

DFSS: An approach to improve the consignment circuit at Hospital CUF Tejo

Inês Filipe Correia Silva

Master in Health Services Management

Supervisors:

Prof. Teresa Grilo, Assistant Professor

Iscte Business School,

Department of Marketing, Operations and General Management

Prof. Abel Camelo, Guest Assistant Professor,

Iscte Business School,

Department of Marketing, Operations and General Management

October 2023



DFSS: An approach to improve the consignment circuit at Hospital CUF Tejo

Inês Filipe Correia Silva

Master in Health Services Management

Supervisors:

Prof. Teresa Grilo, Assistant Professor

Iscte Business School,

Department of Marketing, Operations and General Management

Prof. Abel Camelo, Guest Assistant Professor,

Iscte Business School,

Department of Marketing, Operations and General Management

October 2023

Acknowledgements

The completion of my master's thesis represents the most important achievement of my academic journey. Without the support of everyone who accompanied me, none of this would have been possible.

To my supervisors Professor Teresa Grilo and Professor Abel Camelo, for the opportunity to work on this project, for every advice and orientation and especially for always valuing my input and feedback throughout the project. They were crucial for the realization of this project.

To the CUF Logistics team for accepting the challenge and later allowing me to fully embrace this professional business area. Hélder, Ana and later Raquel I cannot thank you enough for the trust and faith that you have put in me. I also have to mention the operation teams that I have been working with, I learned every day with you and when each day felt like a rollercoaster, I knew that I could count on a good choice of music to accompany. Daniela and Carolina, I will not forget about the words of encouragement and the long calls to check on me. My sincere thanks to all of you.

To my friends for never letting me give up even when I wanted to, for tolerating my irritabilities, understanding my long naps before group plans, taking me into mini vacations to decompress and especially for always cheering me up when it seemed impossible. A special mention to Leonor for always inspiring me to do anything outside of the box and to Bia for all the unconditional support through all the ups and downs. I wouldn't make it without all of you.

Last and most important to my family, namely Mom, Dad and Sister for the unconditional love and support throughout this year full of changes, you are my biggest supporters. This work would not be complete without you.

Resumo

O circuito de consignação na CUF Tejo é controlado através de um documento denominado Folha de Implante (FI). Este é utilizado para regularizar o pagamento de material, reposição e mais importante rastrear material implantável em clientes. O objetivo deste trabalho recaiu sobre o desenvolvimento de uma proposta alternativa para o formato físico atual da FI de modo a minimizar os constrangimentos e fragilidades do circuito atual.

A abordagem para este projeto baseou-se na metodologia Design for Six Sigma (DFSS) de acordo com a estrutura Definir, Medir, Analisar, Desenhar e Verificar (DMADV) juntamente com a metodologia de Action Research (AR). Este modelo combina a necessidade de um projeto estruturado, com passos e tarefas sistematizadas mas altamente focado na participação ativa dos elementos da organização.

Inicialmente foi feito um levantamento das necessidades dos envolvidos diretamente no circuito, Equipa de Enfermagem e Equipa de Logística, assim como o mapeamento do processo atual, através de entrevistas e observação direta. Após recolhidas as necessidades as mesmas foram analisadas, atribuídas métricas para medir o seu impacto, permitindo definir um ponto de partida e um objetivo. De seguida foram priorizadas de acordo com o seu grau de criticidade, assim como a identificação dos pontos críticos no circuito e respetivas razões.

Com base nos dados recolhidos foram desenvolvidas duas propostas de design para a FI e as mesmas foram recomendadas com base em critérios de preferências dos participantes neste estudo e objetivos transmitidos pela organização.

Palavras-Chave: Folha de Implante, rastreabilidade, reposição, DFSS, DMADV

Sistema de Classificação JEL: L25 - Objetivos, Organização e Comportamento da Empresa: Desempenho da empresa; M11 - Administração de empresas: Gestão da Produção

Abstract

The consignment circuit at CUF Tejo is controlled by a document called the implant sheet (IS). This is used to regularize material payment, replacement and, most importantly, to track implantable material in clients. This work aimed to develop an alternative proposal to the current physical format of the IS in order to minimize the constraints and weaknesses of the current circuit.

The approach for this project was based on the Design for Six Sigma (DFSS) methodology according to the Define, Measure, Analyze, Design and Verify (DMADV) framework, together with the Action Research (AR) methodology. This model combines the need for a structured project, with systematized steps and tasks but is highly focused on the active participation of the elements of the organization.

Initially, a survey was carried out of the needs of those directly involved in the circuit, the Nurse team and the Logistics team, as well as mapping the current process through interviews and direct observation. Once the needs had been collected, they were analyzed and metrics were assigned to measure their impact, allowing a starting point and objective to be defined. They were then prioritized according to their degree of criticality, as well as identifying the critical points in the circuit and the reasons for them.

Based on the data collected, two design proposals for the IS were developed and recommended based on the preferences of the participants in this study and the objectives set by the organization.

Keywords: Implant Sheet, traceability, replacement, DFSS, DMADV

JEL Classification System: L25 - Firm Objectives, Organization, and Behavior: Firm Performance; M11 – Business Administration: Production Management

Index

Acknowledgements.....	i
Resumo	iii
Abstract.....	v
Index	vii
Table Index	ix
Figure Index.....	xi
List of abbreviations.....	xiii
1. Introduction	1
1.1 Context and Relevance of the Theme	1
1.2 Research Problem.....	1
1.3 Research Objectives and Approach.....	3
1.4 Methodology.....	3
1.5 Document Structure	4
2. Literature review	5
2.1. Design Approaches.....	5
2.1.1. Business Process Redesign.....	5
2.1.2. Human-Centred Design	6
2.1.3. Axiomatic Design.....	7
2.2. Design for Six Sigma	8
2.2.1. Design for Six Sigma applied for redesigning paper-based systems and promoting traceability	9
2.2.2. Design for Six Sigma applied for redesigning paper-based systems and promoting traceability in the healthcare sector.....	10
2.3. Conclusion.....	12
3. Methodology.....	15
3.1. Action Research.....	15
3.2. DFSS and DMADV Approach	16
3.2.1. Define phase	16
3.2.2. Measure phase	17
3.2.3. Analyze phase	18
3.2.4. Design phase.....	18
3.2.5. Verify phase	19
4. Case Study.....	21
4.1 Organizational Context.....	21

4.2 Research Steps	21
4.2.1 Define Phase	21
4.2.3 Analyze Phase	30
4.2.4 Design Phase	37
4.2.5 Verify Phase	45
5. Conclusion	47
6. Bibliography.....	49
7. Appendix	53

Table Index

Table 2.1 - Summary of the articles on which this literature review was based.....	13
Table 4.1 - Project charter.....	22
Table 4.2 - High-level view of the IS flow.	23
Table 4.3 - Association between aggregated needs and formulated drivers and CTQs.	25
Table 4.4 - Association between need, driver, CTQ, metric(s), goal and as is.....	26
Table 4.5 - Points attributed to the selected criteria and respective score considering the ponderations calculated.....	44
Tabela 7.1 - Aggregated needs collected through interviews with different stakeholders from the IS circuit based on their similarities. Highlighted in red are the ones that were excluded based on the scope of the project.	53

Figure Index

Figure 4.1 - Affinity diagram relating to the needs collected from the different parties involved in the IS circuit.	24
Figure 4.2 - Flowchart showing the average time and respective standard deviation spent on each macro task mentioned in the SIPOC.	27
Figure 4.3 - Swim-lane part 1 refers to the Nurse team's involvement in the circuit, mainly in the filling of IS.	28
Figure 4.4 - Swim-lane part 2 refers to the HLT involvement depending on which speciality IS refers to.	28
Figure 4.5 - Swim-lane part 3 refers to the further HLT involvement in surgery and special exams specialities.	29
Figure 4.6 - Swim-lane part 4 refers to the Logistic Administrative Team's involvement in the circuit.	29
Figure 4.7 - Ishikawa diagram with the series of causes to the nine root causes.	32
Figure 4.8 - Distribution of the answers from the prioritization survey of all 23 participants (no distinction between Nurse or Logistic Team).	34
Figure 4.9 - Distribution of the answers from the prioritization survey of 16 participant nurses.	34
Figure 4.10 - Distribution of the answers from the prioritization survey of 7 participant logistics members.	35
Figure 4.11 - Initial screen to enter in Neptune App.	38
Figure 4.12 – Screen where it is possible to visualize the requisitions per client number and date.	38
Figure 4.13 - Menu to introduce a new surgical episode.	39
Figure 4.14 - Representation of the process to add material to the surgical episode.	39
Figure 4.15 - Error message when the material is not CR or Stock.	40
Figure 4.16 - Confirmation message with document number created.	40
Figure 4.17 - New swim-lane with the alterations proposed.	41
Figure 4.18 - Suggestion of the new label and comparison with the existing one with the client data.	42
Figure 4.19 - Caption to clarify the type of materials regularized via IS.	42

Figure 4.20 - Proposal of segment to introduce in IS to separate the different consumables used.
..... 43

Figure 7.1 - Table of measures for 20 ISs circuit. Step 4 was necessary to include the number of codes per sheet so that the comparison between ISs would take into account their size..... 55

Figure 7.2 - Google forms shared with nurse and logistics team in order to determinate which are the top causes to prioritize in the new design. The participants should order 1 (most important) to 8 (less important) the listed causes. 56

Figure 7.3 - Current IS document. 57

Figure 7.4 - New IS document proposal. 58

List of abbreviations

AD – Axiomatic Design

AR - Action Research

BPM - Business Process Management

BPR - Business Process Redesign

CTQ - Critical-To-Quality Characteristic

DFSS - Design for Six Sigma

DMADV - Define, Measure, Analyze, Design, Verify

DMAIC - Define, Measure, Analyze, Improve and Control

HCD - Human-Centred Design

HLT - Hospital Logistics Team

IDOV - Identify, Design, Optimize and Verify

IS – Implant Sheet

MCDA - Multi-Criteria Analysis

PD - Product Development

QFD - Quality Function Deployment

RON - Requisition Order Number

SIPOC - Suppliers, Inputs, Processes, Outputs, and Customers

VOC - Voice of the Customer

1. Introduction

1.1 Context and Relevance of the Theme

According to the Food and Drug Administration (2019), medical implants are “devices or tissues that are placed inside or on the surface of the body” responsible for replacing missing/damaged body parts, distributing medication, monitoring body functions, or providing support to organs and tissues. Prostheses, artificial joints, or intraocular lenses are part of the future of medicine and have suffered consequent changes through time. With the development of technology combined with progressive and innovative healthcare, the market has grown over the past years and the perspective is to continue, not only to improve the dispositive already existent but also to create new ones for different functions. In order to perform the surgeries needed to place the implants there is a set of steps necessary to i) guarantee the security of the device, ii) ensure that the right one is implanted and iii) assure its traceability.

Traceability is defined as “the ability to track forward the movement of products through specified stages of the supply chain and trace backwards the history, application or location of products under consideration” (Ryu, 2013; p.14). Depending on the industry, the levels of control and methods to ensure the traceability are distinguished. Also, the goals obtained from it and the supply chain have a crucial part in it and are responsible for its specifications (Ryu, 2013).

Information management is required for successful traceability which implicates the associations of informational flow with the physical flow of the item, along with the organisation's logistics department and supplier (Bendavid et al., 2012).

1.2 Research Problem

The registration of implants and additional materials information used in surgeries and other medical procedures belongs to an operation circuit with different teams involved. In healthcare, the majority of the information is to comply with regulatory requirements and guidance on product recall and withdrawal and supply chain trading partner's specifications, increase operations efficiency, and patient safety and ensure product reliability (Bendavid et al., 2012).

Moreover, stricter control is common in order to reduce the risk of undetected loss, needless purchases of costly items already on hand and shortages (Bendavid et al., 2012). For shared information across different units of the organisation, for example, the central warehouse and hospital must use an inter-organizational system, and an automatic identification and data capture

(AIDC) technology like barcodes and more recently radio-frequency identification (RFID) (Bendavid et al., 2012).

Ensuring strict control to promote the tracking of materials is a key challenge in the health sector, more specifically, in the case of implants used in surgeries at CUF Tejo. The implants could be lenses, nets, screws, basically anything that stays inside the patient after the surgical episode. Every implant has a lot which allows us to track it down in case of a recall from the company or to report a malfunction related to the implant.

The challenges currently faced by CUF Tejo concerning the lack of traceability of consigned materials required for surgeries results from the preference given to the physical format of pen and paper to register information as opposed to the digital format. In fact, this is also the current reality of many hospitals, that still feel reluctant when switching to digital options, and the main disadvantage is the limitation of the quality of the data (Smith, 2018). Particularly, nowadays all the implants (and other materials) used in surgeries at CUF Tejo have an “Implant Sheet” which indicates the reference of the item. This information is afterwards used by the financial department to charge the patient, as well as by the logistics department to pay the supplier and return the materials that were not used (when is a non-resident consignment). However, the use of this implant sheet (IS) is associated with several difficulties:

- Delays in IS filling: when the register is not made in a short time after the procedure, the IS is not available to the logistics and administrative team for informatic processing;
- Errors associated with calligraphy: because of calligraphy interpretation a single misunderstood digit could be responsible for materials swipe, or even result in the register of inexistent materials;
- Material omission: the majority of items have associated label barcodes, but some are not attached to the IS, and in some cases, the materials used for the first time do not have a label yet;
- Sheets loss: because it is a paper-based process, ISs are sometimes lost when passing from the operation room to the logistics department;
- Time-consuming register: when filling the IS, the register is made item by item, or sometimes by a set of materials grouped in a kit, providing specific and detailed information, but the process is much harder and not functional, specially for the nursing team

All these concerns are justified because the remaining tasks of the circuit are affected by the possible mistakes and difficulties arising from this process. The longer the delay in detecting errors, the harder it gets to correct them, conditioning supplier, financial, logistics and administrative department activities. Because the health sector we deal with is more responsibility than other areas and involves high-cost dispenses, it is necessary to minimize and potentially eliminate avoidable errors. (Smith, 2018).

1.3 Research Objectives and Approach

Due to all these difficulties, several sources of inefficiencies in the process of registering surgical implants and materials translate into a lack of traceability and a low-efficiency circuit, so CUF Tejo aims to eliminate the physical format of the IS. However, different solutions may be considered as long as verified a significant improvement in the consigned materials.

This work's main goal is thus to propose alternatives for the “implant sheet” that is currently employed at CUF Tejo, in order to eliminate or reduce the difficulties caused by its susceptibilities to human random and systematic errors. Also, the responsibility of tracking the implants is completely assumed by the logistics team, so it would be crucial to have a consistent and trustworthy process to do so, which is not happening with the current process. As so, the main research question is as follows: How can we redesign the consignment circuit followed at CUF Tejo for surgical implants and materials currently relying on the use of the IS, in order to improve its traceability and make it more efficient? To achieve this purpose, several secondary objectives (SO) were defined:

- SO1 - Mapping the current consignment circuit relying on the use of the IS;
- SO2 – Identifying difficulties in the circuit, along with its root causes;
- SO3 - Designing and evaluating alternative solutions to solve the root causes identified before;
- SO4 - Selecting and comparing the proposed options.

1.4 Methodology

For this project, Action Research (AR) and Design for Six Sigma (DFSS) methodologies were combined to reach the previously mentioned goals.

AR features lead to a dynamic process where people's evolution serves as the focal point for improvement and subsequent transformation, combining both theoretical and practical knowledge. The idea is tailored to the organization's business, operational, and social model, and the operations manager plays a key role by working with other intervenients as an internal researcher.

DFSS complements this approach by making use of instruments, instruction, and metrics to help the company create a service or product that lives up to client expectations. The method chosen for delineating the research steps was Define, Measure, Analyze, Design and Verify (DMADV).

1.5 Document Structure

The research is documented in five chapters, introduction, literature review, methodology, case study and conclusion.

In the literature review are presented possible design approaches and practical examples that could be applied to CUF's research problem. The approach "Design for Six Sigma" is deepened in the context of improving traceability and transforming healthcare systems.

The second chapter clarifies the two chosen approaches to the research problem, Action Research (AR) and Design for Six Sigma, specifically the DMADV approach, Define, Measure, Analyze, Design and Verify.

Last but not least, the case study chapter details the five stages of the methodology chosen and the tools used in each one to achieve the new approach to implant registration.

