A master thesis submitted for the degree of MASTER OF TECHNOLOGY AND INNOVATION MANAGEMENT (MTIM)

"Product Adaptation Management: The case of medical device changes in Healthcare Institutions"

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ABSTRACT

In the medical device industry change is inevitable. Innovative healthcare companies are at the constant forefront of new technological advancements, regulations and standards revision. New requirements are enforced and every document, process, and product is subject to change.

Product modifications can be initiated by manufacturers before the product is approved and made available to the public (pre-market product changes) as well as after the device has been approved and is distributed into the marketplace (post-market product changes).

Such modifications are more challenging because products are being actively used in Healthcare Institutions so any change of the medical device or a medical device part will require correction resulting in uncertainty and operational inefficiencies in the interim period. The scope of this thesis is to explore how healthcare institutions adapt to medical device changes initiated by manufacturers due to safety alerts, recalls, software updates or product modifications. The focus will be given on how healthcare institutions are adapting to the changes triggered by safety alerts which is very critical in maintaining patient safety. Also, it seeks to understand the existing processes of handling medical device changes, the challenges and the effectiveness of adaptation management. Based on this, it will explore ways to improve the adaptation management practices within healthcare institutions.

Through interviews with healthcare institutions stakeholders, this thesis uncovers the complexities involved in adapting to these changes. Also, based on the results, this thesis explores potential improvements and/or solutions to the overall medical device adaptation management process of healthcare institutions ensuring better preparedness and adaptability while maintaining both operational continuity and patient and user safety during critical medical device changes.

Keywords: EU MDR; medical device changes; Field Safety Notice; adaptation management; healthcare institutions; challenges;

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF CHARTS

LIST OF TABLES

LIST OF ABBREVIATIONS

EU MDR	European Medical Device Regulation
UDI	Unique Device Identification
EUDAMED	European Database on Medical Devices
EOF	Greek Organization for Medicines
QMS	Quality Management System
PMS	Post-market surveillance
FSN	Field Safety Notice
FSCA	Field Safety Corrective Action
FSE	Field Service Engineer
ICU	Intensive Care Unit
IT	Information Technology
ISD	Information Systems Development

INTRODUCTION

Hereafter is provided an introduction to the current thesis. The following section aims at explaining the research background and motivation, the research objective and tasks undertaken. Finally, a presentation of the structure of the following paper is provided.

Research background and motivation

Product quality is becoming increasingly important in manufacturing especially in medical device industry due to the potential severity of the consequences of introducing inferior or unsafe products to the market-place. Also, continuous improvement of product quality became a goal for many manufacturers as it is a powerful competitive advantage enhancing customer satisfaction and ensuring patient safety. (Vadori, 2020)

Given the high significance in maintaining human health, the processes of manufacturing, marketing and usage medical devices have been regulated globally and nationally. The directives and regulations define all aspects from ideation, design and development phase, up to testing, approval and certification before the production process, production itself (pre-market processes) and post-market surveillance (PMS) of medical devices to ensure that products reaching the public are safe and effective. (McAllister & Jeswiet, 2003; Badnjević et al., 2022)

In the European Union (EU), pre-market and post-market processes have been defined by Medical Device Directives (MDD) since 1992 and recently updated by Medical Device Regulation (MDR). To support the implementation of directives and regulations, international standards have been developed such as ISO 13485- Medical devices– Quality management systems - Requirements for regulatory purposes, ISO 14971- Medical devices– Application of risk management to medical devices, etc. Also, a set of safety and technical standards referring to specific medical device requirements have been developed such as IEC 60601 Medical electrical equipment, ISO 15223 Medical devices– Symbols to be used with information to be supplied by the manufacturer, ISO 10993 Biological evaluation of medical devices, IEC 62304 Medical device software– Software life cycle processes, IEEE Standard for Health Informatics– Point-of-care medical device communication- Part 10201, etc. Manufacturers should ensure legal requirements are met and demonstrate its ability to provide high-quality medical devices and related services that consistently meet customer and applicable regulatory requirements by implementing quality management systems. (Badnjević et al., 2022; Abuhav, 2018)

The process of change control in medical devices is important for regulatory compliance, quality and effectiveness as well as business continuity, cost efficiency and patient safety. Medical device change control processes are required as any type of change can have serious consequences and its proper handling is absolutely critical. Change control in medical device environments may involve updates made to a document, a simple adjustment triggered by a new customer specification, a part replacement, or other production circumstance. Changes can also occur due to a deviation from written procedures or an approved regulatory filing and can be temporary or permanent, routine or emergency, innocuous or serious enough to shut down the production. Regardless of the severity of the change, bad things happen when they are not dealt appropriately. (ComplianceQuest, 2024)

Manufacturer should inform the end user for all changes to medical devices already placed in the market. In case the change is triggered by information about any problem with an already distributed medical

device that poses an unacceptable increased risk when it is used, manufacturer should take a field safety corrective action (FSCA) in order to reduce a risk of death or serious deterioration in the state of health associated with the use of the medical device. Such problems include malfunction or deterioration affecting the performance or operational characteristics of an medical device, as well as any inadequacy in the instructions for use which might lead or might have led to the death of a patient, user or other individual or to a serious deterioration in his/her state of health.

The field safety notice (FSN) is an important means of communicating a field safety corrective action (FSCA) to end users. Manufacturers should ensure that the FSN is distributed to all affected users and must keep track of confirmation of receipt of the FSN. Manufacturer should also take care of the recovery of the goods as well as implement the necessary corrective actions. (Field Safety Notice | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control))

Depending of the type and use of a medical device, end user can be considered a healthcare institution or a patient itself. In case of healthcare institutions, medical device changes can affect multiple users and/or patients so the adaptation management of such changes is highly important.

Research objective

This thesis aims to identify the existing processes, including the steps being followed, in healthcare institutions in regards to the adaptation of medical device changes initiated by manufacturers. Deep dive into understanding all relevant stakeholders, their involvement in the adaptation management process as well as understanding their perspective of successful adaptation. In addition to this, the study is exploring the challenges healthcare institutions face with focus on safety related medical device changes. Last but not least, it aims to provide suggestions for improving the processes.

Therefore, the objective of the research is to investigate the Product Adaptation Management and more specifically the case of medical device changes in healthcare institutions.

In order to achieve this goal, the following objectives have been set:

- Identify the existing adaptation processes of medical device changes in healthcare institutions
- Explore the challenges healthcare institutions face
- Evaluate the outcome of adaptation
- Provide suggestions for improving those processes

This thesis aims at answering the following questions:

- RQ1: How healthcare institutions adapt in medical device changes initiated by manufacturers?
- RQ2: How can healthcare institutions make improvements into the already existed adaptation processes?

On the one hand such analysis is important in ensuring better preparedness and adaptability while maintaining both operational continuity as well as patient and user safety during critical medical device changes. This will also help healthcare institution to understand the importance of better preparedness for an effective way of working. On the other hand, it can reveal the differences in adaptation process of

medical device changes between healthcare institutions so it can be used as an example for other healthcare institutions in order to start improving their adaptation management processes.

In order to achieve the objectives of this study, information will be collected by key stakeholders from some healthcare institutions. The data will be gathered from interviews and will provide an insight into the healthcare's institutions procedures in regards to adaptation management of medical device changes initiated by manufacturers. Based on the results, a proposal of potential improvements can be provided contributing to the overall process.

Structure of the paper

The research is structured in four chapters. The first chapter introduces the theoretical background on the topic under study. Firstly, an introduction of the European Medical Device Regulation will be presented as it is the source of triggering an increasing number of medical device changes by manufacturers. Further, the chapter is covering the definition and classification of medical devices. Also, the different types of medical device changes are presented as well as the process of the initiation of a medical device change. The second section of the literature review focuses on the role of adaptation management in healthcare institutions. More specifically, it will present the definition of adaptation, the types of adaptation, the different adaptation approaches and the steps of adaptation management. In addition, the challenges of adaptation management as well as the definition of successful adaptation will be addressed. The review of the literature concludes with the identification of the links and gaps of the research which will be converted to interview questions.

The second chapter of this thesis introduces to the methodology used for the empirical research. This study applies a qualitative research design with semi constructed interviews with healthcare institution's employees. In this chapter the selection of the sample, collection and analysis of data from interviews will be clarified. Finally, the limitations of the research are presented.

In third chapter the main findings from interviews are presented. The findings are classified in order to answer the research questions previously set. Therefore, the presentation will follow this order: the results on adaptation management of medical device changes in healthcare institutions, the involvement of the stakeholders in the adaptation management process, the challenges that healthcare institutions face, the meaning of successful adaptation of medical device changes and potential improvements into the already existed adaptation management processes.

The forth Chapter focuses on the interpretation of the results of the research compared to the theoretical background. The contribution of this research is presented as well as implications and direction for future research.

CHAPTER 1: ADAPTATION MANAGEMENT OF MEDICAL DEVICE CHANGES IN HEALTHCARE INSTITUTIONS -THEORETICAL BACKGROUND

This chapter presents a review of the literature on the topics under study. Firstly, an overview of medical device changes will be presented. Secondly, the focus moves to the role of adaptation management of such changes in healthcare institutions. Lastly, based on the theoretical background the conclusions and research gap are identified.

1.1. Overview of Medical Device Changes

In this subchapter the dynamic landscape of medical device changes will be presented by exploring the factors that drive these changes and the process of their initiation. It also examines the effects these changes have on healthcare institutions, highlighting the need for adaptability to ensure patient safety and operational continuity.

1.1.1. Introduction of European Medical Device Regulation

The pharmaceutical and medical device industries are some of the most strictly regulated globally. Regardless of a device's intended use or type, it is crucial to ensure that it does not cause unexpected side effects or pose serious health risks to users. Prior to May 2021, in Europe, medical devices were governed by the Medical Device Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD). These directives were deemed insufficient and the European Union introduced the EU Medical Device Regulation (EU MDR) 2017/745. The MDR took effect on May 27, 2021 and aims to enhance regulatory oversight and apply stricter requirements throughout the entire lifecycle of medical devices, ensuring a higher level of patient safety and product reliability. (Kearney & McDermott, 2023)

The urgency of EU MDR was created by the following significant factors:

- To address technological advancements resulted from the rapid pace of innovation in medical technology creating regulatory complexities of advanced medical devices ensuring the safety, efficacy and quality assurance.
- To achieve Global Harmonization of medical device regulations in order to be more closely with international guidelines and ensure consistent safety standards worldwide.
- To address safety incidents and public health concerns resulted from high profile safety incidents by creating stronger pre-market assessments and ongoing post-market monitoring.
- To address deficiency of ISO 13485 in regards to the safety and effectiveness of the entire lifecycle of medical devices by implementing regulations that evaluate clinical evidence, post-market surveillance, risk management, and enhanced transparency in order to safeguard patient safety and ensure the effectiveness of products influenced by the latest technological improvements
- To address the need for increased transparency and traceability by launching the EUDAMED system for more apparent traceability measures and UDI system for improved traceability over their entire lifecycle.
  (Mitrofanskiy, 2024)

1.1.2. Defining medical device

Under the new EU-MDR, a "medical device" is defined as "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. "

(Regulation - 2017/745 - EN - Medical Device Regulation - EUR-LEX, 2021, page 15)

1.1.3. Medical device classification

According to MDR, medical devices can be classified into four risk classes I, IIa, IIb, III with Class I representing the class with the lowest risk potential and Class III representing the class with the highest risk potential. The MDR provides the manufacturer with classification rules and the manufacturer should determine in which risk class the product must be classified. This classification depends on how the device is intended to be used and how long it interacts with the body and where, and whether it is an active product with an external energy source or an inactive medical device. Low-risk non-invasive devices such as bandages, reusable surgical instruments, manual stethoscopes, manual wheelchairs, corrective eyeglasses, hospital beds and thermometers are considered Class I medical devices. Low to moderate risk devices such as hearing aids, nasal sprays, dental crowns, catheters, infusion pumps, ultrasound systems and diagnostic software used for physical examinations are considered Class IIa medical devices. Moderate to high risk levels devices such as ventilators, infusion pumps, surgical lasers, intensive care monitoring/ultrasound equipment, vaginal creams, gels, and suppositories are considered Class IIb medical devices. Highest risk devices, such as life-sustaining or implantable devices (e.g. heart valves, defibrillators, breast implants, implantable pacemakers and joint replacements) are considered Class III medical devices. (Annette Rogge-Toehgiono, 2023; Regulation - 2017/745 - EN - Medical Device Regulation - EUR-LEX, 2021; De Lucca Caetano, 2024)

1.1.4. Types of medical device changes

Manufactures must comply with the EU MDR. This results in some mandatory processes and activities of the manufacturer. More specifically, in case of medical device changes related to design, features or

relevant harmonized standards and specifications, manufacturer must address them in order to maintain conformity to the requirements of the EU MDR. This is being done by implementing and maintaining relevant procedures which are considered mandatory and they should be maintained throughout the whole life cycle of the product. These procedures can include continuous update of clinical evaluation, continuous risk management, the establishment and maintenance of a QMS, application for a conformity assessment procedure from a Notified Body. (Annette Rogge-Toehgiono, 2023; Regulation - 2017/745 - EN - Medical Device Regulation - EUR-LEX, 2021)

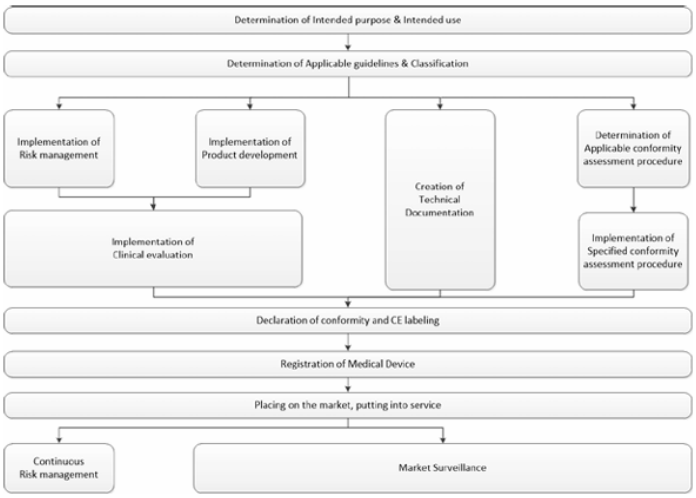

Figure 1: Life cycle of a medical device (Annette Rogge-Toehgiono, 2023, p.29)

The EU MDR outlines the concept of “substantial changes” concerning modifications to a device's quality system or device range changes that must be reported to a Notified Body during the post-certification phase. Guidance on determining whether a change qualifies as "significant" is provided in MDCG 2020-3, which uses a serious of flowcharts to guide manufacturers in decision-making. The guidance was revised in May 2023 to include additional examples and details. A change is deemed non-significant only if all questions in the relevant flowcharts result in a determination of "non-significant change."

Overview of Change Types:

The initial focus is on changes related to corrective actions. If a corrective action has already been reviewed and approved by the competent authority, the change is not considered significant. For other corrective actions or unrelated changes, further assessment is required using flowchart questions concerning intended purpose and device design.

Key areas that necessitate deeper evaluation of change include:

- Intended purpose changes:

  The intended purpose refers to the manufacturer’s specified use for the device, covering indications, contraindications, intended user, intended patient population, and intended environment of use. Changes deemed significant include:

- Expanding the intended purpose (a reduction is not significant).
- Introducing a new user or patient population.
- Modifying the clinical application, such as change in anatomical site, change in delivery or clinical deployment method.

Labeling changes, such as updates to contraindications or warnings, must also be assessed to determine if they affect the intended use

- Device design and performance specifications changes

  - Alterations in operating principles.
  - Modifications that could impact safety or performance, affecting the device's benefit-risk balance.
  - Changes to built-in control mechanisms, energy sources, or alarm systems.

  All design changes, regardless of how they are implemented (e.g. hardware or software), should be carefully assessed.

- Software (embedded or standalone) changes, particularly if they include:

  - New or major updates to the operating system or any component, architecture, or database structure.
  - Algorithm modifications or replacement of user input with closed-loop algorithms.
  - New ways of presenting medical data, such as format, dimension, or measurement unit.
  - Any software change that may negatively affect the benefit/risk ratio of the device.
  - Changes affecting interoperability, adding new features or functionality or adding new user interface

  Non-significant changes may include bug fixes (for errors that do not pose a safety risk), cybersecurity updates or enhancements that do not affect safety, usability or performance. Most software changes are viewed as significant. However, software evolves rapidly, so manufacturers must be extremely cautious to avoid significant changes during transitional periods.

- Materials (of any nature) or substance changes

  - Addition of new or change to materials of human or animal origin.
  - Modifications to medicinal substances or their excipients.
  - Changes to materials or substances in contact with the patient's tissue or fluids for extended periods (more than 30 days) or that are part of surgically invasive, absorbable devices.
  - Changes that affects safety or performance and negatively affects the benefit/risk ratio of the device.

  Material substitutions within the same specifications are typically not significant unless they alter the device's benefit-risk profile.

- Sterilization changes, including packaging design that impacts sterility

- Switching terminal sterilization methods (e.g., ETO to Gamma but also from non-sterile to sterile)
- Alterations that compromise sterility assurance levels (per the corresponding international standards)
- Packaging changes impacting sterility or microbiological stability including seal integrity
- Shelf-life extensions not validated through approved by the Notified Body protocols

Additionally, changes to storage or transportation conditions that could affect sterility or stability of sterile device should also be considered significant.

By the MDCG 2020-3 flowcharts, manufacturers can systematically evaluate whether changes to a device or system require notification to a Notified Body, ensuring regulatory compliance and maintaining patient safety. (Lacalle, 2024)

1.1.5. Initiation of medical device changes

A QMS and a PMS system are required to be implemented by all medical device manufacturers. These systems should be tailored to the risk class and specific type of the device, ensuring that products manufactured in series remain compliant with the EU MDR requirements. Additionally, these systems must account for feedback and experiences from the use of their devices to refine and improve production processes. To reduce risks and prevent incidents associated with their devices, manufacturers must also establish robust risk management systems and procedures for incidents reporting and field safety corrective actions.

