Continuous Improvement of the Sterilization Process of Multiple Use Medical Devices

Centro Hospitalar Universitário Lisboa Central Case Study

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Abstract

The sterilization of multiple use medical devices (MUDs) is a crucial process for the success of the surgeries happening in the Operation Room (OR). MUDs must be properly sterilized in order to avoid surgeries' delays, postponement and cancelations. This dissertation is motivated based on an increment of incidents' report related with MUDs in the Centro Hospitalar Universitário Lisboa Central (CHULC) in 2018. This work's objective is to reduce the number of incidents in CHULC, relatively to the reported in 2018. These incidents include three problems: 1) lack of quality when sterilizing MUDs; 2) delayed MUDs in the OR; 3) disorganization associated with the washing and storing areas of MUDs. It's observed waste and lack of standardization along the phases of the sterilization process. This can potentiate human errors and, consequently, the incidents arising. Lean methodology focuses on improving fragile processes, in which human error happens easily, so, the literature review concentrates on Lean tools used, mainly, in the OR and SCS. Tools like PDCA cycle, standardized work, *spaghetti* diagram, 5S and A3 are applied in the necessary phases of the process and the results show reduction above 80% in each incident report. Three of these incidents obtained statistically significant reduction. This dissertation provides contributions to the literature: it utilizes of Lean tools in an SCS in Portugal, it illustrates A3 and *spaghetti* diagram, and it details the 5S tool, something not found in the literature review.

Keywords: Sterilization, Incidents, CHULC, Lean, Plan-Do-Check-Act, Spaghetti Diagram.

1. Introduction

The sterilization process consists in the eradication of any microorganism existing in a surface, such as virus and bacteria. This process avoids the transmission of diseases to patients through MUDs during an operation (Solon & Killeen, 2015). MUDs are sterilized on specific machines, called autoclave. In Portugal, the sterilization process is performed by Operating Assistants (OAs) in SCS and coordinated by nurses. The SCS have the objective of efficiently sterilizing MUDs of the hospitals in time for their next utilization. The SCS are physically organized in several work areas. It starts with the reception area, where the contaminated MUDs are delivered in containers to an OA. The second is the washing area in which the MUDs are removed from the containers, pre-washed if necessary, put in medical sterilization baskets, and placed in the washing machine. The third area is the inspection area. This is physically separated from the washing area, in order to divide contaminated MUDs and clean MUDs flows. The inspection area is where OA inspect every single MUD, looking for any kind of organic matter. If so, the MUD returns to the washing area. If not, the MUDs go to the packing area, where they are packed in a box, sterilization basket or individually, depending on the OR needs. After this area, the MUDs are ready to go to the autoclaves (sterilization area). When the sterilization cycle finishes, the MUDs remain in the interior of the machine so they can efficiently dry. Then, the MUDs are stored in the storage area, waiting to be dispatched in transportation cars, that can accommodate several MUDs containers. The services in a hospital that depend on the SCS sterilized MUDs are: OR, Emergency Room, Inpatient and Outpatient Services. DGES (2001) affirms that the SCS must be closer to the OR, where the Sterilized MUDs demand is the greater, followed by the Emergency Room, the inpatient service and, for last, the outpatient service. It is crucial that the process of sterilizing MUDs is efficiently executed. Otherwise it can lead to infections in the patients or delays or cancelations of surgeries because of delays in the MUDs sterilization. In order to prevent this type of problems, it is necessary that the processes in the SCS are organized and adequate.

2. Problem Statement

The CHULC is a gettering of six hospital in the region of Lisbon, Portugal. There are two SCS that sterilize MUDs for the six hospitals, located in Hospital Curry Cabral (HCC) e Hospital Santa Marta (HSM). The six hospitals that belong to CHULC are: HCC, HSM, Hospital São José (HSJ), Hospital Dona Estefânia (HDE), Hospital Santo António dos Capuchos (HSAC) and Maternidade Alfredo da Costa (MAC). The SCS of HCC receives around 70% of the total contaminated MUDs from the hospitals. In 2018, there were reported 4705 incidents in CHULC, 15.5% of them related to problems with MUDs (the second most reported issue in CHULC, after patients' falls). The problems associated with the MUDs are of the following types:

- Sterilization process failures;
- Defects of MUDs;
- Delays in the delivery of the MUDs;
- Stockout in the services;
- Others.

Along with these reports, the observations performed in the SCS of HCC provided some information related to the existing disorganization in the washing area and the storage area. A disorganized area can potentiate human error, generating problems related to MUDs. These increase the incidents reporting and, possibly, decrease patient satisfaction when they are affected, due to infections of surgery delays/cancelations. Because the majority and more critical users of the SCS are the OR of the six hospitals, this work focuses on the OR and, more specifically, in the resolution of the following problems related to MUDs:

- Lack of quality in the MUDs sterilization process;
- Delays in the MUDs delivery to the OR;
- Disorganization of the SCS.