2. Literature review

2.1. Design Approaches

In this chapter there are reviewed multiple design approaches, among which are business process redesign, human-centred design, axiomatic design and design for Six Sigma. DFSS is explored in greater detail along with its utility in healthcare projects, collaborative with an action research approach. The design approaches presented have advantages and disadvantages and through the examples presented, it is possible to see their applicability to this research project. Customer focus is the key to the success of the new design, but simplicity and literature review are crucial to determine the best way to come up with a new solution for the IS circuit. So in Chapter 2.2, DFSS is presented as the best methodology to reunite these bullet points.

2.1.1. Business Process Redesign

Business process redesign (BPR) is an approach which follows the Business Process Management (BPM) thinking phase, despite being focused on operational management improvement, is more directed to implement new transformations. BPR focus could be divided into customers, products, business processes, organization, information, and technology to build a new design for a specific problem (Dumas et al., 2018).

BPR goals are to create new ways of organizing tasks and people and redesigning information systems so the performance of the operation in the study is increased in terms of cost, quality, service, and speed (Hammer & Champy, 2009). If it is an asset, organizational restriction could be a course of action in order to accomplish business objectives (Pereira et al., 2020).

Applied to a practical situation is the example of the possibility of transitioning from a traditional Government to an e-government. The BPR bases were applied by first analysing stakeholders and detecting the critical ones to include their points of view, through semi-structured interviews (Hughes et al., 2006). Implementation took place to fulfill the goals established like improving the quality of services to customers, administrative efficiencies, and enhanced control of public funding services (Hughes et al., 2006).

Another case study refers to redesigning an emergency hospital. First business processes were evaluated, and non-essential or redundant tasks were eliminated (Pereira et al., 2020). The advantages gained were decreasing execution time, cost reduction, output quality improvement and increasing odds of successful reaction when a variation occurs (Pereira et al., 2020). Again,

interviews took place to redesign the process being customers' needs as the focus of the redesign and were able to come up with different options (Pereira et al., 2020).

As demonstrated, BPR has an important role when the main purpose is to redesign the totality of a circuit, having as a starting point an issue appointed by the client. As so, because the methodology is ambitious to transform all circuits, it could have limitations when it pretends to apply just improvements to the original one.

2.1.2. Human-Centred Design

Human-Centred Design (HCD) is an approach responsible for demonstrating both life-cycle service design and effective service provided by placing customer needs and stakeholders' priorities first (Dos Santos et al., 2018; Kwon et al., 2021; Lee et al., 2019).

Different approaches have been taken into account when developing the ultimate process design framework and characteristics need to be incorporated when using HCD methodology. Key elements are life product/service cycle design, stakeholder networks, new features developed and design skills (Nguyen et al., 2022). The main advantage is to consider human actors' interaction with non-human actors, which means, it is easy to judge the non-functional requirements like user usability for example (Cimini et al., 2020).

In Farooqui, Rana et al. (2019) the HCD was used to develop software with high usability and quality user experience by improving and applying human-centric activities (Farooqui et al., 2019). The authors proposed to incorporate five phases where relevant stakeholders are detected to link business objectives to usability goals because factors related to the software are identified and established as priorities when considering key areas of intervention (Farooqui et al., 2019). As a final result, the team was able to achieve considerable results by using HCD and avoiding costly processes for correcting design defects (Farooqui et al., 2019).

The health sector was applied in Paper-based Health Information Systems in Comprehensive Care (Bosch-Capblanch et al., 2021). The main goals of the project were to create a new health information system for primary healthcare regarding data use, data quality and healthcare tools (Bosch-Capblanch et al., 2021). For this, the research team turned to co-design methods (involving both design specialists and healthcare professionals) and created a group to produce and select tool versions based on their in-country experience, technical expertise, and contextual understanding (Bosch-Capblanch et al., 2021). Also, testing activities were used with frontline workers to

interrelate the ideas and user feedback, for later (fifth phase) perform random controlled trials (Bosch-Capblanch et al., 2021; Sanders & Stappers, 2008).

HCD's main limitation relies on the bias to narrow context, which implicates a redesign process considering just users' opinions and not organization goals (Farooqui et al., 2019). Especially on a project like an implant the user opinion, despite its importance, should be combined with existing knowledge and organisational feedback.

2.1.3. Axiomatic Design

Axiomatic Design (AD) was developed by N. P. Suh in 1990. This methodology maps four product-related domains, transferring customer attributes to functional requirements, to design parameters, and to process variables (Suh & Suh, 1990). It starts with a complex design problem and goes on to a set of small problems from the highest to lowest design levels, allowing designers to follow a detailed redesign process step by step (Suh & Suh, 2001).

It considers two principles (axioms) which are: the independence axiom and the information axiom, responsible for maintaining the independence of functional requirements and minimising information contentment, respectively (Suh & Suh, 1990). It is necessary to define a design matrix for customer attributes, functional requirements, design parameters and process variables which means specifying if there is a relationship between them or not and do it for every detected level (Suh & Suh, 2001).

A study led by Hongyan Dai and collaborators aimed to design a method for supply chain traceability systems. The goal was to minimize the overall costs of systems investments and deficiencies in the supply chain process related to traceability (Dai et al., 2015). The mathematical approach to this problem consists of elaborating different matrix equations and testing the variables in question: RFID or barcode, cost minimization for supplier or manufacturer (Dai et al., 2015). As a result, they conclude optimal design turns out to be item-level RFID implementation for the whole supply chain because all parties could afford advanced technologies and were motivated to overcome this problem.

Another way to apply AD is to improve management software. The study goals were, to redesign management tools, and achieve higher productivity outcomes with the lowest possible use of resources (Rauch et al., 2018). Functional requirements and design parameters were determined to be smartly managed by the production shop floor and smart shopfloor management

software are the main functional requirements and design parameters respectively (Rauch et al., 2018). Improvements made were able to transition from a traditional paper-based system to a digital one, due to the enumeration of every process step and prioritizing customers' needs (Rauch et al., 2018). Major benefits were the adaptability to different medical areas, and decreased volume of data to health workers deal with and connect with previous existing digital systems so that the change would be smooth and not upbrought (Bosch-Capblanch et al., 2021).

When selecting this methodology for project redesign is important to understand both axioms, knowing that variables not contemplated in the independence axiom will not be considered as well as the inclusion of restrictions and requests in the evaluation process (Delaš et al., 2018).

2.2. Design for Six Sigma

DFSS is a design methodology focused on embracing customers' voices by building a framework from the perspective of product/service cycle management (Antony, 2002). Also, possible variations are taken into account so performance is a guaranteed factor, optimizing design function and validating customer concerns and limits (Banuelas & Antony, 2004). When redesigning processes, it is necessary to make changes and eliminate non-value-added activities, associated costs that may exist, and errors (Hammer, 2007).

Customer/collaborators' involvement is considered the element of success in DFSS projects, and the attention taken to internal users manifests in external customers (Macnamara, 2020). Tools like Quality Function Deployment (QFD) and Conjoint Analysis can be useful when writing down customer needs, expectations and preferences (Gijo et al., 2021).

One of the impacts of the DFSS approach is the creative and innovative environment promoted at companies and organizations, as well as its adequacy to high criticality and rigorous deadlines (Awad & Shanshal, 2017). The fact that it is possible to quantify the achievements in every design phase is an advantage to take into account in organizational projects (Lobo & Samaranyake, 2020).

When applied in the company or organizational context it is important to be aligned with the intern strategy and mission of the company and to guarantee that the expectations meet the researcher's goals (Gijo et al., 2021). Top management support is crucial, more concretely people at the decision-making levels, because a lack of organisational involvement can lead to repercussions and delays in the entire DFSS project (Campanerut & Nicoletti, 2010).

Different approaches may be considered when developing a DFSS project based on a define-measure-analyze-improve-control procedure with multiple variations, depending on the project context (Hasenkamp, 2010).

2.2.1. Design for Six Sigma applied for redesigning paper-based systems and promoting traceability

DFSS can be applied in different sectors and with multiple goals when designing or redesigning processes.

Ericsson et al. 2015 analysed where DFSS was being applied in product development (PD) due to its activities' positive success in PD performance. For the study, the researcher analysed four companies, however, company B is the most relevant for this study because the customer focus was on creating a traceable circuit (Ericsson et al., 2015).

Company B uses the DMADV approach to continue the improvement of organization and tools like QFD and the house of quality to guarantee customer focus (Ericsson et al., 2015). Furthermore, focuses on risk management as well and uses failure mode and effect analysis and design of experiments to establish new ideas and different solutions until a final product. Finally, the theory of inventive problem-solving was sometimes used when exploring why innovative ideas did not work out (Ericsson et al., 2015).

The main strategy and focus were to create a traceable circuit between customer satisfaction requirements and engineering requirements using QFD and risk management were crucial to process steps, review them and create gates (Ericsson et al., 2015). Continuous communication with the customer was the key factor to successfully implementing this methodology and including it through the process of PD.

Beliatis et al. (2019) used DFSS to sustainably redesign disposable food packaging using IoT technologies such as radio-frequency identification and wireless sensor networks to connect devices. Other mentioned technologies are near field communication, barcode, and quick response code, but all have the same purpose which is to point out the necessity to sustainably track products when transported and continue to modify the information reusable package through an informatic application (Beliatis et al., 2019).

The approach used was a mix between Define, Measure, Analyze, Improve and Control (DMAIC) and DMADV merging in the Define, Measure, Analyze, Design-Measure, Analyze,

Improve and Control, however, Improve and Control phase wasn't possible to implement due to schedule (Beliatis et al., 2019). The data were collected through interviews, focus groups and online surveys and qualitative data were collected by interviewing the consumers in the focus groups and individuals (Beliatis et al., 2019). This was in understanding the people's behaviour through the problem faced and which population the new design will impact.

The design phase includes the development of a mobile phone capable of recognising quick response code tags to purchase and return stations. The data are stored in a cloud database accessible to different users of the chain like food providers, suppliers or customers (Beliatis et al., 2019). The verify/measure phase encompasses a trial run with both customers and end users after analysing its performance (Beliatis et al., 2019).

At last, Luiten (2019) applied the Identify, Design, Optimize and Verify (IDOV) to replace hardware-based experiments with digital innovation for a thermal design process. Product lifecycle management describes product information's flow from conception to disposal (Politecnico di Milano et al., 2019).

The author chooses the V model to represent product development and systems engineering, and thermal design to test drive innovations due to its complexity and multidomain parameters and simulations to perform multiple virtual experiments (Politecnico di Milano et al., 2019). In the define, identify and design phase, the design of experiments tool is used again especially at higher levels of the V model to compare the effects and choose the concept, technology and architecture (Politecnico di Milano et al., 2019). For optimize and verify phase Monte Carlo simulations, used to investigate input variations on the output and capability analysis, for failure rate and capability metrics assessment (Politecnico di Milano et al., 2019).

Then, all the workflow was combined in digital optimization from the tools used to choose the best option to implement. This comparison is made by spreadsheet, stand-alone statistics software and integrated statistics software (Politecnico di Milano et al., 2019).

2.2.2. Design for Six Sigma applied for redesigning paper-based systems and promoting traceability in the healthcare sector

In the healthcare sector, where the available literature is less abundant when compared to the industrial sector, the following up to date studies aim to enrich the bibliography of this project and then self-become study support for further studies.

In a Swedish hospital was applied a DFSS approach, using DMADV methodology, with a focus on the QFD tool, based on data collected through face-to-face interviews and project documentation (Gremyr & Raharjo, 2013). The goal of this case study was to design a new in-patient medication process to reduce mistakes and improve security, through traceability improvement (Gremyr & Raharjo, 2013).

To map the process (define phase) was used swim-lane scheme to identify the groups, locals and activities involved (Gremyr & Raharjo, 2013). Then, in the analysis and design phase, was used a QFD matrix to map the needs and evaluate its importance, Critical-To-Quality Characteristics (CTQs), with a scale of “3-6-9”, a second matrix translating CTQs into critical functions and a third one (verify phase) for mapping critical functions to critical process parameters (solutions) (Gremyr & Raharjo, 2013).

Traceability improvement in the process was accomplished because it is now possible to trace back from the solution to customer needs (Gremyr & Raharjo, 2013). Using QFD in the analysis and design phase allowed to the creation of a systematic way to process staff needs for forming a new process organization (Gremyr & Raharjo, 2013).

Mouaky et al. (2018) used the DFSS and DMADV approach to redesign and improve a pharmaceutical supply chain by proposing an Adaptive Kanban System considering the Moroccan Pharmaceutical Supply chain requirements. Simultaneously, although not representing a key aim of the study, increasing item traceability through a rigorous inventory system and error reduction in register material was one of the improvements accomplished by the chain redesign (Mouaky et al., 2018).

In the define and measure phase, the needs were identified through a survey of patients, doctors, nurses, management and other staff in the public pharmaceutical supply chain (Mouaky et al., 2018). Then QFD tool was used to create a criteria rating matrix with the CTQs collected, weight importance, services features that meet CTQs and evaluate how each feature satisfies each CTQ (Mouaky et al., 2018). A Pareto Chart uses sort design requirements in order of priority a Kano’s evaluation table, to measure the importance of each feature from the patient’s point of view, and a customer satisfaction coefficient to indicate how much the system features may lead to customer satisfaction or dissatisfaction (Mouaky et al., 2018).

The analysis used a Failure Modes and Effects Analysis diagram to evaluate the gap between the desired level of performance of the system/process and the existing level and CTQs collected

(Mouaky et al., 2018). Moreover, the design and verification phase adapts de collected to the organisation's reality and problem, resulting in a new design Kanban system whose performance was compared to the system in use (Mouaky et al., 2018).

Kothari (2020) also developed research focused on improving traceability in healthcare. Particularly, this author has used a DMAIC approach in a redesign process for a 28-day medicine supply cycle. The main goal was to decrease discrepancy rates between repeat re-order requests made from the care home to the prescriptions generated at the surgery. Tracking errors was one of the main causes and consequently, the authors aim to eliminate them secondary, as well as planning efficiently the subsequent cycle by anticipating risks and acting upon them (Kothari, 2020).

For this, the author analyses the main causes through Voice of the Customer (VOC) and CTQ tree to register request discrepancies, which means, differences between the request made by the doctor and the medication that is delivered (Kothari, 2020). The main causes reflect omitted and additional items, incorrect quantities and misprescribed items, which is transversal to other healthcare register procedures.

In the measure, phase was elaborated a CTQ Tree with measurements and a Pareto chart showing the type of discrepancies encountered, in highest to lowest frequency from left to right (Kothari, 2020). Then in a lysis phase, sigma performance levels were calculated to determine where each care home currently stands and fishbone diagrams were created, to identify the root causes of discrepancies, focusing on omitted items and incorrect quantities. Furthermore “As is” cross-functional process map like swim-lane, workflow, and supplier-customer relationships (Kothari, 2020).

2.3. Conclusion

The literature review allowed us to present different ways of approaching the research question. DFSS is considered a good fit for the present research due to its easy application, concretely the DMADV approach, because we want to change the IS circuit, and not exclusively improve it. Also adding an AR viewpoint will be an asset because of collaborators' involvement in all processes, especially the define and design phase.

The case studies available for improving traceability in healthcare are in less quantity when compared to other industry sectors. Summarized in Table 2.1 is the literature he referenced during his chapter when facing the challenges for this project and if they are healthcare-related or not. As

a side note, despite the case study presented not being focused on the same research question as CUF's the goals and improvement achieved are transversal to this research project.

Table 2.1 - Summary of the articles on which this literature review was based.

Study	Redesign of a paper-based process	Improving Traceability	Sector
Ericsson (2015)		x	non-healthcare
Beliatis (2019)	x	x	non-healthcare
Luiten (2019)	x	x	non-healthcare
Gremyr & Raharjo (2013)		x	healthcare
Mouaky (2018)		x	healthcare
Kothari (2020)	x	x	healthcare

3. Methodology

3.1. Action Research

Action Research is a methodology which aims to include both theoretical knowledge and practice experience so that a researcher can choose the finest approach to the research question (Coughlan & Coughlan, 2016). It isn't restricted to a specific and unique practice, but rather to a set of assumptions, contexts and starting points, that intend to create new information through a new action and research collection (Coughlan, 2010; Coughlan & Coughlan, 2016).

When framed in operations, the concept adapts to the business, operating and social model of the organization and the operations manager plays a central part by acting as an inside researcher who collaborates with other intervenients (Coughlan & Coughlan, 2016). The goals consist of achieving outputs, operational improvements and learning experience as a result of an improvement of a real operation problem so that the implementation of the changes is not restricted only to one cycle, but to the following ones too (Coughlan & Coughlan, 2016).