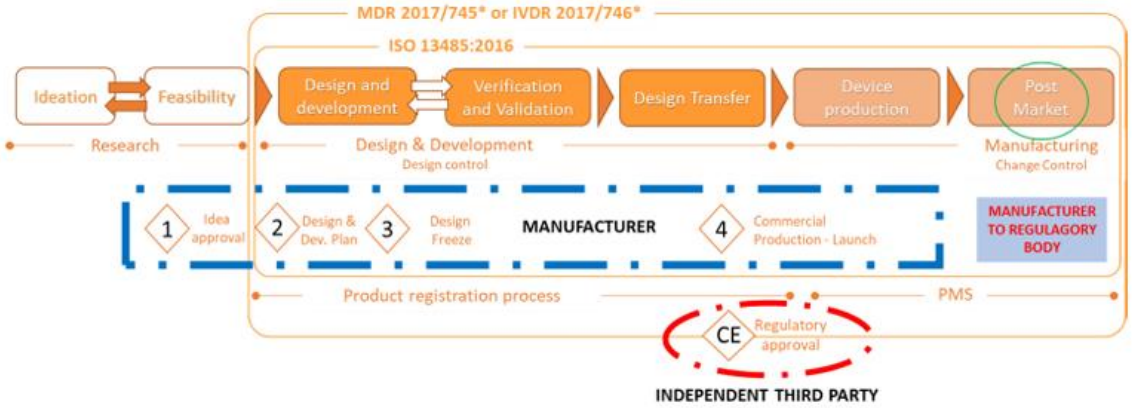

Figure 2: Medical device process-from idea to market (Badnjević et al., 2022)

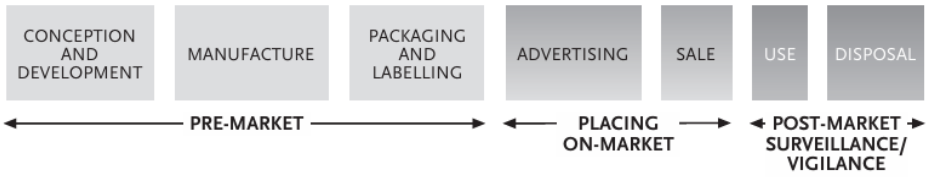

Figure 3: Common stages of government regulations (World Health Organization, 2003b)

A field safety corrective action refers to the steps taken by a manufacturer, for technical or medical reasons, to mitigate or prevent the risk of serious adverse events related to a medical device already available on the market. (Regulation - 2017/745 - EN - Medical Device Regulation - EUR-LEX, 2021; Field Safety Notice | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control))

A field safety corrective action (FSCA) can be:

- Return of device to supplier (recall)
- Device modification (including changes made to labelling and IFU)
- Device exchange (swap-up)
- Device destruction
- Retrofit by purchaser of device according to manufacturer modification/design control

(Safety Information for Medical Devices Including in Vitro Diagnostics , WHO)

In urgent cases, manufacturers should undertake the FSCA immediately. In non-urgent cases, manufacturers are required to report FSCA without undue delay, in advance of the FSCA being undertaken. The communication to customers or users regarding such actions is known as FSN. This safety notice must provide clear and transparent information about the rationale for the corrective action issued, referring to the device's malfunction and its potential risks to patients, users, or others. It should also outline, without minimizing the severity of the risk, the recommended action(s) recipients need to take. Where appropriate, it should include the likelihood of occurrence taking into account the intended audience and provide timeframes by which the action(s) should be taken by the manufacturer and user(s). (Regulation - 2017/745 - EN - Medical Device Regulation - EUR-LEX, 2021; Field Safety Notice | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control))

Users involved in the innovative process can be medical professionals (general practitioners, specialists e.g. surgeons, anesthetists, allied health professionals (e.g. nurses), professional societies), patients (individual patients, patient organizations), family members, caregivers, academic researchers, biomedical engineers, medical students, biomedical engineering student. Other stakeholders are manufacturers, vendors/distributors, international regulators, national/domestic regulators, health ministry. (World Health Organization, 2010)

As a result, prompt dissemination and implementation of recommendations in any medical device safety notice or FSCA is one of the implications of the new EU Regulations for individual user and healthcare institutions. (Fraser et al., 2020)

According to EOF, FSN or in Greek the "Ενημερωτική Επιστολή Ειδοποίησης Ασφαλείας" should be sent to all customers in Greek language. The FSN should include a response form which should be signed by customers to acknowledge that they have received and accept the attached FSN letter. The FSN or the customer response form must be returned signed by the customer to the manufacturer. (EOF, 2010)

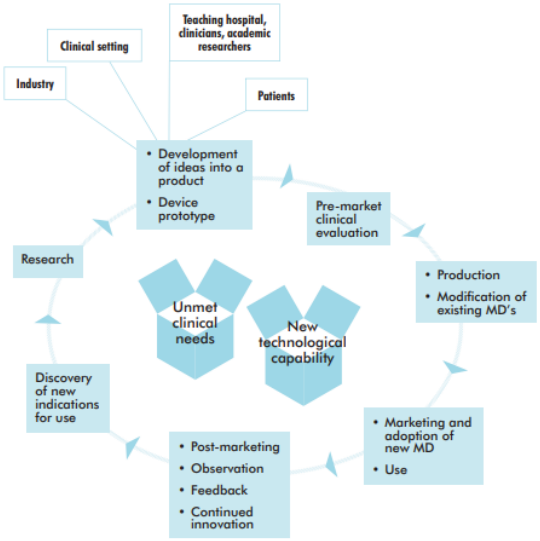

Figure 4: Dynamics of medical device innovation (World Health Organization, 2010)

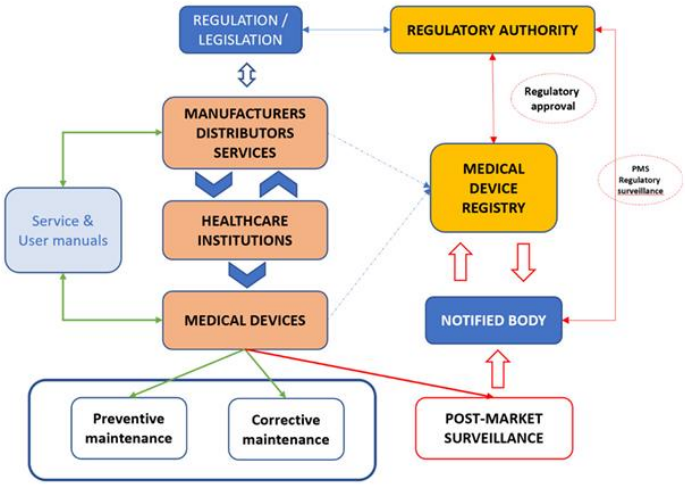

Figure 5: White-space for standardization and harmonization of PMS framework (Badnjević et al., 2022)

According to WHO the ideal conditions that will ensure the safety and performance of medical devices require shared responsibility by all stakeholders. This cooperation is presented in the image below. More specifically, the circle formed by the stakeholders illustrates the shared responsibility, the diamond handshake symbolizes cooperation and two-way communication (2-way arrow) and the star highlights how the fundamental elements for cooperation function best when all stakeholders communicate with each other. (World Health Organization, 2003b)

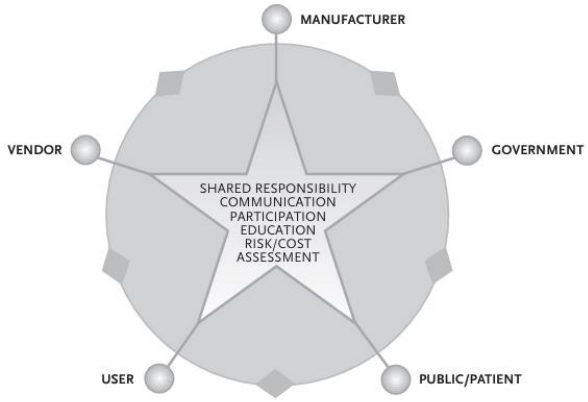

Figure 6: Ideal conditions for ensuring the safety and performance of medical devices (World Health Organization, 2003b)

1.2. The role of adaptation management

In this subchapter the overview of adaptation management of changes will be presented by exploring the different adaptation types, approaches and steps. Also, the criteria of successful adaptation will be defined and the relevant challenges in adaptation will be explored.

1.2.1. Defining adaptation

Adaptation is often explored through three key perspectives: as a process, a product, and an act of reception.

- Adaptation as a process refers to how one or more entities are adjusted or reconfigured through their interaction with or relationship to other texts or objects. This may involve necessary omissions, additions or modifications.
- Adaptation as a product represents the outcome of that interaction as the resulting entity or synthesis of multiple elements. This could be a compositional blend of features, altered habits or shifts in personal traits and identity due to environmental changes.
- Adaptation as an act of reception focuses on how audiences interpret or engage with the work, shaping their enjoyment and understanding. From this perspective, interpretations vary based on individual backgrounds, while a community might differently assimilate or resist a new cultural member.

This tripartite framework has informed the traditional and contemporary understanding of adaptation, revealing how the concept itself continually evolves by redefining prior definitions. (The Oxford Handbook of Adaptation Studies, 2017)

1.2.2. Types of adaptation

Adaptation can be anticipatory (respond to expected changes/ ex-ante) or reactive (respond to unexpected changes/ ex-post). Anticipatory measures aim to reduce risk and promote resilience before

an issue strikes, have significant benefits over reactive measures, both in terms of ensuring patient safety and reduction in economic costs. Reactive adaptation has an important role to play, particularly in decisions with short lead-times and short lifetimes. Facilitating reactive adaptation is particularly important in allowing the ecosystems to adapt naturally to changes. While both ex-ante and ex-post measures are required, economic analysis provide evidence that by investing in ex-ante measures, the costs of impacts and ex-post measures can be significantly reduced. Adaptation plans should however also recognize and promote autonomous (individual) adaptation. At a public policy level, this can be done by raising awareness and providing information, setting in place appropriate regulatory frameworks and financial incentives. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

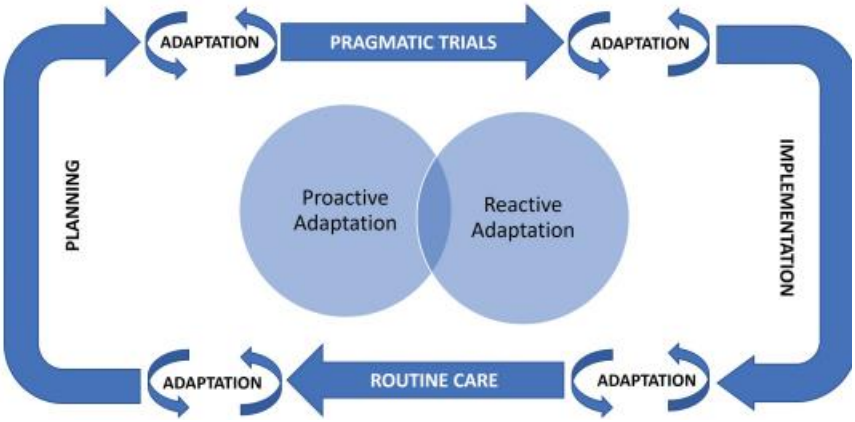

Figure 7: Adaptive implementation research mode (Bender et al., 2023)

There are two different types of approaches for adapting business processes to ensure compliance in case changes are made to process activities or process flows. On the one hand, there are approaches aimed at ensuring compliance within business processes by removing or reordering flow elements, such as gateways or activities. On the other hand, there are approaches aimed at modelling and storing compliant process fragments separately from the business process model. Each compliant process fragment serves to fulfil a compliance requirement. The fragments can be integrated into the business process either at design time or during run time. The separate modelling and storage of fragments offers the possibility for reuse in different business process models. Adaptation planning therefore requires a series of processes and tools aimed at supporting decision-makers in both private and public sectors in developing adaptation strategies in ways that manage time-evolving, spatially heterogeneous and highly uncertain risks (Seyffarth & Kuehnel, 2020)

1.2.3. Adaptation approaches

Based on the Fourth Assessment Report (AR4) of the Intergovernmental Panel on Climate Change, there are four main approaches to adaptation that are becoming incorporated into mainstream decision-making: Impact-based, Adaptation-based, Vulnerability-based and Risk-management approaches.

1. Impact-based approaches focus on evaluating anticipated impacts of change and identifying adaptation strategies to minimize resulting vulnerabilities.
2. Adaptation-based and Vulnerability-based approaches prioritize understanding the processes that influence vulnerability and adaptive capacity, typically without relying on specific future predictions. These methods aim to enhance the resilience or robustness of a system to a wide range of changes, making them less sensitive to uncertainties.
3. Risk-management approaches emphasize decision-making and provide a framework for integrating various adaptation methods while addressing uncertainties directly.

The Impact-based approach follows a science-first model, taking a linear process of prediction followed by action. It begins with producing change projections and concludes by assessing both economic and non-economic effects of different adaptation strategies. In contrast, adaptation-based, vulnerability-based and risk-management approaches exemplify policy-first processes. These processes typically start by defining the scale of the adaptation challenge, setting clear objectives and constraints, and identifying potential adaptation strategies. Only after these steps are complete are the strategies evaluated for their suitability based on established objectives and future projections. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

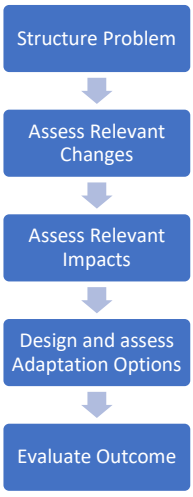

Figure 8: Science-first approach (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

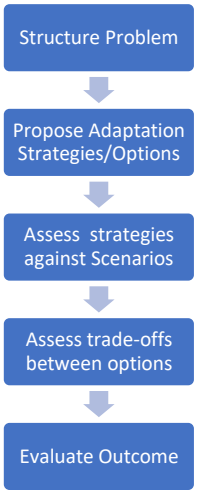

Figure 9: Policy-first approach (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

The key distinction between science-first and policy-first approaches lies in the sequence of their analytical steps. More specifically, in a science-first approach, the detailed risk analysis comes before the adaptation options identification which could lead to identification of missing information and as a result the analysis should be repeated. So, from practical point of view, policy-first approach is better the overall efficiency of the process as this could be avoided.

Also, the science-first approach is also far more vulnerable to growing uncertainties. As the analysis progresses the range of potential impacts and corresponding adaptation responses can expand to the point of becoming unmanageable. This approach relies heavily on impact models to produce precise, high-quality data that can inform adaptation planning. However, decisions often depend on optimizing outcomes based on subjective probability distributions. Under conditions of ambiguity, this can result in solutions that are overly sensitive to incomplete sampling of plausible scenarios and secondary uncertainties in estimating the likelihood of different outcomes.

On the other hand, policy-first approach can constrain the explosion of uncertainty by identifying the inputs that is important to the decision e.g. the benefits of adaptation options that are both feasible and appropriate given the objectives and constraints and focusing on the adaptation assessment. By beginning with a careful analysis of feasible adaptation options and their characteristics, it is possible to identify much more accurately what kind of information will be useful for deciding between these options. Only then it becomes necessary to consult detailed quantitative predictions. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

ISO 13485:2016 requires the application of a risk based approach to the control of the appropriate processes needed for the quality management system of the organization (ISO 13485:2016, 4.1.2). It also limits application of risk to the safety or performance requirements of the medical device or meeting applicable regulatory requirements (ISO 13485:2016, 0.2). Risk is considered the combination of the probability of occurrence of harm and the severity of that harm (ISO 13485:2016, 3.17) and its management is the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk (ISO 13485:2016, 3.18). The significance of a design and development change is determined during the evaluation of the change effect which should be made on products in process and on the outputs of risk management and product realization processes (ISO 13485:2016, 7.3.9). Last but not least, feedback from production and post-production activities should be utilized in risk management processes in order to monitor and maintain product requirements. (ISO 13485:2016, 8.2.1).

1.2.4. Steps of adaptation management

The comprehensive decision making framework put forward by UK Climate Impacts Programme (UKCIP), the Department for Environment, Food and Rural Affairs (Defra) and the Environment Agency (EA) in 2003 and extended by the Grantham Research Institute on Climate Change and the Environment and the Centre for Climate Change Economics and Policy on adaptation planning by providing up to-date, comprehensive and pragmatic guidance on approaches to decision-making under deep uncertainty is an example of a risk-management approach that does emphasize the efficiency gains possible through identifying relevant high value information, interpreting uncertain projections and selecting appropriate decision-making methods. The process involves five steps that are grouped into two stages: The planning stage which consists of (i) structuring the problem and (ii) appraising solutions and the implementation stage which is referring to (iii) implementation which can lead to routinization/institutionalization. This framework emphasizes that adaptation is not a one-off but an iterative process involving planning, implementation and review. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1.2.4.1. Planning stage

(i). Structuring the problem

Structuring the problem is a crucial first step in any decision making process. It sets the context and allows a decision-maker to identify sensitivities in the decision and choose appropriate approaches to appraise options and come to a decision. There are three steps (not necessarily independent) for structuring the problem: define adaptation objectives and constraints, assess current vulnerability and identify potential future sensitivities, define and characterize adaptation options. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

(i)a. Defining adaptation objectives and constraints

The first step in any decision analysis is to define the relevant objectives and constraints. This process often begins by identifying key stakeholders and understanding their concerns. To make well-informed decisions, it's essential to assess risks and options based on their impact on a set of objectives. These objectives are not necessarily adaptation-specific and in fact using broader objectives such as broader risk or resource management objectives, can be useful in helping to mainstream adaptation into organizational decision making. Setting and prioritizing adaptation objectives will be a complex process, particularly for national adaptation policy decisions. For example, there may be difficult trade-offs to make between adaptation relevant objectives and also between adaptation and other priorities. Addressing these challenges requires extensive engagement and negotiation among stakeholders, including collaboration within government departments and between government, the private sector, and the public. While these challenges are not new, established principles for managing risks such as openness and transparency, involvement, proportionality and consistency, evidence and responsibility can help guide the process. At this stage, it is equally important to identify all relevant constraints that could limit action, such as economic, political, geographical, or environmental factors. For instance, a budgetary cap or a regulatory requirement may serve as a constraint. Identifying these limitations early ensures that resources are used efficiently, as adaptation options that do not meet these constraints can be ruled out from the outset. Summary of decision factors relevant to these steps: economic constraints (budget, economic performance targets, competitiveness), socio-political constraints (regulatory, political, social, geographical, environmental), decision criteria (metrics of performance), weighting factors (treatment of temporal aggregation, treatment of disruptive effects, risk and ambiguity aversion, treatment of non-monetary impacts). (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

$(i)_b$. Assessing current vulnerability and identifying potential future sensitivities

Understanding current vulnerability is a vital step in making informed adaptation decisions. This process helps decision-makers evaluate the system's capacity to adapt, anticipate future risks, and identify actions that can deliver benefits regardless of uncertainties ("no-regrets" options). It starts with analyzing how the system has been affected in the past and identifying pathways through which risks may cause harm. Key thresholds, such as design risk standards, are especially important since exceeding them can significantly increase impacts. Additionally, looking at past vulnerabilities can offer valuable insights into

what might make the system sensitive in the future. Next step is assessing potential future sensitivities to future changes. This involves scanning for potential risks (vulnerability) and gathering general information about the scale and scope of possible changes, whether they are immediately relevant or not. By combining this forward-looking perspective with an understanding of past and present vulnerabilities, decision-makers can create a clear picture of where the system may face adaptation challenges in the future. This helps them pinpoint areas where adaptation is most needed and identify practical solutions that can effectively mitigate future impacts. Summary of decision factors relevant to these steps: current vulnerability (current susceptibility to environment, autonomous adaptive capacity, potential sensitivities e.g. thresholds, interdependencies with other sectors, economy & population), related risk drivers (range of direct and indirect impacts (shocks vs stresses), scale of expected changes, scale of uncertainties (including adequacy of models), irreversibility of impacts, distribution of impacts (by location, income, etc.), non related-risk drivers (including adequacy of models), irreversibility of impacts, distribution of impacts (by location, income, etc.). (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

$(i)_c$. Defining and characterizing adaptation options

With the information gathered about objectives, constraints, and the range of plausible impacts, the next step is to identify viable and effective adaptation options. "Feasible" refers to options that are technically feasible and suitable for the specific context, while "appropriate" means they align with established objectives, work within constraints, and successfully reduce current and future vulnerabilities. Breaking the analysis into key categories can make this process more structured:

- Type: By whom the implementation of the solution is done, kind of action (anticipatory or reactive)
- Outcomes: Cost and benefits under different scenarios, potential solutions and how they interact with each other (substitutes or complements, co-benefits, trade-offs)
- Temporal Characteristics: Time dependence of costs and benefits, project lead-time and life time, flexibility (sunk-costs, irreversibility, lock-in)
- Distributive Characteristics: Distribution of costs and benefits (who pays, who benefits) across society (e.g. income, ethnicity, age)
- Uncertainty: Risks associated with adaptation option, ability to cope with potential future scenarios or extreme events

An essential part of evaluating these options is distinguishing “no-regrets” solutions that deliver benefits regardless of future uncertainties from measures that are more sensitive to changing conditions or assumptions. Most situations provide a variety of "no-regrets" options, which can either complement or substitute other types of options. Genuinely "inflexible" options where decisions carry a high risk of regret are relatively rare. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1.2.4.2. Planning stage

(ii). Appraising solutions

By the end of the previous stage, the decision maker(s) should have developed a comprehensive understanding of the adaptation challenge. This includes identifying objectives and constraints, the key current and future risk factors, system sensitivities requiring adaptation, and the range of feasible and desirable adaptation options. The next step involves conducting a more specific assessment, qualitative, quantitative, or a mix of both, to evaluate these options, choose, prioritize them based on earlier decision criteria, and consider how they might be sequenced over time. This deeper analysis isn't always necessary. In cases where the problem-structuring phase identifies clear solutions such as when there is a well-defined single objective, there are few options to consider, and these options are "no-regrets". Additional analysis may be minimal or even unnecessary. Such situations might allow for quick evaluations using basic qualitative insights or rough quantitative estimates. However, detailed assessments become critical when the choice between options is more subtle, depends heavily on uncertain assumptions (e.g., future conditions), or involves significant trade-offs between competing objectives. This complexity is common in public or large private sector contexts, especially when planning long-term projects with substantial upfront investments or developing strategic, sector-wide plans and regulations. A structured decision-making process helps pinpoint where detailed analysis is essential and guides the selection of the appropriate tools for that analysis. At the outset of this stage, decision-makers must consider whether additional assessments will meaningfully enhance the decision-making process. Regardless of the level of detail, transparency is vital throughout the planning process. This includes clearly documenting assumptions, analyzing their sensitivity, and providing robust qualitative and quantitative evidence to support conclusions. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