The objective of resolving those problems is to, essentially, reduce the number of incidents report, which in 2018 were 727.

3. Literature Review

The observation of the SCS and the identification of the problems related to MUDs allowed to understand that exists the need to improve the processes inherent to the sterilization. The processes are performed in very different ways, depending on the OA performing the activity, Also, if there are incidents occurring, it means the processes are not robust, tending to fail frequently (Toussaint & Berry, 2013). The Lean methodology allows, exactly, the improvement of processes with low efficiency and a high probability to making mistakes (human error). This methodology is highly implemented in the health services since the year 2000 and it was initiated in this area by Virginia Mason Institute (Blackmore et al., 2013).

The Lean thinking is focus on trying to do more with less (Mullaney, 2010), improving process efficiency, and it is based on five principles: identifies **specific value** of a product/service, specifies the **value stream**¸ creates **continuous flow**, and tries always to reach **perfection** (Mullaney, 2010). A continuous improvement performed with Lean thinking, always starts with a *Gemba Walk*, this is, a visit to the area where the process needing the improvement is performed (Cohen, 2018). The objective of the *Gemba Walk* is to know well all the process. When observing and mapping the phases of a process, is important to acknowledge the wastes along the process. There are seven types of waste: waiting times, movements, transportation, inventory, underproduction, overproduction and defects (Castaldi et al., 2016). There are various Lean tools that can be used to improve processes.

3.1. Value Stream Mapping (VSM)

VSM is a tool developed to map the phases of a process. It can be applied to the materials flow and the information flow. It shows all the process and details the different phases regarding cycle times, work area, professionals that perform the activity, restrictions, among others. The VSM can be developed in two ways: having in consideration the actual process (actual VSM) and the ideal process (ideal VSM). With these two VSM, it is easier to know where to improve the process, in order to reach the desired results. In the literature, this tool is used to identify tasks with no added value (Cerfolio et al., 2017), calculate the total time of the process, and the work in progress (WIP) between the process phases (Migita et al., 2018). It is applied in many health services, such as, sterilization centers, OR, Intensive Care Units (ICU), among others. Cookson et al. (2001) applied the VSM in an emergency department, with the objective of understanding the current process and identifying waste in each step of the process (movement, transportation, waiting times, etc.).

3.2. Simulation-based Learning

The SBL is a tool whose objective is to develop group learning and standardization work (another Lean tool, explained in the section 3.3.). This provides the exchange of knowledge, allowing professionals to discuss about the best practices for each procedure applied in a process. Cant & Cooper (2010) developed a study about SBL benefits to a group of nurses, and the results demonstrated that

50% of them said the simulation-based learning was important to gain of knowledge in the area which the simulation-based learning was applied. McGaghie et al (2011) reached similar results by concluding that simulation-based learning allowed health professionals to attain better clinical competences.

3.3. Standardized Work

Standardized work is a tool that allows different professionals to perform equally the same activity. There are three stages to create standardized work: process sequencing, *takt time* calculation and WIP accounting. *Takt time* is the time interval at which a product must be ready (developed), in order to accomplish the demand (Migita et al., 2018). It is calculated by the following equation:

$$Takt\ Time = \frac{Available\ time\ to\ do\ the\ work\ at\ a\ time\ period}{Demand\ for\ the\ same\ time\ period}$$

If *takt time* is greater than the total time of a process, it means there is space to satisfy the demand. If not, the demand cannot be completely satisfied, as the offer is lower. The WIP is the pending work between phases of the process and it only exists when it´s not possible to create continuous flow. Completing these three steps, allows the process to be standardized and with a continuous flow, whenever is possible. Kim et al. (2007) uses this tool to reduce the variability of patients' inscription process in a hospital by decreasing the number of steps in 41%. In another field, Ngu (2010) improved the surgical table of the OR by standardizing the location of each MUD and equipment. Perkins et al. (2014) developed standardized work in the whole OR, and not just in a step of a specific process.

3.4. Checklist

Checklist is a standardized list of information or procedures to follow by the professionals. This tool avoids forgetting important steps of a given process and allows the process to be standardized. Also, it can be used to collect specific data during the steps of a process (Rawson et al., 2016). The checklist can be used to gather information on cycle times, process errors, delays, among others (Porta et al., 2013). This tool avoids the execution of unnecessary steps (Toussaint & Berry, 2013).