Moreover, the characteristics of the methodology appoint to a dynamic process where the people involved are the central point to improve and consequently change. According to (Gummesson, 2000) ten major points of success reflect the four critical terms mentioned before, among which are the active working requirement to get the final process, the duality of the goals to be achieved (solving a problem and contributing to science), the interactivity of all process and the main focus being about change. Others are related to the development of holistic understanding and compressibility recognition, knowledge about ethical values and norms, coverage of different methods to collect data, pre-understanding of the organization and the process being studied, real-time to conduct the investigation and the necessity of having one own criteria to judge the final product (Gummesson, 2000).

The majority of the research part will turn around the logistics and nursing teams and their perception of the circuit and where we can act to make it more efficient and safer. Their contribution on giving information, participating in interviews, and learning and implementing the changes suggested is crucial to the success of the project. The new circuit should be adapted mainly to their needs, along with the ethical values and CUF interests.

3.2. DFSS and DMADV Approach

DFSS complements the AR approach by utilising tools, training and measurements to enable the organization to have a design product/service that meets customer expectations (Mader, 2002). It aims to maximize the positive impact during the development stage and reduce the minimum defect rates by using a variety of quality-oriented tools and techniques (Kwak & Anbari, 2006).

Furthermore, includes a cross-functional designing process, drives quality measurement and predictability improvement in early design phases and monitors process variances to verify that customer requirements are met (De Feo & Bar-El, 2002). When adapting to healthcare is important to add the necessity of having zero tolerance for mistakes and the potential for reducing medical errors (Kwak & Anbari, 2006).

Following the five steps of the DMADV approach, the Define, Measure, Analyze, Design and Verify, customer needs (logistics team and nursing team mainly) and organizations' requirements are taken into account when developing a modified circuit. This approach was selected to focus on rebuilding an existing process or product to ensure that it satisfies Six Sigma standards, while other approaches focus on redesigning a completely new product like IDOV.

3.2.1. Define phase

This phase includes a contextualization of the project and organization, formation of the involved team and elaboration of the project plan. This is achieved by building a project charter including details of the project scope, goals and team members' roles and the project plan, with the latter reflecting the guidelines and how the project is taking place (Furterer, 2009; Hahn et al., 1999).

Then a Suppliers, Inputs, Processes, Outputs, and Customers (SIPOC) diagram will be built to provide a high-level overview of the process and detail its main interventions (Furterer, 2009). SIPOC will be developed through direct observation of the process and based on an interview with the logistics team to know the teams involved (Question 1: Who participates in the material register flow?), the steps taken through the material register flow (Question 2: Which are the main steps of the IS process?) the purpose of the IS (Question 3: What are the reasons to have an IS?) and what are the outputs expected (Question 4: What are the outputs expected from IS circuit?). The developed SIPOC will afterwards be validated with the CUF Tejo logistics coordinator.

Then it will be detected the needs of the customers, logistics and nurse department through semi-structured interviews with different participants (five nurses and five logistics operators) of

the material register flow (Furterer, 2009). The baseline open-ended questions to collect this information had the goal of understanding the process in detail (Question 1: What's your role on the IS circuit?), what the interviewers considered advantageous and disadvantageous (Question 2 and Question 3: What are the added/lesser values of this circuit?) and which improvements were a priority to introduce in the redesigned system (Question 4: What would you like to see in the new circuit?).

Then it will be used an affinity diagram to organize the needs statements into categories and then reduce them, through a brainstorming session with the logistics operators, to a small number (Duffy et al., 2012; Vanzant-Stern et al., 2011). With the aggregate needs, it is possible to detect the CTQ factors (Vanzant-Stern et al., 2011). These CTQs represent the concerns that are considered critical for key stakeholders of the process and translate the VOC obtained through the aforementioned interviews. These CTQs should be specific, actionable and measurable factors that will provide measurable targets for the new process (Jones & Womack, 2005).

3.2.2. Measure phase

The measurement phase focuses on understanding and documenting the current process to be improved, collecting detailed VOC information and validating the measurement system (Furterer, 2009).

To better understand the process, a swim-lane diagram (or cross-functional flowchart) will be designed through Visio Software, documenting step-by-step the IS process, interventions and team involvement (Furterer, 2009). The information required to build this diagram will be collected through direct observation of the IS process and semi-structured interviews with the professionals involved (nurses and logistic workers) in order to clarify each step and possible doubts that might come. The based structure questions were to understand the different steps of the flow (Question 1: What are the steps that you participate in the register material flow?), the critical points (Question 2: Which steps contribute to the difficulty of the process?) and the subprocesses in the flow (Question 3: What are the sub-processes included in the IS flow?).

It then follows the generation of ideas about how to measure CTQ factors and associated metrics, validated with the Cluster Tejo Logistics Manager. If there is no method established for measuring a given CTQ, there is a need to establish one (Gitlow, 2006; Vanzant-Stern et al., 2011). In order to obtain realistic data the Hospital Logistic Team (HLT) will be crucial to measure the

data, due to being in contact with all the teams involved. This will be through specific tools developed for the CTQs obtained like a shared data file intuitive and accessible to the team.

3.2.3. Analyze phase

The analysis phase's goal is to examine the data gathered about the VOC to pinpoint the underlying causes of process issues and build the process's capacity (Furterer, 2009).

To identify the causes of the deviation problems identified in the process it will be used a “5 Whys” diagram, where the question “why?” is asked until the root cause is revealed (Vanzant-Stern et al., 2011). The focus group for this part will be formed with the logistics operators and nurse managers from the surgical specialities. For the same purpose, the analysis will be schematized in a cause-effect/Ishikawa diagram in order to brainstorm the root causes adapted from the 8P method (Furterer, 2009; Vanzant-Stern et al., 2011).

The stakeholders will then rank the root causes to decide which ones have the most effect on the circuit through a prioritization survey distributed via Google Forms to the Logistics Team and Nurse Team where they should sort which are the most critical to less (more details can be found in Chapter 4).

3.2.4. Design phase

The second letter “D” in DMADV stands for designing a better version of what is thought to be the best alternative in the analysis step (Johnson et al., 2006).

Once again brainstorming sessions were important to discuss not only ideas but also if they were possible to implement, under which conditions and how well the CTQs will be satisfied once a new solution is implemented. The management area will have an important word to say, besides the logistics and nursing team, in this specific subject. Also, bibliographic research is essential to analyse possible solutions already implemented in other healthcare facilities.

After gathering a group of alternative designs for the process, collaborators involved in the process were once again involved, but now for the evaluation of the proposed solutions (Johnson et al., 2006). A multi-criteria analysis (MCDA) was developed for that purpose, to determine which of the proposals developed would best suit the stakeholders' key concerns. These analyses assist organizations in considering the most relevant alternative when making purchasing (management) decisions (Jones & Womack, 2005). The criteria will be defined based on the results

from the prioritization survey, where the identified as critical will be the ones to be considered with higher scores along with the validation of the management team from the Cluster Tejo logistics department.

3.2.5. Verify phase

Lastly, the new design circuit needs to be validated by collecting and evaluating performance data after the new process is implemented, thus allowing its comparison with the baseline measurements (Johnson et al., 2006). The verification measurements are the same metrics used in the analysis phase which allows us to understand if the improvements made fulfil the listed needs by its utilizers (Rahman et al., 2018).

4. Case Study

This chapter will describe the methodology chosen, detailing each step and tool used in order to answer the research question presented in the introductory chapter. Topic 4.1 it is described the organisational context of the organizations and topic 4.2 is focused on the research process followed.

4.1 Organizational Context

CUF Tejo is a private hospital which belongs to a large group of clinics and hospitals being number one in quality healthcare provision in Portugal. CUF Tejo constitutes cluster Tejo along, CUF Sintra, CUF Cascais, CUF Almada and other minor clinics like CUF Miraflores, CUF Belém, CUF São Domingos de Rana and CUF Braancamp.

The logistics of the supply chain depend on its main internal supplier, Centro Logístico CUF, and outdoor suppliers for a specific material, mainly for surgical specialities. In these materials, it is included material managed by lot, which is implanted on the patient and therefore, when used, needs to be made an IS. This material could come from Centro Logístico (like abdominal nets) or from external suppliers placed on consignment, which means that the material is only paid for when used. In a resident consignment, the material is replaced after use and in a non-resident consignment, material is not replaced after use.

4.2 Research Steps

4.2.1 Define Phase

As presented before, nowadays CUF Tejo uses an IS to track the consigned material used in surgeries and procedures, as well as medical implants which remain in the patient's body after medical intervention. The concerns about the IS filling sum up to the mistakes associated with handwriting and delays in material tracking and billing so was lunged to redesign an alternative to the IS or its circuit.

It was necessary to collaborate with different teams to understand the roles in the circuit and their impact on daily work, being the Nurse Team, LHT team and Administrators Team as the focus.

The nurse team, for this project, counted on nurses from each surgical speciality, ophthalmology, surgery, angiography and special exams. They articulate with the LHT to make functional IS circuits and material daily occurrences.

The Logistics Hospital Department is divided into two groups, the storage team and the surgery team, with five and seven members respectively, however, when necessary, members can swipe depending on the activity flow. The surgery team, focused on the project, is responsible for receiving consigned material (resident mostly) from external suppliers, and material from CUF's Logistics Center, arranging it through hospital services and attending to nurses' team requests and issues. The team is also in charge of doing ISs, and surgery bags, which control the material used per surgery/procedure and receiving non-resident consigned material.

The Administrative Logistics Team is a recent work group created with the purpose of being focused on processing ISs only. Located in INova, is managed by Cluster Norte and counts on one coordinator and two administrative responsible for the consignment circuit of ophthalmology and angiography of CUF Tejo.

The first phase of the project was to build a project charter to schematize the project organization, illustrated in Table 4.1.

Table 4.1 - Project charter.

Project Name		Improving the consignment circuit at CUF Tejo
Description and Goals		Propose alternatives for ISs which allow lot traceability without depending on a physical and manual document
Scop	In	<ul style="list-style-type: none"> • IS circuit • Implanted material • The nurse team and logistics team input
	Out	<ul style="list-style-type: none"> • Supplier and billing team input • Consigned material not implanted
Business Case		Eliminate the problems resulting from the manualist of the IS
Teams	Nurse team	Manager and Circulating Nurse from each speciality
	Logistics hospital team	Operators focused on IS filing
	Logistics administrative team	Administrative responsible for IS filing and process
Timeline	Start	December 2022
	End	October 2023
Main Steps		1) Interview teams involved

	<ol style="list-style-type: none"> 2) Map IS circuit 3) Identify top needs 4) Develop metrics and baseline measurements to address top needs 5) Brainstorming alternatives with different teams' feedback 6) Develop possible alternatives 7) Implement the new circuit 8) Collect verifications measurements 9) Compare the old process with the implemented one
--	---

Then was developed a supplier, SIPOC diagram in order to better understand the IS implications, involved personnel and outcomes, illustrated in Table 4.2. The process starts with the filling of the IS in the operation room by the circulating nurse and then putting it in the designated place for the HLT to collect. Depending on the surgical speciality, the document is processed in CUF Tejo or sent to the logistics administrative team in Porto to process it. The inputs of the circuit are mainly human resources and informatic tools like SAP and ticket platform and the outputs are implant tracking and correct invoicing.

Table 4.2 - High-level view of the IS flow.

Suppliers	Inputs	Process	Output	Customer
RH Department Medical Material Suppliers and other Vendors	Nurses Logistics Department Staff Administrative Staff Paper Patients SAP Software Neptune Software Invoicing ticket Platform	Nurses <ol style="list-style-type: none"> 1. Fill out the IS after the surgery 2. Left the sheets in the department secretariat or collection window Logistics Staff <ol style="list-style-type: none"> 3. Collect IS/open ticket 4. Detect the material codes used 5. Give consumption if the materials are resident-consigned or lot-managed 6. Modify requisition order number 7. Request purchase order number 8. Send to invoicing 9. Archive IS/close ticket 	Implant material registration and tracking (ex: prosthetics) Correct invoicing of customers and suppliers Control of consigned material inventories	Logistics staff Administrative Staff Medical Material Suppliers Patients Nurses Financial Department

Moreover, it was developed an affinity diagram (Figure 4.1) to present the collected needs through a four-question interview referred in Chapter 3. The interviews were performed with six nurses, two members of the logistics hospital team and two members of the logistics administrative team, collecting a total of 26 needs, grouped into four categories.

The needs were then selected and grouped based on their similarity (Appendix A) and excluded if it did not make sense in the project ambit. These were the desire of not have so much

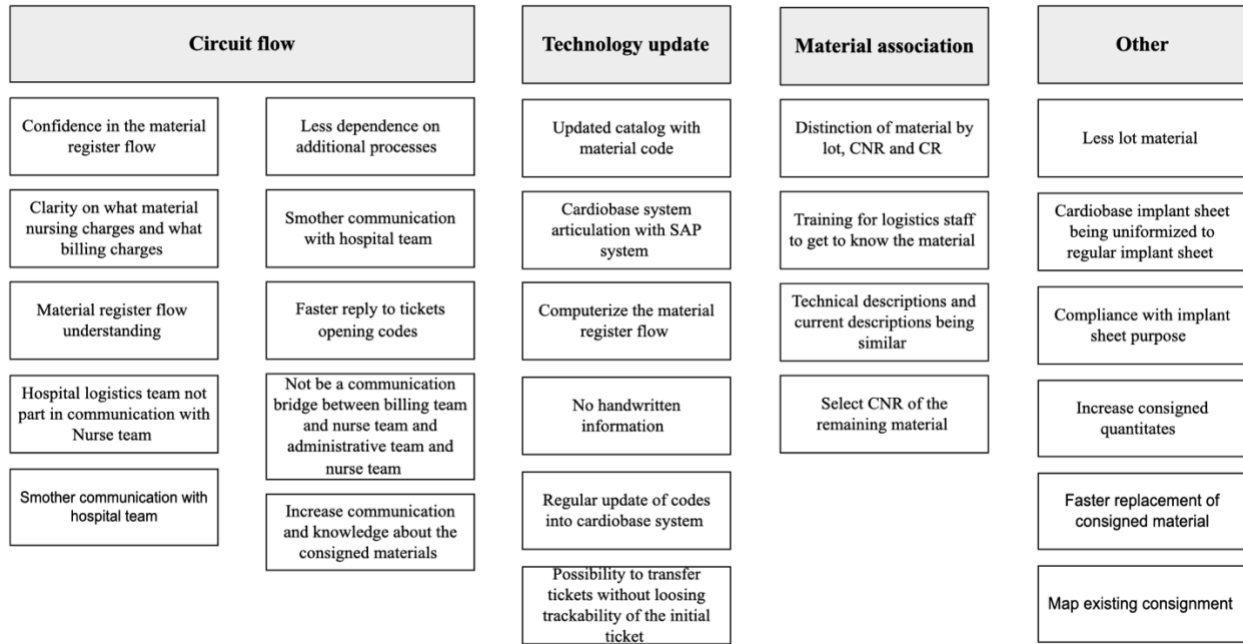


Figure 4.1 - Affinity diagram relating to the needs collected from the different parties involved in the IS circuit.

managed by lot material, which is regulated by Instituto Nacional da Farmácia e do Medicamento guidelines, the faster replacement of consigned material, which is related to supplier lead time and the mapping of the existing consignment, not related with IS circuit.

Then, a driver refers to the element clients would consider while judging the quality of your goods or services, and a CTQ to each aggregated need, as shown in Table 4.3. Each need could have more than one driver and consequently more than a CTQ. To the nine needs detected were formulated ten drivers and ten CTQs.

Table 4.3 - Association between aggregated needs and formulated drivers and CTQs.

Need	Driver	CTQ
Compliance with IS purpose	Enforce the material register flow	IS only for implant material
Computerize the material register flow by nurses	IT investment	Software (Neptune app) must allow registration of the material
	Material register flow review	Minimal manual tasks
Regular updates on the online catalogue	Define/Review process	Materials information updated to avoid outdated data
Overall awareness regarding the material register flow	Knowledge sharing	Staff (nurses) know material register flow end-to-end
		Staff (logistics hospital team) know material register flow end-to-end
Articulation between ERP (SAP) and angiography software (Cardiobase system)	Systems Integration	Data synchronization in both software
Distinction in the IS between materials (lot material, CNR and CR)	Alignment between the material and consumption register	Correct register of the material
Less dependence on additional processes	Process integration	SLA defined and agreed on additional processes
The HLT is not part of the communication with the Nurse team	Process review	Nurse team with access to ticket platform
Ensure traceability of the initial ticket	Ensure process	All tickets are traceable within the system

4.2.2 Measure Phase

The second phase's main goal is to measure and document the current circuit based on the stakeholders' points of view.