$(ii)_a$. Assess individual adaptation options

The goal of this step is to create a clear set of metrics that can be used to compare and rank the adaptation options. The level of detail of this analysis will depend on the specific context and data available as well as how much value the additional analysis adds to making an improved decision making. These measures/metrics computed should be linked to the objectives and the chosen decision making approach. For instance, where economic criteria are important, decision-makers might evaluate options based on their costs and benefits over time under different change scenarios. Alternatively, metrics could focus on other factors such as risk levels, equity impacts, or effects on non-monetary environmental concerns. The sensitivity of these metrics to underlying assumptions should be tested in order to ensure that the evaluation accounts for different perspectives and uncertainties. For example, how would varying assumptions about the valuation of ecosystems affect the relevant metrics? The outcome of this step should be a comprehensive set of metrics that clearly describe the performance of each adaptation option. These metrics can then be directly integrated into a structured decision analysis framework. In some cases, detailed quantitative analysis of the scale and likelihood of risks may be required in order to evaluate the effectiveness of options. Where there is high sensitivity of decisions to risk, it is crucial to identify projections that are both trustworthy and tailored to the specific decision context. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

(ii)$_b$. Decision analysis to generate implementation plan

In this step, decision-making methods are applied to rank the effectiveness of options in the context of the combined objectives of adaptation. This involves objectively assessing outcomes across multiple criteria while accounting for uncertainty. From this, decision-makers can develop actionable plans (one or several 'best' options), specifying which options to implement, where, and when. Decision analysis usually take as inputs information about the risks and opportunities and available options, then applies structured methods to generate recommendations that adhere to consistency and rationality principles. This process builds on the metrics calculated earlier, ranking the options using a chosen decision-making framework. The recommendations that emerge from a good decision analysis need not be a simple 'pick option A' but could instead provide conditional strategies, such as: "If X happens by date Y, then implement Z." Flexible options or those with varying lifetimes and effectiveness are particularly suited to such conditional planning. The grading of different options can be sensitive to the choice of decision method. For this reason, it's essential to assess how the final adaptation plan depends on the assumptions made during analysis and it is vital to assess how the adaptation plan generated depends on the underlying assumptions of the analysis and choice of decision method. For example, a cost-benefit analysis should include sensitivity testing to understand how ranking of adaptation options might shift based on variables like the magnitude and likelihood of future impacts. If the ranking of options is highly sensitive to assumptions that are uncertain or likely to change, alternative decision methods may be required. These methods could prioritize options that offer greater flexibility or are less sensitive to known unknowns (uncertainties). Robustness checks are a critical part of this process, ensuring that decisions remain reliable even when certain assumptions are violated. Such checks might involve revisiting earlier steps like the appraisal of adaptation options and iterating the analysis to refine outcomes. This iterative approach helps to ensure that the final recommendations are both practical and resilient to the complexities of uncertainty. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1.2.4.3. Implementation stage

(iii)a. Implement Plans

The implementation of plans is the initial realization of the adapted process innovation. The implementation of plans demands some adjustments. The sustainable functioning of new (emerging) processes can be achieved by context adaptation. What makes an innovation accepted is not only its evidence of benefits but the adaptation effort that should be done according to norms and rules of the organizational context. Context adaptation is a series of actions to make the fit between process innovation and the system and reveals in three forms of technical adaptation (a combination of information and technological tools), cultural adaptation (human resources) and strategic adaptation (organizational change management). Also, there are several factors which influence the execution of processes. Change determinants are facilitating or even complicating the regular running of the adaptation process. Context change determinants can be change enablers and changes inhibitors. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1. Context Adaptation

- *Technical adaptation*

  Integrated intra-organizational information systems enable the different units of an organization to communicate and collaborate in the process change project or process execution. Technical modification can be manifested through data privacy consideration, clinical needs/preferences consideration, end-user needs/preferences consideration, acceptance, process consideration, simplifying bureaucratic/administrative and legal processes by platform, using new technologies (evolution of IT tools), securing electronic exchanges and digitalization of all or part of the process. (Khodadad-Saryazdi, 2021)

- *Strategic adaptation*

  This process takes into account the interest for institution, interest for medical staff, interest for patients and interest achievement policy. Strategic adaptation is ensuring that innovation is aligned with organizational interests, goals and values and that these are aligned with the innovation as well. In the monitoring and improving of this process, the contribution of users by providing feedback is playing an important role. Staff engagement and involvement is increasing the successful adoption and sustainability of innovations. On the contrary to top down decisions, the collective bottom up decisions can be more effective as members have a sense of ownership which lead to sustainability. This is happening when innovations are adapted to fit organization and its employees so stakeholders are more likely to embrace and sustain changes. Strategic alignment in the implementation stage is crucial for avoiding resistance from healthcare professionals, non-cooperation of managers and, ultimately, rejection and non-sustainability of the new practices. Many implementation failures stem from the inability to integrate new changes, technologies or processes into the healthcare organization's strategy and business model. This can be avoided by emphasizing strategic alignment and staff involvement. In this way, organizations can ensure the successful and lasting adoption of changes. (Khodadad-Saryazdi, 2021)

- *Cultural adaptation*

  Culture adaptation includes all activities designed to facilitate the adoption of new processes by engaging the members involved or affected by the process change. It leverages the skills and expertise of the organization's human capital and its broader ecosystem to develop and sustain improved processes that enhance overall performance. Certain activities organized to manage this change are staff awareness, communication, staff consensus, commitment, attribution of responsibility, training, incitation, persuasion, staff integration, assignment of roles, coordination, and motivation. The success of process innovation relies heavily on the contributions of key human resources, including the director and their team, the personnel directly involved with the new processes, and the change project's champion. The director plays a pivotal role in driving progress toward the desired outcomes, whether acting as a leader, communicator, or decision-maker. A lack of management support, whether financial or strategic, is a primary reason for the failure of process transformation initiatives, particularly those driven from the bottom up. Providing staff a clear vision of the process change can motivate and foster active engagement and participation. By involving employees from the beginning of a project in setting objectives, designing processes, making decisions and recognizing the project's benefits can greatly enhance

their motivation and commitment. Moreover, implementing process change is very complex which requires coordinated efforts, contextual understanding and adaptive knowledge that often cannot be fully outlined in a predefined process model. Collaboration and open communication are therefore critical for discovering, exploring and sharing of process-related knowledge while connecting stakeholders to the change efforts and fostering acceptance of the transformation. Leaders play a vital role in fostering collaboration by building trust, articulating a clear purpose and inspiring energy and enthusiasm among all participants. However, process reform can also emerge from a bottom-up approach initiated by an individual or a small group of motivated individuals are in favor of the change. These individuals are known as "Champions" and act as catalysts for transformation. They work to gain support from directors, management teams and other members of the organization while ensuring the effective execution of the processes or projects involved. (Khodadad-Saryazdi, 2021)

2. Context change determinants:

Change enablers and inhibitors encompass the determining role of process actors and their beliefs, information technology and systems, promoting activities, as well as limits and restrictive rules and obligations.

- *Change enablers/agents/angels*

  Change enablers arises from administrative body cooperation, management support activities, participation and engagement of health staff, collaboration among health professionals, collaboration among leaders of health institutions and IT specialists, the efficiency of IT systems, the effectiveness of ISD, the involvement of champions, clear process definitions, feedback mechanisms, patient-centered support activities, positive attitudes and interests and spirit of initiative. The department heads are the real agents of change and the promoters of implementation, however, the two bodies, medical and administrative of the hospital must cooperate to succeed in process innovation. Department heads are pivotal change agents and key drivers of implementation. However, the success of process innovation requires close collaboration between the hospital's medical and administrative teams. General Manager acts as a crucial link between medical/technical and administrative staff forming the success chain. Champions are those who act as advocates, who recognize the value of innovations, securing cooperation from the hospital's administrative team. By fostering collaboration and communicating the benefits of new processes, champions help engage staff members who might otherwise remain less involved. (Khodadad-Saryazdi, 2021)

- *Change inhibitors*

  Change inhibitors arises from supply burden, administrative burdens, evaluation burden, work habit change, financial limits, staff overloading, negative belief or no interest. (Khodadad-Saryazdi, 2021)

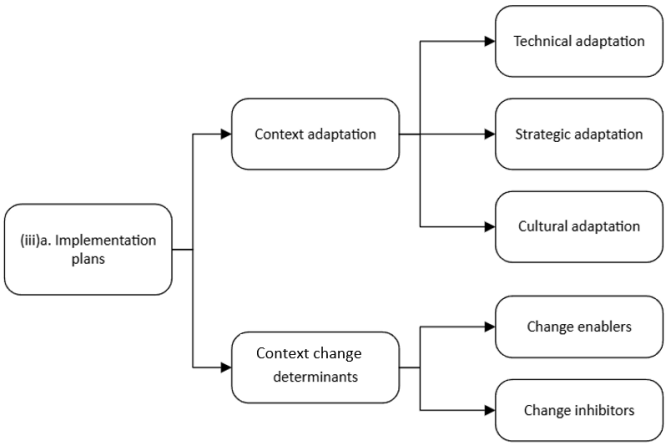

Figure 10: Implementation of plans (Khodadad-Saryazdi, 2021)

$(iii)_b$. Monitor, Evaluate and Review adaptation plans

It is essential to monitor, evaluate and periodically review the performance of implementation plans to ensure that they remain effective and relevant. Adaptation is an iterative process of planning, implementation and review (see below the arrow from (iii)b to (ii)a and (i)b) . The frequency of these reviews should be determined by the nature of the decision but must be planned and conducted on a regular basis. Reviews may also be initiated by specific triggers, such as new observations, updated information or changes in adaptation objectives and constraints. Adaptation plans that include flexibility, in regards to sequencing of actions or the ability to adjust measures, should be designed to respond to new information. For instance, the detection of a particular level of impact might prompt the activation of a specific adaptation measure. Additionally, the broader context of the adaptation challenge may shift over time, necessitating responsive strategies. This could include adjustments in objectives or constraints, such as a heightened risk aversion or increased valuation of ecosystems as well as the adoption of new and more effective adaptation options as they emerge. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

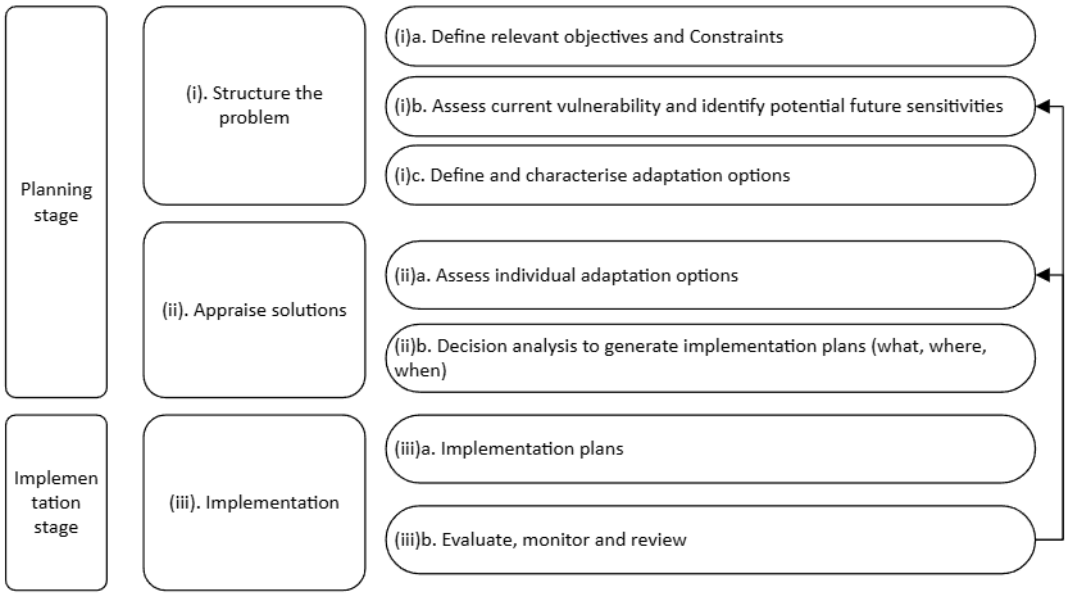

Figure 11: Generic framework for adaptation decision-making (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1.2.4.4. Routinization/institutionalization of process innovation/change

When implementation becomes fully integrated into the organization's regular/routine activities, the implementation of change/innovation ends. So, the innovation transitions into a sustainable practice, contingent on factors such as the organization's context, capacity and internal processes, as well as the introduction of new programs or practices (Khodadad-Saryazdi, 2021). Institutionalization occurs when the change becomes a stable part of employees' behavior (Pasmore & Woodman, 2007). The development of routine is based on the action-specific knowledge acquired as part of the stability of the decision problem and repetition of the action which leads to an improvement in the results and at the same time it reduces the need for planning. According to Kesting, different types of routine change (routinization, adaptation, problem fixing and revision) with different characteristics have been identified and deliberate routine exchange. Some takes place against the background of an unaltered decision problem while other are reactions to changes in the decision problem. Moreover, the drivers, the tasks, and central challenges as well as the responsibilities of change differ. Some key aspects of this distinction are summarized in Figure 12 (Kesting, 2023). Once solutions have been developed for different configurations, acts can routinely be adapted to different parameters. In consequence, also the decisions for appropriate configurations can be routinized and be turned into "routine decisions". (Kesting, 2023)

Change type	Routinization	Adaptation	Problem fixing	Revision
Characterization	Learning by doing, increasing replication	Routine decisions, adaptation of solutions	Development of new solutions to bring about an unchanged intention	Formulation of a new intention; development of new solutions
Decision problem	Unaltered	Extended	Unchanged intention, but changed context	Changed intention and/or changed context
Key drivers	Feedback, learning	Comprehensive knowledge	Decision making to enable continuation	Decision making to disrupt continuation
Tasks and key challenges	Feedback, improvement of solutions, development of new solutions	Appropriate configuration of complex routines	Planning, finding new solutions	Planning, finding, and development of new solutions, resistance, status quo biases, lack of reflection, planning effort, inefficiency, uncertainty
Responsibility	Transferred from management to operational levels in the course of the routinization	Primarily operational	Depending on the severity of the problem	Management

Figure 12: Overview of the four types of routine (ex)change (Kesting, 2023)

1.2.5. Defining success in adaptation

An essential outcome of stakeholder engagement is establishing a clear understanding of what constitutes "successful" adaptation and translating this understanding into quantifiable and measurable criteria. These criteria for success serve as a foundation for appraising adaptation options. (Adger et al., 2005)

Criteria for success

Adaptation actions are driven by a variety of objectives, but defining success solely as the achievement of these objectives is insufficient for two key reasons. Firstly, because of temporal and spatial trade-offs. More specifically, an action that appears successful in achieving short-term goals may have unintended consequences at larger spatial or temporal scales. For instance, while an action may address immediate risks, its long-term sustainability or broader impact might be less favorable. Secondly, because of externalities and spillovers. More specifically, an action may be effective for the entity implementing it (the adapting agent) but could inadvertently produce negative consequences for others. This might include increasing risks or reducing the capacity of others to adapt, thereby creating inequities or conflicts. The broader definition of success includes spatial and temporal considerations and should not simply be assessed in terms of the stated objectives of individual stakeholders. Key aspects to consider include issues of governance (the processes and structures in place to manage adaptation actions) and the wider effectiveness of adaptation which can be assessed through reference to the equity by ensuring fair distribution of benefits and burdens across different groups and regions, the legitimacy (extent to which actions are perceived as justifiable, inclusive, and acceptable) and the economic efficiency of adaptation by balancing the costs of adaptation with the benefits achieved. Adaptation to change, therefore, can be evaluated through broader principles of policy evaluation seeking to promote actions that are equitable, effective, efficient and legitimate while supporting wider sustainability goals. It is important to recognize that these criteria of efficiency (optimal use of resources to maximize benefits), effectiveness (the ability to achieve desired objectives), equity (fair and just distribution of outcomes) and legitimacy (alignment with societal values and inclusion in decision-making processes) are context-specific and influenced by

competing values. The relative importance attached to each criterion can vary significantly between countries based on cultural, economic and governance systems. It can also varies between sectors within countries depending on specific industry needs and priorities and over time as societal attitudes, expectations, and environmental conditions change. Furthermore, the relative weight placed on these values varies between actors engaged in adaptation processes. Different actors will prioritize these criteria based on their perspectives, responsibilities and worldviews. In order to foster cohesive and sustainable adaptation efforts, balance of these varied priorities is essential. Conflicts over resource allocation, for adaptation and other purposes, often highlight differing views on progress, reflecting a core challenge in development. Private-sector decisions are frequently guided by economic efficiency, particularly when outcomes are evaluated through metrics like stock market performance. Public-sector decision-making is often driven by the pursuit of economic efficiency, focusing on objectives such as delivering "best value." However, considerations like distributional impacts and the legitimacy of decisions play also a significant role. The weight assigned to various decision criteria often depends on how responsibility is perceived and defined. A public-sector agency, for example, might overlook the environmental or developmental impacts of an action by externalizing these effects, essentially categorizing them as "someone else's problem." The geographic and societal scale at which an action is evaluated also shapes how different criteria are prioritized. (Adger et al., 2005)

1.2.5.1. Effectiveness of adaptation measures

Effectiveness relates an adaptation action's ability to achieve its expressed objectives. It can be evaluated in terms of reducing impacts and exposure to them or reducing risk, avoiding danger and promoting safety and security. While the effectiveness of some adaptation measures can be directly measured, in many cases it is more complex and depends on the sequence and interaction of multiple adaptations over time. For example, in public health, the impacts of interventions aimed at mitigating risks from extreme situations can be estimated using established methods. These include assessing avoided burdens or projecting cases based associated to specific risks. However, estimating effectiveness is complicated by the complex causal chain of behavioral feedbacks which can make measuring the outcomes of public health interventions of individual actions challenging. There are challenges in measuring effectiveness of adaptation measures. Firstly, the performance of an adaptation measure under specific conditions may be uncertain, making its effectiveness harder to predict or evaluate (uncertainty in outcomes). Secondly, the success of an adaptation measure implemented by an organization often depends on the actions of other stakeholders (dependency on collaborative actions). For instance, measures that rely on individual adoption face significant variability and constraints, as evidenced by empirical studies. As a result, assessing the effectiveness of measures requiring individual participation can be particularly difficult. Thirdly, the effectiveness of an adaptation action often hinges on future uncertain conditions. The social and economic context, including shifting attitudes towards regulations can influence how well adaptation measures perform. Two key indicators of the effectiveness of an adaptation action are therefore robustness to uncertainty and flexibility or ability to change in response to altered circumstances. An effective adaptation action should perform well across a range of potential future scenarios even as conditions evolve (robustness to uncertainty) and the ability to adapt or modify a measure in response to changing circumstances enhances its long-term effectiveness (flexibility). Some measures are inherently more robust and less sensitive (adaptable) to changing conditions than others making them better suited to uncertain conditions. Fourthly, adaptation actions can have ripple effects that extend beyond their

immediate objectives. A measure that effectively reduces impacts or creates opportunities in one area or timeframe might inadvertently shift burdens "downstream" or reduce the ability of others to adapt (spatial and temporal impacts). Actions aimed at reducing exposure and sensitivity to hazards may disrupt other natural or social systems. For example, interventions targeting short-term objectives without considering long-term sustainability can strain ecological or social resilience. Evaluating the impact of adaptation actions involves navigating significant uncertainties. Some actions bring clear and immediate results but others may reveal their full effects over time as natural and social systems adjust (immediate vs long-term impacts). For novel or untested interventions, the outcomes may be unpredictable making it harder to identify their effectiveness in advance (innovative measures). The spatial and temporal scale of evaluation matters. Short-term or localized assessments may uncover broader or downstream effects that become evident over larger areas or longer periods (scale of assessment). Effective adaptation planning should take into consideration these complexities, striving for solutions that are both resilient to uncertainty and mindful of their broader implications. Adaptation measures, therefore, require careful evaluation, considering these complexities and uncertainties, to ensure that their intended objectives are met. (Adger et al., 2005)