3.5. Ishikawa Diagram

The Ishikawa diagram is a cause-effect diagram whose objective is to analyze the causes that may be in the origin of a specific problem, concerning 6 areas (machines, measures, method, environment, manpower and materials) (Figure 1). This tool provides information for the next steps, as it gives us the possible reasons for the problems' occurrence. After this, it is generated a set of improvement ideas for the process. In the literature, problems such as OR patient allocation (Simon & Canacari, 2012), low efficiency in cardiac patient clinical path (Yeh et al., 2011), or respiratory morbidity increment (Cerfolio et al., 2017) are analyzed in terms of root causes.

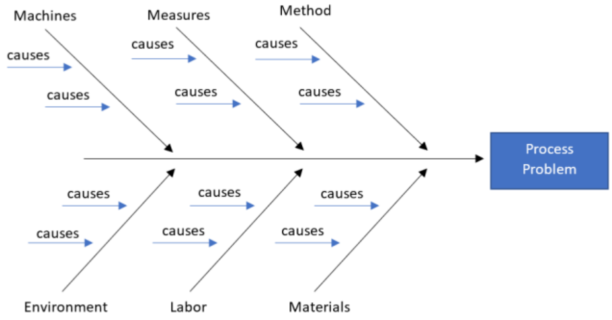

Figure 1: Layout of the Ishikawa diagram tool.

3.6. Pareto Diagram

The Pareto diagram is a bar chart whose objective is to organize decreasingly the causes or problems in the abscissa axis by their impact. The Pareto rule demonstrates that 20% of the causes generates 80% of the problems. Tagge et al. (2017) built a Pareto diagram with the causes of delays over 11 minutes in the first pediatric attendance, in order to understand the causes that impacted the delay the most.

3.7. Impact-Difficulty Matrix

This tool, shown in Figure 2, is utilized for prioritizing the causes of a problem. In an impact-difficulty matrix, the causes are prioritized according to their impact (ordinate axis) and easiness to solve them (abscissa axis) (Simon & Canacari, 2012). This step is important since not all causes are solved at the same time. For this reason, the first causes to be solved are the ones that, at the same time, impact the most and are easier to solve, located in the first quadrant. Simon & Canacari (2012) used this tool to prioritize problems related to delays in surgeries, in order to start the improvements in the OR with the solutions that are easier to implement and impact the most.

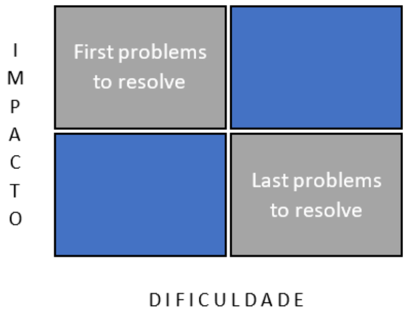

Figure 2: Quadrants of the impact-difficulty matrix.

3.8. PDCA Cycle

The Lean tool that determines an order for continuous improvement is the PDCA cycle. This cycle is constituted with four steps: Plan, Do, Check, Act (Varkey, 2007). The "Plan" step consists in choosing the problem to approach in a process through observation, generating ideas for improvement and planning the possible changes in the process. The "Do" step is for implementing the improvement ideas for a part of the process. In the "Check" step, the results of the improvement are analyzed and in the last step, "Act", the lessons learned are shared and, if the improvement process goes well, the ideas of improvement are extended for the whole process (Varkey, 2007; Simon & Canacari, 2012). This tool is used by Ben-Tovim et al. (2008) in an emergency department to improve the patients' clinical pathway. Also, in a different hospital area, Mullaney (2010) used the PCDA cycle in a OR scenario to resolve issues related to surgery delays and cancelations.

3.9. A3

A3 is a Lean tool used to show the PDCA cycle, in an illustrative and simple way. There are seven steps to consider when developing this tool: background, current situation, desirable situation, root-causes analyses, countermeasures and recommendations, implementation plan and follow-up (Mullaney, 2010). The "Plan" phase is constituted by the first five steps (background to countermeasures and recommendations), the "Do" and "Check" are illustrated in the step "implementation plan" and, for last, the "Act" phase corresponds to the follow-up step. Ballé & Régnier (2007) utilized the A3 tool to organize and synthetize improvement actions related to waste reduction in a warm of an hospital. Mullaney (2010) used the A3 tool also in a hospital, but to illustrate a problem solving on surgeries delays and cancelations in an OR.