As a starting point, a goal for each CTQ was defined and an initial measure for a future point of comparison (Table 4.4). This will allow us to quantify the impact of the problems raised in the define phase and whether improvements have taken place when an alternative is implemented. The goals were set with the Cluster manager.

Some measures were completed with the collaboration of different CUF teams involved in the circuit, among them the percentage of codes included in the system, frequency of updates of material information, percentage of data synchronization between two systems, waiting time until the administrative logistics team receive clarification from HLT, waiting time until receiving a Purchase Order and waiting time until new code creation. On the other hand, some were through direct observation and contact with the teams involved like informatic register/manual register per specialty, percentage of manual tasks for the Nurse team and percentage of tickets that are traceable.

The remaining "as is" were measured based on three days of surgeries through direct observation of the filled ISs. The percentage of not implanted material was extracted from a total

of 151 materials counted on 80 sheets (only surgery ISs), 78 aren't implant material. In the 175 ISs analyzed, 11 were necessary to clarify with the Nurse team due to inconsistencies, specifically 9 of them were transmitted first to the HLT and then to the Nurse team which made it impossible to continue the process of the IS. This means that the percentage of ISs that do not need clarification from the nurse team results from the other 164 ISs that are correct.

Table 4.4 - Association between need, driver, CTQ, metric(s), goal and as is.

CTQ	Metric	Goal	As is
IS only for implant material	Percentage of not implanted material	0	49,0%
Software (Neptune app) must allow registration of the material	Informatic register/manual register per speciality (binary variable)	All steps	0 for all specialities
Minimal manual tasks	Percentage of manual tasks for the Nurse team	0	100%
Materials information updated to avoid outdated data	Percentage of codes not included in the system	100%	70%
	Frequency of updates of material information	Weekly	0
Staff (nurses) know material register flow end-to-end	Percentage of ISs with errors	0%	6,29%
Staff (logistics hospital team) know material register flow end-to-end	Waiting time until the administrative logistics team receives clarification from the HLT	48h	24h
Data synchronization in both software	Percentage of data synchronization between two systems	>98,0%	0%
Correct register of the material	Percentage of ISs that do not need clarification by the Nurse team	100%	93,71%
SLA defined and agreed on additional processes	Waiting time until receiving a Purchase Order	48h	24h
	Waiting time until new code creation	2 days	5 days
Nurse team with access to ticket platform	Percentage of ISs that need clarification by Nurse team through hospital teams	0%	10,05%
All tickets are traceable within the system	Percentage of tickets that are traceable	100%	0

Based on the measures made there is one metric that already exceeds the expectations before any action takes part, which is the waiting time until the administrative logistics team receives clarification from the HLT. Currently, these responses take an average of 24 hours when the limit is 48 hours.

Then is represented an overview of the circuit steps and how much time was allocated to each of them (Figure 4.2). The measures were based on a complete circuit of 20 ISs and are detailed in

Appendix B. Step one is split into the four specialities analyzed due to the size difference between ISs.

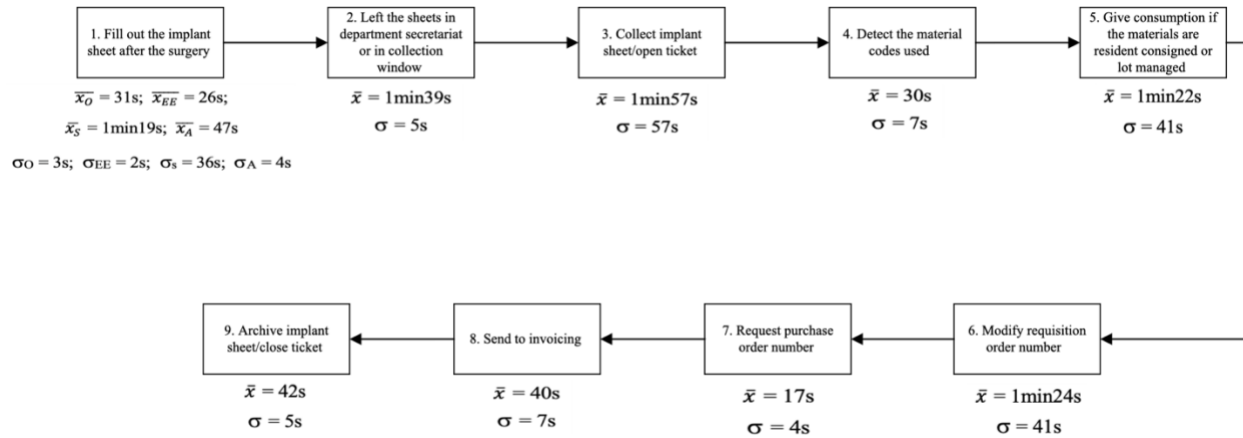





Figure 4.2 - Flowchart showing the average time and respective standard deviation spent on each macro task mentioned in the SIPOC.

Figures 4.3, 4.4, 4.5 and 4.6 detail each step, with the different decision nodes and stakeholders involved depending on the surgical speciality. There are some abbreviations and symbols to take into account when interpreting the swim-lane:

- IS: IS
-  : critical points in the circuit
-  : IS physical format is being used
-  : IS information is being processed into digital format

The schematization of each step allows a clear view of all process, so it is easier to understand the circuit, what the critical points to focus on are and where a specific team take part. This swim-lane was built based on direct observation of the different teams, except for the filling of the IS, which was made in the operating room, where access is restricted.

Figure 4.3 refers to the filling of IS and its transference to the HLT via the Nurse Team. The first five steps occur in the operating room where the circulating nurse notes the necessary information. The following three steps influence the flow of the circuit depending on the surgical speciality and where the IS should be left for later be collected by the logistics operators.

Implant Sheet Circuit

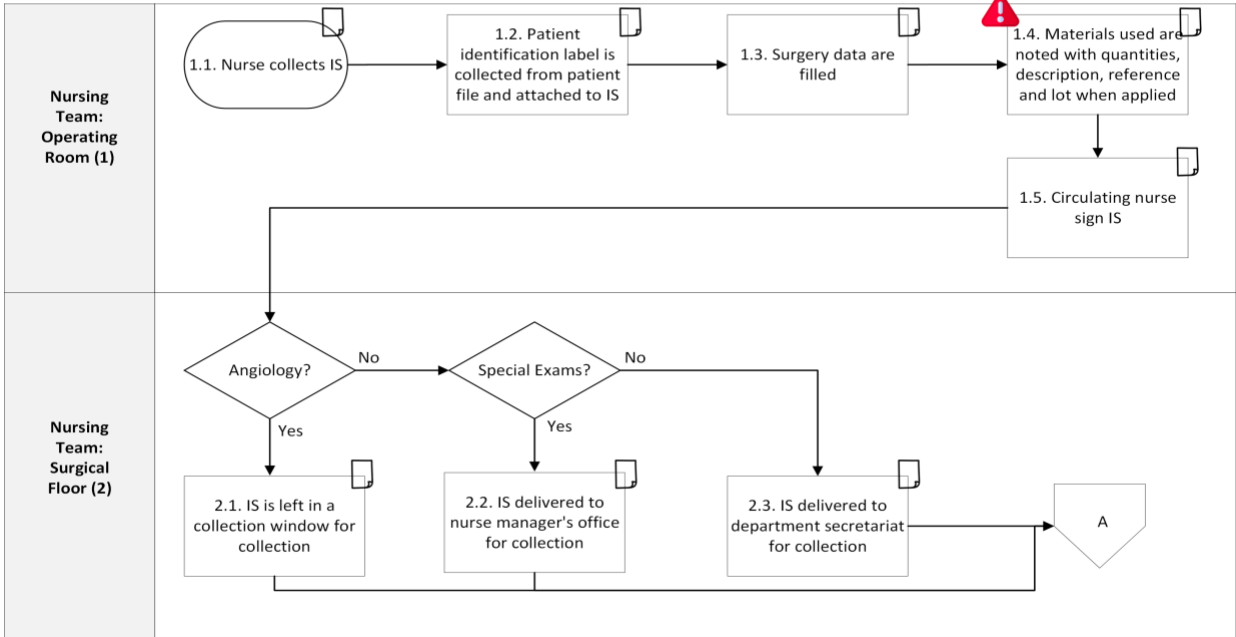


Figure 4.3 - Swim-lane part 1 refers to the Nurse team's involvement in the circuit, mainly in the filling of IS.

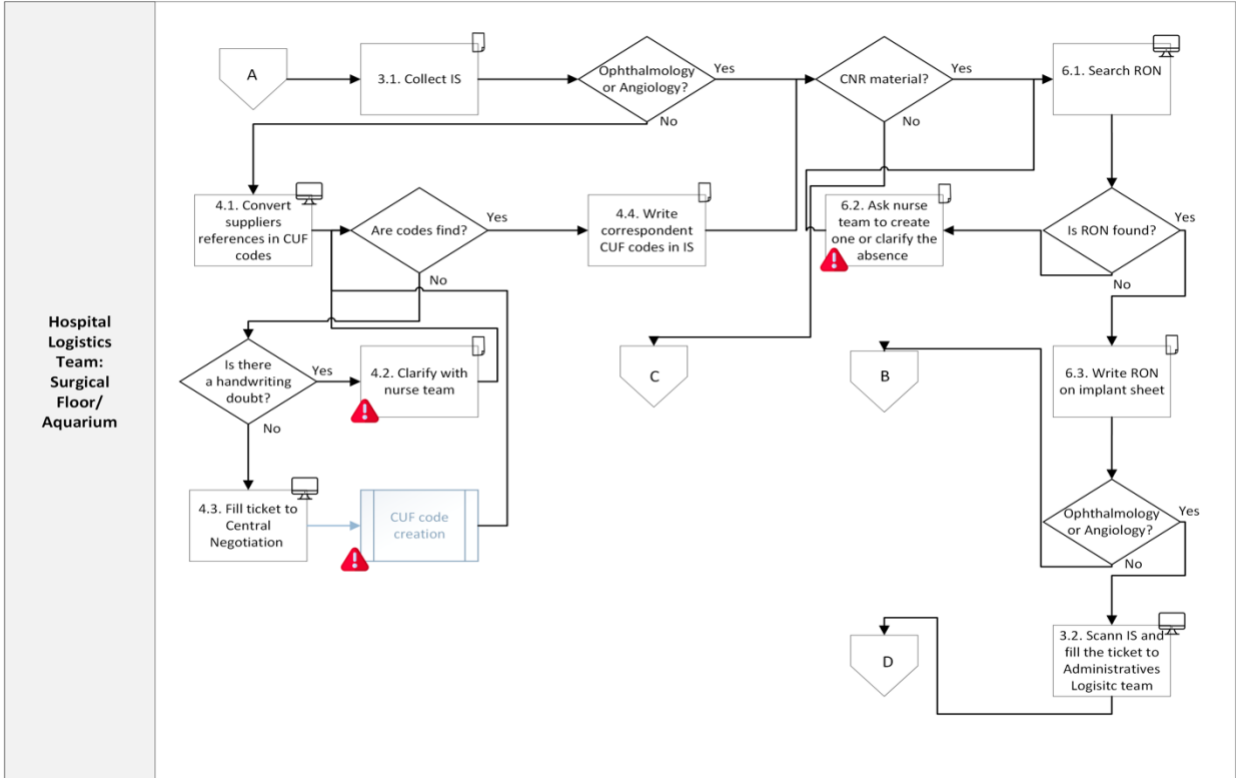


Figure 4.4 - Swim-lane part 2 refers to the HLT involvement depending on which speciality IS refers to.

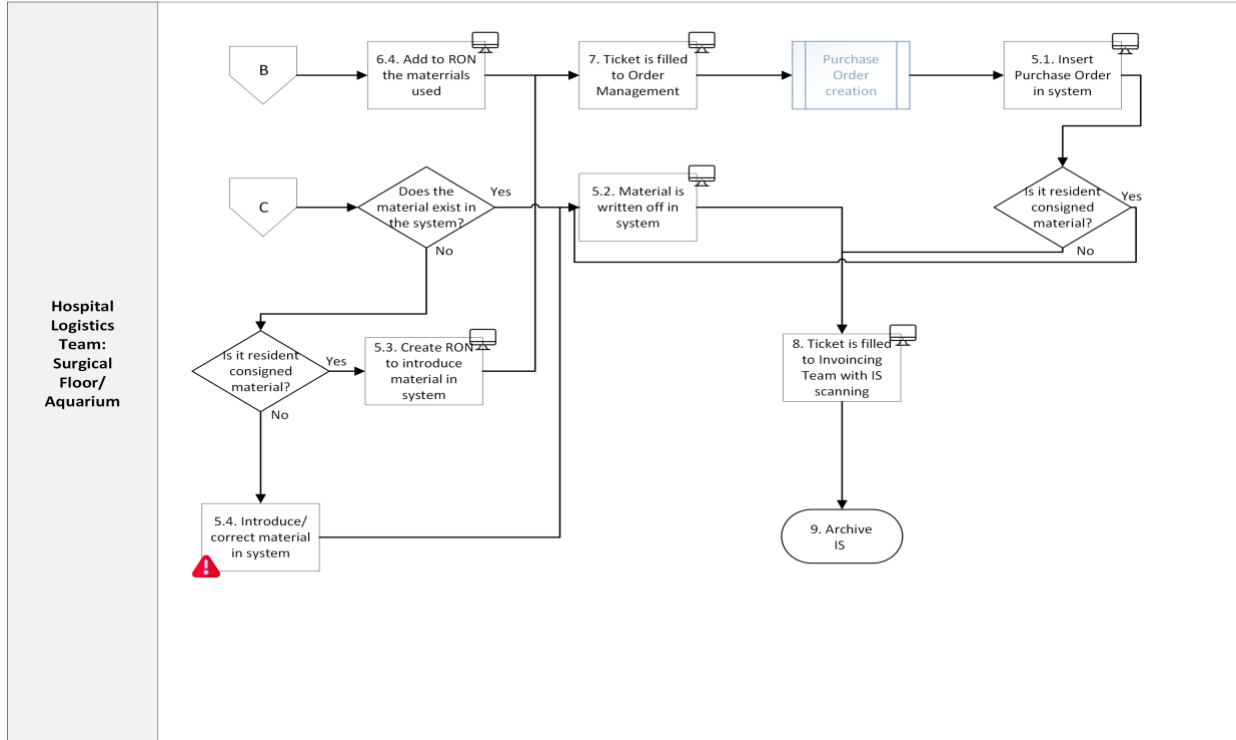


Figure 4.5 - Swim-lane part 3 refers to the further HLT involvement in surgery and special exams specialities.

