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.

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.

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. To carry out these improvements, the Lean Six Sigma DMADV tool was selected. This tool consists of 5 steps that is aimed at the implementation of a new process or product. 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 toxicology staff.

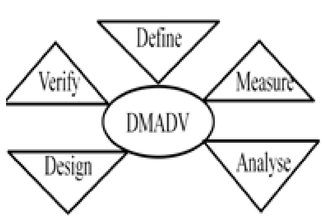


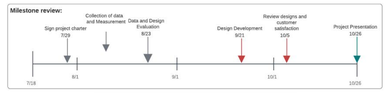
Figure 1
DMADV Process Road Map [8]

Results and Discussion

DEFINE PHASE

Project name: Redesign of a Space in the Autopsy Room Assigned for the Preparation of Biological Samples for Toxicological Analysis by Using DMADV Technique	**Date:** 07/20/2022
Project manager: Valerie O. Gómez Morán	**Project sponsor:** Dr. Rafael A. Nieves Castro
Purpose: The purpose of the project is to **maximize the time involved in the handling, preparation, and verification of biological samples for toxicological analysis** by reducing and eliminating rework and waste.	**Description:** Design and establish an appropriate and equipped space to carry out the process of preparing and verifying biological samples collected in the autopsy room.
Objective: • To describe what factors affect the handling, preparation, and verification of biological samples for toxicological analysis. • To describe the process of handling, preparation and verification of biological samples collected in the autopsy room for toxicological analysis.	**Project specification:** • To become a lean laboratory that ensure the quality of the services that the Institute of Forensic Sciences offers. • To exceed 80% of certified cases by the beginning of December.
Budget: • The project budget will be discussed once the proposed design for the autopsy room areas of the Institute of Forensic Sciences is completed and presented.	**Deliverables:** • Autopsy certification within 30-90 days. • Cross-docking practices performed at warehouse.
In scope: • Improvements in the current process of receiving biological samples. **Out of scope:** • Improve the collection of biological samples in autopsies.	**Project risk:** • Given the high volume of homicide cases, the implementation process may take time due to limited time and personnel.

Milestone review:



Key stakeholders	Roles and Responsibilities
Institute of Forensic Sciences of Puerto Rico	Valerie O. Gómez Morán | Project manager | Responsible for completing project and submit it for the Graduate School and Institute of Forensic Sciences.
Polytechnic University of Puerto Rico	Dr. Rafael A. Nieves Castro | Project Sponsor | Responsible to ensure the project complies with the requirements from the Graduate School and provides reviews and approvals.
Pathology| Medico-Legal Division	Dra. Luz A. Silva Torres | Supervisor Chemist | responsible for making decisions and directing the operations of the toxicology laboratory.
Toxicology Laboratory	Dra. Maria S. Conte | Executive Director ICF | Responsible for decisions, project approvals and acquisitions of the Institute of Forensic Sciences of Puerto Rico.
Project approval requirements: Executive Director approval for the new design of the autopsy rooms.	**Signature of project sponsor:** *Dr. Rafael A. Nieves Castro* **Date approved:** 07/29/2022

Table 1: Project Charter

MEASURE PHASE

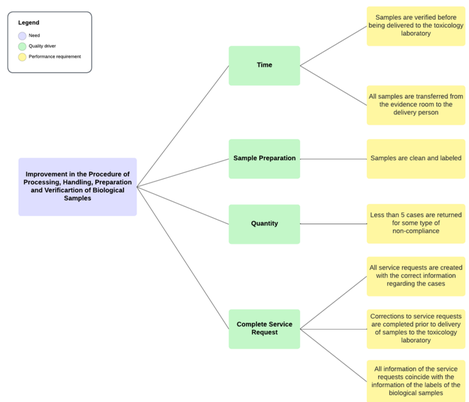


Figure 1: Critical to Quality Tree (CTQ)