3.10. *Spaghetti* Diagram

The *spaghetti* diagram can be used in the second phase of the A3 tool, and the objective is to draw the movements performed by workers, in order to identify wastes (Rawson et al., 2016). After this, the diagram is analyzed in order to identify waste movements, discuss their causes and the generate improvement ideas to eliminate or reduce these waste movements. Bhat et al. (2016) applied the *spaghetti* diagram in a medical file room, reducing the movements performed by the workers when performing their activities. Patrão (2018) use this tool in an OR of Hospital Santa Maria, with the objective of identifying the waste of movements performed by a nurse (Figure 3). This method facilitates the layout redesign, considering the equipment and material that must be nearer and farther from the nurse.

3.11. 5S

The 5S tool exists for layout improvements in working areas. For that, the 5S uses five different steps to perform a standardized layout change (Varkey, 2007). The steps are (Sorooshian et al., 2012):

- Separating, in which the necessary equipment and materials are identified;
- Organizing, where all the equipment and material are organized considering the workflow and the utilization order;
- Cleaning, providing the best equipment and work conditions;
- Standardizing, where it is defined standard movements and functions to all the existing tasks;
- Maintaining, so the previous steps don't regress.

The 5S tool was applied in patients' clinical path in an emergency room (Chadha et al., 2012). With this, it was possible to reduce the waiting times and to eliminate the tasks with no added value.

Figure 3: Spaghetti diagram of an OR (extracted from Patrão (2018)).

3.12. Six Sigma

Six Sigma is a tool developed to statistically analyze extensive data and provide answers on how to decrease the defects per million productions, improving the product/service quality (Bhat et al., 2016; Rawson et al., 2016). The application of this tool provides a reduction in variability, becoming the process more uniform. The origin of the name "Six Sigma" derives of an intended success rate of 99.9996% when reducing variability of data (Porta et al., 2013). This tool, in the Lean methodology, is used with DMAIC approach (similar to PDCA cycle). DMAIC is acronym for define, measure, analyze, improve and control (Porta et al., 2013). Six Sigma has been utilized for professionals and surgeries scheduling, increasing the utilization rate of the OR, decreasing waiting times (Niemeijer et al., 2010) and medical errors (Khoo et al., 2012), and, consequently, increasing the number of surgeries performed per time interval (Bender et al., 2015). Yeh et al. (2011) used Six Sigma to reduce the time interval between the entrance of a patient in a hospital and the catheter placement (called door-to-ballon time).

4. Results and Discussion

The case study discussed includes three different problems. These problems are approached with some tools described in the literature review. However, there are some actions to be performed before the tools' utilization, in order to efficiently monitor the improvement process.

4.1. Mapping the Sterilization Process in the SCS

To begin the improvement process, it's necessary to know well the sterilization process and the MUDs delivery to the destination hospitals. For that reason, it's carried out a *Gemba Walk* that allows to know better the sterilization process. After this step, it's developed the current VSM for sterilization process in the SCS. The current VSM shows, for each phase of the sterilization process, the cycle times, the professional/machine that performs the activity, the area of the SCS where the activity is performed and the constrains to each phase. The inspection is the longer phase with 37 minutes. This is a critical phase, since, if not correctly performed, the MUDs might be packed and dispatched to the ORs with organic matter or other problems. It is, also, possible to see the waiting time and the WIP between phases. The process has four bottlenecks, this is, four stages in which the process slows down because of MUDs accumulation along the process. The four bottlenecks are located between: reception and preparation of MUDs (before washing), washing and inspection, packing and sterilization, sterilization and storage. In this sense, it's possible to notice that the materials flow (MUDs flow) is not continuous. Drawing the desired VSM according to Lean thinking, the important changes to make are the elimination (or substantial reduction) of WIP and, consequently, waiting times between phases.

4.2. Applying simulation-based Learning to the Sterilization Process

The "simulation-based learning" tool is utilized with the intervention all the MUDs sterilization process actors, this is, with the OAs of the SCS and the nurses of the ORs. This tool objective is to engage and acquaint every professional in the process. This way, the professionals are more able to help and generate ideas in the improvement process, because they are familiarized with all the steps of the MUDs sterilization and delivery. The simulation-based learning is performed in the Hospital de São José. The application of this tool in the beginning of the improvement process, allows to clarify the procedures for each step and to notice the methods utilized by each professional. There are detected some differences regarding the utilized methods in the preparation of MUDs before washing, the MUDs inspection and some OAs devalue these steps of the process.

4.3. Beginning of Process KPIs Monitoring

In order to know the current state of the problems, it´s established five key performance indicators (KPIs) to monitor along the improvement of the MUDs sterilization and delivery process. This allows to quantify the current scenario and the scenario after the implementation of the improvement ideas. The five KPIs are:

- **Root delay**: when MUDs arrive at the ORs after the established schedule because of a transportation delay only;
- **MUDs delay**: when MUDs arrive at the ORs after the established schedule because of SCS delays only;
- **Wrong identification of MUDs**: when the MUDs arrive at the wrong hospital or OR, because of inscription mistakes of MUDs destiny;
- **MUDs devolution**: when there is a problem with the MUDs in the OR, stopping them from being safely used in an operation;
- **Damaged MUDs**: when the MUDs are no longer in condition to be used.