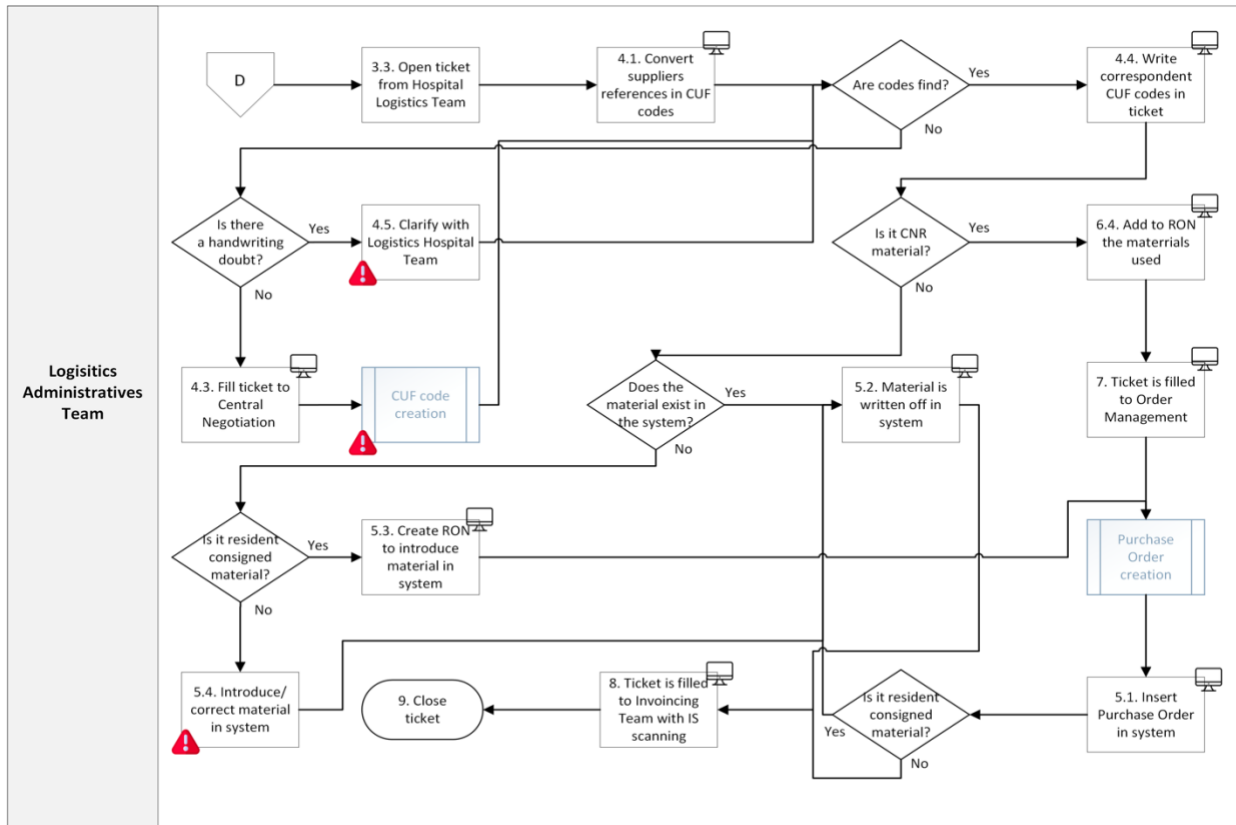


Figure 4.6 - Swim-lane part 4 refers to the Logistic Administrative Team's involvement in the circuit.

Figure 4.4 describes the start of the circuit where the logistics department is included. The collection step depends on the surgical specialities since the documents are in different collection points. Depending on each specialty the next steps are taken according to the IS are sent to the Administrative Team or are processed in CUF Tejo. If it is the first case, it is necessary to distinguish the CR/lot material IS from the CNR IS, but if it is the second option the HLT searches for the CUF codes (or SAP codes) before taking into account the type of material, because if it is not detected a CUF code it is necessary to have a sub-process, CUF code creation.

Next are schematized the two processes (Figure 4.5), B and C, which are the steps to follow depending if it is CNR or CR/Lot, respectively. This phase also contains a sub-process outside of the scope of Logistics and Nurse Team, but essential to the payment of the materials, and purchase order creation. The HLT involvement technically ends in step 9 by archiving the IS after regularising the stock, introducing the Purchase Order to regularize with the supplier, introducing the lot in the system for traceability sending it to the Invoicing Team to regularize with the client.

Lastly, Figure 4.6 represents the processing of IS from Angiography and Ophthalmology which are responsible for the Administrative Team in Porto. After being received via ticket from HLT follow an identical sequence of steps from CUF codes search and processes C and B. The main difference are when asking for clarifications because it is necessary to establish contact with the Nurse team via HLT and instead of archiving the physical IS document this team closes the initial ticket opened by HLT.

4.2.3 Analyze Phase

The swim-lane elaborated before refers to the complete IS circuit and is divided into 26 microtasks, which could be classified into three types: movement, inspection and waiting. The majority of the activities are inspection activities (1.2 to 1.5, 4.1 to 6.4 and 9), then movement activities (1.1, 3.1, 3.2, 7 and 8) and lastly waiting activities (2.1 to 2.2).

While mapping the circuit, were identified the critical points with the involved stakeholders. In the nurse team part task 1.4 (materials used are noted with quantities, description, reference and lot when applied) the reason for this being a critical point is that an amount of material does not have a batch to stick in the IS, which entails that the information has to be noted in handwriting. This adds time to the filling of IS and raises the odds of errors associated with calligraphy and omission of material for not having a specific reference to the consumable.

The HLT and Administrative Logistics Teams identified tasks 4.2, 6.2 and 4.5 respectively. Despite being different tasks, the reason for this being a critical point falls on the fact that the clarification of some kind of doubt or inconsistency is not a priority when asked and could be “lost” and pending further developments. This blocks the IS circuit from regularization with the supplier and consequently repositions and the impossibility of traceability. Both teams also identified the dependency of sub-processes in the circuit that could increase the time expended in processing an IS. The process of “CUF code creation” takes an average of 5 days which implies that the circuit will be on hold for those 5 days. Usually, this happens when dealing with new materials in the CNR method but could be implant material, which will delay the informatization of the lot in the informatic system. Last, task 5.4 was identified as a critical point because it is an alternative step to correct some mistakes due to incorrect lots uploaded in CUF software. This associates an increasing time to the circuit and complexity to fix something that should not be wrong in the first place, which means that besides the correction of the mistake, it is necessary to understand why that happened in the first place, which is not always easy and linear.

In order to provide more precise specifications for the revised process, this project's work concentrated on identifying the most critical needs. Based on the CTQs mentioned before was constructed an Ishikawa Diagram (Figure 4.7) to realize which are the root causes for the lack of traceability and replacement of the implant material.

The causes were grouped into three categories: product, directly related to the IS paper; procedure, related to the circuit; and people, related to the stakeholders involved in the circuit. To determine each root cause, the question “Why?”, three, four or five times depending on the answers obtained, and each answer corresponds to a branch of the diagram. The root causes could have more than one branch connected, which means that different series of causes could combine into one root cause for its similarities. In total, we had three root causes in each group being them inconsistent circuit monitoring, increased complexity and time added to the circuit and incorrect sap codes matching with material references in the “Procedures” categories. In the “People” category ineffective onboarding process for new members, inconsistency in the execution of tasks, material not included in the IS and in the “Product” category incorrect interpretation of handwriting, lack of IT updating and ineffective/Misleading SAP codes association. The root causes “incorrect SAP codes match with material references” and “ineffective/misleading SAP codes association” are in two distinguished categories, however have different CTQs associated,

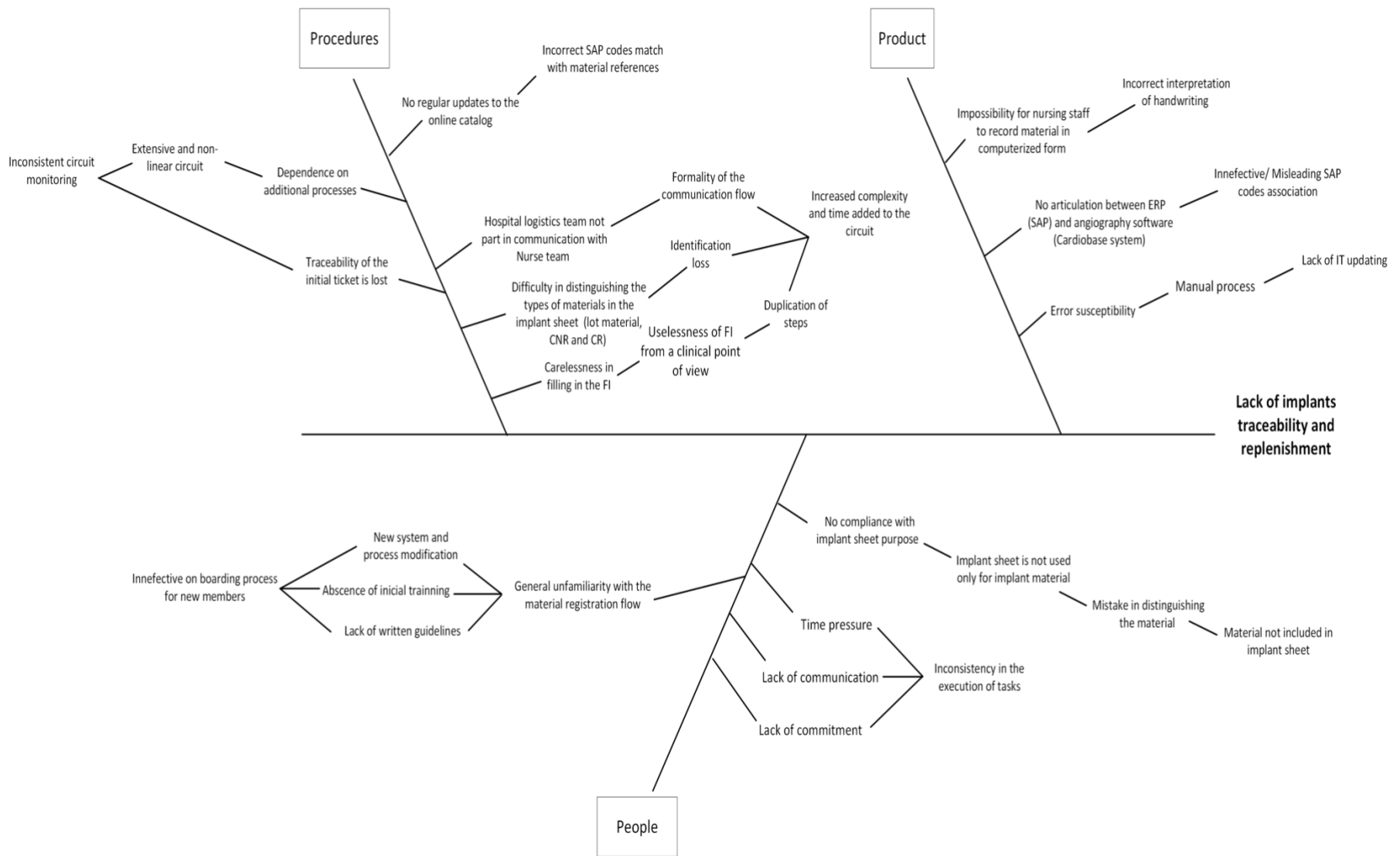
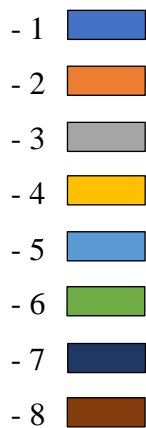


Figure 4.7 - Ishikawa diagram with the series of causes to the nine root causes.

the first one is related to the materials information not being updated to avoid outdated data, and the second is due to the inexistence of synchronization between Cardiobase software and SAP software. Despite this difference, it was considered the existing eight root causes to focus on.

With the eight root causes it was elaborated a questionnaire to the stakeholders to determine which root causes were more critical to the correct function of the IS circuit. The questionnaire can be found in Appendix C and was distributed via Google Forms to the nurse team and logistics team. The questionnaire counted with a total of 23 answers from the CUF Tejo nurse team (16 participants), and the CUF Tejo logistics team (7 participants).

Figures 4.8, 4.9 and 4.10 present the results obtained from the prioritization survey referent to the distribution of answers in the percentage of all participants, only of the Nurse Team and only from the Logistic Team. The colour distribution refers to the score given by the participant, with being 1 the most critical and 8 being the least one, for each root cause the caption is shown below:



The first chart (Figure 4.8) evidences the distribution of the answers of all 23 participants. The critical root causes classified as “1” with the biggest percentage are the “lack of computerisation/manualisation of the circuit” (34,8%), “complexity and time spent on the circuit” (30,4%) and “Illegible handwriting” (17,4%). Classified with 2 are again “complexity and time spent on the circuit” (30,4%) and “lack of computerisation/manualisation of the circuit” (21,7%) but “Omission of implant/consigned material” has a 39,1% response, having the greatest degree of agreement as the root cause.

On the other hand, the root causes were classified with 8 “Incorrect matching of SAP codes with references” (39,1%) followed by “Inconsistent circuit monitoring” and “Illegible handwriting” (both with 21,7%). The ones classified with 7 are “Illegible handwriting” (30,4%),

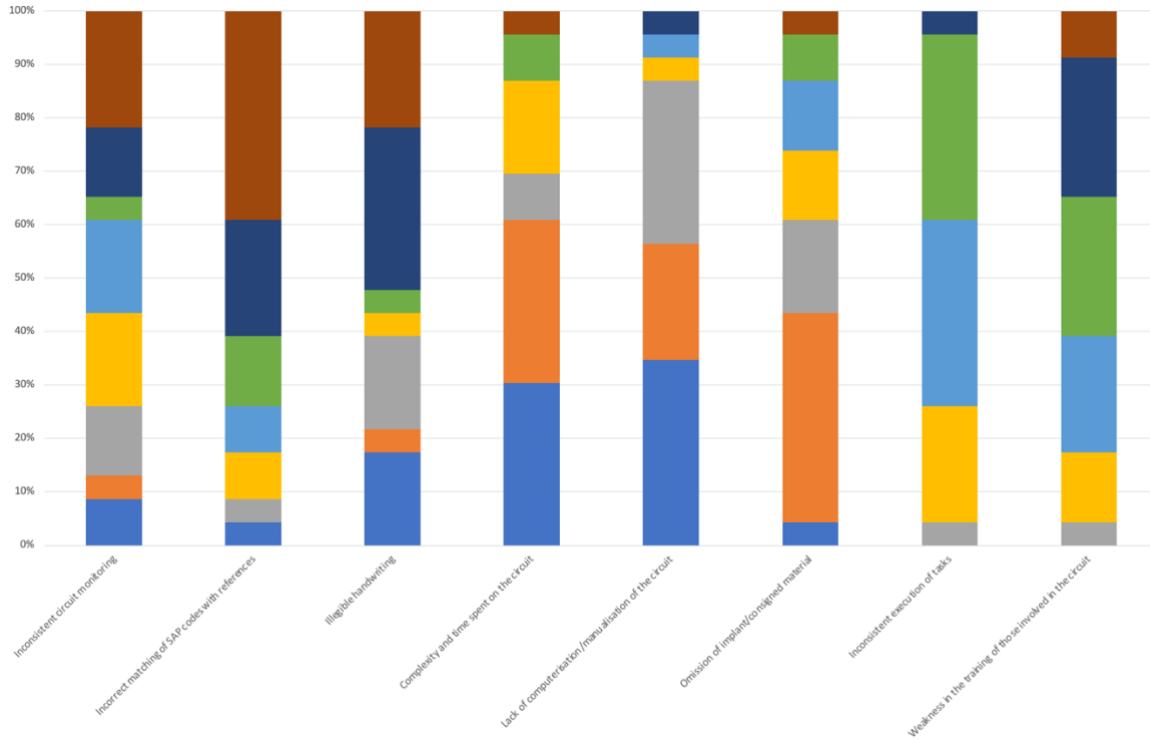


Figure 4.8 - Distribution of the answers from the prioritization survey of all 23 participants (no distinction between Nurse or Logistic Team).

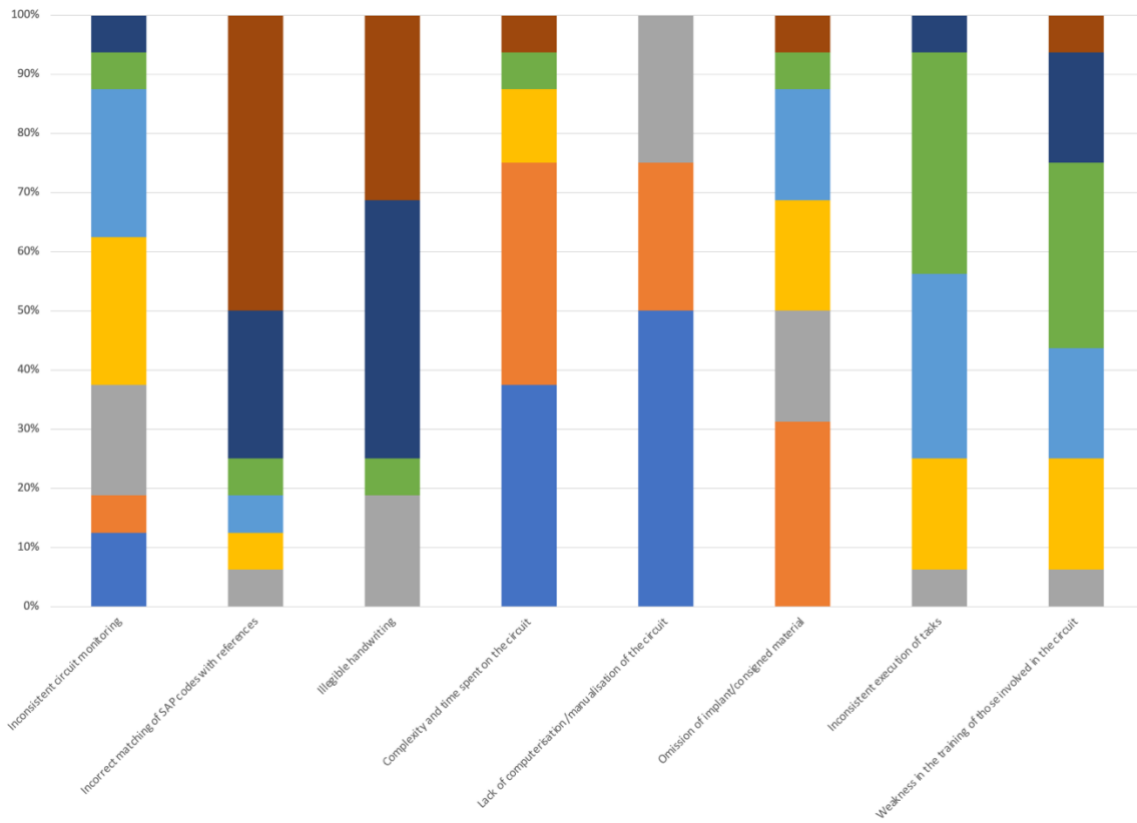


Figure 4.9 - Distribution of the answers from the prioritization survey of 16 participant nurses.