1.2.5.2. Efficiency of adaptation measures

Adapting to change creates certain costs but at the same time can have substantial benefits. Considering an individual organization, these costs include implementation costs, transaction costs and costs from inaccurate predictions as well as benefits which include minimizing negative impacts or enhanced opportunities. However, effective adaptation, particularly from an economic perspective, extends well beyond a simple comparison of quantified costs and benefits. Evaluating economic efficiency of adaptation actions requires consideration of several factors. Firstly, it is essential to assess the distribution of costs of the actions as well as the benefits of the actions. Secondly, attention must be given to the impact of costs and benefits of changes in those goods that cannot be easily expressed in market values and finally the timing of adaptation actions. The issue of distribution of adaptation has two key dimensions. The balance between private and public costs and benefits and the regulatory framework that defines how widely the benefits are shared or experienced. Understanding these dimensions is vital for making informed and equitable adaptation decisions. Some aspects of adaptation to change function as public goods, such as conserving nationally or internationally significant habitats, preserving shared cultural heritage and safeguarding resources for future use. On the other hand, certain adaptation efforts are more aligned with private goods. For instance, if private industry firms invest in understanding risks associated with change, both the costs and benefits primarily remain within the private sector. Currently, government-led change planning largely focuses on delivering public goods. This includes generating scenario information, conducting publicly accessible risk assessments and running public awareness campaigns. Consequently, many existing response programs refrain from subsidizing private adaptation decisions. However, the distinction between public and private elements of adaptation is not static but it is shaped by the institutional and regulatory frameworks of different economic sectors. Further, these elements may shift between public and private spheres reflecting evolving needs and priorities. A critical consideration in evaluating the efficiency of adaptation relates to decisions about non-market benefits. Focusing solely on goods with market proxies such as property, human health, or economic productivity can significantly undervalue both the costs and benefits of adaptation. Government-led adaptation efforts often emphasize the broader public good, accounting for ecological and aesthetic impacts as well as non-

traded ecosystem goods and services rather than focusing solely on private market effects. The timing of the adaptation actions relative to the impacts of change significantly influences their perceived economic efficiency. For organizations or individuals with short planning horizons, e.g. less than a year, high capital turnover, and flexible systems, addressing short-term variability is often sufficient for an economically efficient response. In contrast, when planning horizons are long, capital investments have extended lifespans and systems cannot adapt quickly accounting for long-term changes becomes essential to avoid costly errors. Balancing the timing of adaptation measures with the nature and scale of potential impacts is therefore crucial to achieving economic efficiency. (Adger et al., 2005)

1.2.5.3. Equity and legitimacy of adaptation measures

The success of an adaptation is influenced not only by its effectiveness in achieving stated objectives but also by considerations of equity and the on perceived issues of equity and perceived legitimacy of the action. It is essential to recognize that today's adaptations to changing risks are shaped by past actions. This means that the starting point for adaptation is inherently suboptimal and inequitable, as the challenges we face are the result of decisions made by previous generations. The intergenerational nature of this issue underscores the need for thoughtful, inclusive approaches to adaptation that acknowledge and address these inherent disparities. Equitable adaptation can be assessed both by its outcomes (who benefits or is disadvantaged) and by how decisions about the adaptation are made. The distributional consequences of these decisions can vary widely, from the uneven spatial effects of change to the political and social consequences of those decisions. The fairness of decision-making processes is deeply influenced by the balance of power within institutions, responsible for managing resources, which often play a role in creating vulnerabilities. There are diverse principles of equity in outcome which are the desert (who is most deserving), equality or addressing specific needs. In the context of adaptation, ensuring equity means carefully evaluating who stands to benefit and who may bear the costs or burdens of an impact or adaptation policy. Recognizing and addressing these disparities is key to creating fair and sustainable solutions. Assessments of this nature often demonstrate that many present-day adaptation actions reinforce existing in equalities and do little to alleviate underlying vulnerabilities. Reactive adaptation in particular tends to exacerbate vulnerabilities (e.g. after impacts of extreme events). On the other hand, anticipatory adaptation actions seek to cushion the effects and facilitate recovery from impact (e.g. measures to improve the ability to respond to impacts). Assessments often reveal that many current adaptation efforts unintentionally reinforce existing inequalities and fail to address the root causes of vulnerability. Reactive measures frequently worsen these vulnerabilities. In contrast, proactive adaptation strategies aimed at mitigating the effects of change on vulnerable populations and enhancing their ability to recover can help reduce disparities. These forward-looking measures which strengthen communities' capacity to respond effectively to impacts have the potential to create more equitable outcomes and foster resilience. Efforts to reduce poverty and enhance resource access play a significant role in mitigating existing vulnerabilities while also addressing those arising from variability and change. Achieving equitable outcomes in adaptation measures depends on the legitimacy of decisions which is shaped by the fairness of decision-making processes and the balance of power that guides them. Prioritizing equity and legitimacy in these processes enhances the credibility and acceptance of adaptation efforts. Legitimacy refers to the extent to which decisions are accepted by both those involved in making them and those impacted by them. The evolution of adaptation strategies can either enhance or undermine this acceptance. Since cultural expectations and interpretations shape perceptions of legitimacy there are no

universal procedural rules that guarantee it. However, the social acceptability of the processes used to implement adaptation measures remains a critical factor. Legitimacy and trust also vary depending on the scale of action. While individuals may consent to adaptation strategies and policies implemented by their governments for the greater public good, they are often less inclined to recognize the legitimacy of actions taken by other countries to address their own adaptation goals. This emphasize the importance of fostering transparency and inclusivity at every level to build and maintain trust. In addition, the legitimacy of government adaptation decisions depends on the credibility of the information shaping public perception of risks of change and the trustworthiness of the policy instruments used to address them. Equity is critical for practical reasons such as inequitable development which undermines the potential for future welfare improvements while policies that lack legitimacy face challenges in gaining full implementation. Beyond their instrumental value, equity and legitimacy are also intrinsic goals. Fair public actions not only shape our relationship with the natural world but also form a cornerstone of long-term sustainability. Furthermore, equity influences how individuals respect and relate to different segments of society, fostering connections both locally and globally. In summary, both equity in outcomes and legitimacy in decision-making are fundamental to building resilience and ensuring the perceived success of adaptation efforts. (Adger et al., 2005)

1.2.5.4. Evaluating successful adaptation

Achieving successful adaptation requires balancing effectiveness, efficiency and equity within decision-making frameworks that foster learning and are perceived as legitimate. However, in practice, adaptation efforts often fall short of this ideal. A key idea emerging is that the sustainability of adaptation is closely tied to the varying adaptive capacities of different stakeholders. Interestingly, this contrasts with resource management theories which suggest that heterogeneity in capacity, benefits and objectives can hinder sustainable resource management. This divergence applies to both present and future adaptive capacities. Ultimately, the success and longevity of future adaptation efforts will hinge on how institutions evolve and how social and cultural attitudes shift in response to changing circumstances. Balancing the four success criteria (effectiveness, efficiency, equity and legitimacy) often involves trade-offs where prioritizing one criterion may come at the expense of another. When planning for change, the extent to which these trade-offs can be managed or resolved remains uncertain. Additionally, shifts in the decision-making process itself may influence how each success criterion is weighted which complicates the balance between them. (Adger et al., 2005)

1.2.6. Challenges of adaptation management

1.2.6.1. Uncertainty (in adaptation planning stage)

Uncertainty is a situation where there are multiple potential outcomes for each decision but the decision-maker is either unable to identify those outcomes or cannot determine their exact probabilities. In other words, uncertainty is an expression of the level to which a quantity or outcome is unknown. The state of uncertainty often exists due to the complexity of variables involved, insufficient knowledge about those variables or a combination of both. Also, disagreement about what is known or even knowable can raise uncertainty. Essentially, uncertainty represents a challenging scenario where estimating an accurate probability distribution is impossible. The sources of uncertainty vary and not all can be quantified.

Aleatory uncertainty is arising from natural, unpredictable variation and it can be measured but it cannot be reduced. Epistemic uncertainty is caused by a lack of understanding or knowledge about a system and it can be quantified and reduced by gathering more information. Most managerial decisions are made under conditions of uncertainty or risk. In practice, managers typically navigate decision-making between the extremes of certainty and uncertainty. Under conditions of uncertainty, rational decision-making becomes more challenging, often relying on subjective judgment. While some general guidelines exist to assist financial and administrative executives in making decisions under uncertainty, these rules have inherent limitations. They serve only as directional aids, as no scientific discipline can provide definitive solutions when probabilities are unknown. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024; Matsatsinis N. "Operations Research & Decision Making", Lectures on Decisions & Decision Makers, Interdepartmental Postgraduate Studies Program, (2024)

- Manage uncertainty

Managing uncertainty in decision-making requires structured approaches that enable thoughtful evaluation of adaptation options. These frameworks support decision-making at various scales, from individual projects to sector-based and national strategies. There are some strategies for managing uncertainty and balancing trade-offs between robustness and optimization. Adaptation planning seeks to prevent systems from becoming maladapted, which can lead to unnecessary costs or missed opportunities. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

The most well-known criteria or rules, used to make decisions under conditions of uncertainty are the Maximax criterion or Minimin criterion, Maximin criterion, Laplace criterion, Minimax regret criterion, Hurwicz a-criterion. Which criterion will be applied depends on the organization's goals and on the specific course of action it is asked to choose. Each criterion leads us to make a different decision, none of these criteria leads to safe actions and that in all the above techniques the subjectivity of the decision maker dominates. In addition to the above techniques for dealing with uncertainty, companies have a large variety of methods, practices and policies with which they try to control the environment in which they operate in order to reduce uncertainty. Decision makers often try to deal with uncertainty by gathering additional information. Due to the complexity and dynamism of the business environment and the many issues of day-to-day management, managers, to be able to make the best possible decisions, should have the right information at the right time. The acquisition of information, on the one hand, reduces uncertainty and, on the other hand, gives its holder a comparative advantage over its competitors. However, the collection and processing of additional information has a cost and in this sense it should be treated as an investment good, with which the business or, more generally, the decision maker will be able to successfully complete its actions. For this reason, the collection of information must be carried out up to the point where the marginal benefit of obtaining additional information is equal to the marginal cost of obtaining it. (Matsatsinis N. "Operations Research & Decision Making", Lectures on Decisions & Decision Makers, Interdepartmental Postgraduate Studies Program, (2024); Tsafarakis S. "Introduction, Decision Making Under Uncertainty", DECISION ANALYSIS, TECHNICAL UNIVERSITY OF CRETE, Postgraduate Program, School of Production Engineering & Management, (2024))

Due to uncertainties in projections, decision-makers cannot confidently predict how today's choices will impact future outcomes. Two primary strategies help address this challenge, robustness-based strategies and optimization-based strategies.

a. Robustness-based strategies

This approach prioritizes solutions that remain effective across a wide range of future scenarios even if this incurs upfront costs or trade-offs. Optimization strategies often rely on precise knowledge of future probabilities, which is rarely available. When confidence in projections is low, adopting a robustness-focused approach reduces the risk of maladaptation. Robustness strategies emphasize avoiding premature commitments that limit future flexibility, thereby reducing vulnerability to maladaptation. This approach involves carefully evaluating the benefits of flexibility versus the costs of delay.

Building robustness

- Implement measures that perform well across multiple plausible futures, such as "no-regrets" actions like early warning systems
- Incorporate flexibility into measures, allowing for adjustments as conditions evolve.
- Build flexibility into the decision-making process itself, such as adopting a "wait-and-learn" approach. Sequential decision-making ensures early actions focus on low-regret options, with more complex or inflexible actions delayed until better information is available.

b. Optimization-based strategies

Optimization focuses on achieving the highest expected utility based on available probabilities of future outcomes. While robust strategies mitigate uncertainty, they may involve trade-offs, such as higher costs or reduced productivity. For example, a healthcare system preparing for all possible climate-related diseases may dilute its ability to address specific, high-probability risks. Delaying action to await better information can sometimes result in costs that outweigh the benefits of waiting.

Economic considerations for flexibility

- Physical flexibility: For investments with high upfront costs and long lifespans, designing flexibility at the outset is often more cost-effective than retrofitting or replacing later.
- Waiting and learning: In cases where the likelihood of high-risk scenarios may become clearer over time, postponing decisions can be beneficial. However, this is only desirable if the costs of delay are outweighed by the advantages of gaining better information.

In practice, decision-making does not involve choosing between robustness and optimization but finding the right balance along a spectrum of trade-offs. Leveraging tools and methods for decision-making under uncertainty help determine this optimal balance to make informed transparent choices that adapt to changing circumstances while considering long-term

sustainability. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1.2.6.2. Balance competing objectives (in adaptation planning stage)

A significant challenge in adaptation, particularly for public policy and large organizations is navigating competing objectives such as balancing risk reduction with economic development while managing diverse stakeholder preferences. This includes accommodating varying public attitudes toward risk and addressing the uneven distribution of costs and benefits associated with adaptation measures. These challenges are often magnified by uncertainty and the scale of potential risks. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

- Manage competing objectives:

  Any framework for adaptation planning must provide a structured approach to address these challenges while remaining aligned with and integrated into broader decision-making processes. Additionally, proactive or anticipatory action can offer distinct advantages particularly when technological innovation is essential to mitigating future impacts. (Adaptation in the UK: A Decision-making Process - Grantham Research Institute on Climate Change and the Environment, 2024)

1.2.6.3. Resistance (in implementation stage)

One more challenge is related to the resistance at various levels to process change and policy. The source of individual resistance can be fear of the unknown (not understanding what is happening or what comes next), disrupted habits (feeling upset when old ways of doing things can't be followed), dislike of the uncertainty and ambiguity, surrounding change and poor timing (feeling overwhelmed by the situation or that things are moving too fast), potential loss of power base/control (feeling that things are being done to you rather than by or with you), potential loss of rewards, perceived lack of skills for new situation and potential loss of current skills which results to loss of confidence (feeling incapable of performing well under the new ways of doing things), lack of purpose (not seeing a reason for the change and/or not understanding the benefits). The source of organizational resistance can be inertial forces deriving from the systemic nature of organizations, interlocking aspects of structure, control systems, ritual and routines, signs and symbols, inertial forces deriving from group norms, potential loss of power group bases, entrenched interests of stakeholders, lack of organizational capacity-work overload (not having the physical or physic energy to commit to the change, lack of resources, threat to resource allocation). Kitsios F. "Innovation Management & Entrepreneurship", Master of Technology & Innovation Management, Technical University of Crete, (2022)

- Manage resistance:

  Managers have a crucial role in increasing organizational productivity. Managers have implementation and control role. Managerial duties include friendly organizational environment, communication with workers, taking responsibility, employee participation in decision making, and employee recognition. They make sure that resources are allocated and controlled appropriately, monitoring performance and behavior of staff and, where necessary, explaining

the strategy to those reporting them. They are in the position to translate change initiatives into a message that is locally relevant. They are also considered advisors to more senior management on what are likely to be blockages and requirements for change. Any organization's greatest asset is skilled management. Managerial skills include "management interest to raise employee productivity, participating in the performance management process, consistency in a good performance, clear direction, understanding employee problems, treating employees with respect, sharing employee opinions with management, making decisions on the spot, adapting to technological changes, and training employees. Managerial skills significantly and positively contribute to product/process innovation and productive performance. This leads to improved workflow, reduced stress levels and improved overall performance. Additionally, implementing managerial competencies and roles enhances organizational performance and fosters a culture of accountability and responsibility among employees. Change agents take responsibility for helping to change the behavior of people and organizational systems. Change agents understand the nature force-coercion, rational persuasion and shared power change strategies. Change agents deal with resistance positively and in variety of ways, including education, participation, facilitation, manipulation and coercion. Change agents take action to initiate planned changes to deal with them. Organizations focus on delivering appropriate training to improve management skills. Research findings illustrate that managerial skills are most beneficial in achieving goals, managing resources, managing conflict, improving communication and measuring performance decision-making. (Asghar, Khattak, Danish, Bokhari, & Waris, 2023)

1.2.6.4. Readiness/ Preparedness for change

Organizational readiness for change is achieved when the environment, the structure and the attitudes within the organization create a receptive atmosphere for upcoming transformations/changes. In other words, employees demonstrate openness to change driven by a conducive environment, clear processes and supportive leadership. Readiness for change is shaped by four interdependent elements. The content (the specifics of what is being changed), the process (how the change is implemented), the internal context (the circumstances surrounding the change) and the individuals' attributes (the characteristics of those involved in or affected by the change). These factors collectively determine the cognitive and emotional willingness of individuals or groups to embrace and adopt a plan to the status quo. Dynamic nature (readiness is a state, not a trait, which does not occur in isolation but is influenced by the organization as a whole), variability (levels of readiness can differ based on the specifics of the change, the strategies employed, the surrounding environment or the individuals involved) and influence of leadership (leaders play a crucial role in shaping readiness by understanding and addressing the organization's context and the attributes of its members) are the key characteristics of readiness. At any particular time or in any particular organizational setting, an individual may be more or less ready for a particular change which implies that readiness may vary or be altered over time. (Pasmore & Woodman, 2007)

- Manage readiness/ preparedness for change

Effectively managing readiness is crucial for successful implementation. Middle managers, organizational leaders and change agents can enhance the likelihood of successful adaptation by tailoring strategies with their organization's unique context and the characteristics of its members. Creating an environment where adaptation plan of the change is not only accepted but actively embraced ensures smoother transitions and long-term organizational stability. This

requires an understanding of organizational traits and employee attributes to identify potential enablers or barriers to change. It also involves employing facilitation methods that build readiness progressively, adapting to the evolving needs and attitudes of the workforce. By incorporating robust measures of readiness organizations can better understand the attitudes and preparedness of their members at every level. This understanding enables targeted interventions to close readiness gaps, align expectations and foster a supportive environment for change. Assessing readiness not only mitigates potential resistance but also lays the groundwork for a well-informed and cohesive change strategy. Failing to address these gaps can lead to resistance and jeopardize the change effort. Thus, readiness assessments are strategic guides for planning and implementing organizational change. It involves three stages:

- **Readiness/preparedness**: Employees demonstrate openness to change driven by a conducive environment, clear processes and supportive leadership.
- **Adaptation**: Temporary shifts in attitudes and behaviors occur as employees adjust to meet the expectations of the change.
- **Routinization/institutionalization**: The change becomes a permanent and stable part of organizational behavior.

Organizational readiness can be evaluated using a variety of instruments designed to measure different aspects of change. These tools examine the content (what is being changed), the process (how the change is introduced), the context (where the change occurs), the individual attributes (who is involved) and the reactions to the change (responses of those involved). (Pasmore & Woodman, 2007)

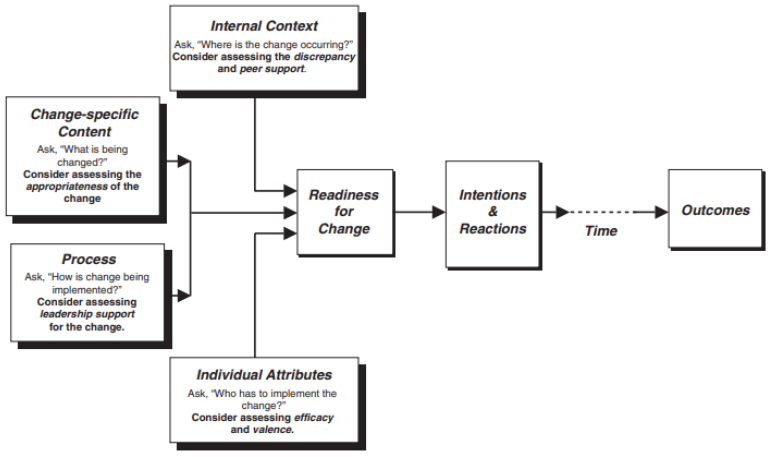

Figure 13: An integrated model of readiness for change that includes content process, context, individual, reactions and outcome variables (Holt et al., 2007)

1.3. Conclusions of literature review and research gap

A review of the literature covered in general the topic of adaptation management with a focus on medical device changes. Despite the critical role these changes play in ensuring patient safety and improving care, there is limited understanding of how healthcare institutions effectively manage and adapt to them. Regarding the objective of identification of the existing adaptation processes of medical device changes

in healthcare institutions, literature review revealed that the adaptation management was rich regarding the implementation of planned medical device changes but there was a gap in the implementation of unexpected medical device changes initiated by manufacturers. Also, there was no literature related to the planning stage of medical device changes initiated by manufacturers in healthcare institutions so major concepts were borrowed from other industries in order to bridge the gap in our interpretation. Regarding the objective of exploring the challenges healthcare institutions face, literature revealed that there are some identified challenges in both planning and implementation stage. The challenges at planning stage are more general and these related to the implementation stage are coming from healthcare institution environment and focuses on the operational and organizational challenges during the anticipatory adaptation of medical device changes. This gap allows us to explore if these challenges are valid in adaptation management of unexpected medical device changes and/or identify additional challenges and the factors that influence the ability of healthcare institution to respond successfully to such changes. Additionally, regarding the objective of evaluation of the outcome of adaptation management, literature revealed that there are four criteria for successful adaptation. However, these are general which allow us to potentially identify other criteria resulting in successful adaptation management of medical device changes. Regarding the objective of the suggestions on improving the adaptation management of medical device changes initiated by manufacturers in healthcare institution, the literature provided some suggestions on the identified challenges but it also give us the opportunity by exploring more challenges related to this specific topic to explore how healthcare institutions can improve their processes and provide actionable insights to enhance preparedness, streamline processes and support them in navigating the complexities of medical device changes initiated by manufacturers. In fact, with the rapid pace of technological advancement in healthcare, medical devices are constantly evolving. Regulations are becoming stricter in order to control them and ensure patient safety. Therefore, it is important healthcare institutions to be prepared to follow the technological advancements.

