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EXECUTIVE SUMMARY OF THE THESIS

Evaluation of the Technological Impact of New Equipment and Implementation of a Productivity Dashboard for the Central Sterile Services Department at Humanitas Research Hospital

TESI MAGISTRALE IN CLINICAL ENGINEERING – INGEGNERIA CLINICA

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1. Introduction

Sterilization plays a pivotal role in preventing hospital-acquired infections, ensuring patient safety, and guaranteeing the operations of the surgical wards.

In the period from 2021 to 2023, extensive efforts were made at the Humanitas Research Hospital to restore the Central Sterile Services Department (CSSD), aligning it with UNI EN ISO 13485 standards. These efforts, which included the acquisition of new equipment and a refunctionalization of CSSD's physical and infrastructure layout, were successfully completed by August 2022.

The thesis focuses on the modernization of the Central Sterilization Department at the Humanitas Research Hospital, encompassing the integration of new technologies, the implementation of traceability measures, and the introduction of a productivity dashboard. The study investigates three hypotheses:

Hp 1: The adoption of new technologies reduces process times, potentially improving efficiency.
Hp 2: A productivity dashboard assists operators and nursing staff by providing a centralized platform for monitoring production.
Hp 3: Operating room traceability can expedite the packaging process.

2. State of art

Until the 1940s, medical and surgical supplies were typically processed and stored within the departments where they were used. However, this decentralized approach led to significant duplication of effort and made it challenging to maintain consistent standards for sterilization techniques. With the growth in surgical procedures, medical devices and equipment, it became clear that a more centralized processing system was needed for efficiency, cost-effectiveness, and patient safety. This need gave

rise to the Sterile Processing Department (SPD), also known as the Central Sterile Services Department (CSSD), within hospitals, dedicated to the cleaning and sterilization of medical devices used in medical procedures.

A typical sterilization service involves several key steps[1]:

- **Utilization** of Reusable Medical Devices (RMDs) sets during surgical procedures.
- **Pre-disinfection** by manually submerging RMDs in a chemical solution to reduce the population of microorganisms and facilitate washing.
- **Rinsing** and **washing** to remove stains and obtain a clean device. Automatic washers are often used to clean multiple sets simultaneously.
- **Visual Inspection** to ensure there is no deterioration that might affect safety, integrity, or function.
- **Packing**, that serves as a barrier to microorganisms, where instruments are arranged in bags or containers that allow good penetration of the sterilizing agent.
- **Sterilization**: surgical instruments, typically made of heat-stable materials, can be sterilized using steam in autoclaves. However, the increasing use of heat-sensitive materials has led to the development of low-temperature sterilization methods like ethylene oxide (ETO) gas, hydrogen peroxide gas plasma (HPGP), vaporized hydrogen peroxide (VHP), and others.[2]
- **Transfer Steps** which involve moving soiled medical devices from operating rooms to the sterilization service and transferring sterile devices from the CSSD to storage areas near the operating rooms.

Current sterilization practices in hospitals are based on international standards, including UNI EN ISO 13485, which defines requirements for quality management systems in healthcare companies. [3] Despite these standards, challenges persist, including operational efficiency, traceability, and time management.
Emerging technologies, like advanced traceability systems, productivity dashboards and new sterilization equipment, offer opportunities to enhance service quality, reduce processing times, and boost patient safety. This thesis explores the adoption of such technologies at Humanitas Research Hospital's sterilization department, aiming to evaluate their potential to improve process efficiency, effectiveness, and quality.

3. Materials and methods

3.1 Data analysis

In order to validate the first hypothesis, an exploratory analysis was conducted using the software *Splunk*. The research was based on a comprehensive dataset provided by *Sixster*, the software used for traceability in the sterilization department. The data spanned from February 2022 to July 2023 and comprises several Excel files organized according to the different stages of the sterilization process: acceptance, clean acceptance, washing, packaging and sterilization. The research was divided into two distinct periods: before August and after August 2022, the month that saw the introduction of the new equipment. In particular, to mitigate the effects of seasonality, the months of February to July of the two years were compared.

