laboratory: • **Chemist** • **Laboratory Technicians**	• Receive 90% of the cases ready for toxicological analysis. • Reduce the time of the delivery process of biological samples in the toxicology laboratory.	• Evidence/biological samples delivery process takes approximately 5 hours. • Incomplete documentation. • Failures in the verification of biological samples. • Lack of trained personnel to carry out the process of the preparation of biological samples.

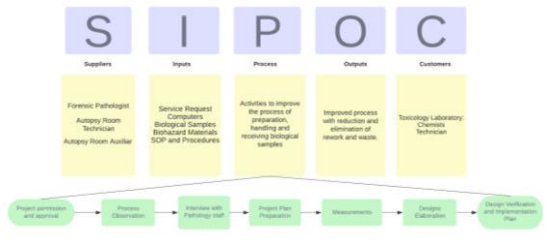

Figure 4

SIPOC Chart

Measure Phase

In this phase, the client's needs were identified, and the information was translated into measurable project requirements. Through this process it was possible to determine which processes and data are key to be able to implement improvements to the process of handling and preparing biological samples for toxicological analysis. The measurable

requirements of the project are represented through a diagram better known as the CTQ Tree.

In the CTQ Tree we can get the information that all the measurable requirements of the project are characterized by affecting the time that the sample handling and preparation process takes. To measure the time involved in the process of receiving biological samples in the toxicology laboratory, a series of inspections and observations were carried out during the days of said process (Monday, Wednesday, and Friday) in one week. During the observations, time measurement was implemented using a chronometer. With these data it was possible to calculate the average of the time it took to receive the evidence, which was 5.33 hours.

Although the time and duration of the process varies depending on the number of cases and samples received, this analysis allowed us to determine that there is no assigned or fully equipped area to carry out the sample handling process. This exercise allows the evaluation of the possible changes that are required to improve the process under study. For this reason, photographs were taken of the areas that are used to carry out the sample handling process. The areas used for the process of handling and preparing samples are located in the autopsy room and is divided into 3 rooms. Room 1, where the pathologists prepare the samples to be stored (Figure 5); Room 2 is where the sample verification and service request preparation process is carried out (Figure 6), and room 3, where the refrigerators for sample storage are located (Figure 7). Next, Figures 5, 6 and 7 present the photographs of the rooms used for the process of handling and preparing samples from different angles.

Once the taking of photographs of the rooms located in the autopsy room had been completed, measurements of said rooms were taken. A tape measure was used as an instrument to take the measurements. For purposes of reading the measurements, the units of inches and meters were used. These measures were taken for purposes of enabling and equipping the rooms in an ideal way to the needs and requirements that autopsy processes entail. Measurements were documented in a draft of the areas from the autopsy room.

Figure 5

Room 1: Sample Preparation Area (different angles)

Figure 6

Room 2: Sample Verification and Service Request Preparation Area (different angles)

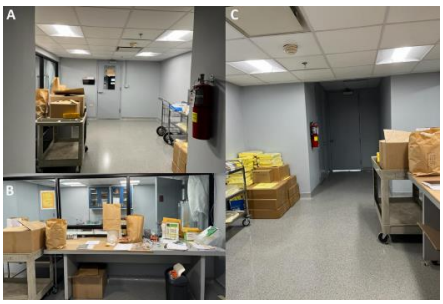

Figure 7

Room 3: Samples Storage (different angles)

Analyze Phase

The information collected through the execution of the project was evaluated and discussed in a meeting with the pathology and the toxicology laboratory supervisors. As a result of the meeting, the possible identified causes that affect the process of handling and preparing biological samples for toxicological analysis were specifically established. For this analysis, the visual tool of cause and effect, the fishbone diagram, was used.

Figure 8 is a representation of the causes identified that affect the time of the sample handling process by category. The diagram was organized into 6 categories: people, process, equipment, materials, environment, and management.