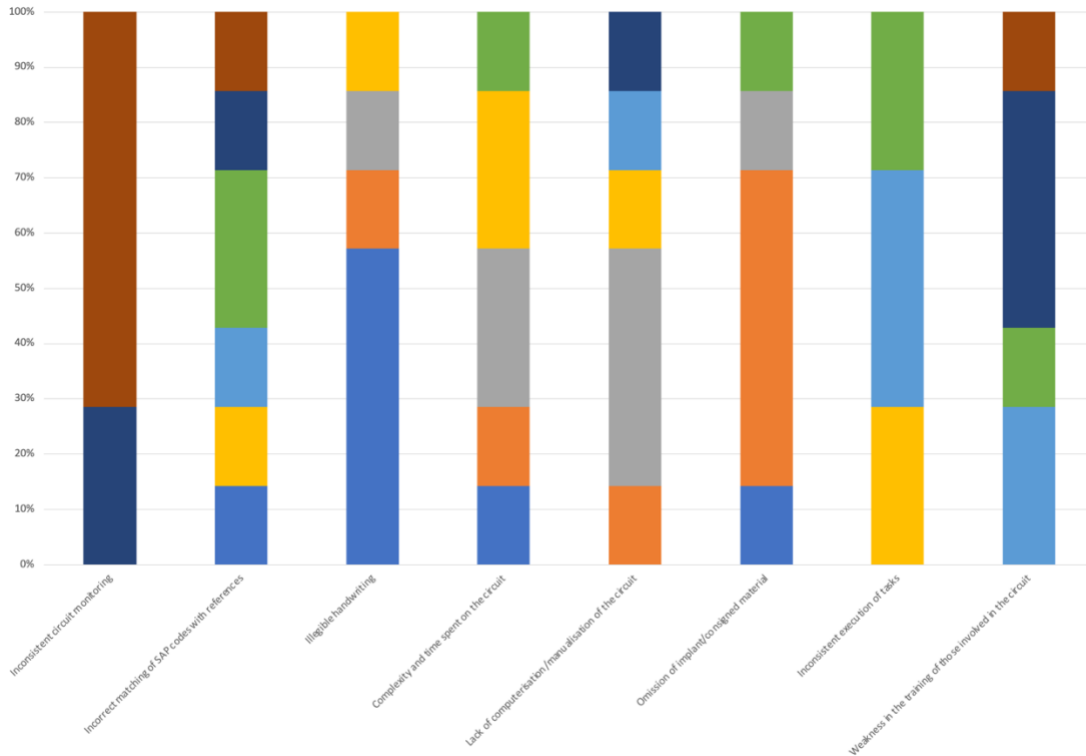


Figure 4.10 - Distribution of the answers from the prioritization survey of 7 participant logistics members.

“Weakness in the training of those involved in the circuit” (26,1%) and “Incorrect matching of SAP codes with references” (21,7%). The root causes with the biggest percentage classified with 7 and 8 are almost the same, except for “Inconsistent circuit monitoring” which is the fourth highest percentage classified with 7 and it is the second highest when classified with 8.

Opinions on "Omission of implant/consigned material" are the most widely distributed. A similar percentage placed it in the middle to lower prioritization categories, despite the fact that 39.1% ranked it as a second priority. This implies that there is a wide range of viewpoints among participants on its significance, related to the mixed categories analysed. With the largest percentages in prioritization levels in 5-7, "inconsistent execution of tasks" appears to be regularly considered as a moderately significant to non-critical worry. "Inconsistent execution of tasks" and "Weakness in the training of those involved in the circuit" have 0% in the most critical category, indicating that no participants in general found these issues to be of the utmost concern.

When analysing exclusively the nurse answers (Figure 4.9) "Lack of computerisation/manualisation of the circuit" stands out as the most pressing concern with 50% of participants classifying it as critical and receiving consistent ratings in prioritization level 2 and 3, with 25% in each. "Complexity and time spent on the circuit" is another major concern, with 37.5%

of participants rating it as critical and having a consistent spread of opinion with 37.5% in level 2 and 12.5% in level 4. This is justified because the steps taken by the Nurse Team are all manual and involve the biggest error percentage in the circuit.

Many participants, particularly those classified with levels 3 to 5, considered "Omission of implant/consigned material" and "Inconsistent circuit monitoring" to be concerns of moderate importance. The first one has the particularity of having a diverse distribution, ranging from level 2 (31.3%) to level 7 (6.3%). This suggests mixed feelings about the urgency of this issue. This is probably related to the fact that some of the nurses recognize the necessity of the IS to be correctly filled in to have a quicker reposition of the material. "Weakness in the training of those involved in the circuit" is another concern with varied opinions, as seen from the spread from level 4 to level 8, associated with the fact that the majority of nurse managers see as an added value the consistent training to their teams in order to contribute to the flow of the circuit and some not.

A sizable portion of participants consider the issues "Incorrect matching of SAP codes with references" and "Illegible handwriting" to be the least serious, ranking 50% and 31.3% of level 8 participants, respectively. The percentage of the first mentioned root cause is probably not higher because this particular subject influences the angiography specialty which uses the SAP codes for internal organization.

The majority of participants did not consider several concerns to be very important. In the most critical category (1 and 2 classification), for example, "Incorrect matching of SAP codes with references," "Inconsistent task execution," and "Weakness in the training of those involved in the circuit" all have 0%.

Lastly, Figure 4.10 shows the distribution of the answers for the logistics team members, both LHT and the administrative team.

Out of all the concerns, "illegible handwriting" is the most urgent, as most participants (57.1%) rated it as critical, which is in concordance with the opinions expressed in the interviews, due to the implications of the change of a letter for a number or vice versa when introducing lots for traceability. 14.3% of respondents view "Omission of implant/consigned material" as critically important and received a significant 57.1% as classified as top 2 priority, indicating that despite of not being the most critical, it is still a major concern for many. This is related to the importance of regularising the materials with the supplier and client.

The distribution of "Complexity and time spent on the circuit" and "Lack of computerization/manualization of the circuit" across categories 2–5 suggests that different people have varying degrees of concern. This is related to the maturity and ease with the processes of each operator. Among the participants, "Inconsistent circuit monitoring" was ranked in level 8 by a significant 71.4%, making it the least critical, due to the multiple checkpoints while processing the IS, like the subprocesses identified which alert when something is not right.

Ratings for "Inconsistent execution of tasks" vary, particularly between levels 5 and 7. It is interesting to note that, leaning more towards the less critical end, 42.9% of respondents ranked it in category 6 and another 28.6% in level 7. The distribution of "Weakness in the training of those involved in the circuit" is likewise widely distributed, with levels 4 (28.6%) and 7 (42.9%) falling between them. On the other hand, "Inconsistent circuit monitoring" and "Weakness in the training of those involved in the circuit" both have 0% for categories 1-5, indicating they are not seen as high priorities by the majority.

To summarize, when considering the distribution of the answers of all the participants some concerns such as complexity and lack of computerisation/manualisation are largely agreed upon as critical, while other areas have a wider spread of opinions, indicating the need for further discussions or evaluations. When analysing Nurse Team input it seems that the circuit is computerization or manualization and its complexity or duration are the most urgent challenges, being in agreement with the general answers. Even though there is general agreement that some issues are not critical, there are some areas where opinions differ, indicating the need for further in-depth research or discussion, like the matching of CUF codes to references or illegible handwriting. In contrast, the main issue to the Logistics Team seems to be illegible handwriting, with concerns regarding SAP code matching, circuit complexity, and material omission trailing behind. Inconsistent circuit monitoring, however, is not as concerning to participants. It is also crucial for the decision-makers to focus on the highest priority concerns to ensure safety and efficiency.

4.2.4 Design Phase

After gathering the information from the previous phase, brainstorming was taken with the logistics department in order to optimize the new design of the IS and the circuit as an all. One of the major department goals was to eliminate the IS in physical format, which means,

dematerialization of IS, combined with the desire to decrease the time to fill the IS and eliminate handwriting misinterpretation so it was developed as an informatic alternative to the IS. It will be presented with two design options and both will have incidence in the IS itself instead of the circuit transformation since it is in the nurse team that the constraints are bigger and most of the complications in the circuit come from filling it out.

Option 1

The first design option consists of an upgrade extended to the current app (Neptune) used by the nurse team to request CNR material. Figure 4.11 represents the current view of the online application that the nurse team uses and Figure 4.12 the menu where is possible to see the requisitions for each surgery per customer.

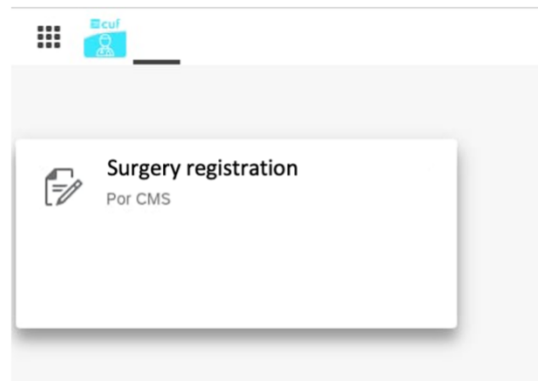


Figure 4.11 - Initial screen to enter in Neptune App.

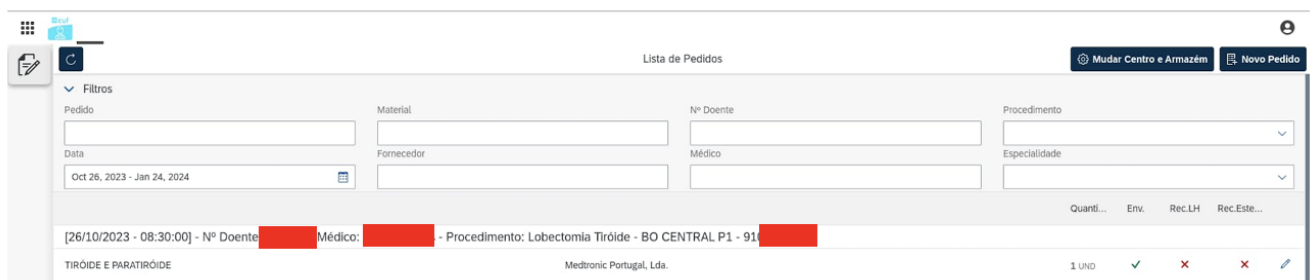


Figure 4.12 – Screen where it is possible to visualize the requisitions per client number and date.

If a requisition is not created for the client, it is because the material to register it is from hospital stock or CR, for this situations is necessary to create an episode by clicking the button “add order” in the initial menu and adding the surgery date, surgeon name, client number and type

of requisition modified to “none” (Figure 4.13). This would substitute the initial part of the IS where the client data label is stuck and the headline surgery information.

Figure 4.13 - Menu to introduce a new surgical episode.

To register each material used, circulate nurse should enter the requisition and click on the button “add material”. The next menu allows the registration of the material with two options, scanning the bar code via a personal digital assistant (PDA) or introducing manually the characteristics of the clinical consumable. In the first option, the material will appear with the description and SAP code and if it corresponds to the material used the next step is to record the register. Then the sector to introduce the lot will appear and circulate nurse should select one of the options existent in the system and the record. If the lot does not exist is possible to click on the option “others” and add a photograph of the information via PDA, and if desired an observation, of the material and then record it. The example of the circuit is represented in Figure 4.14.

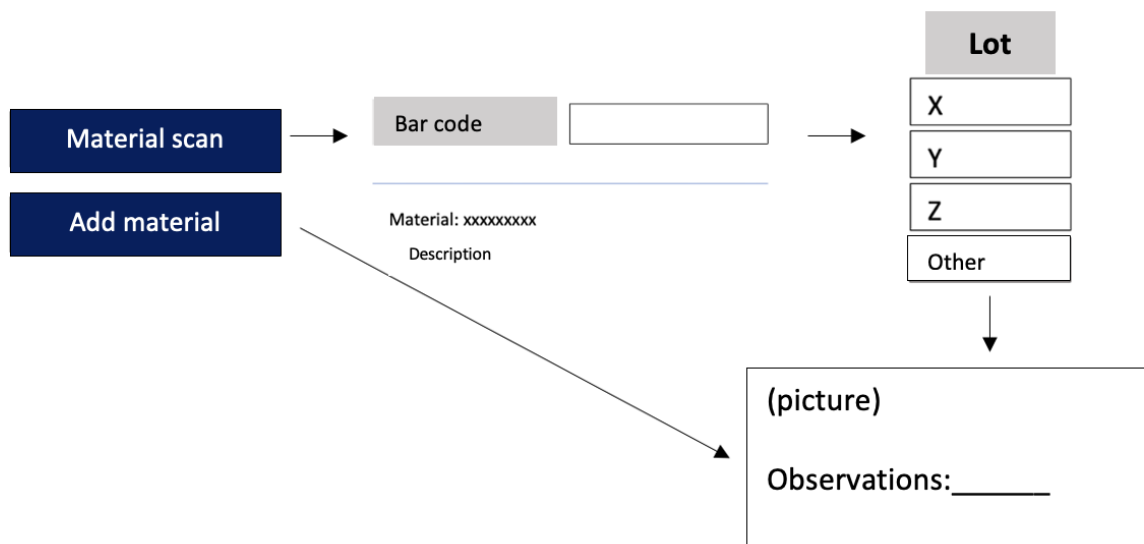


Figure 4.14 - Representation of the process to add material to the surgical episode.

The second option is designed for the materials that are not yet introduced in the system, CNR materials. For these will not be possible to scan the bar code, and if the nurse tries to do so, a message will come up (Figure 4.15). The option “introduce material” should be selected and will go to the menu “others” mentioned in Figure 4.12.

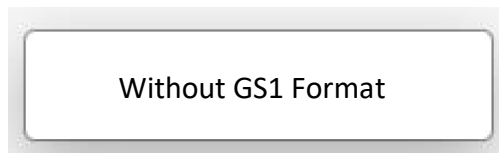


Figure 4.15 - Error message when the material is not CR or Stock.

The main reason for registering the material via photograph instead of introducing the information is to decrease the time in the process of the nurse filling it and have evidence of the material used in case doubts come up associated with mistyping of lots for example. After the process is concluded, a message will appear confirming the correct record of the information (Figure 4.16).



Figure 4.16 - Confirmation message with document number created.

The alterations proposed differ mainly in the fact that the physical document is eliminated (Figure 4.17). The nurse team's contribution would remain unaltered because they would have to introduce the material used during the procedures, however, the number of manual tasks would be significantly reduced, and the handwriting problems would be eliminated. The circulating nurse is responsible for certifying that the client has a requisition order number (RON) created and would have to add the material after the surgical episode, similar to the current process. Another significant improvement is that eliminating the physical format is not necessary to continue with step 2, which means, the transportation of IS from the operating room to collecting points does not occur anymore. The main concern about this system is if the internet fails, however, this is taken

into account in this software that records up to 48 hours the registers made with conditioned internet access.