These five KPIs are registered manually in a monitorization sheet, through dash drawing, every week in the ORs of CHULC, whenever happen an incident (Figure 4). The KPIs are registered by the OR professionals every time it happens one or more incidents. The initials "NA" stand for "Not Applied". The first two weeks of monitorization give the first data about the current situation of the sterilization and delivery of MUDs process (Figure 5). The monitored KPI with the most incidence is MUDs delay, with 28% of the total incidents' records. The hospital with more incidents in the end of the first two weeks is HSJ, with 81 incidents of a total 176 reported incidents in the ORs. The five monitored KPIs are directly related with three problems observed:

1. **Lack of quality in MUDs sterilization and delivery process** is related with MUDs devolution and damaging;
2. **Delayed MUDs when arriving at the ORs** is related with MUDs delays and roots delays;
3. **SCS disorganization** is related with MUDs delays, wrong identification of MUDs and MUDs devolution.

Monitorization Sheet of the KPI

Hospital: ___________ OR: _______________ Room: _______________ Week: ___/___/____ to ___/___/____

<table>
<tr><th>Day of the Week</th><th colspan="2">EXEMPLO</th><th colspan="2">Monday</th><th colspan="2">Tuesday</th><th colspan="2">Wednesday</th><th colspan="2">Thursday</th><th colspan="2">Friday</th><th colspan="2">Saturday</th><th colspan="2">Sunday</th></tr>
<tr><th>Location</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th><th>OR</th><th>Room</th></tr>
<tr><td>Root delay</td><td>HH:MM
HH:MM
HH:MM</td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td></tr>
<tr><td>MUDs delay</td><td>|||</td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td><td></td><td>NA</td></tr>
<tr><td>Wrong identification of MUDs</td><td>|</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>MUDs devolution</td><td>||</td><td>|</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Damaged MUDs</td><td></td><td>|</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
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Figure 4: Monitorization sheet where the KPIs are registered in the ORs

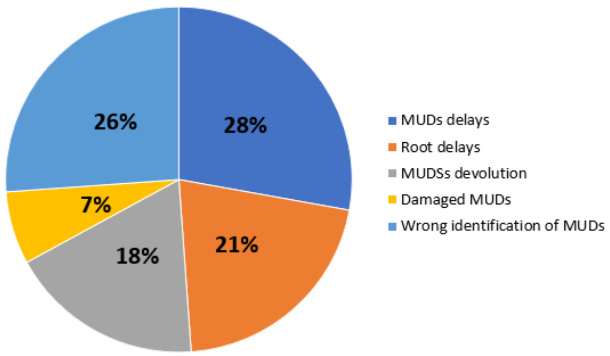

Figure 5: Percentage of KPIs after two weeks of monitorization.

It is developed, for each problem of the sterilization and delivery process, a PDCA cycle with the objective of generate and implement improvement ideas that lead to the reduction of incidents in the ORs.

4.4. PCDA Cycle: Lack of Quality of MUDs Sterilization Process

The PDCA cycle is divided in four phases: plan, do, check, act. These are performed and, then, illustrated taking into consideration the A3 method, which has seven different steps.

Background

The problem "lack of quality of MUDs sterilization process" is detected with the appearance in the ORs of organic matter and wet MUDs, fissures in the MUDs packaging and damaging in MUDs impeding its usage. This way, this problem is related to "MUDs devolution" and "damaged MUDs". In 2018, these two incidents have reached 36% of the total MUDs-related reports.

Current Situation

The KPIs MUDs devolution and damaged MUDs, related to this problem, are initially with 18 and 7% of the total incidents.

Desired Situation

The desired situation is **zero** for both KPIs.

Root-Cause Analysis

This steps of the A3 method is performed with a specific tool, the Ishikawa diagram. Some root-causes are recognized as being a possible origin of the approached problem:

- Inefficiency of the washing and sterilizing machines;
- Wrong placement of the MUDs in the machines;
- Lack of light in the inspection workbench;
- Lack of training of the OAs in the SCS, that are not sensitized for the importance of a correct sterilization of MUDs;
- Low dry time of the MUDs after its sterilization;
- Disorganization of SCS, causing delays in the sterilization process and, consequently, obligating the OAs to work faster, leading to an inefficient sterilization.