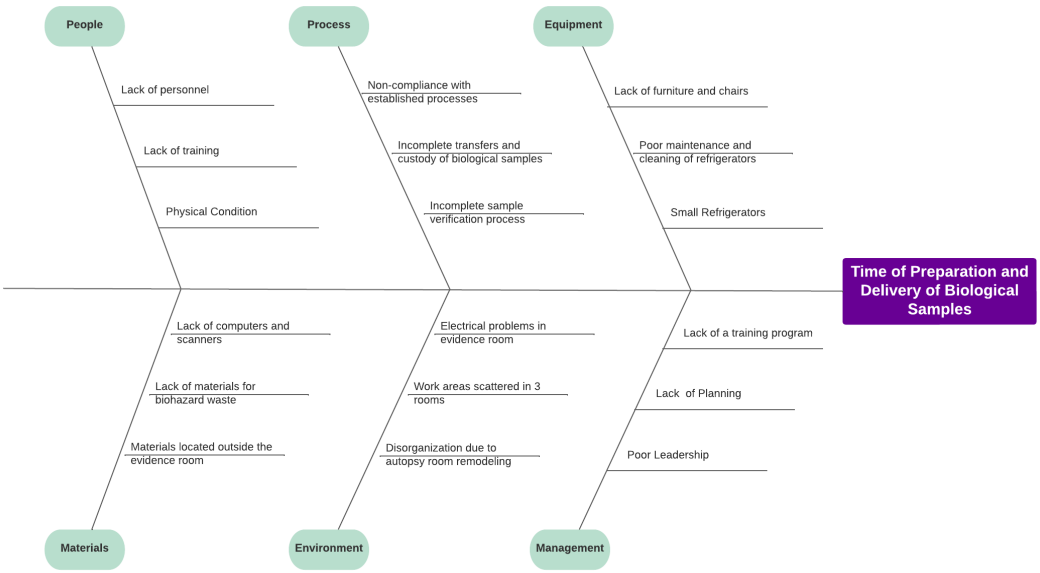

Figure 8
Cause and Effect Analysis

In relation to the data presented in Figure 8, a more exhaustive analysis was carried out regarding the causes that prolong the time currently involved in the process of handling and preparing samples. Therefore, we proceeded with the evaluation and analysis of the step-by-step process of handling and preparing biological samples. In said analysis, the factors that have affected the execution of quality compliance were identified and through the application of the FMEA tool. For the purposes of this analysis, a scale from 1 to 5 was used for the categories of severity, occurrence, and detection. Next, the description of the scale established for the FMEA tool:

- **Severity -** a score of 1 indicates no risk to the customer and a score of 5 indicates a high risk to the customer.
- **Occurrence-** a score of 1 implies zero probability of the risk occurring, and a score of 5 implies a very high probability of the risk occurring.
- **Detection –** a score of 1 implies the ability of some process to probably detect a failure/deficiency, and a score of 10 means that the process probably will not detect a failure /deficiency.

The main reason for knowing the scores for each category is to be able to obtain the Risk Priority Number (RPN), which is obtained by multiplying the scores qualified for Severity, Occurrence, and Detention. Through this analysis, it is possible to establish priorities on the identified risks and determine possible corrective actions for said findings. For the purposes of the project, it was determined that the processes with the highest RPN are the first and third steps, being the collection of biological samples (RPN= 40) and the preparation of the services request (RPN= 32), respectively. This implies that these process steps must be a priority in order to carry out the necessary improvements so that the sample handling and preparation process is one of compliance.

At the end of the analysis of the causes and risks of the deficiencies identified in the sample handling process, we proceeded with the elaboration of design alternatives for the autopsy room areas. The designs were made through the Internet page, Floor Planner, taking into consideration the needs and recommendations of the customer. The designs were prepared in 2D and 3D images.

During the development of the design, some errors in the measurement of the rooms were detected. Therefore, a second round of measurement of the identified areas was carried out to continue the project.