A *kit* is a collection of specialized medical instruments used by surgeons during surgical procedures. In the CSSD at the Humanitas Research Hospital each kit identified by a unique barcode: this allowed the computation of several key parameters, that were compared for the years 2022 and 2023:

- **Output Volumes Produced**: number of processed kits produced during the analysis period.
- **Number of Partially Processed Kits**: kits that are only partially processed within the same working day (colloquially called *remains*).
- **Process Durations**: the time taken for each step and for the entire sterilization process.
- **Equipment Operativity and daily cycles**: the operational hours per day and the number of complete cycles for both washing and sterilization equipment.

Results are shown in the paragraph 4.1.

3.2 Productivity Dashboard

In order to validate the second hypothesis, a productivity dashboard was created using *Microsoft Power BI*. For the thesis implementation,

the dataset provided by *Sixster*, cited earlier, was loaded in batches using Power BI. However, when the solution goes into production, an ETL (Extract, Transform, Load) job will be implemented to extract data from the traceability software, transform it and finally load it into Power BI.

To assess the potential impact of its adoption, a questionnaire, realized with *Google Forms*, was administered to personnel involved in the sterilization process. This survey gathered feedback on the dashboard's usability and its perceived ability to enhance work planning and reduce delays. The results are shown in the paragraph 4.2.

3.3 Implementation of Traceability Measures

To validate the third hypothesis, comprehensive training for both operating room and sterilization personnel was conducted to introduce traceability measures within the operating rooms. These measures involved two key steps: the check-in of sets to be used during a surgical procedure, ideally performed at the beginning of the operation, and the check-out of utilized sets at the conclusion of the procedure. For the check-out process, it was necessary to associate each set with the corresponding storage grids, identified by unique barcodes. This approach differed significantly from the current practice, where used sets are randomly placed within storage grids, often leading to mixing and disarray. This mixing of items causes substantial challenges in the sterilization facility, particularly during the packaging phase, where operators have to search for individual kit components.

The implementation of such measures was then tested through timed pilot tests in the cardiothoracic surgery block. The results are shown in the paragraph 4.3.

4. Results

4.1 Hp 1: The adoption of new technologies reduces process times.

Analyzing the entire process duration, it becomes clear that in 2023, with the only exception of the month of July, significant improvements in process efficiency and productivity compared to 2022 have been achieved (Fig.1).

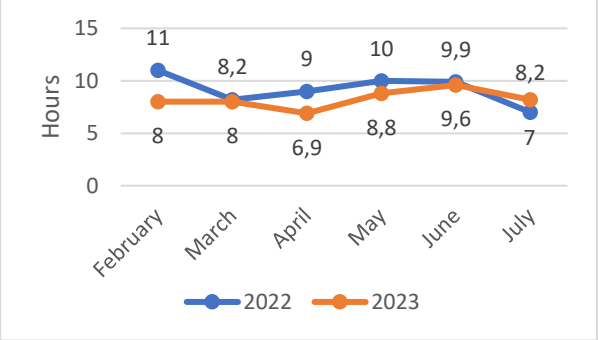

Fig. 1: median values of entire process duration

By delving into the single phases, it is possible to spot some differences between the stages predominantly impacted by equipment operations and the stages strongly influenced by human actions.

The washing and sterilization phases can be considered equipment-intensive stages: they are both accomplished through cycles utilizing respectively washer disinfectors and steam sterilizers. These stages have shown a noticeable enhancement: the efficiency gains here are primarily attributed to increased throughput (Fig.2), with shorter washing and sterilization durations (Fig.3) for a higher number of processed kits.