Recommendations

The root-causes are prioritized by the professionals considering the impact and easiness of its solutions through an impact-difficulty matrix. All the root-causes located in the first quadrant are resolved.

Countermeasures & Improvement Implementation Plan

There are implemented improvement measures, such as:

- Creating with the professionals of best practices regarding the MUDs placement in the machines;
- Setting lights in the inspection workbenches;
- Training and sensitizing OAs for the importance of their work;
- Obligating a 30 minutes dry time after the sterilization of MUDs is over;
- Reorganization of SCS, through 5S tool.

Follow-up

The process is monitored for six weeks and, by the end of the sixth week the two KPIs experience a reduction of 81.8 and 100.0% for the MUDs devolution and damage MUDs, respectively.

4.5. PCDA Cycle: delayed MUDs in the ORs

Background

The problem "delayed MUDs in the ORs" is detected when there are delays and cancelations of surgeries, because of MUDs that are not in the OR at the time of the surgeries. This has consequences related to patients' satisfaction and the surgery waiting list outflow. This problem is related to the "MUDs delays" and "root delays".

Current Situation

The KPIs MUDs delays and root delays, related to this problem, are initially with 28 and 21% of the total incidents.

Desired Situation

The desired situation is **zero** for both KPIs.

Root-Cause Analysis

With the application of the Ishikawa diagram, it's possible to identify some root-causes that are a possible origin of the approached problem:

- Insufficient number of washing and sterilizing machines;
- Insufficient number of MUDs deliveries to the hospital during the day;

- Delays in the delivery of large quantities of MUDs from the entry of the hospitals to the entry of the OR;
- Lack of prioritization of MUDs;
- Lack of a notification document for each MUDs container;
- Disorganization of SCS, causing delays in the sterilization process of MUDs.

Recommendations

In order to know if there is insufficient number of machines to wash and sterilize MUDs, it is computed the *takt time* and the utilization rate (UR) of the machines. For this it's necessary to investigate the number of washing and sterilizing cycle performed by each machine, the cycle time for each machine and the number of machines.

$$Takt\ Time = \frac{24h * 60minutes * nº\ machines}{nº cycles\ completed\ in\ one\ day}$$

$$UR = \frac{nº\ cycles\ completed\ in\ one\ day * cycle\ time}{24h * 60minutes * nº\ machines}$$

The *takt time* for washing and sterilizing machines is, respectively, 184 and 171 minutes. This is more than 80 minutes longer when comparing to the machines cycle time (97 and 73 minutes for washing and sterilizing machines). This means that the SCS has enough time available in each machine to perform every wash and sterilization cycle of the MUDs. The UR for washing and sterilizing machines is, respectively, 52 and 57%, meaning the machines are only being used for a little more than half of the time.

The root-causes are prioritized by the professionals considering the impact and easiness of its solutions through an impact-difficulty matrix. All the root-causes located in the first quadrant are resolved.

Countermeasures & Improvement Implementation Plan

There are implemented improvement measures, such as:

- Addition of a delivery of MUDs to the ORs in the morning and in the afternoon;
- Obtaining three OAs to deliver the MUDs from the entry of the HSJ to the entry of the ORs, given that there are, always, large quantities of MUDs being received in the hospital;
- Reorganization of SCS, through 5S tool.

Follow-up

The process is monitored for six weeks and, by the end of the sixth week the two KPIs experience a reduction of 86.7 and 90.9% for the root delays and MUDs delays.

4.6. PCDA Cycle: SCS Disorganization

Background

The problem "SCS disorganization" is related to the nonexistence of standardized procedures in the washing and storage area and nonexistence of specific locations for each equipment and material. This problem causes delays and inefficiencies in the MUDs sterilization process. It can, also, generate identification problems in the MUDs because of the necessity of rapid dispatch of the MUDs. These problems is related to the KPIs "MUDs delays", "MUDs devolution" and "wrong identification of MUDs".

Current Situation

The KPIs MUDs delays, wrong identification and devolutions, related to this problem, are initially with 28, 26 and 18% of the total incidents. Because the MUDs delays and devolution are already approached in the two first PCDA cycles, this PDCA cycle focuses only in the wrong identification of MUDs KPI.

Desired Situation

The desired situation is **zero** for the KPIs.

Root-Cause Analysis

The Ishikawa diagram is utilized to discover some root-causes that are in the origin of the approached problem:

- Lack of standardization in the identification of the MUDs containers;
- Lack of training of the OAs in the SCS regarding the differentiation of all the MUDs existing in the ORs;
- Disorganization of SCS, causing delays in the sterilization process and, consequently, obligating the OAs to work faster, leading to an inefficient sterilization and identification of MUDs;
- Stress of OAs because of the large quantities of MUDs delivered and dispatched at a time.