Design Phase

In this phase, a real representation was obtained in 2D and 3D images of the areas identified for improvement in the autopsy room. Said images were made with the measurements taken in the second measurement round carried out in the previous phase (Figure 9). As part of the final design process, AutoCAD and SketchUp tools were applied to complete the main idea of organizing the work area to maximize the time and resources of the processes that are carried out in the handling and preparation of samples. In order to develop the design with the needs and specifications of the customer, a series of calls, face-to-face meetings and classes in the university were coordinated in order to master the design platforms and thus obtain the final design.

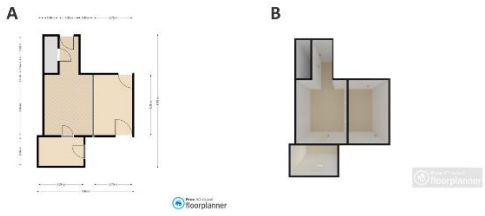

Figure 9
Final Layout of the Areas of Autopsy Room in 2D and 3D

According to the data collected, the final design consists of some changes that allow concentrating the work and processes related to biological samples in a single space. Therefore, the final design consists of the following:

- ***Room 1***- Enable it to store Pathology materials (Figure 7).
- ***Room 2*** – Set up with computers, biohazard waste bins, 2 large lab fridges, and ergonomic desks and chairs for the staff (Figure 8).
- ***Room 3***- Enable it with a small sink, a table for the preparation of samples, biohazard waste bins and elimination of the existing refrigerators (Figure 9).
- Elimination of access door from room 2 to room 3.

Verify Phase

Due to the activities carried out in the past phases of the project, the design was discussed with the supervisors of the autopsy room and the toxicology laboratory. As soon as the approval of the design and the proposed suggestions for the implementation of improvements in the biological sample handling and preparation process were received, the project was discussed with the quality department staff. In the meeting with the quality personnel, certain tasks were established in order to carry out an implementation plan for the project. As part of the assigned tasks, a non-conformity was filed in the Qualtrax tool to document the deficiencies identified in the sample handling process. With the filing of the non-conformity, and the approval of the quality department, the development of a corrective measures plan began, in which it is expected to be able to make the suggested changes that are represented in the proposed design. For the purposes of corrective measures, a presentation on the project and the Lean Six Sigma methodology was given to the toxicology staff. In the presentation, the deficiencies identified were discussed in detail and even received feedback from the staff. In addition, an official presentation of the project was scheduled for both departments, pathology, and toxicology, for November 2, 2022. On the other hand, it was considered to carry out the 5S methodology (sort, set-in-order, shine, standardize and sustain) to be

able to carry out changes in the identified areas of the autopsy room for improvement. Currently, the itinerary is being coordinated in order to start with the changes and the implementation of the design in the autopsy room areas, given to the large workflow.

CONCLUSION

The purpose of this project is to enable and equip an area in the autopsy room to maximize time and resources, thus allowing a quality process in an ideal time. With the identification of deficiencies and suggestions for improvements, it is expected to be able to meet the requirements and specifications of the client. With this project it is expected to be able to reduce the time of the process of receiving biological samples to the toxicology laboratory from approximately 5-6 hours to a maximum of 2 hours. This guarantees the reduction of rework and waste due to non-compliance or deficiencies in the processes. In addition, this allows the cases received to be worked on in real time, complying with the accreditation requirements of being able to certify the cases within a period of 30-90 days of receiving the case at the agency.

During the execution of the project, it was possible to apply Lean Six Sigma tools, in which little by little improvement has been seen in some processes and/or activities that are carried out on a daily basis. However, an interest was observed on the part of the quality department to identify areas of opportunity in other departments in order to develop a lean culture in the Institute of Forensic Sciences. Lastly, it can be determined that if this project is implemented correctly and the steps are revised and applied to the day-by-day duties, the ICF agency will successfully continue in a path of improvement.

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