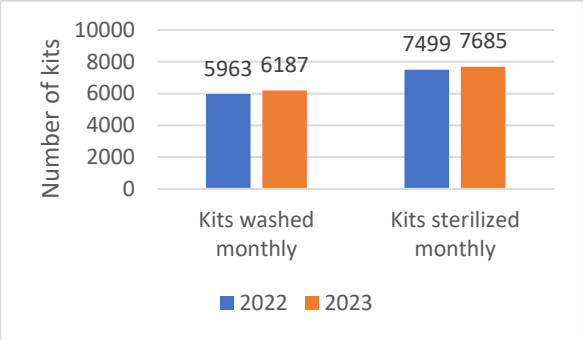

Fig. 2: median values of monthly washed and sterilized kits in the two years

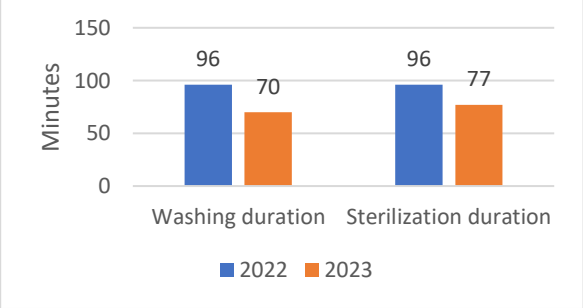

Fig. 3: median values of washing duration and sterilization duration in the two years

The efficiency improvements in these two phases are also evident when comparing the average operational duration over a 24-hour period. Both the washer disinfectors (Table 1, Table 2) and sterilizers (Table 3, Table 4) have managed to reduce operational hours while maintaining a similar number of daily cycles and increasing throughput. This reduction is not only beneficial in terms of energy consumption but can also extends equipment lifespan, reducing maintenance costs, and contributing to sustainability goals.

2022	Operativity [h/24]	Daily cycles
STERIS HAMO T21/1	14	7
STERIS HAMO T21/2	13,3	7
STERIS HAMO T21/3	13,2	6
LAVAFERRI GETINGE	8,7	5

Table 1: operativity and daily cycles of the washer disinfectors (washing equipment) in 2022

2023	Operativity [h/24]	Daily cycles
AMSCO 7053 HP /1	10,7	8
AMSCO 7053 HP /2	10,8	7
AMSCO 7053 HP /3	10,3	7
One Vision 1300	6	2

Table 2: operativity and daily cycles of the washer disinfectors (washing equipment) in 2023

2022	Operativity [h/24]	Daily cycles
CISA 6412H/1	12,3	7
CISA 6412H/2	13,7	7
CISA 6412H/3	13,3	8

Table 3: operativity and daily cycles of the steam sterilizers (sterilization equipment) in 2022

2023	Operativity [h/24]	Daily cycles
AMSCO 600/1	11,4	8
AMSCO 600/2	12,4	8
AMSCO 600/3	12,6	9

Table 4: operativity and daily cycles of the steam sterilizers (sterilization equipment) in 2023

Furthermore, these efficiency gains positively impact water usage, especially during the washing phase. The new washing disinfectors, operational for around 10 hours a day, consume less energy (230 kWh/day compared to 260 kWh/day) and less water (72,000 liters/day compared to 102,000 liters/day) than the old machines. This translates to significant savings in both energy and water consumption, aligning with responsible resource management and environmentally conscious practices.

Regarding the stages mainly influenced by human action, the acceptance (which is the first phase, spanning from the entrance of the soiled kits in the sterilization department to the beginning of the washing phase) has seen a reduction of its duration during all the months considered in the analysis (Fig.4).

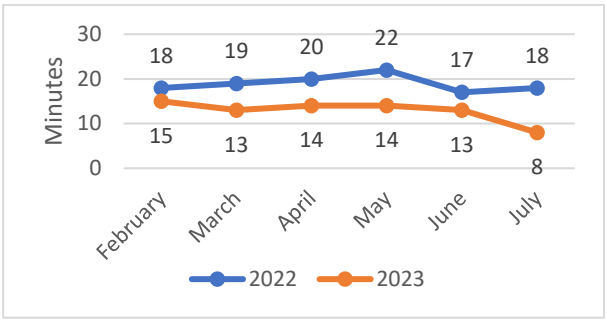

Fig. 4: median values of acceptance duration

Different, instead, are the results for the packaging phase which remains relatively stable or shows a tendency to deteriorate in terms of time efficiency (Fig.5).