Recommendations

The root-causes are prioritized by the professionals considering the impact and easiness of its solutions through an impact-difficulty matrix. All the root-causes located in the first quadrant are resolved.

Countermeasures & Improvement Implementation Plan

There are implemented improvement measures, such as:

- Creation of a standardized identification sheet for MUDs containers;
- Training OAs to recognize each MUD and its origin;
- Reorganization of SCS, through 5S tool.

4.6.1. Washing Area

The washing area is evaluated taking in consideration the distance traveled by the OAs during the reception and preparation of MUDs before washing, through a spaghetti diagram (Figure 6). The distance is analyzed in a qualitative was (spaghetti diagram) and in a quantitative way, through a pedometer. It's applied the 5S tool in the area, to eliminate longer distances performed by OAs. This way, it is possible to reduce the traveled distance in 55.1% (Figure 7).

4.6.2. Storage Area

The storage area is evaluated the same way as the washing area and the tools applied are, also, the *spaghetti* diagram (Figure 8) and the 5S tool. The experienced reduction in the traveled distance is similar with 52.5% (Figure 9).

Figure 6: Spaghetti diagram in the washing area before improvements.

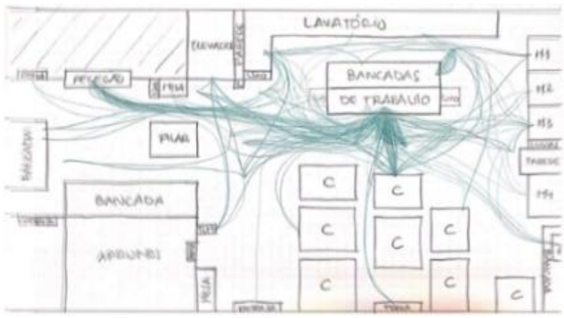

Figure 7: Spaghetti diagram in the washing area after improvements.

Figure 8: Spaghetti diagram in the storage area before improvements.

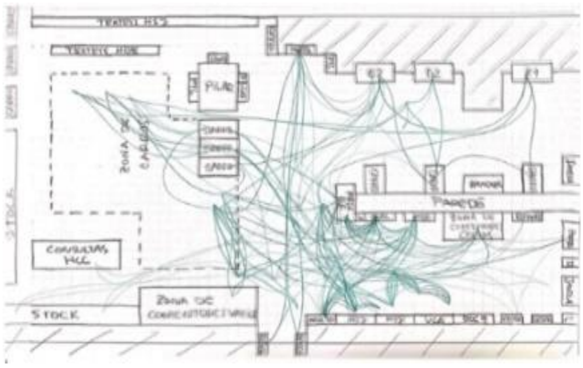

Figure 9: Spaghetti diagram in the storage area after improvements.

Follow-up

The process is monitored for six weeks and, by the end of the sixth week the KPI wrong identification of MUDs experiences a reduction of 91.2% for the MUDs devolution and damage MUDs, respectively.

4.7. End of Process KPI Monitoring

The KPIs are monitored for six straight weeks in the ORs, while the process is analyzed and improved. All KPIs suffer a reduction of more than 80% each (Figure 10). The KPIs with the lower and highest reduction are, respectively, MUDs devolution and damage MIUDs. In the graph, the indicator "nothing" indicates the number of days without reported incidents in the ORs. It is possible to confirm that this indicator suffers an increment of 69% comparing to the beginning of the monitorization. Considering the incidents reported in the ORs of the hospitals, there are hospitals that experience higher reduction than others. The hospitals with a higher incidents' reduction are MAC and HSM, with 100.0 and 90.3% of decrement, respectively. The hospital with the lowest reduction is HCC with 30.0%. This fact may be related with the lowest experience of this hospital regarding MUDs and root delays, two of the KPIs with higher reduction percentages, since the SCS is in HCC.

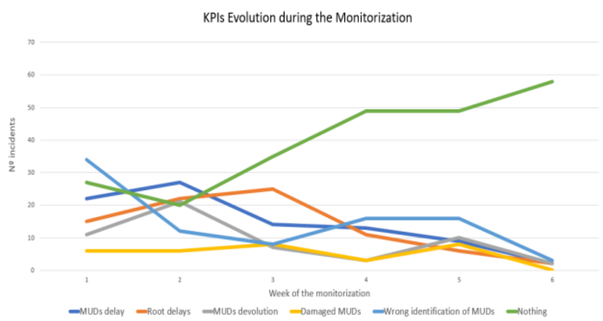

Figure 10: KPIs evolution during six weeks of monitorization.