CHAPTER 2: RESEARCH METHODOLOGY

This chapter presents the methodology applied for the empirical research. The theoretical background analyzed in Chapter 1 of this research helped to identify the research gap and provided the framework upon which the research was conducted. The research aims at exploring the adaptation of medical device changes in healthcare institutions. Firstly, the selection of the qualitative methodology and design will be explained and justified. Secondly, the data sample and collection will be presented. The chapter concludes with the presentation of technique applied to analyze data from interviews and limitations of the methodology applied.

2.1. Research design and methodology

In order to address the research objectives and research gap, different research design strategies were evaluated in order to select the suitable one for this study. There are three research design approaches: qualitative, quantitative or mixed. Since the early twenty-first century, there has been a growing interest in situating in the middle position and combining both approaches into a single study or a series of studies. Qualitative research is based entirely on innumerable “soft” data in the form of impressions, words, sentences, pictures, symbols, etc. It is used to acquire factual and descriptive information providing additional explanation of the individual perspectives. It is not a single agreed-upon approach to research but a dynamic and competitive field with many inconsistencies and points of view. It is characterized by open-ended questions so responses are not given in a predetermined format. Also, it allows for analysis of customer behavior in detail independently of the small number of respondents. The results are based on the answers given by respondents as well as the observation. In other words, a summary of unstructured data which leads to subjective conclusions whose generalization is not possible. This kind of research is appropriate for studies concerned with gaining new insights into the subject under investigation rather than confirming existing theories through statistical procedures. Quantitative research is based on numerical “hard” data and is focusing on creating statistical valid information. It is suitable for testing hypothesis or theories by assessing the relationship among variables, generalizable findings, measuring the causal relationship, predicting one variable from others, maintaining the researcher’s independence, avoiding bias and demonstrating validity and reliability. It provides the ability to understand the meaning that people construct, having an in-depth understanding of educational phenomena, considering the cases of individuals, taking into account contexts, its dynamic nature and the ability to generate new theories. The results are based on structured data collected by surveys, such as mail, online or telephone surveys, with the use of a short structured questionnaire or by experiments or individual interviews. The survey sample must be large enough to provide a statistic reliable results which are analyzed using specific statistical techniques and quantitative tools and provide objective conclusions. Mixed research emerged as a third approach as a result of the combination of both quantitative and qualitative approaches which considers philosophical and theoretical frameworks for research, data collection and analysis methods. In mixed research, both numeric and non-numeric data are collected, processed, validated and interpreted in a systematic process. (Mulisa, 2021; Dr. Evangelia Krasadaki. School of Production Engineering & Management Postgraduate Course Market Research & Consumer Behavior (MBA & MTIM))

As the current dissertation aims at gaining a deeper understanding of the adaptation of medical device changes in healthcare institutions, an exploratory qualitative method is chosen because it is more suitable to address the aim of the research. The qualitative design of research includes different data collection methods among which ethnography, participant observation, in-depth interviewing and conversational interviewing. These techniques can be summarized in: focus groups, advisory groups, observations and in depth interviews. Focus groups are useful for collecting views of different participants (5-10 persons) with common characteristics on a topic through discussion. Advisory groups are similar to focus group and consist of volunteers who meet regularly in the period around 1-2 years and provide suggestions and directions to a company e.g. for a product. Observations are used when there are problems with the other qualitative methods. For example, it is particularly appropriate for gathering information on a subject that participants may be uncomfortable to discuss. Or it can be used via direct observation when the persons are working which is being done e.g. by other trained employees. In depth interviews are personal interviews with participants, which generally do not have a formal structure. The questions are general and answers are not given according to a predetermined order but allow the respondent to state any his thoughts. Qualitative interviewing aims at gaining information about the context by an insight into the experiences of the person interviewed. While observations could be taken into consideration at exploring the adaptation of medical device changes in healthcare institutions, it was chosen to collect data via in-depth semi structured interviews with healthcare institution employees due to time constraints and avoidance of privacy issues. (Mulisa, 2021; Dr. Evangelia Krasadaki. School of Production Engineering & Management Postgraduate Course Market Research & Consumer Behavior (MBA & MTIM))

The aim of this research is to understand how healthcare institutions, in this particular case by healthcare institution employees, adapt to medical device changes, their involvement, their perspective of successful adoption and the challenges they face. It is particularly relevant for this study to understand their role, and attitude towards new situations in different contexts. Qualitative interviewing permits to uncover the individual's view on the healthcare institution environment and the challenges they have experienced.

2.2. Data sample

The primary data source derives from interviews with healthcare institution employees who are involving (directly or indirectly) in different steps of adaptation management of medical device changes in healthcare institutions. In order to have a more homogeneous sample, public healthcare institutions have been selected for the study, in particular those that operate in Greece.

As of 2024, Greece has 283 healthcare institutions of which 55% are publicly owned. Public healthcare institutions represent the 2/3 of all healthcare institutions beds (~19,800). The remaining 45% of healthcare institutions are privately owned and provide about 1/3 of the total beds (~10,200). This distribution underscores a continued dependence on public healthcare facilities despite substantial private sector participation. Based on 2024 World Index of Healthcare Innovation, Greece ranked in #25 and it was stated that its healthcare system is marred by low quality and lack of investment due to its continuing fiscal troubles. (Girvan, 2024)

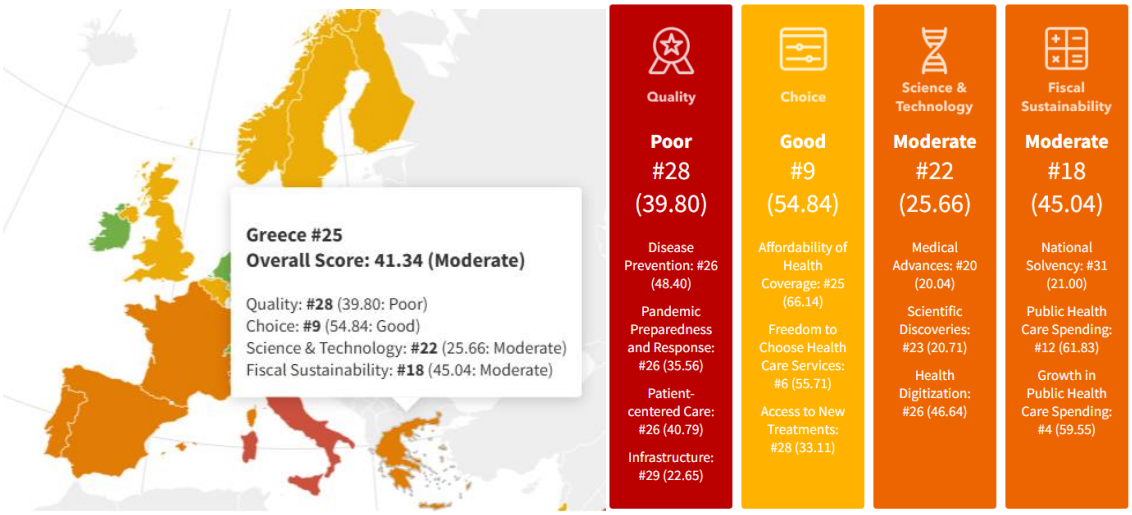

Figure 14: 2024 World Index of Healthcare Innovation, Greece ranked in #25 (Girvan, 2024)

All the healthcare institutions were selected according to the following criteria and steps: (1) all are public healthcare institutions (2) located in Greece (3) equipped with multiple medical devices (4) consisting of different departments including the biomedical engineering department (5) the employees interviewed can be considered users of medical devices so they have potentially faced changes initiated by manufacturers.

In total 12 healthcare institution employees participated in the interviews from four selected public healthcare institutions as presented in the table in Appendix 1.

2.3. Data collection

Primary data was collected using the technique of in-depth semi-structured interviews with public healthcare institution employees in order to gather deeper information and knowledge allowing us to focus on the individual participant's thoughts and experience.

- Healthcare institution 1 (H1): Initially one participant from biomedical engineering department was contacted via telephone who agreed to participate. Interview was planned to be done in person. Then, with the help of this participant, the other two participants were contacted in person during the visit at healthcare institution and agreed to participate as well. So, all participants were interviewed in person depending on the interviewee's schedule. Each interview lasted between 25 and 50 minutes in length, depending on the answers of the participants.

- Healthcare institution 2 (H2): Initially one participant from biomedical engineering department was contacted via telephone who agreed to participate. Interview was planned to be done in person. Then, with the help of this participant, one more participant was contacted in person during the visit at healthcare institution and agreed to participate as well. Finally, this participant helped on finding one more participant willing to be interviewed. So, all participants were interviewed in person depending on the interviewee's schedule. Each interview lasted between 25 and 50 minutes in length, depending on the answers of the participants.

- Healthcare institution 3 (H3): Initially one participant from biomedical engineering department was contacted via telephone who agreed to participate. Interview was planned to be done in person. Then, with the help of this participant, the other two participants were contacted in person during the visit at healthcare institution and agreed to participate as well. So, all participants were interviewed in person depending on the interviewee's schedule. Each interview lasted between 25 and 50 minutes in length, depending on the answers of the participants.

- Healthcare institution 4 (H4): Initially one participant from biomedical engineering department was contacted via telephone who agreed to participate. Interview was planned to be done in person. Then, with the help of this participant, one more participant was contacted in person during the visit at healthcare institution and agreed to participate as well. Finally, this participant helped on finding one more participant willing to be interviewed. So, all participants were interviewed in person depending on the interviewee's schedule. Each interview lasted between 25 and 50 minutes in length, depending on the answers of the participants.

At the beginning the purpose of the study and interview structure was explained to each participant and was informed that the interviews are anonymous. Interviews were conducted in Greek so later the relevant sections of the interviews were translated from the original language (Greek) to English.

2.4 Interview design

In order to answer the research questions, the interviews were designed according to specific themes. The interview guideline presented in Appendix 3 was derived inductively from the theoretical background presented in Chapter 1 enriched with the topics needed to be further researched to address the identified gaps. Following the guidelines for in-depth interviews, participants were initially explained the purpose of the research and the interview started with simple questions to understand better the participant and his/her background as well as the healthcare institution. Then, some general transitional questions were used to understand the familiarity of the participant of medical device changes and regulation. Then, the focus was given on the stages of adaptation management of medical device changes and the role of the participant in this. Finally, some examples and suggestions for improvements were asked to understand their perspective of successful adaptation. To summarize, the interviews aimed at the following:

- understanding the participant's background and healthcare institution context
- identifying the familiarity of medical device changes and EU MDR
- Identifying the existing adaptation management process of medical device changes in healthcare institutions
- understanding the stakeholders and their involvement in the adaptation management process
- identifying the challenges healthcare institutions face
- understanding their perspective of successful adaptation
- identifying the potential improvements into the already existed adaptation management processes

Interviews were therefore semi-structured and they were used as a discussion outline in order to control the interview through the order of questions and the structure of the discussion. Interview guideline included questions which could be addressed by all participants independently of their role. So, based on

their perception, their experience and their involvement in the adaptation management process different answers were given. Also, participants were provided with a helping guide about different medical device change types and success criteria definitions as an explanation before answering some questions.

According to Saunders there are three kind of research: exploratory, descriptive and explanatory research. The purpose of the exploratory research is to clarify the understanding of a problem, the purpose of the descriptive research is to portray an accurate profile of persons, events or situations and the purpose of the explanatory research is to study a situation or a problem in order to explain the relationships between variables. Exploratory research combines literature review with qualitative data in form of expert interviews and focus groups while descriptive and explanatory research consists of quantitative data (Saunders et al., 2007). For this thesis qualitative data was decided to be used so an exploratory research was conducted in order to gain a deeper understanding of the adaptation of medical device changes in healthcare institutions.

More specifically, an interview was decided to be used as an instrument of data collection. In this way, respondents receive questions which are mostly open-ended in structure with the intention to gather necessary information by having the respondents define the situation. Interviews can be formulated in three major kinds: structured, non-structured and semi-structured interviews. The interviews conducted for this research were semi-structure which means that a list of questions and themes were provided. The interviews were conducted in the one-to-one format and were used to gather data from experts working in Greek public healthcare institutions in different departments (Guest et al., 2020). Qualitative interviewing permits to uncover the individual's view on the healthcare institution environment and the challenges they have experienced.

From the other hand, a focus group could be used as a non-standardized interview as it consists of two or more participants. In a focus group the topic is clearly and precisely defined with the focus on maintaining it during an interactive discussion among participants which is being recorded. In this case, there should be boundaries of the subject being discussed among participants and researcher should ensure to remain on this. The focus groups help to find other gaps and opportunities (Guest et al., 2020). In this research this method was impossible as participants were from different departments within healthcare institution and it was not feasible to gather them at the same place at the same time as each of them had its own heavy schedule which made it challenging to even contact them individually.

2.5. Data analysis

All data during interviews were collected, saved, transferred in electronic files, translated in English and analyzed. All of them were saved and kept for dependability and trustworthiness of the qualitative study. Interviews were analyzed on the basis of participants' experiences and deductive as drawn on the theoretical framework used in the research. Topics were sorted into categories which reflected subject areas identified in the research design and new sub-categories. Finally, cross-questionnaire analysis was conducted in order to compare the answers of participants based on their role in the healthcare institution and involvement in the adaptation management of medical device changes. In conclusion, the first two chapters of the research provide an explanation of the topic under study, upon which findings on the empirical part and discussion are based. These chapters provide a description of the research problem, objectives, questions and the methodology followed for conducting the qualitative research.

The quantitative research design and variables are determined before the collection of the data starts. In this case a careful description of variables that may be counted with numbers is needed as they are measured objectively. However, in the qualitative research design and variables are flexible which can depend on the context of data that will be collected. In contrast, in this case, a complete or holistic perspective which includes underlying values and the context as a part of phenomena is needed e.g. what factors, with whom, where, when, how, and other related details, which may be the key interest of the qualitative investigator (Mehrad & Zangeneh, 2019). In order to be able to answer the research questions there was a need to deep dive on the process of adaptation management of medical device changes and therefore qualitative data would be needed to collect all necessary information.

2.6. Limitations of the research

Measures were taken to ensure the validity of data collected through semi-structured interviews, nonetheless the nature of the qualitative research implies some limitations related to the generalizability of findings. While the exploratory qualitative research with semi-structured interviews allowed to have a deeper understanding of the topic under study, the study focused on a particular empirical setting, which is that of public healthcare institutions in Greece. It can be argued that in other settings, evidence of the adaptation management of medical device changes may vary due to other variables. For example across different countries, such as cultural differences, and/or different type of healthcare institution, different size of healthcare institution, existence of a biomedical engineering department etc. Moreover, the findings of this study rely on a relatively small sample size of participants (n=12) from four public healthcare institutions in Greece. However, these limitations do not invalidate the conclusions drawn from the findings but the generalizability of results must be made with caution. In conclusion, this study proposes to give insights of the adaptation management of medical device changes initiated by manufacturers in healthcare institutions. However, as current research is limited on adaptation management in public healthcare institutions in Greece, it cannot provide any conclusive results until further research is conducted across different contexts, for example in other healthcare institutions settings and countries.

CHAPTER 3: FINDINGS

This chapter presents findings derived from the analysis of data from interviews. Results are presented by reporting statements of conversations from interviews which were translated from Greek to English. The presentation of the findings follows the structure of the research objectives. Initially, the adaptation management of medical device changes in healthcare institutions and the involvement of the stakeholders in the adaptation management process are presented. In addition, the challenges that healthcare institutions face are introduced and discussed. In conclusion, the meaning of successful adaptation and the potential improvements into the already existed adaptation management processes are identified.

3.1. Adaptation management of medical device changes in healthcare institutions

3.1.1. Participant background and healthcare institution context

At the beginning of the interviews participants were asked to talk about their background and more specifically about their role and years of experience. The purpose of this initial questions was to get acquainted with the person interviewed and also gain information about the healthcare institution as well as the department.

Q1: A brief overview of the size, scope and services of each healthcare institution was provided and it is available in APPENDIX 1: PROFILE OF HEALTHCARE INSTITUTIONS.

Q2: The role of the participant within the healthcare institution, the department size and years of experience were described and are available at APPENDIX 2: PROFILE OF PARTICIPANTS INTERVIEWED.

3.1.2. Identifying the familiarity of medical device changes and EU MDR

Q3: *The answers of the participants about the average frequency of medical device changes received per month are the following:*

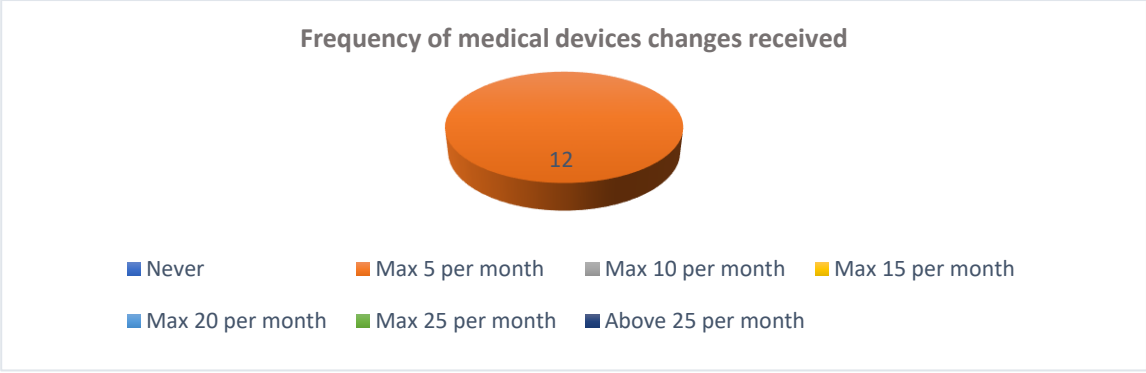

Chart 1: Frequency of medical device changes received

All participants stated that the maximum medical device changes they can receive per month is five. But they also explained that maybe one month it can be two but next month it can be zero. Participants working in biomedical engineering department receive all the changes related to all medical devices - systems in the healthcare institution. On the other hand, the participants working in specific departments, where few systems are installed, are receiving less changes as expected. Biomedical engineers from the different healthcare institutions provided also an approximate number of medical device changes per year.

- H1, P1: ~12 per year
- H2, P1: ~2 per year
- H3, P1: ~3-4 per year
- H4, P1: ~10-15 per year

From the numbers provided we notice that there are more medical device changes in medium hospitals (H1 and H4) which was expected as bigger size means more medical devices so more probabilities to receive medical device changes. Also, it is important to note that these are estimations as there was not any tracking file for all medical device changes received in the last year. E.g. H1, P1 saves the notifications in local PC folders and H3,P1 is saving them in his email address.

One more interesting finding is that the biomedical engineering department is not managing all medical devices but only those which are considered systems and require maintenance activities. For example, the medical devices which are consumables e.g. PADs for defibrillators are not managed by them.