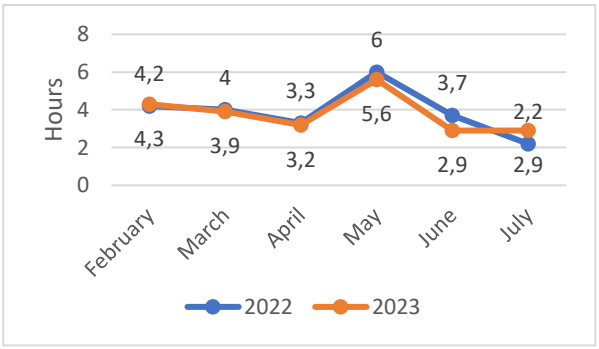

Fig. 5: median values of packaging duration

The decline in efficiency in this step is also evident from the number of partially processed kits: the median value of the *remains to pack* (kits that are washed but not packed in the same working day) appears to be generally higher in 2023 compared to the previous year (Fig.6).

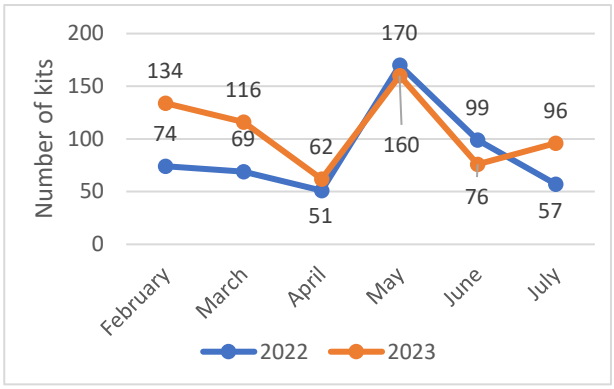

Fig. 6: median values of daily remains to pack in the two years

4.2 Hp 2: A productivity dashboard assists operators and nursing staff by providing a centralized platform for monitoring production.

A comprehensive productivity dashboard has been developed to facilitate real-time monitoring of the sterilization process. This dashboard was tailored to meet the specific needs and requests of the personnel involved in the process. It is organized into dedicated pages for each stage: acceptance, acceptance of clean kits, washing, packaging, and sterilization. For these phases, the layout of the dashboard is consistent (Fig.7), presenting users with the following elements:

a) A date filter for selecting specific dates.
b) A filter for choosing a specific surgical kit.
c) A panel displaying the number of processed kits on the selected date.
d) An hourly trend panel.
e) A trend panel that allows users to analyze productivity over a custom-defined period.
f) A detailed view of processed kits, including date and time.

Fig. 7: dashboard's layout

The dashboard includes two pages dedicated to partially processed kits (remains to pack and remains to sterilize) that share an identical structure and comprise the following elements (Fig. 8):

- Trend analysis of leftover items in a period defined by the user through a date filter.
- A panel presenting the number of remaining items for the selected date.
- Comprehensive listings of remains, inclusive of timestamps marking the end of washing (or end-of-packaging for sterilization remains).

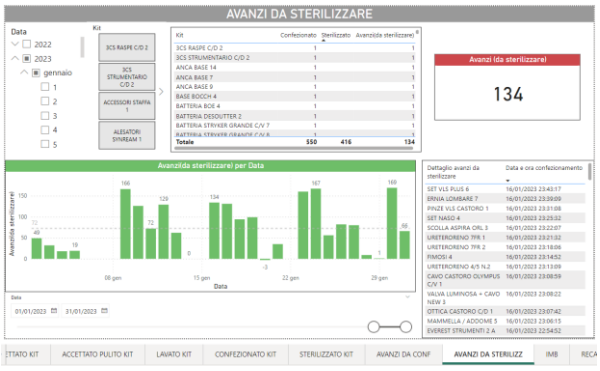

Fig. 8: layout of the dashboard pages dedicated to remains to pack and to sterilize

The dashboard includes a dedicated page for single bagged items (Fig.9), which lack complete traceability within the process. As a consequence, the assessment of these items is limited to determining their quantity in the process, without the ability to pinpoint their individual identities.