4.8. Statistical Tests

In order to determine if the reductions experienced in all the five KPIs, it is necessary to compute statistical tests to each KPI decrement. Because the monitorization is performed for six weeks, there are two samples for each KPI:

- The first sample includes the number of reported incidents in the first three weeks for each day of each OR;
- The second sample includes the number of reported incidents in the last three weeks for each day of each OR.

Because the samples don't have a normal distribution, it is utilized the Wilcoxon test to evaluate the statistical significance between each two related samples. Knowing that, for a confidence interval of 95%, p-value must be inferior to 0.05, there are only two of the five KPIs whose reduction is not considered statistically significant. Those are damaged MUDs and wrong identification of MUDs, with p-values of 0.162 and 0.269, respectively (Figure 11). The indicator "nothing" has a statistically significant increment, meaning that the number of days in the ORs without any incident record increased significantly.

KPIs	Wilcoxon test (*p-value*)
MUDs delays	0,000
Root delays	0,000
MUDs devolution	0,022
Damaged MUDs	0,162
Wrong identification of MUDs	0,269
Nothing	0,000

Figure 11: P-values calculated through the Wilcoxon test for each KPI.

4.9. Insights for Project Management

This work, in order to be correctly developed, needs the direct communication between professionals of the SCS and ORs. It's this communication that allows the detection of some steps during the monitorization and implementation of improvement ideas that are not well succeeded. This detection permits the identification of improvement suggestion for this type of work related to communication and organization of a project:

1. Starting the monitorization before any implementation of improvement ideas;
2. Becoming the incidents' registration in the monitorization sheet simpler, in order to have more adherence by the OR professionals;
3. Becoming simpler and more efficient the communication between professionals, so they work better as a team;
4. Avoiding changing parts of the process without everyone's knowledge about the change;
5. Creating proactive reunions between professionals to discuss generate improvement ideas for the existing problems.

5. Conclusions and Future Work

This work provides a characterization of the CHULC problem related to MUDs incidents' reports made by the ORs, appearing in the ORs incorrectly sterilized, delayed, wrongly identified and damaged. In 2018, CHULC came across 4705 incidents' reports about MUDs, being this the second bigger problem of CHULC, right before patient falls. In this sense, the sterilization and delivery process of MUDs is observed and mapped in order to define, with the ORs and SCS professional, improvement ideas for changing the process. In the observing and mapping steps, there are detected three different problems in the SCS: 1) lack of quality in the sterilization process of MUDs; 2) delayed MUDs in the ORs; 3) disorganization in the SCS. This disorganization is relatively to the lack of standardized procedures and lack of specific locations for each equipment and material. The Lean methodology is the one chosen to approach these three problems, given that its tools provide a better organization in the SCS and in the process, standardizing them and, consequently, avoiding human errors. Before the application of the Lean tools, the MUDs incidents are monitored in the ORs, considering five different KPI: root delay, MUDs delay, wrong identification of MUDs, MUDs devolution and damaged MUDs. The tools utilized are the VSM, simulation-based learning, PDCA cycle and A3 (for each problem), Ishikawa diagram, impact-difficulty matrix, standardized work, *spaghetti* diagram and 5S. The monitorization of the sterilization and delivery of MUDs process for six weeks shows reductions of more than 80% in all five KPI. Three out of these five KPI, through the Wilcoxon test, demonstrated a statistically significant reduction. These are: root delay, MUDs delay and MUDs devolution. This paper contributes to the literature in the sense that it utilizes a bigger set of Lean tools (nine out of 12) in a SCS in Portugal, something that was never done until now. Also, the A3 tool was not, in any of the research papers, illustrated its seven steps in an A3 document, as this project has.
For future work in practical terms, this project can be amplified to the SCS in HSM, where it goes 30% of the MUDs of CHULC. There, the OAs only beneficiated of the trainings given by nurses. Beyond that, it is not performed any physical transformation of the process. Also, the KPIs monitorization can be extended, in order to collect more data about the beginning and the end of the improvement measures implementation. In methodological terms, it's possible to explore new methods that allows improvement of fragile processes with the objective of reducing human error beyond Lean methodology. Six Sigma allows fragile processes improvement with the DMAIC

approach (similar to PDCA cycle) and enables a more robust data analyzes when there are large quantities of data collected. In this work it was not possible to use Six Sigma because of the few existing data. The Service Design Thinking is a methodology that also provides tools to improve this type of processes. This methodology, in this dissertation, is replaces by Lean methodology, as this last one uses observation and mapping to know the process and identify problems/waste. Service Design Thinking, however, identifies the problems of the processes by interviewing each professional. This is not always be the more accurate way of approaching the problems, because professionals' complaints may not be the biiger problems in the process.

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