Q4: *Based on their experience, the answers of the participants about the types of medical device changes they experience mostly (when 1 means "Not at all" & 7 means "All the time") are the following:*

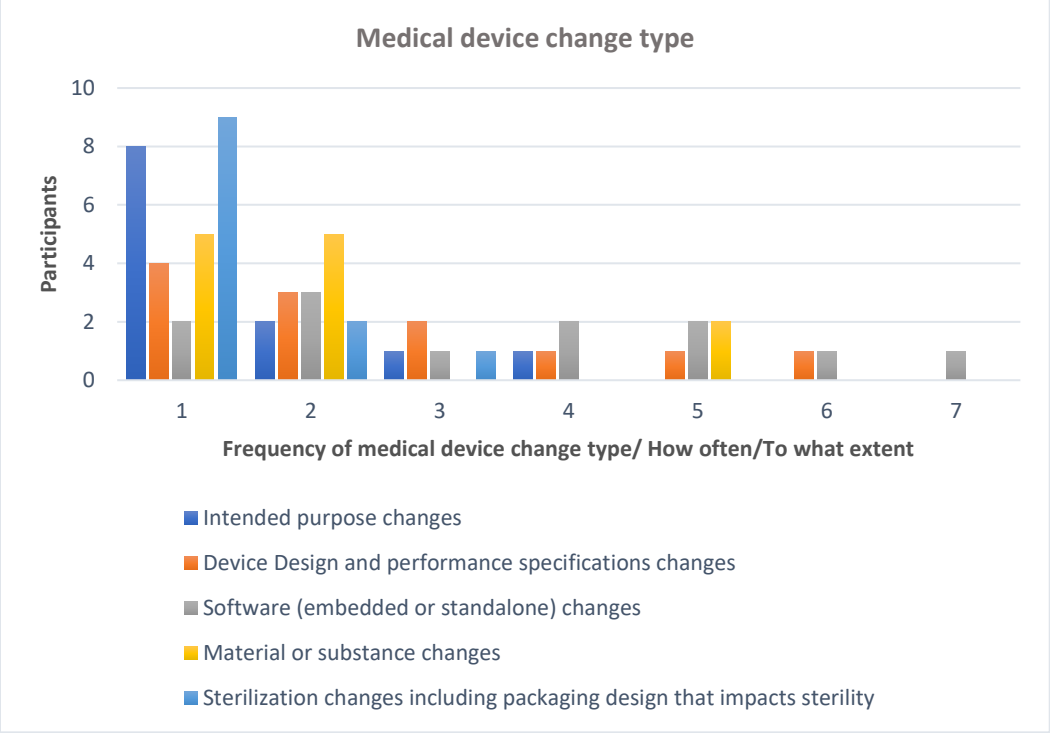

Chart 2: Frequency of medical device change type

According to H1,P1 a big increase of medical device changes has been noticed lately. Most common medical device changes in all healthcare institutions are related to software (embedded or standalone) changes. According to H1,P2 if the system is under maintenance contract the software updates are even more. But when the end of life of the system comes, only maintenance is being done until it moves to end of support level and its maintenance relies on the availability of spare parts. Also, based on H4,P3 some systems are monitored remotely by the company.

Second most common changes are the device design and performance specifications changes. Some examples provided by H3,P1 are related to instructions provided by manufacturers regarding updates on instructions for use e.g. change on the direction of the contrast injectors in order to not drip and stick, change of the footswitch cleaning to avoid its stuck which could result in unintended radiation, stop use of a consumable which is not compatible with the system so a new kind of catheter should be ordered from now on or the use of an adaptor would be necessary. According to H3,P2 some changes e.g. the change in radiation setting does not influence their work directly.

Then, material or substance changes are following such as the change of the intra-aortic pump due to material aging (H3,P1). Finally, intended purpose changes and sterilization changes including packaging design that impacts sterility are the less common types of medical device changes. One example shared by H1,P2 and H3,P1 is related to the change in the method of sterilization and disinfection which affected the system so a new liquid was introduced instead of chlorine that was usually used. Or for surgical instruments by using medical steam furnace in a specific program to prevent the survival of pathogenic organisms.

Q5: *The answers of the participants about the time allocation of managing medical device changes in their daily activities (when 1 means "0%" & 7 means "100%") are the following:*

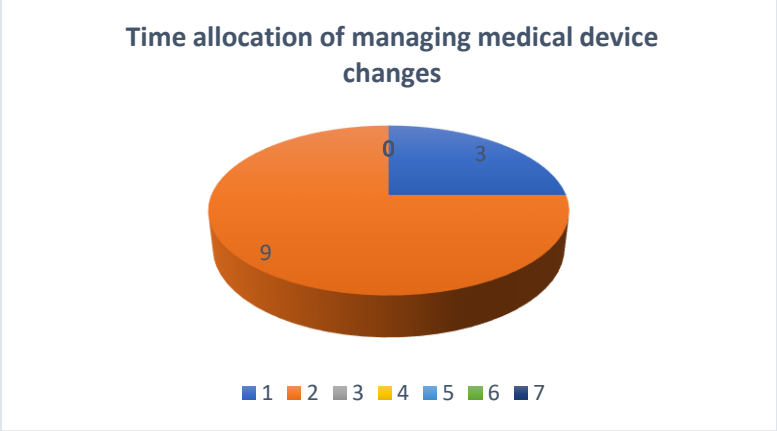

Chart 3: Time allocation of managing medical device changes

It seems that 75 % of the participants use a very few time for management of medical device changes. More specifically, participants stated that it can take from 1 hour to 2 working days per month to handle them. 25% of the participants stated that they don't do anything regarding these changes by stating that manufacturer and biomedical engineering department are handling them. This statement came from people from medical and diagnostic department (technologists and an interventional cardiologist).

Q6: *The answers of the participants about the familiarity with European Medical Device Regulation which took effect in May 2021 (when 1 means "Not familiar at all" & 7 means "Extremely familiar") are the following:*

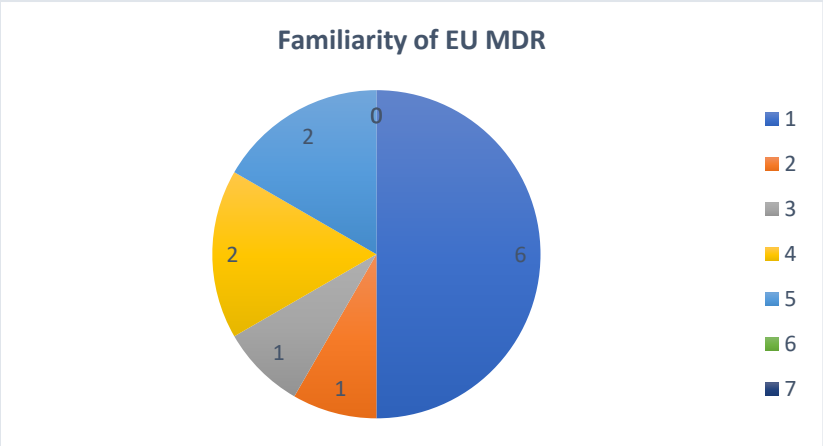

Chart 4: Familiarity of EU MDR

Half of the participants (50%) stated that they don't have idea of the existence of this regulation. Mostly biomedical engineers were aware of this regulation.

3.1.3. Adaptation management process of medical device changes

Q7: *The answers of the participants about how medical device changes initiated by manufacturers are communicated to the healthcare institution/them (when 1 means "Not at all" & 7 means "All the time") are the following:*

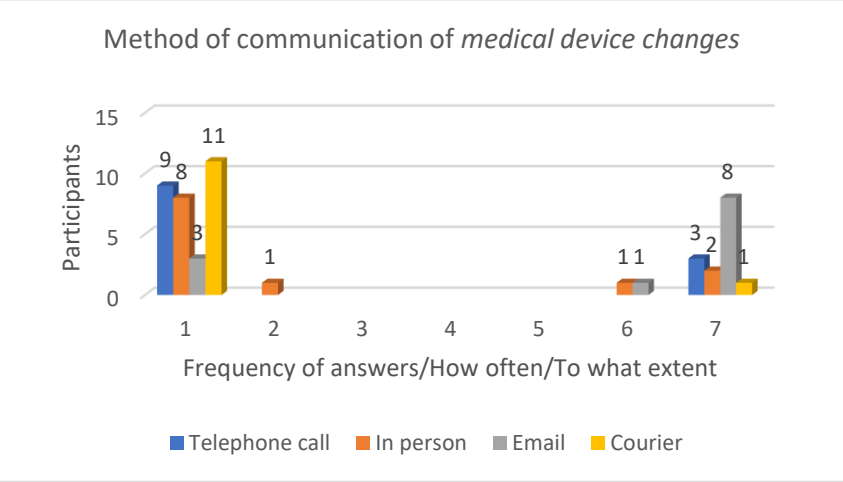

Chart 5: Method of distribution of medical device changes

The most common method of communication seems to be via email. Biomedical engineering department is usually the first contact. H1,P1 and H3,P1 indicated that they always receive such notifications related to medical device changes initiated by manufacturers via email and when Field Service Engineers are

visiting them for the implementation of the field safety corrective action they are contacted in person by them as well. Also, it was mentioned by H3,P1 that in the past they received courier from abroad which was not functional at all as for example the contact was in English and courier could not find the recipient. According to H2,P1 the methods used for the notification of medical device changes are always via email and courier. For H4, P1 the most common method of communication is via email but it was also mentioned that sometimes they are being informed via registered documents from protocol (administrative department). After the communication to biomedical engineering department, the notification is being sent by them to different departments. In H1, this is done always via email. The same for H2 but in some cases it is combined with a telephone call and an in person visit as well. In H3 and H4, the distribution of a medical device change is being done via email and it is done one more communication with the department for scheduling the visit of the Field Service Engineer who is informing them as well.

3.1.3.1. Planning stage

Q8: *The answers of the participants regarding the plan of the adaptation process before the implementation are the following:*

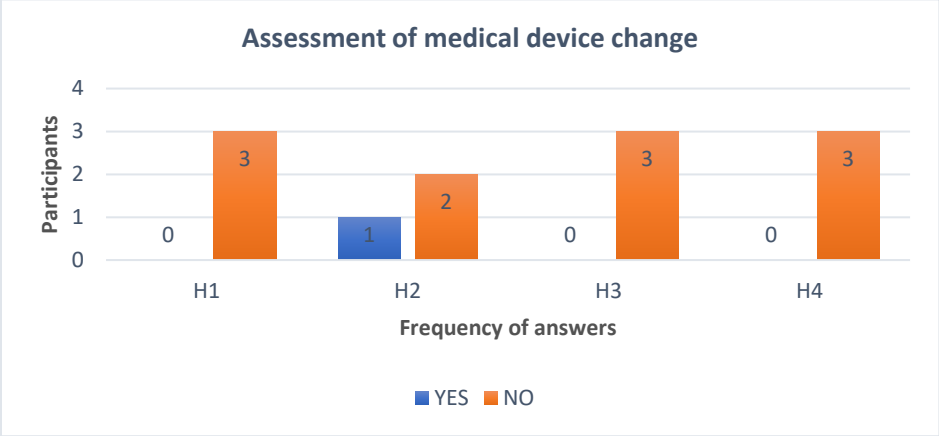

Chart 6: Assessment of medical device change

Only in one out of the four hospitals an assessment of adaptation plans to the medical device changes is being done. According to H2,P1 an initial inspection is conducted by biomedical engineering department (95% by them) in order to identify if there are the mentioned problems. Also, the relevant department and users are being informed by providing them the notification of the medical device change as well as the steps they need to follow. Lastly, the user manual is being updated.

In most of cases, only a notification to all relevant departments is being done in order to be shared to all users. According to H4,P1 this notification is being sent by biomedical engineering department to the protocol (administrative department), independently if the medical device change is safety related or not, in order to be officially shared to the relevant department(s). After this, the customer response form at the end of the notification is signed by biomedical engineering department and sent back to the vendor/distributor/manufacturer (medical device provider).

According to the H3,P1 only an initial evaluation of applicability is being done but not an assessment of the adaptation of medical device change. More specifically this is done via a simple check of the system impacted and if it is applicable for their healthcare institution as maybe it is a general non relevant notification. If the healthcare institution doesn't own an impacted system, nothing is being done. If yes they need to apply the change so biomedical engineering department sends it to protocol (administrative department) so the original document is registered so it doesn't get lost. Protocol registers this under a specific number for identification. And then the notification is sent to the relevant department (e.g. to biomedical engineering and interventional cardiology departments). Finally a call by biomedical engineering department is being done to confirm receipt of the notification and that necessary action will be taken. After this, the customer response form at the end of the notification is signed by biomedical engineering department and sent back to the vendor/distributor/manufacturer (medical device provider).

According to the H1,P1 the notification is being sent by biomedical engineering department directly to relevant departments and they request confirmation of receipt by signing the response form and provided it back to them (sometimes mediation is needed). In this way, the relevant impacted users are being informed and the response form is signed by the responsible of the department and sent to biomedical engineering department in order to provide it to the vendor/distributor via email for confirmation.

Q9: *The answers of the participants regarding the established procedures in the healthcare institution for assessing adaptation to medical device changes are the following:*

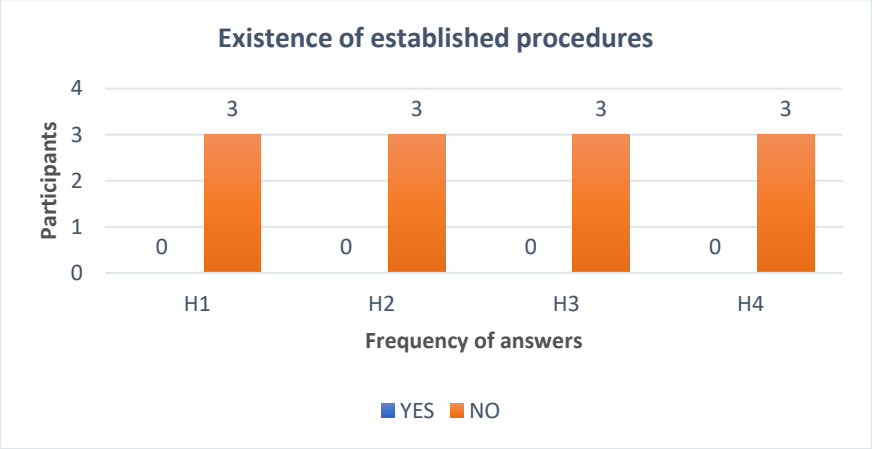

Chart 7: Existence of established procedures for assessing adaptation to medical device changes

Based on all participants, there is no written procedure for assessing medical device changes in all healthcare institutions. According to H3,P1 the healthcare institution is now learning what quality means. He is aware of a very vague description of 2012 for the general hospital organization. H1 and H4 are not certified with ISO as well. On the other hand, the diagnostic department of H2 has recently received ISO9001 certification (H2,P2 and H2,P3). Nevertheless, there is no established procedure about medical device change management.

Q10: *The answers of the participants regarding to what extent are the following steps being done during the planning stage of the adaptation of the medical device change (when 1 means "Not at all" & 7 means "All the time"), are the following:*

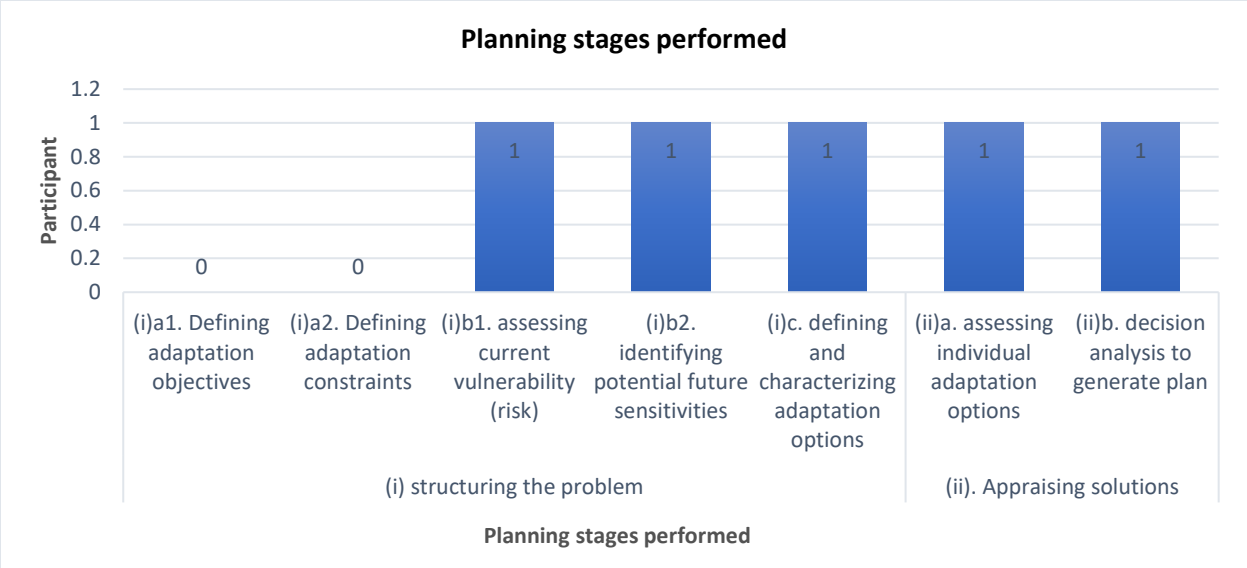

Chart 8: Planning stage of adaptation management

This question was relevant for the H2,P1 only as it is related to the planning of adaptation of medical device changes which is done only by this participant for healthcare institution 2.

(i) Structuring the problem:

(i)a1.Defining adaptation objectives: Objectives are defined in the notification shared by vendor/distributor. It seems that no further action is being done by participant.

(i)a2.Defining adaptation constraints: Objectives are defined in the notification shared by vendor/distributor. It seems that no further action is being done by participant.

(i)b1.Assessing current vulnerability (risk): Assessment of the described risk is done via an on-site inspection following the recommended actions described in the notification. At this point an on-site inspection is being done according to FSN. If necessary, the system can be put out of operation if necessary.

(i)b2.Identifying potential future sensitivities: Participant is assessing the action(s) that should be taken by manufacturer and its timeline in the FSN. If a permanent solution by manufacturer is available healthcare institution should adapt to a temporary situation until the implementation of the permanent solution by manufacturer. If there is only an “instructions for use” update, it means that this update should be taken into account for the entire lifecycle of the medical device.

(i)c.Defining and characterizing adaptation options: The participant stated that in reality there are no adaptation options. Healthcare institution will follow the instructions provided by medical device manufacturer so the option is one.

(ii) Appraising solutions:

(ii)a.Assessing individual adaptation options: Sometimes only some additional steps are provided to users in combination with the recommended actions from manufacturers.

(ii)b.Decision analysis to generate implementation plan: The participant is always informing the impacted department and asking users to follow the instructions from manufacturer as well as additional action(s) if needed. But what eventually will be done in the department is up to each department.

3.1.3.2. Implementation stage

Q11: *The answers of the participants regarding the established procedures in the healthcare institution for implementing adaptation to medical device changes are the following:*

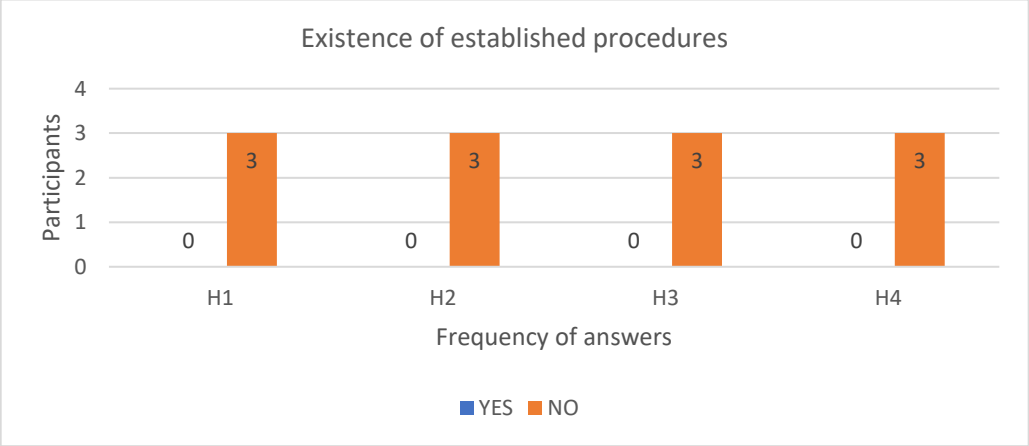

Chart 9: Existence of established procedures for implementing adaptation to medical device changes

Based on all participants, there is no written procedure for implementing medical device changes in all healthcare institutions. According to H3,P1 the healthcare institution is now learning what quality means. He is aware of a very vague description of 2012 for the general hospital organization. H1 and H4 are not certified with ISO as well. On the other hand, the diagnostic department of H2 has recently received ISO9001 certification (H2,P2 and H2,P3). Nevertheless, there is no established procedure about medical device change management.