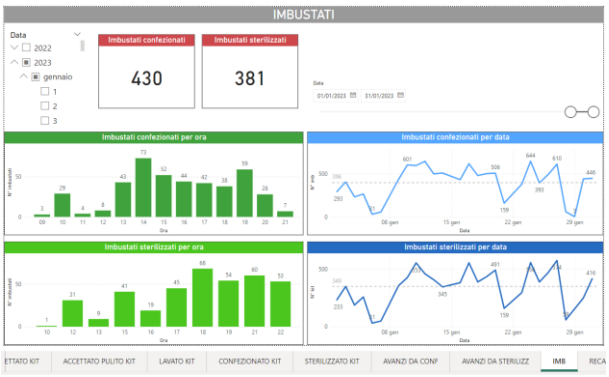

Fig. 9: dashboard's page dedicated to single bagged items

Lastly, the dashboard encompasses a recap page that offers a comprehensive overview of recently processed kits the current count of remains to pack and sterilize.

In order to get valuable insights related to the implementation of the productivity dashboard, a

questionnaire was administered to individuals actively engaged in the sterilization process. Based on the provided answers, it is evident that the personnel generally hold a favorable view regarding the dashboard's configuration, features, and user-friendliness. Additionally, there is a consensus among respondents that the dashboard can be a useful tool to identify process inefficiencies and enhance work planning. However, some uncertainties exist concerning its potential to effectively reduce process delays.

4.3 Hp 3: Operating room traceability can expedite the packaging process.

While full traceability implementation was challenging, a pilot test conducted in the cardiovascular operating ward demonstrated promising results. It showed a reduction in packaging times, improving overall efficiency, and simplifying kit reassembly for personnel. However, the check-out process did lead to increased times within the operating room's post-procedure phase. In timed trials, storing sets without check-out took about 20-22 minutes, whereas the check-out process extended this to 28-30 minutes. This change introduced a learning curve, and ongoing training and experience are expected to optimize the check-out process, potentially reducing the time difference between the two approaches.

5. Conclusions

In conclusion, the adoption of new equipment has proven crucial in enhancing productivity and streamlining the sterilization process. However, opportunities for further improvement exist, particularly in optimizing the packaging phase. To fully harness the advantages of new equipment throughout the process, specific strategies must be implemented.

Firstly, a focus on comprehensive training for personnel and an increased staffing allocation to the packaging phase are imperative. To aid less experienced staff, the introduction of visual aids, such as photographic guides, should be considered to facilitate kit reassembly.

Furthermore, effective coordination between different phases is essential. Aligning the utilization hours of washer disinfectors and autoclaves, especially during peak times, can mitigate kit accumulation. Exploring the possibility of extending washer disinfector hours during morning and night shifts, while considering operational constraints, could be beneficial.

Addressing outlier cases remains crucial. Thorough analysis of extended durations can uncover root causes, be they procedural inefficiencies, equipment-related issues, or other variables. Identifying these sources of delays enables targeted interventions and process improvements.

Moreover, it's vital to recognize the potential contributions of the productivity dashboard and operating room traceability. The productivity dashboard can aid in monitoring the process, enabling better work planning, and facilitating the nursing staff's duties. Additionally, operating room traceability, aside from ensuring more effective instrument management throughout the facility, simplifies the packaging phase by providing real-time information on the location of each instrument, streamlining the process.

These integrated tools should be carefully considered for further enhancements to the sterilization process, ultimately contributing to improved efficiency, patient safety, and the overall quality of healthcare services provided.

References

1. Di Mascolo M, Gouin A. A generic simulation model to assess the performance of sterilization services in health establishments. *Health Care Manag Sci*. 2013;16(1):45-61. doi:10.1007/s10729-012-9210-2
2. Rutala WA, Weber DJ. Disinfection and Sterilization in Health Care Facilities: An Overview and Current Issues. *Infect Dis Clin North Am*. 2021;35(3):575-607. doi:10.1016/j.idc.2021.04.004
3. https://www.iso.org/standard/59752.html.