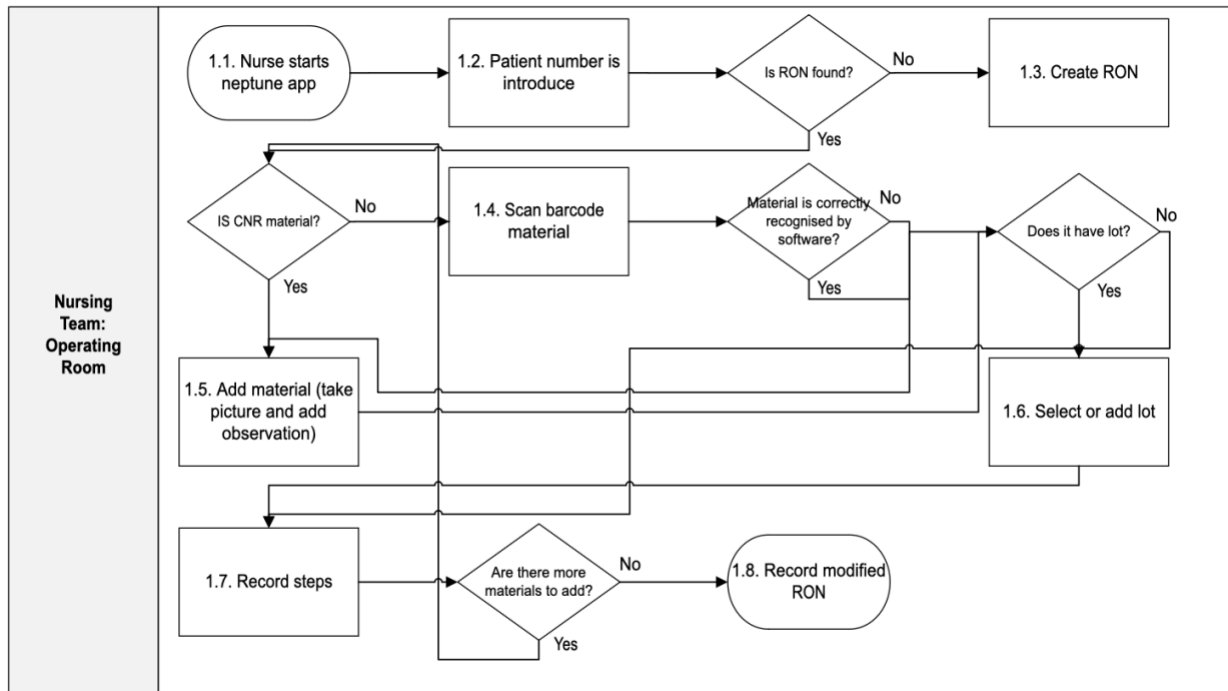


Figure 4.17 - New swim-lane with the alterations proposed.

The circuit will continue with logistics teams by entering each client episode and access to the information, replacing step 3.1. The information available for each client allows the logistic teams to regularize the materials depending on their type (CR, CNR or lot) and consequently secure implant traceability as the current process does. The main difference falls in how the information is presented.

The main advantages are the elimination of manual steps, the elimination of handwriting and a decrease nurse team in filling the IS. Despite this, it is important to note that the major disadvantage of this design is the financial investment necessary to do an informatic upgrade of this dimension, especially after a software change during this current year in the logistics department.

Option 2

The second design consists of an alteration of the current configuration of the IS, which aims to increase the optimization of the time spent in the filling, reduce manual tasks, and implement a more structured organization of the materials included in the document. This proposal is based on

the IS already existing in the CUF for the Da Vinci surgeries (medical robot), which is standardized because it has a limited number of consumables (only used for this type of surgery).

The first alteration suggested is the creation of a label for the surgery, similar to the ones that existed for the client. This would indicate the surgeon's name, type of surgery and date which would remove the top left header which has information that is not used and most of the time not even filled (Figure 4.18). It would still be necessary to indicate the circulating and instrument nurse which are not planned or could change.

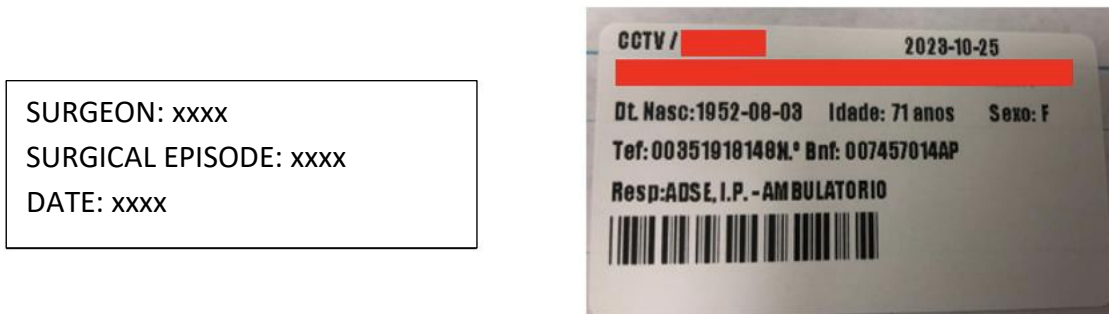


Figure 4.18 - Suggestion of the new label and comparison with the existing one with the client data.

The line to indicate the supplier would be unaltered but would be added a caption summarizing the colour code materials like presented in Figure 4.19. This will allow new team members to be always aligned with the procedures and both logistics and nurses have the same designation for the type of material.

CR	CNR	Stock
Replacement - Yellow Label	Loan - Without Label	Managed by Lot - Green Label

Figure 4.19 - Caption to clarify the type of materials regularized via IS.

Lastly, this design includes a segmentation of the spaces to introduce the clinical consumables information according to Figure 4.20. Adding these specific areas to delineate the material, will obligate an improved organization of the IS, avoid mixing references or noting them too close together, ensure the type of the material that is being regularized by the item instead of IS and associate the reference of the consumable to a type of material when associating the reference to a CUF code, adding an extra checkpoint to a constraint raised by the teams (missassociation of references to CUF codes). The information space has the dimension to stick the label if the material

has one or to handwrite the necessary information (lot, expiration date and reference). The comparison between the current and the suggested complete design can be found in Appendix D.

Type	CR <input type="checkbox"/>	CNR <input type="checkbox"/>	Stock <input type="checkbox"/>			
Material	Screw <input type="checkbox"/>	Plaque <input type="checkbox"/>	Len <input type="checkbox"/>	Net <input type="checkbox"/>	Kit <input type="checkbox"/>	Other <input type="checkbox"/>
Quantity	_____					
Notes						

Figure 4.20 - Proposal of segment to introduce in IS to separate the different consumables used.

In contrast to the first design, this would not eliminate the manual tasks and handwritten information, despite decreasing it. On the other hand, the financial investment would be considerably lower, keeping in mind that would not meet the main objectives of the logistics area, above all. The current swim-lane would not have any changes, due to the fact that the only alterations are in the way how the information is introduced.

MCDA

When there are multiple criteria or objectives involved, multicriteria analysis, also referred to as multi-criteria decision analysis (MCDA), is an organized method chosen for decision-making.

The three criteria in the analysis are the ones which could make it possible to tackle the problems arising by root causes selected from the prioritization survey classified as the most critical, being them in the general answers distribution “lack of computerisation/manualisation of the circuit” and “complexity and time spent on the circuit” and in the logistics department answers

“Illegible handwriting”. The chosen criteria are “computerisation of IS”, “no handwritten information” and “decrease time dismissed in the circuit”.

To each criterion was attributed a prioritisation order and points, being this 1) “computerisation of IS” (100); 2) “no handwritten information” (75); 3) “decrease time dismissed in the circuit” (50). This allows us to calculate the weight of each criterion through the percentage of points of the criteria divided by the total points allocated (225):

- “computerisation of IS” - 44,4%
- “no handwritten information” - 33,3%
- “decrease time dismissed in the circuit” - 22,2%

Then was allocated a score for each criterion for the two options as seen in Table 4.5. The points were distributed as follows: 10 points if the criterion is met in full, 7 points if the criterion has significant improvements over the current circuit and 4 points if the criterion has some improvements over the current circuit. The score was calculated through the multiplication of the allocated points for the weighted percentage attributed to each criterion.

Table 4.5 - Points attributed to the selected criteria and respective score considering the ponderations calculated.

Criteria	Option 1		Option 2	
	<u>Points</u>	<u>Score</u>	<u>Points</u>	<u>Score</u>
Computerisation of IS	10	4,44	4	1,78
No handwritten information	10	3,33	7	2,33
Decrease time dismissed in the circuit	7	1,55	7	1,55
		9,32		5,66

Option number one, as anticipated, more closely aligns with the goals of the stakeholders than it does with the logistics department's goals, with a score of 9,32 when compared to the score of 5,66 for option 2.

4.2.5 Verify Phase

It is noteworthy that the 'Verify' phase was skipped in the DMADV methodology's application to our project timeline and financial investment because the two proposals were not carried out. Because of this, even though the design may satisfy requirements, there is no official confirmation that it complies with the time and budget constraints established at the beginning of the project.

5. Conclusion

For the sake of patient safety, operational efficiency, regulatory compliance, and product reliability in the healthcare industry, tracking implants and surgical materials is essential. Improved control is essential to manage shortages, prevent unreported losses, and avoid wasteful spending. It is imperative to have shared information systems, such as inter-organizational systems, and automatic identification technologies, like radio-frequency identification and barcodes. It is difficult to track implants at CUF Tejo, from lenses to screws. The current manual, paper-based system is prone to errors and inefficiencies, even though every implant has a traceable lot. An "IS" is used in this analogue system to record item references, which are then used for billing and logistics. These issues cause problems for many departments within the system, including finance and logistics. Reducing or eliminating such preventable errors is crucial in the healthcare industry because of the heavy responsibilities and high costs.

To support the implementation strategies put forth in order to achieve this objective and address the research question, a literature review was prepared to ascertain the work existing in this sector, as well as possible methodologies. The Design for Six Sigma approach along with Action Research was the methodology chosen to develop the new design and aims to increase the literature existing on redesigning paper-based processes and traceability of medical implants. The process initiated with the mapping of the current circuit and needs assessment, their analysis and then developed two possible options aligned with the goals exposed by the organisation.

To answer to the research question made initially "How can we redesign the consignment circuit followed at CUF Tejo for surgical implants and materials currently relying on the use of the IS, in order to improve its traceability and make it more efficient?" was made an important conclusion that the IS circuit is complex and counts on with many different teams. To redesign IS and make it more trustful is necessary to make an alternative that the Nurse Team is comfortable with because they are the ones who make the necessary information to trace implants available. So, the focus point would be on transforming the way that the information would be presented to the teams responsible for processing it. After weighing the two options, it was determined that the first design would more effectively satisfy the logistics department's initial objectives. However, a financial investment is necessary to make such IT alterations. This design eliminates the necessity for having a physical document and relies exclusively on the Neptune app to register the material used in surgical episodes, which would be done by the Nurse Team via PDA.

The developed project had limitations like the timeline of this project which prevented concluding the verification phase and testing if any of the designs proposed could efficiently improve the consignment circuit. The financial investment was a constraint as already mentioned especially if option 1 was tested. Another obstacle is related to the sector itself, due to the uncertainty of the day the stakeholders were not able to observe and collect the information needed without influencing their routines and daily challenges. Also, CUF's organisational culture requires constant change to procedures that do not fit in department goals and vision, so the IS circuit did not remain unaltered during the project's timeline.

Future's perspective of this work, would be interesting to work with the current consultant, who is monitoring the new changes made to the logistics software, to explore design 2 and if its implementation would add value to the circuit.

6. Bibliography

- Antony, J. (2002). Design for Six Sigma: a breakthrough business improvement strategy for achieving competitive advantage. *Work Study*.
- Awad, M., & Shanshal, Y. A. (2017). Utilizing the Kaizen process and DFSS methodology for new product development. *International Journal of Quality & Reliability Management*.
- Banuelas, R., & Antony, J. (2004). Six Sigma or design for six sigma? *The TQM Magazine*.
- Beliatis, M. J., Acharya, K. S., Lohacharoenvanich, N., Presser, M. A., & Aagaard, A. A. (2019). *Internet of Things for a sustainable food packaging ecosystem insights from a business perspective*.
- Bendavid, Y., Boeck, H., & Philippe, R. (2012). RFID-enabled traceability system for consignment and high value products: A case study in the healthcare sector. *Journal of Medical Systems*, 36(6), 3473–3489. <https://doi.org/10.1007/s10916-011-9804-0>
- Bosch-Capblanch, X., O'Donnell, D., Krause, L. K., Auer, C., Oyo-Ita, A., Samba, M., Matsinhe, G., Garba, A. B., Rodríguez, D., Zuske, M., Njepuome, A. N., Lee, S. M. M., Ross, A., Gajewski, S., Muloliwa, A. M., Yapi, R. B., & Brown, D. W. (2021). Researching, co-creating and testing innovations in paper-based health information systems (PHISICC) to support health workers' decision-making: protocol of a multi-country, transdisciplinary, mixed-methods research programme in three sub-Saharan countries. *Health Research Policy and Systems*, 19(1). <https://doi.org/10.1186/s12961-021-00768-0>
- Campanerut, M., & Nicoletti, B. (2010). Best practices for DFSS in the development of new services: evidence from a multiple case study. *The Journal of American Business Review*, 16(1), 1–8.
- Cimini, C., Pirola, F., Pinto, R., & Cavalieri, S. (2020). A human-in-the-loop manufacturing control architecture for the next generation of production systems. *Journal of Manufacturing Systems*, 54, 258–271.
- Coghlan, D. (2010). Seeking common ground in the diversity and diffusion of action research and collaborative management research action modalities: Toward a general empirical method. *Research in Organizational Change and Development*, 18, 149–181. [https://doi.org/10.1108/S0897-3016\(2010\)0000018009](https://doi.org/10.1108/S0897-3016(2010)0000018009)
- Coughlan, P., & Coghlan, D. (2016). *Action research* (pp. 235–260). <http://ebookcentral.proquest.com/lib/dartmouth-ebooks/detail.action?docID=4530592>.
- Dai, H., Ge, L., & Zhou, W. (2015). A design method for supply chain traceability systems with aligned interests. *International Journal of Production Economics*, 170, 14–24. <https://doi.org/10.1016/j.ijpe.2015.08.010>
- De Feo, J., & Bar-El, Z. (2002). Creating strategic change more efficiently with a new design for six sigma process. *Journal of Change Management*, 3(1), 60–80.
- Delaš, J., Škec, S., & Štorga, M. (2018). Application of Axiomatic Design principles in conceptual design. In *MATEC Web of Conferences* 223.
- Dos Santos, R., Bueno, E. V., Kato, H. T., & Corrêa, R. O. (2018). Design management as dynamic capabilities: a historiographical analysis. *European Business Review*.
- Duffy, G. L., Scriabina, N., Ramu, G., Wagoner, K., Laman, S., & Mehta, P. (2012). Beyond the basics. *Quality Progress*, 45(4), 18.
- Dumas, M., Marcello, ·, Rosa, L., Mendling, J., & Reijers, H. A. (2018). *Fundamentals of Business Process Management*.