Q12: *The answers of the participants regarding to what extent are the following steps being done during the implementation stage of the adaptation of the medical device change (when 1 means "Not at all" & 7 means "All the time") are the followings:*

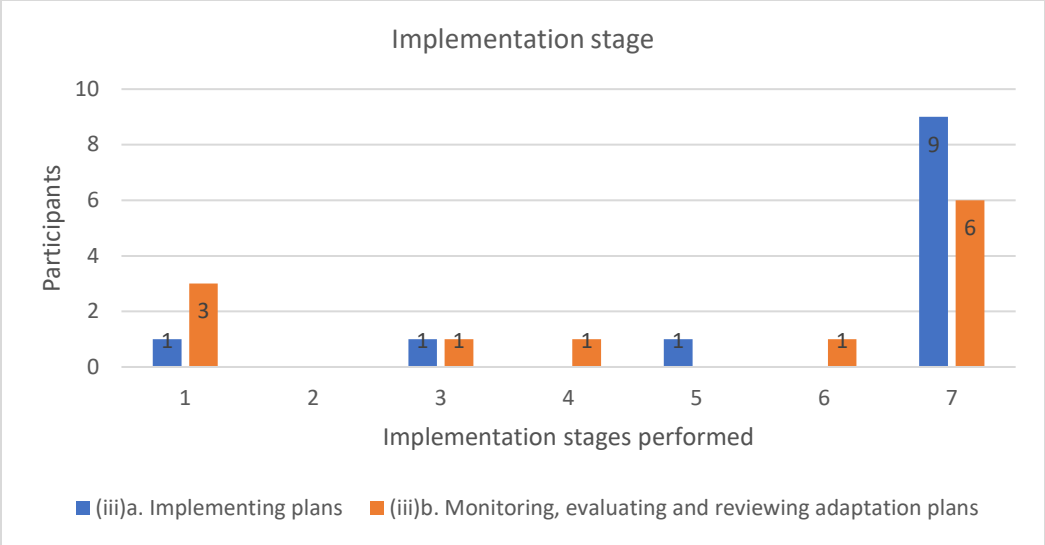

Chart 10: Implementation stage of adaptation management

(iii) Implementation: Most participants are involved in the implementation stage of adaptation plans.

(iii)a. Implementing plans: Most of the participants are involved in implementation at different process steps. According to H1,P2 and H1,P3 the implementation of the instructions/ recommendations provided by manufacturers is being done by them considering that they are the users. Same is valid for H2,P2 and H2,P3 and H3,P3 which are technologists. In case of physician H3,P2 his involvement is not always needed. Participants from biomedical engineering department are always involved. One of them is assessing the problem (H2,P1) and all of them are informing the relevant department(s) as well as contacting manufacturer/distributor/vendor for corrective action(s) implementation (H3,P1). The appointment of the FSE visit is being done after alignment with the relevant department.

(iii)b. Monitoring, evaluating and reviewing adaptation plans:

Participants in biomedical engineering department are monitoring the adaptation by checking different things depending on the healthcare institution. H1,P1 is checking if users have provided the customer response form to the vendor/distributor/manufacturer. H2,P1 and H3,P1 are checking the job sheet of the field service engineer for the successful implementation of corrective action or check if follow up visits are needed. Usually this is done once per year per medical device change. Participants in specific departments are monitoring the medical device change every day even after correction by field service engineer (H1,P3 and H2,P2), others during field corrective action implementation and then checking the functionality by testing the image quality after completion of the correction (H4,P3 and H4,P2) or when image quality testing is needed depending on the system (H2,P3).

3.2. Involvement of the stakeholders in the adaptation management process

***Q13**: The answers of the participants regarding the stakeholders involved in adaptation management (planning and/or implementing) of medical device changes (when 1 means "Not at all" & 7 means "All the time"), are the following:*

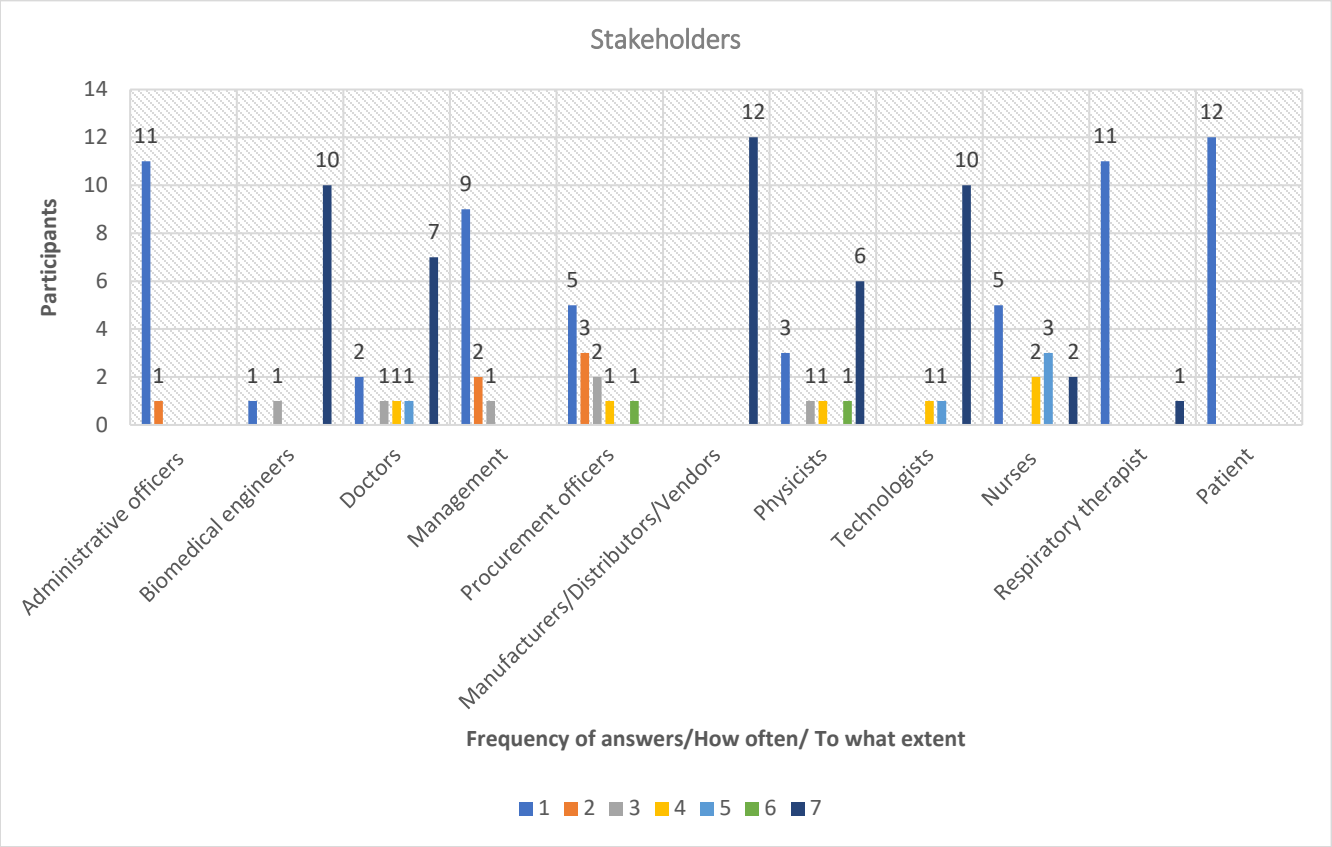

Chart 11: Stakeholders of medical device changes

Most involved stakeholders are: manufacturers, biomedical engineers and technologists. Doctors are following as well as Physicists. More specifically manufacturers are initiating the medical device changes and then vendor/distributors notify healthcare institutions and if there is a permanent solution they implement it (all participants). Biomedical engineers is the initial contact of vendor/distributors for activities related to medical devices. They are being informed about medical device changes, they inform the relevant impacted departments (directly or indirectly), provide the signed reply form to manufacturers/vendor/distributors (directly or indirectly), and arrange the scheduling for the implementation of field corrective action if any. Technologists are receiving the notifications about medical device changes independently if they are safety related or not and they are following the instructions provided to minimize or eliminate the direct or indirect risks to patients/users safety. Physicists are usually being involved when the change is related to radiation and after its implementation from FSE as the system should be tested before clinical use.

Less involved stakeholders are: Procurement officers and nursing staff. Procurement officers are being involved only in case the healthcare institution should buy something regarding the medical device change (H1,P2). Or if the manufacturer stops the production of specific consumables so they are involved in order to know what should bought from now on (H2,P3 & H3,P1). Nursing staff is involved when medical device change has to do with general issues (H1,P3) such as the transportation of patients (H2,P1) and the contrast injector (H3,P3).

Even less involved stakeholders are: Administrative officers and Management. Administrative officers who are involved are usually the protocol which is the formal way to save and distribute documents to the different departments (H3,P1). Also, Management is usually informed only for their reference mostly when the medical device change is because of safety reasons and especially when it is advised to stop its use (H3,P3 & H3,P1).

Never involved stakeholders are: Respiratory therapists and patients. Participants did not know any case that a respiratory therapist should be informed and maybe in some healthcare respiratory therapists are not existed at all so it depends on healthcare institution (H3,P1). Also, patients are never being involved in medical device changes according to all participants.

Potential involved stakeholders could be: other external partners. For example, IT person who is working in healthcare institution with a contract if the change is related to the PACs (H1,P1), external partners working on research programs who use the systems so they should be notified (H1,P2), external partner who places the transplant e.g. stent applicator (H3,P1).

3.3. Challenges that healthcare institutions face

***Q14**: The answers of the participants regarding the different challenges when planning and/or implementing plans for adaptation to medical device changes they experience mostly (when 1 means "Not at all" & 7 means "All the time"), are the following:*

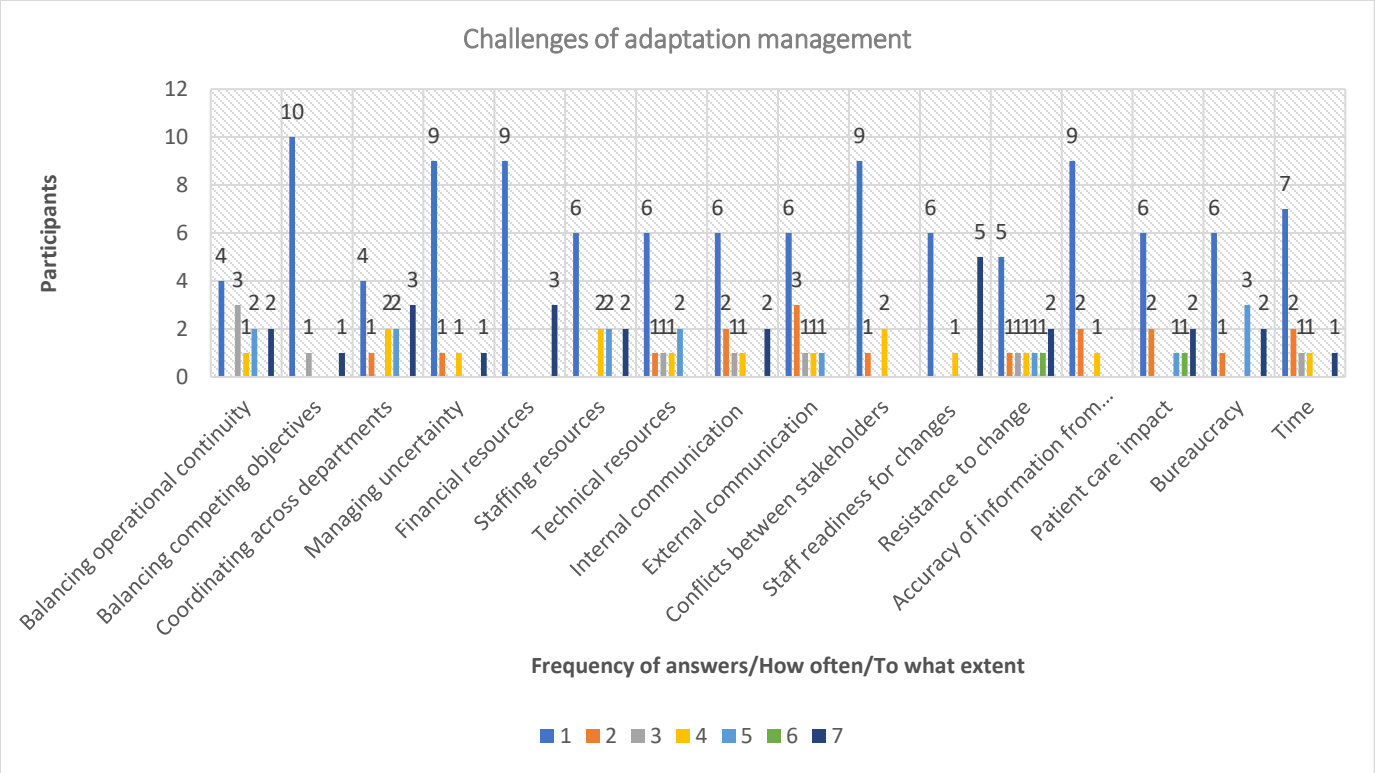

Chart 12: Challenges of adaptation management of medical device changes

Staff readiness for changes & resistance to changes:

Most common challenge seem to be the staff readiness for change (~42%). This depends on the type and size of the change (H3,P3 & H4, P1) and its impact. Some of participants have faced only minor changes so it wasn't a challenge for them. Mostly this is applicable for technologists (users) as they need to adapt to a new way of working in many cases and they are not in favor of changes (H3,P1). So, the challenge of staff readiness is also linked to the resistance to changes which exists but varies.

Coordinating across departments & internal communication:

One more common challenge is the coordinating across departments. This is mostly happening between people of different specialties (H3,P3) and usually the difficulty has to do with taking responsibility (H1,P1) or personal benefits (H3,P1). It was also mentioned that it seems that there is no understanding of what is needed to be done (H4,P3). This is also linked to the internal communication which was noticed to be better for the department which has been certified with ISO9001. In addition, the internal communication across departments via emails is not ensuring that all of relevant people are informed because not all users have emails but only the managers of the departments such as in H4.

Balancing operational continuity:

Balancing operational continuity is a challenge mostly in case the system will be requested to not be used for safety reasons which has a big impact (H1,P2). On the other hand, it was mentioned that if the healthcare institution is on call for emergency cases, system will continue to be used considering the risk-benefit ratio (H3,P3). Also, the duration of the corrective action implementation by field service engineers

is impacting the operational continuity as depending on the change it can take a few or a full day to be corrected (H1,P2 & H3,P1) so system can't be operational in this period (H1,P3).

Resources (financial, staffing, technical):

Most of participants (75%) stated that the financial resources is not a challenge for them. This is because the manufacturervendor/distributor is providing the corrections/technical solutions for free. In rare cases the healthcare institution should buy something additional (H1,P1). It was mostly highlighted that only in case they need to buy new systems or upgrades financial resources is a challenge (H1,P2 & H1,P3 & H3,P3) as well as the limited budget for service activities (H3,P1).

Staffing resources is considered a bigger challenge. Biomedical engineers stated that the departments are understaffed and not permanent people are hired (H1,P1 & H2,P1 & H3,P1 & H4,P1). This has impact in the management of adaptation of medical device changes considering that they can't dedicate more time for adaptation management and they mostly do the basic activities. Also, if one person is on vacation there is the risk to have delays in the necessary actions as there is no back up (H2,P1).

Technical resources is considered for some healthcare institutions a challenge and for others not. According to H1,P2 there are some changes e.g. product improvements that are covered by the manufacturer/vendor/distributor only in case the system has an active maintenance contract. So, the healthcare institutions which doesn't have such contract they don't receive these updates.

Accuracy of information from manufacturers:

Accuracy of information from manufacturers is almost never a challenge as 75% of participants stated that are very clear. According to H4,P1 sometimes the instructions are received in English so they are not understandable for people who don't have a good knowledge of English. Also, in some cases clinical instructions could be a bit more detailed (H2,P2).

Balancing competing objectives:

Most of participants (83%) consider that balancing competing objectives is not a challenge. According to H2,P2 the instructions from manufacturer are always been followed otherwise the responsibility is up to the healthcare institution. But there is also the case that there is an emergency so the risk of using the system is less than not using it so it is being used even if suggested to not be used (H3,P1).

Conflicts between stakeholders:

Most of participants (75%) stated that there are no conflicts between stakeholders. According to H3,P3 conflicts exist but they don't manifest. Also, disagreement is a result of not accepting responsibility (H1,P1).

Managing uncertainty

Most of participants (75%) do not consider managing uncertainty a challenge. According to H1,P1 there is a big uncertainty in regards to the confirmation that all users are being informed about such notifications as in many cases they do not receive the signed customer response form as requested.

Patient care impact

Participants who stated that this is a challenge were referring to the case that it would be requested from manufacturers to stop the use of the system (H2,P1 & H4,P1) or in case the system is not operational during the implementation of the correction (H4,P4).

Bureaucracy

According to participants bureaucracy is a challenge when it comes to the response form completion (H1,P1) and in general when money are involved (H1,P3).

External communication

External communication is not considered a common challenge. According to H1,P2 and H3,P3 it depends on the company/vendor/manufacturer. Also, there is a difficulty for biomedical engineers because of the multiple communications with them (many emails etc.).

Time

Time for managing the medical device changes is considered a challenge only when it comes to continuous monitoring that is needed for ensuring confirmation of receipt which is not done currently (H1,P1). Also, it was mentioned that depending of the change and if there was not a positive impact then it will be considered as waste of time the non-operational status of the system (H1,P2).

***Q15**: The answers of the participants regarding the most significant challenges the healthcare institution faces when planning and implementing plans for adaptation to medical device changes are the following:*

Participant	Most significant challenge on their perspective
H1,P1	Identification of the affected department(s) and informing all relevant stakeholders as well as the collecting their confirmation that have been informed and follow instructions as there is difficulty of getting the signed response form from them
H1,P2	Adaptation to changes which impact the daily routine of department resulting in decreasing productivity until routinize the new way of working. Also, no funding for product enhancements via maintenance contracts
H1,P3	Internal communication for implementation of change as there is the so called force of habit and needs extra explanation and effort
H2,P1	Manage changes related to Magnetic Resonance Imaging systems which are very often and take the most resources. And considering that there is lack of staff resources
H2,P2	No challenges as the communication has been improved when department was certified with ISO9001
H2,P3	Readiness and responsibility for proper examination
H3,P1	Continuation of system operation - reduction of system downtime
H3,P2	Technical resources shortages which downgrade the patient care
H3,P3	Disability to serve the emergencies when healthcare institution is on call and we have been requested to stop use of the system. So, the closure of the emergency room is the biggest problem. Also, the lack of staff as there is a big impact when one person is sick as it will not be manageable when healthcare institution is on call.
H4,P1	Time consuming to contact the different departments and companies in order to organize the issues resolution
H4,P2	Work with people who are not in favor of changes
H4,P3	Smooth and proper operation of systems and departments

Table 1: Most significant challenges

3.4. Meaning of successful adaptation of medical device changes

***Q16**: The answers of the participants regarding the following success factors prioritized when managing adaptation of medical device changes (when 1 means "Not at all" & 7 means "All the time") are the following:*

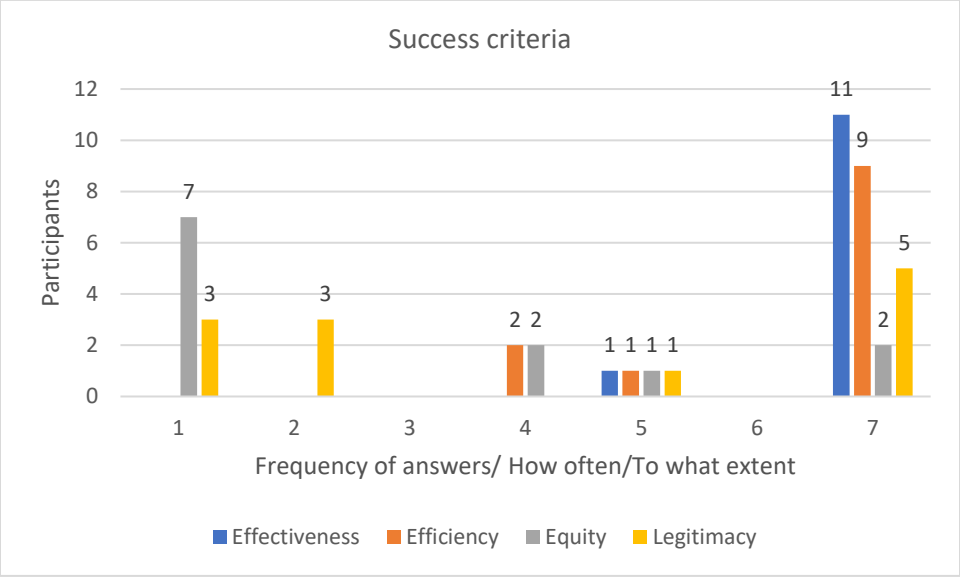

Chart 13: Success criteria of adaptation management

Effectiveness: Almost all participants (~92%) confirmed that the effectiveness is the top success criterion prioritized for the successful adaptation of medical device changes.