Figure 2: Room #1

Figure 3: Room #2

Figure 4: Room #3

ANALYZE PHASE

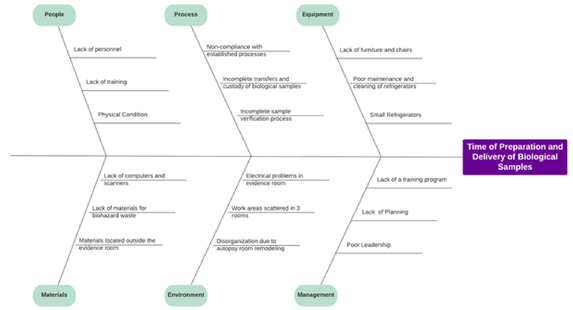


Figure 5: Cause and Effect Analysis

Process steps	Potential failure mode	Potential failure effects	SEV (1-5)	Potential failure cause	OCC (1-5)	Current controls	DET (1-5)	Risk profile number (RPN)
Collection of Biological Samples	Pathologist doesn't collect all the necessary samples according to the assigned case.	• Perform second autopsy to collect remaining samples. • Additional paperwork.	5	• Inexperienced pathology personnel • Mixed-up of autopsy cases.	2	• Assign cases in advance to perform autopsies. • Assign technicians to assist in sample collection. • Verify and review the necessary samples and analyses of an autopsy before proceeding with other autopsies.	4	40
Preparation of Biological Samples	Samples are not packaged correctly. (Packaging error)	• Samples spillage • Total loss of collected samples • Morose process of handling biological samples	4	• Poorly sealed samples • Sample closure without security seal.	2	• Place security seal on all samples. • Verify lids are properly closed before storing them in biohazard bags	1	8
Preparation of Service Request	Service Request fulfilled with wrong information.	• Preparation of samples with incomplete and/or incorrect information. • Additional paperwork/documentation for correction requests. • Longer time may take in case certification.	4	• Lack of information on cases at the time of data entry. • Inexperienced staff on data entry and use of the BEAST program. • Lack of a training program on data entry and navigation on the BEAST platform.	4	• Training for data entry for the preparation of the services request of the different analyses and tests to be requested depending on each case. • Verification process of the information boxes of the BEAST platform are completed before submitting any service request.	2	32
Verification of Biological Samples	Samples are not verified before submitting them to the necessary analyses.	• Information from the service request does not match the samples collected. (Name of the deceased, quantity, and type of samples) • Returned by the toxicology laboratory. • Incomplete samples kit	2	Not paying attention of every detail of the cases and the protocol of the collection of samples and data entry.	3	• Verify samples and service requests of each of the submitted cases once the autopsy is finished. • Assigned the reviewer to verify the samples collected	1	6
Storage of Biological Samples	Samples are not stored in the assigned area.	• Alteration and/or exudation of the decomposition of the samples. • Lost samples.	3	• Problems with the refrigerators assigned for biological samples • Too many refrigerators without labeling. • Small refrigerators without storage capacity.	2	• Quotation process for large refrigerators. • Refrigerate as soon as the autopsy process is finished. • Label the assigned areas for the storage of samples.	4	24
Custody Transfer	Pathology personnel doesn't complete the Chain of Custody.	• Problems in the search for biological samples. • Samples appear under someone else's name or in an area other than where it is located. • Future technicalities in court hearings for the custody of biological samples. • Required paperwork not completed.	2	• Failure to complete the custody transfer process at the time of storage or delivery of the samples to the assigned areas or persons. • Perform multiple autopsies at the same time. • Have a single person to carry out the entire process of sample handling and custody transfer of several autopsies from different pathologists.	3	• Store and/or deliver samples once the autopsy is finished. • Document the transfer of custody of the samples in the corresponding form and on the BEAST platform.	2	12

Figure 6: Failure Mode and Effects Analysis (FMEA)

DESIGN PHASE

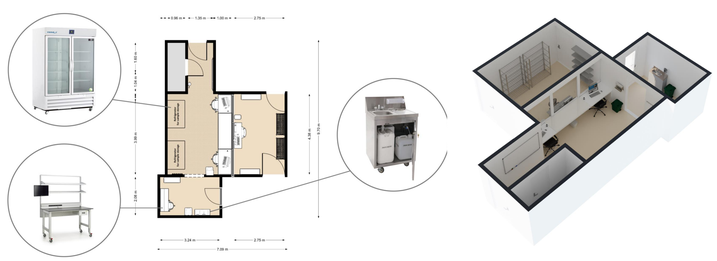


Figure 7: Final Design in 2D and 3D

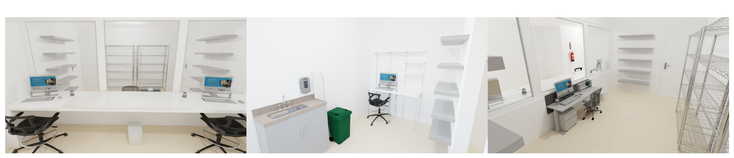


Figure 8: Final Room Designs in 3D

VERIFY PHASE

With the results obtained, it proceeded with the creation of a non-conformity, that with 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 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 9, 2022.

Conclusions

With the identification of deficiencies and suggestions for improvements, and the autopsy room work areas redesign, 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.

Acknowledgements

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