- Ericsson, E., Gingnell, L., & Lilliesköld, J. (2015). Implementing Design for Six Sigma in large Swedish product developing organisations – an interview study. *Total Quality Management and Business Excellence*, 26(5–6), 648–660. <https://doi.org/10.1080/14783363.2013.870782>
- Farooqui, T., Rana, T., & Jafari, F. (2019). *2nd International Conference on Communication, Computing and Digital Systems (C-CODE) : 6-7 March 2019, Islamabad, Pakistan*.
- Furterer, S. L. (2009). *Lean Six Sigma in service : applications and case studies*. CRC Press.
- Gijo, E. V., Bhat, S., Antony, J., & Park, S. H. (2021). Ten commandments for successful implementation of Design for Six Sigma. *TQM Journal*, 33(8), 1666–1682. <https://doi.org/10.1108/TQM-01-2021-0014>
- Gitlow, H. S. (2006). *Design for Six Sigma for Green Belts and Champions: Applications for Service Operations--Foundations, Tools, DMADV, Cases, and Certification (with CD)*. Pearson Education India.
- Gremyr, I., & Raharjo, H. (2013). Quality function deployment in healthcare: A literature review and case study. In *International Journal of Health Care Quality Assurance* (Vol. 26, Issue 2, pp. 135–146). <https://doi.org/10.1108/09526861311297343>
- Gummesson, E. (2000). *Qualitative methods in management research*. Sage.
- Hahn, G. J., Hill, W. J., Hoerl, R. W., & Zinkgraf, S. A. (1999). The impact of Six Sigma improvement—a glimpse into the future of statistics. *The American Statistician*, 53(3), 208–215.
- Hammer, M. (2007). The process audit. *Harvard Business Review*, 85(4), 111.
- Hammer, M., & Champy, J. (2009). *Reengineering the corporation: Manifesto for business revolution, a*. Zondervan.
- Hasenkamp, T. (2010). Engineering design for Six sigma - A systematic approach. *Quality and Reliability Engineering International*, 26(4), 317–324. <https://doi.org/10.1002/qre.1090>
- Hughes, M., Scott, M., & Golden, W. (2006). *The role of Business Process Redesign in creating E-Government in Ireland*.
- Johnson, J. A., Gitlow, H., Widener, S., & Popovich, E. (2006). *Designing New Housing at the University of Miami: A “Six Sigma”® DMADV/DFSS Case Study* (Vol. 18).
- Jones, D. T., & Womack, J. P. (2005). Lean consumption. *Harvard Business Review*, 83, 58–68.
- Kothari, M. (2020). *USING SIX SIGMA DMAIC METHODOLOGY TO ENHANCE MEDICINES MANAGEMENT WITHIN UK CARE HOMES Improving the 28-day Supply of Medicines Cycle for Resident Repeat Medications MEDHA KOTHARI USING SIX SIGMA DMAIC METHODOLOGY TO ENHANCE MEDICINES MANAGEMENT WITHIN UK CARE HOMES: Improving the 28-day Supply of Medicines Cycle for Resident Repeat Medications THESIS SUMMARY*.
- Kwak, Y. H., & Anbari, F. T. (2006). Benefits, obstacles, and future of six sigma approach. *Technovation*, 26(5–6), 708–715. <https://doi.org/10.1016/j.technovation.2004.10.003>
- Kwon, H., Baek, B.-H., Jeon, Y.-S., Kim, Y.-L., & Jung, H.-B. (2021). Key factors of service design methodology for manufacturing servitization. *Cogent Business & Management*, 8(1), 1883220.
- Lee, C.-H., Chen, C.-H., & Trappey, A. J. C. (2019). A structural service innovation approach for designing smart product service systems: Case study of smart beauty service. *Advanced Engineering Informatics*, 40, 154–167.
- Lobo, S., & Samaranyake, P. (2020). An innovation management assessment framework. *Benchmarking: An International Journal*, 27(5), 1633–1656.

- Macnamara, J. (2020). Corporate listening: Unlocking insights from VOC, VOE and VOS for mutual benefits. *Corporate Communications: An International Journal*, 25(3), 377–393.
- Mader, D. P. (2002). Design for six sigma. *Quality Progress*, 35(7), 82–86.
- Mouaky, M., Benabbou, L., & Berrado, A. (2018). DMADV approach to evaluate the Adaptive Kanban performance for inventory management process: the case of Moroccan public pharmaceutical supply chain. *Supply Chain Forum*, 19(3), 178–190. <https://doi.org/10.1080/16258312.2018.1484249>
- Nguyen, H. N., Lasar, G., Iriarte, I., Atxa, A., Unamuno, G., & Galfarsoro, G. (2022). Human-centered design for advanced services: A multidimensional design methodology. *Advanced Engineering Informatics*, 53. <https://doi.org/10.1016/j.aei.2022.101720>
- Pereira, R., Velez Lapão, L., Scalabrin Bianchi, I., & Amaral, D. (2020). Improving Emergency Department Through Business Process Redesign: An empirical study. In *Australasian Journal of Information Systems Pereira* (Vol. 24).
- Politecnico di Milano, Institute of Electrical and Electronics Engineers, & IEEE Electronics Packaging Society. (2019). *THERMINIC 2019 : 25th International Workshop Thermal Investigations of ICs and Systems : 25- 27 September 2019, Politecnico di Milano, Lecco Campus, Lecco, Italy*.
- Rahman, A., Shaju, S. U. C., Sarkar, S. K., Hashem, M. Z., Hasan, S. M. K., & Islam, U. (2018). Application of six sigma using define measure analyze improve control (DMAIC) methodology in garment sector. *Independent Journal of Management & Production*, 9(3), 810–826.
- Rauch, E., Vickery, A., Garcia, M., Rojas, R., & Matt, D. T. (2018). Axiomatic Design based Design of a Software Prototype for Smart Shopfloor Management. *MATEC Web of Conferences*, 223. <https://doi.org/10.1051/mateconf/201822301012>
- Ryu, J. (2013). *Global Traceability Standard for Healthcare Business Process and System Requirements for Supply Chain*.
- Sanders, E. B.-N., & Stappers, P. J. (2008). Co-creation and the new landscapes of design. *Co-Design*, 4(1), 5–18.
- Scholtes, P. R., Joiner, B. L., & Streibel, B. J. (2003). *The team handbook*. Oriel incorporated.
- Smith, A. J. (2018). *Framework for Establishing Asset Visibility and Traceability of Medical Devices*.
- Suh, N. P., & Suh, N. P. (2001). *Axiomatic design: advances and applications* (Vol. 4). Oxford university press New York.
- Suh, N. P., & Suh, P. N. (1990). *The principles of design* (Issue 6). Oxford University Press on Demand.
- Vanzant-Stern, T., Fultus, A., & Books, T^M. (2011). *Lean Six Sigma Practical Bodies of Knowledge*. <http://writers.fultus.com/stern/>

7. Appendix

A. Aggregate Needs

Table 2.1 - Aggregated needs collected through interviews with different stakeholders from the IS circuit based on their similarities. Highlighted in red are the ones that were excluded based on the scope of the project.

Stakeholder	Interview	Need	Aggregate need
Special Exams Nurse	“the materials inserted in IS aren’t exclusively implanted”	Compliance with IS purpose	Compliance with IS purpose
Special Exams Nurse	“it is necessary to introduce a lot of information by hand that is already available digitally”	No handwritten information	Computerize the material register flow
Special Exams Nurse	“is an archaic process”	Computerize the material register flow	
Surgery Nurse	“non-resident material does not always include a label, which means that we have to write many references by hand, which is which is more prone to error”	No handwritten information	
Logistics Hospital Team	“a lot of the references are not pasted and instead they write it down or it is not possible to paste it all”	No handwritten information	
Special Exams Nurse	“many of the material codes and references used aren’t updated”	Updated catalogue with material codes	Regular updates on the online catalogue
Angiography Nurse	“the informatic descriptions from products usually don’t make sense with the used by nurses”	Technical descriptions and current descriptions are similar	
Special Exams Nurse	“logistics staff does not know the material and is frequently confirmed information, particularly when double checking possible mistakes”	Training for logistics staff to get to know the material	Overall awareness regarding the material register flow
Nurse Team	“the team is not aware of the purpose of the IS”	Material register flow understanding	
Special Exams Nurse	“not sure if the steps taken are right”	Confidence in the material register flow	
Ophthalmology Nurse	“it is difficult to coordinate with logistics to know about the circuit flow of lenses already implanted”	increase communication and knowledge about the consigned materials	
Ophthalmology Nurse	“the IS filling is clear however not trustworthy, always keep a process of the IS per surgery” “duplicate the lot register to reinsure traceability”	Confidence in the material register flow	
Surgery Nurse	“too many surgeries to keep track of ISs, so we	Confidence in the material register flow	

	lose track of material replacement and lot tracking”		
Logistics Hospital Team	“nurse team makes frequent mistakes that don’t make the information transmitted reliable”	Instructed nurse team to correct filling of IS	
Special Exams Nurse	“the debits of the material client are not clear which are by the nurse team and team”	Clarity on what material nursing charges and what billing charges	
Logistics Hospital Team	“the time waiting for open SAP code could be more week”	Faster reply to tickets opening codes	
Logistics Administrative Team	“it is not easy to communicate with Lisbon colleagues, sometimes don’t respond to us for two weeks”	Smother communication with the hospital team	
Angiography Nurse	“many of the SAP codes don’t exist in the cardiobase system making it impossible to introduce digitally the references in IS”	Regular update of codes into the cardiobase system	Articulation between ERP (SAP) and angiography software (Cardiobase system)
Angiography Nurse	“the cardiobase system does not match with the SAP system”	Cardiobase system articulation with SAP system	
Logistics Administrative Team	“Angiography IS has frequent mistakes and unnecessary information and sometimes misses information”	Cardiobase IS being uniformized to regular IS	
Angiography Nurse	“most of the material is CR so when they fill out the sheet they sometimes mistakenly assume it is CR causing an error for the logistics team”	Select the CNR of the remaining material	Distinction in the IS between materials (lot material, CNR and CR)
Nurse Team	“it is very difficult to distinguish the different labels for the material types because the majority of them don’t have clinical reason to have different processes”	Distinction of material by lot, CNR and CR	
Logistics Hospital Team	“it is a long process which depends on different departments and people to complete it”	Less dependence on additional processes	Less dependence on additional processes
Logistics Hospital Team	“because the nurse team don’t have access to the ticket platform we are the ones to communicate with them and then transmit the information not asked by us”	HLT is not part of the communication with the Nurse team	HLT is not part of the communication with the Nurse team
Logistics Administrative Team	“if we transfer the first information to billing we lose the trackability of the ticket because we can’t see it”	Ensure trackability of the initial ticket	Ensure trackability of the initial ticket

	it on the platform anymore”		
Special Exams Nurse	“there is a lot of material cu managed by a lot that before wasn’t”	Less lot material	Less lot material
Nurse Team	“the replacement of the consigned materials takes too much time”	Faster replacement of consigned material	Faster replacement of consigned material
Ophthalmology Nurse	“80% of the materials are ordered via CNR despite having it in consigned material” “nurse team and logistics don’t know what materials the hospital has”	Map existing consignment	Map existing consignment

B. Detailed measures from macro tasks Flowchart

	Step 1				Step 2	Step 3	n° SAP codes	Step 4		Step 5	Step 6	Step 7	Step 8	Step 9
	O	EE	S	A										
	00:00:35	00:00:28	00:00:35	00:00:45	00:01:30	00:02:00	1	00:00:31	00:00:31	00:00:35	00:01:01	00:00:15	00:00:38	00:00:40
	00:00:32	00:00:26	00:01:32	00:00:56	00:01:32	00:02:00	2	00:01:03	00:00:32	00:01:35	00:00:35	00:00:24	00:00:36	00:00:42
	00:00:34	00:00:25	00:02:01	00:00:40	00:01:40	00:01:00	4	00:02:15	00:00:34	00:00:33	00:01:55	00:00:13	00:00:43	00:00:38
	00:00:32	00:00:30	00:00:55	00:00:48	00:01:35	00:01:00	6	00:03:27	00:00:35	00:00:27	00:01:00	00:00:22	00:00:35	00:00:34
	00:00:35	00:00:24	00:01:13	00:00:52	00:01:42	00:01:00	3	00:01:06	00:00:22	00:00:29	00:00:53	00:00:19	00:00:53	00:00:39
	00:00:29	00:00:26	00:01:41	00:00:48	00:01:37	00:01:00	2	00:00:47	00:00:23	00:02:18	00:00:57	00:00:17	00:00:50	00:00:45
	00:00:28	00:00:25	00:00:43	00:00:40	00:01:44	00:02:00	6	00:03:33	00:00:35	00:00:29	00:01:02	00:00:23	00:00:46	00:00:49
	00:00:27	00:00:26	00:01:27	00:00:41	00:01:37	00:02:00	8	00:04:47	00:00:36	00:00:48	00:00:45	00:00:14	00:00:44	00:00:37
	00:00:33	00:00:25	00:01:33	00:00:45	00:01:39	00:02:00	1	00:00:28	00:00:28	00:01:29	00:01:08	00:00:17	00:00:37	00:00:37
	00:00:32	00:00:28	00:02:32	00:00:51	00:01:40	00:03:00	5	00:04:04	00:00:49	00:00:37	00:01:14	00:00:19	00:00:30	00:00:40
	00:00:30	00:00:23	00:00:30	00:00:52	00:01:38	00:03:00	4	00:02:54	00:00:44	00:01:02	00:02:00	00:00:15	00:00:44	00:00:42
	00:00:29	00:00:29	00:01:18	00:00:50	00:01:43	00:01:00	6	00:02:49	00:00:28	00:01:55	00:02:00	00:00:17	00:00:45	00:00:44
	00:00:29	00:00:24	00:01:09	00:00:49	00:01:44	00:02:00	3	00:01:19	00:00:26	00:01:04	00:01:00	00:00:10	00:00:38	00:00:48
	00:00:31	00:00:26	00:00:38	00:00:41	00:01:47	00:01:00	7	00:03:12	00:00:27	00:02:00	00:01:00	00:00:25	00:00:42	00:00:32
	00:00:34	00:00:25	00:01:12	00:00:44	00:01:38	00:02:00	6	00:02:43	00:00:27	00:02:00	00:01:00	00:00:19	00:00:41	00:00:46
	00:00:36	00:00:27	00:00:53	00:00:50	00:01:32	00:05:00	4	00:02:04	00:00:31	00:02:00	00:01:00	00:00:10	00:00:26	00:00:49
	00:00:33	00:00:22	00:02:33	00:00:49	00:01:48	00:02:00	3	00:01:26	00:00:29	00:02:00	00:02:00	00:00:13	00:00:47	00:00:43
	00:00:27	00:00:21	00:01:32	00:00:46	00:01:40	00:02:00	4	00:01:35	00:00:24	00:02:00	00:02:00	00:00:16	00:00:35	00:00:38
	00:00:25	00:00:28	00:01:54	00:00:48	00:01:35	00:02:00	4	00:01:02	00:00:16	00:02:00	00:02:00	00:00:23	00:00:31	00:00:43
	00:00:31	00:00:30	00:00:31	00:00:49	00:01:36	00:02:00	2	00:00:52	00:00:26	00:02:00	00:03:28	00:00:18	00:00:34	00:00:44
x	00:00:31	00:00:26	00:01:19	00:00:47	00:01:39	00:01:57			00:00:30	00:01:22	00:01:24	00:00:17	00:00:40	00:00:42
sd	00:00:03	00:00:02	00:00:36	00:00:04	00:00:05	00:00:57			00:00:07	00:00:41	00:00:41	00:00:04	00:00:07	00:00:05

Figure 21 - Table of measures for 20 ISs circuit. Step 4 was necessary to include the number of codes per sheet so that the comparison between ISs would take into account their size.

C. Questionary distributed to participants in the IS circuit

Circuito Folha de Implante (FI)

Este questionário tem como objetivo determinar quais são as maiores dificuldades no circuito da FI, desde o seu preenchimento ao processamento. Das seguintes dificuldades listadas ordenem por ordem de preferência, de 1 (mais importante) a 8 (menos importante), as que consideram mais críticas serem corrigidas para o correto funcionamento e poderiam facilitar o circuito da FI. Os resultados não serão divulgados e têm um propósito exclusivamente académico. Obrigada pela colaboração de todos!

** Indica uma pergunta obrigatória*

Posição (ex: operador logística hospitalar, enfermeiro circulante etc.) *


A sua resposta _____

Constrangimentos no processo: *

	1	2	3	4	5	6
Monitorização inconsistente do circuito	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Correspondência incorreta de códigos SAP com referências	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Caligrafia ilegível	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Complexidade e tempo despendidos no circuito	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inexistência de informatização/manualidade do circuito	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Omissão de material de implante/consignado	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inconsistência na execução de tarefas	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fragilidade na formação dos envolvidos no circuito	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 22 - Google forms shared with nurse and logistics team in order to determinate which are the top causes to prioritize in the new design. The participants should order 1 (most important) to 8 (less important) the listed causes.

Unidade CUF: _____

<p>CCTV / [REDACTED] 2023-10-25</p> <p>[REDACTED]</p> <p>Dt. Nasc: 1952-08-03 Idade: 71 anos Sexo: F</p> <p>Tef: 00351918148N.º Bnf: 007457014AP</p> <p>Resp: ADSE, I.P. - AMBULATORIO</p> 	<p>SURGEON: xxxx</p> <p>SURGICAL EPISODE: xxxx</p> <p>DATE: xxxx</p>
--	--

Circulate Nurse: _____

Firma: _____

Instrumental Nurse: _____

	CR	CNR	Stock
	Replacement - Yellow Label	Loan - Without Label	Managed by Lot - Green Label
Type	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Material	Screw <input type="checkbox"/> Plaque <input type="checkbox"/>	Len <input type="checkbox"/> Net <input type="checkbox"/>	Kit <input type="checkbox"/> Other <input type="checkbox"/>
Quantity	_____		
Notes	<div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>		

Figure 24 - New IS document proposal.