Efficiency: Second prioritized criterion is the efficiency according to 75% of participants

Legitimacy: This success criterion is prioritized by some healthcare institutions but for others not.

Equity: Approximately half of the participants (~58%) stated that equity is not considered as a success criteria for the adaptation to medical device changes as they have to follow specific instructions so no equity is considered in general. Some of them are trying to keep a balance after the change adaptation (H1,P2 & H3,P3).

***Q17**: The answers of the participants regarding examples of a medical device change that was successfully adopted in your healthcare institution are the following:*

Healthcare institution 1:

According to HI,P1 the biomedical engineering department was informed by the vendor/distributor about a Field Safety Notice which was related to a design change of an image guided therapy system and more specifically an angiophaphy system for which a problem with the support of a cover was identified. More specifically there was a possibility of the cover to detach and falling on the patients during

examination/therapy. The field service engineer of the vendor/distributors visited the healthcare institution and performed the corrective action successfully (implementation of redesigned cover) and in valid timeline. Then, biomedical engineering department was informed by FSE who provided them the relevant job sheet about its completion and they attached it to the FSN for closure of the case. Based on H1,P2, the product changes can be mandatory or proactive. Mandatory changes are mostly safety related. Proactive changes are usually covered by the maintenance contract. If there is no maintenance contract, the manager of the department should request it in order to get its approval before its supply and implementation. After approval distributor/vendor implements the product change/update and the users are informed in order to adapt to it. According to H1,P3 healthcare institution 1 received a Field Safety Notice related to the software of a computed tomography system for which the reduction of the dose would be necessary to be done. The FSE of the distributor/vendor/ company corrected the issue by installing the updated version of software which would reduce the x-ray dose. Then, x-ray physicist did new measurements in order to check and confirm the operation of the system and that the software really reduced the x-ray doses. As all protocols of the computed tomography system were revised, the clinical application specialist of the company/distributor trained technologists, x-ray physicists and doctors on the new way they should work. The software update and training were done in different hospital visits.

Healthcare institution 2:

According to the H2,P1 the biomedical engineering department received a Field Safety Notice regarding a malfunction of the pneumofascial diagnosis device (insulfator which inflates the abdomen with CO_2). The issue with this device was identified when a patient death was happened abroad. More specifically, the notification stated that both software and hardware correction should be implemented for the safe use of the device. The device was taken out of use for two months until the solution would be available and be implemented by the company/vendor. In the meantime, healthcare institution replaced it with a spare device in order to ensure operational continuity. The department received a Field Safety Notice about the magnetic resonance system related to a problem with the base of the table which was not installed correctly. This could result into patient fall of the table. So, until the company/manufacturer/FSE implement the correction they followed the recommended actions for users provided in FSN e.g. to not place overweight people on the table, pay attention on how they put the patients on the table etc. Company/manufacturer corrected this problem but the technologists continue to be careful about this (H2,P2).

Healthcare institution 3:

According to H3,P1 healthcare institution 3 received a Field Safety Notice about a footswitch of an image guided therapy system. The problem identified was that inappropriate cleaning could lead to stuck of the pedal of the footswitch and as a result to unintended radiation. Field service engineer of the company visited the healthcare institution and implemented the field corrective action successfully and returned the system to its full operation/functionality. Biomedical engineer performed a visual check of the footswitch after the implementation of the solution. According to H3,P2, another example was a notification received which was related to changes to the doses of the system. FSE visited the healthcare institution and implemented the necessary changes. Doctor was informed of the successful implementation. The doctor didn't remember if there were precautionary measures before the solution provided by FSE. In any case, if it had been requested to stop use of the system, they would still continue to use it if the patient was in critical situation for his life so they would take whatever it takes to keep him

alive. Based on H3,P3 healthcare institution 3 was informed about a Field Safety Notice related to a computed tomography system. More specifically, it was accidentally discovered by manufacturer/company that there was a problem with the head protocol and the head would be overdosed if it would not be corrected. An immediate correction was made by the company/manufacturer and as far as the participant remembers they was nothing needed to be done by the technologists.

Healthcare institution 4:

According to H4,P1 healthcare institution 4 received a Field Safety Notice regarding an angiograph intra-aortic pump system which was critical for life. A leak had occurred due to the aging of the material and as a result the pressure couldn't be kept constant. For this reason the manufacturer issued a field safety corrective action. Until the implementation of the correction by the company, the user had to monitor the measured pressure and at the same time what it was showing up on the system. The correction was implemented but not immediately most probably because it was a small company.

3.5. Potential improvements into the already existed adaptation management processes

***Q18**: The answers of the participants regarding what could be improved in your hospital's approach to managing the adaptation of medical device change are the following:*

Participant	Suggestions for improvement
H1,P1	More time in order to be able to handle new changes immediately and monitor the acknowledgement status from relevant department(s) e.g. who have been informed and if they have started implementing the actions needed.
H1,P2	All departments to get ISO in order the healthcare institution to be obliged to cover all the systems via a maintenance contract
H1,P3	More information to be shared when it comes to updates in order to be able to evaluate the changes before their implementation by FSE (some may affect their work but some others not). Some updates are being done by companies without asking/updating the department during the 6 month maintenance so they don't become aware (usually product enhancements).
H2,P1	Better staffing of the involved departments so that management of changes can be more direct and efficient.
H2,P2	Training on new handling protocols
H2,P3	Seminars about management of medical device changes and providing updates before the change is implemented.
H3,P1	- More technical department staff with priority to monitor the changes and their adaptation e.g. by having a schedule to check the next day, next week, month etc. - Training to the department regarding changes (e.g. training about software update)
H3,P2	- Provide general information about the product change and inform all users
H3,P3	- Tightening of referred exams with protocols according to age, gender, etc. without legal consequences - Stricter controls by the Hellenic Energy Commission - Increase in staff - Change of obsolete equipment

H4,P1	- Notifications to be sent in local language (not in English) - Managers/department heads who have emails and receive these notifications from protocol or biomedical engineering department to ensure that all relevant user/stakeholders are informed. (90% of the time it won't reach all users because users don't have emails so the best scenario is the manager to inform the persons who are there at that time. What about the people in different shifts?) - Monitoring if the recommended actions have been taken by users (before the final resolution of the issue by FSE) - Healthcare institution to start treat these notifications with the appropriate importance and with priority. - Healthcare institution to start using the Medical Device Incident Report Card or "White Card" and report incidents to manufacturers and EOF. Now it is not used as it is not in our culture to report such cases.
H4,P2	- Public medical device evaluation by users (general suggestion)
H4,P3	- Close cooperation between different departments to optimize implementation time - Direct communication with technologists (general suggestion)

Table 2: Suggestions for improvements

CHAPTER 4: CONCLUSION

This final chapter provides a discussion on the major findings of the research. Findings will be discussed in relation to the theoretical background of the research and research questions will be answered. Section 4.2 presents the theoretical and practical implications of this study and finally suggestions for future research are presented.

4.1 Interpretation of the results

The current thesis aimed at investigating the adaptation management of medical device changes in healthcare institutions. To achieve this objective, firstly a review of the existing literature was performed. The theoretical framework included an introduction to EU MDR, the different kind of medical device changes, their initiation by manufacturers and the impact to healthcare institutions. Also, the adaptation management including the challenges and the criteria for successful adaptation in healthcare institutions was explored. In particular, one theoretical framework was generalized in order to investigate the adaptation management to medical device changes. Based on the above-mentioned theoretical framework, a qualitative study involving in depth interviewing with Greek public healthcare institutions has been carried out. A total of 12 participants were interviewed using the technique of in depth semi-structured interviews.

The public healthcare institutions that took part in the study have faced medical device changes. When such changes are initiated by manufacturers, healthcare institutions receive a notification from the vendor/distributor of the medical device. And more specifically, for safety related changes this is done though an FSN initiated by manufacturer as it is indeed described in EU MDR. Half of the participants stated that they don't have any idea of the existence of the EU MDR. From the rest, mostly biomedical engineers had average knowledge about this regulation. From the one hand this makes sense considering that this regulation impacts directly Manufacturers, Authorized Representatives, Importers and Distributors as it lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the European Union. From the other hand, this regulation impacts the users as well and in this particular case healthcare institutions.

The majority of participants were familiar to all types of changes and based on their classification (with the help of the*helping guide and an extra explanation of FSN definition given to some of them) it was observed that the most common type of changes are related to software (embedded or standalone) and the device design and performance specifications. Then, material or substance changes, intended purpose changes and sterilization changes including packaging design are following. At that point it was observed that for some system operators and medical professionals it was not clear the difference of medical device changes initiated by manufacturers with the changes performed after a common failure of the system so explanation was provided.

All participants stated that the maximum amount of notifications for medical device changes they can receive per month is five but it can happen to have e.g. a month without any notification. For this reason, an average of received notifications per year was provided as well which is ~10-15 for medium hospitals and ~2-4 for small hospitals. At this point, it was observed that there is not a standard tracking of medical

device changes initiated by manufacturers and so approximate numbers were provided. Also, it was observed that lately more medical device changes have been issued comparing to the past.

FSN includes a factual statement explaining why the field safety corrective action has been issued, including a description of the problem encountered with the product and a clear description of the hazards associated with the specific failure of the device for patients, users or other persons, and where appropriate, the likelihood of occurrence. Based on the examples shared by participants, the most common Field Safety Corrective Action issued by manufacturers is the device modification (including changes made to labelling and IFU). Also, the FSN should clearly indicates all recommended actions to be taken by users. The majority of participants dedicate very few time (1 hour to 2 working days per month) for handling medical device changes and few participants stated that they don't do anything considering that this is a job of biomedical engineers and manufacturer. At this point, the lack of awareness of the shared responsibilities was detected.

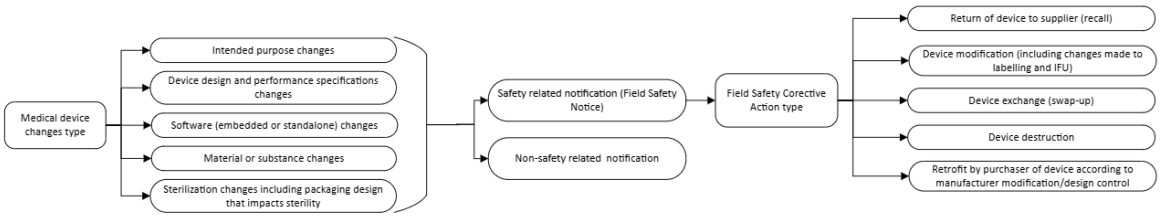

Figure 15: Summary of medical device change types and field safety corrective action types

In order to reply to the first research question on "How healthcare institutions adapt to medical device changes initiated by manufacturers" one general theoretical framework on adaptation to changes was used to explore the existed process.

Adaptation as a process refers to how healthcare institutions are adjusted or reconfigured through their interaction with medical device changes initiated by manufacturers. Healthcare institutions respond to these unexpected changes so they need to facilitate reactive adaptation. Every FSN describes a different issue for which healthcare institutions should take into consideration and act in a short lead time. The analysis showed that there are differences in the adaptation management of medical device changes per healthcare institution. Also, according to all participants in all healthcare institutions there is no established procedure about how medical device changes should be handled internally.

The most common method of the distribution of the FSN by vendor/distributor seems to be via email. First point of contact is mostly biomedical engineering department so the distribution in the healthcare institution starts from them. Below there are the different distribution flows per healthcare institution:

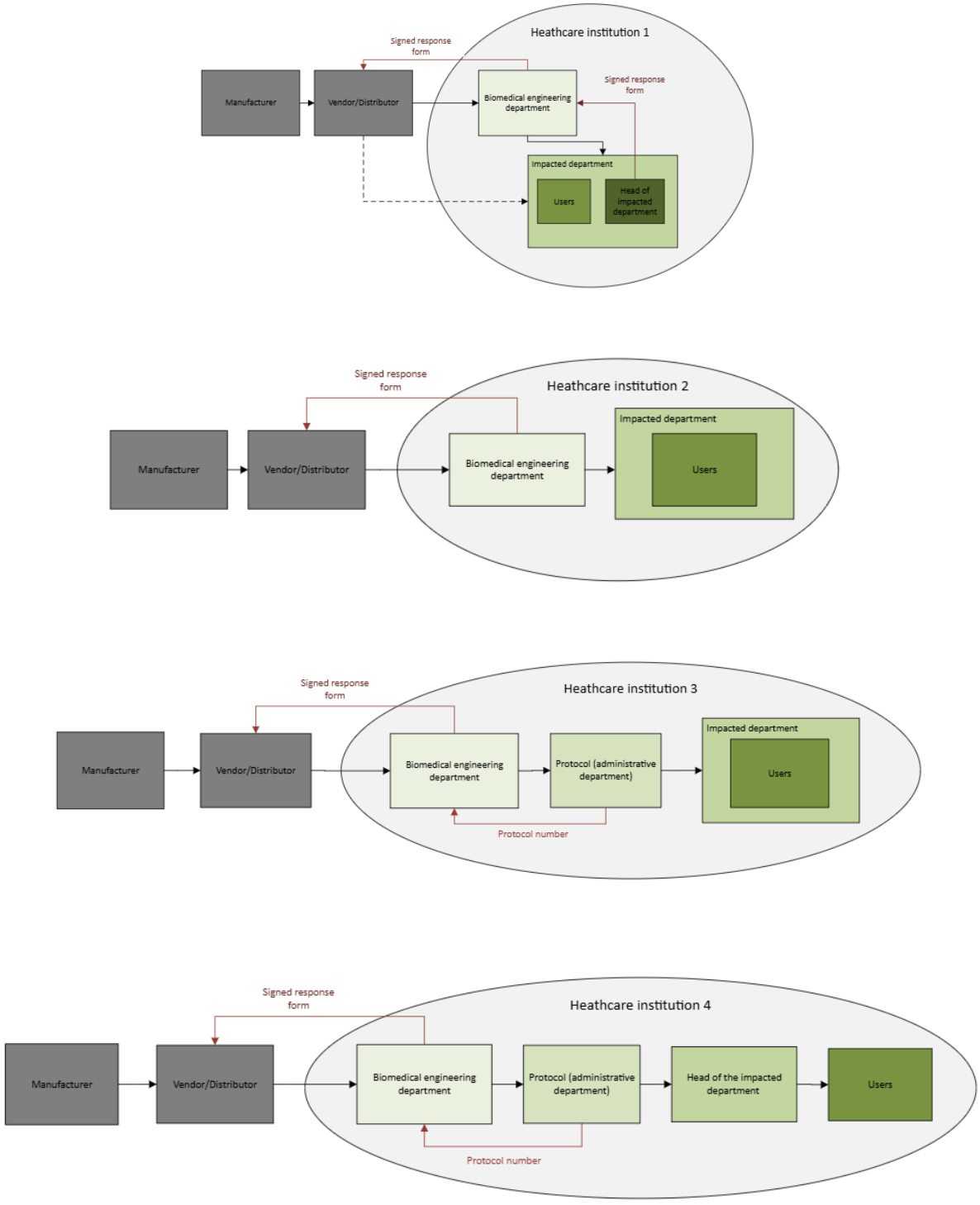

Figure 16: Different distribution of FSN in healthcare institutions

Comparing these activities with the customized general framework of adaptation management the following are observed:

As far as the planning stage is concerned, it seems that only in one out of the four healthcare institutions a kind of assessment of adaptation plans to the medical device changes is being done. Regarding the first step (i) structuring the problem and more specifically about i)a1.Defining adaptation objectives, participant doesn't perform any further action. Objectives are defined in the FSN from manufacturer shared by vendor/distributor. So, it is confirmed that FSN describes the recommended action(s) to be taken by the recipient of the FSN as well as users. About (i)a2.Defining adaptation constraints, it hasn't happened to healthcare institution to have any constraint so the participant doesn't perform any further action as well. About (i)b1.Assessing current vulnerability (risk), it was confirmed that FSN includes a clear description of the hazards associated with the specific failure of the device as manufacturer is performing a risk-based approach for the adaptation of the appropriate risk control measures. Participant performs an internal assessment of the described risk/current vulnerability via an on-site inspection following the actions/instructions describing in the FSN. About (i)b2.Identifying potential future sensitivities, the action(s) that should be taken by the manufacturer and its timeline available in the FSN are being assessed. If there is a technical solution, healthcare institution should adapt to a temporary situation until the implementation of the permanent solution by manufacturer. On the other hand, if there is only an "instructions for use" update, it means that this update should be taken into account for the entire lifecycle of the medical device. In this case, user manual is updated. About (i)c.Defining and characterizing adaptation options, participant confirmed that healthcare institution should follow the already defined recommended action(s) by manufacturer based on FSN which should be followed to minimize or eliminate the relevant risks and ensuring patient safety. So, the participant considers that in reality there is only this option except if healthcare institution decide to not follow these instructions for some reason. Regarding the second step (ii) appraising solutions, about (ii)a.Assessing individual adaptation options, only an extra assessment is being done for additional steps that may be needed. Lastly, about ii)b.Decision analysis to generate implementation plan, participant is always informing the impacted department and asking users to follow the instructions from manufacturer as well as additional action(s) if needed. But what will be done eventually in the department is up to them.

As far as the implementation stage is concerned, it seems that most of the participants are involved in the implementation stage of adaptation plans but depending on their role in different process steps. About (iii)a. implementing plans, the impacted department is suggested to implement the recommended action(s) provided by manufacturers as they are the users (e.g. technologists). Depending of the corrective action released by the manufacturer these recommendations can be temporary or permanent for healthcare institutions. Participants from biomedical engineering department are involved afterwards for contacting vendor/distributor for corrective action(s) implementation. About (iii)b. monitoring, evaluating and reviewing adaptation plans, the monitoring of adaptation is being done in a different way depending on the role of the participant and the healthcare institution. Participants in biomedical engineering department are monitoring the adaptation by making sure that users have provided the signed response form which is the acknowledgement receipt that should be provided to /vendor/distributor/manufacturer or by checking the job sheet of the field service engineer for the successful implementation of corrective action(s). Some participants in specific departments are monitoring the implementation of the recommended action(s) for users. Others are monitoring the field corrective action implementation by FSE and evaluate it by checking the functionality e.g. via image quality testing.

As a result and summarizing all mentioned above, there is not a structured process for medical device adaptation management in public healthcare institutions in Greece. Also, there is not a specific person or department managing the entire medical device adaptation management process but it is a combination of actions performed by different departments. Almost all participants are involved in implementation stage in different steps depending on their role but only in one healthcare institution an assessment of the change is performed before starting the implementation.

In the adaptation management process of medical device changes most involved stakeholders from public healthcare institutions in Greece are the biomedical engineers and technologists. Doctors are following as well as x-ray physicists. Less involved stakeholders are the procurement officers and nursing staff as well as administrative officers and Management. Also, potential involved stakeholders could be other external partners such as research partners, IT partners, stent applicators etc.

Figure 17: Key stakeholders in healthcare institutions

In order to reply to the second research question on "How can healthcare institutions make improvements into the already existed adaptation processes", existed challenges were explored as well as ideas for improvement.

Most common challenge seem to be the staff readiness for change and most specifically for system operators and medical professionals. According to theoretical background, readiness for change is shaped by four interdependent elements (the content, the process, the internal context and the individuals' attributes). Considering that the specifics of what is being changed (content) and how the change will be implemented (the process) are provided through the FSN, the remaining two elements which are the circumstances surrounding the change (internal context) and the characteristics of those involved in or affected by the change (individuals' attributes) seems to be the determinant factors for staff readiness in healthcare institutions. It was observed that in some cases this is related to resistance to changes due to disrupted habits which create the feeling of upset when new ways of working should be followed. Also, refusal of adaption can be rooted in a lack of awareness about their beneficial role towards society. Creating an environment where adaptation plan of the change is not only accepted but actively embraced by raising awareness among members by the manager and department heads is one of the efforts towards smoother transitions deployment and routinizing process which can lead to long-term organizational stability. The readiness is characterized by its dynamic nature as it is influenced by the organization as a whole. Therefore, managers, organizational leaders and change agents can enhance the likelihood of successful adaptation by aligning expectations and fostering a supportive environment for change.

Another common challenge is the coordination across different departments among employees from different backgrounds. It was observed that there was a difficulty for some users/medical professionals to separate the medical device changes initiated by manufacturers with the changes needed after a common failure of the system. It seems that except the lack of awareness for FSN it is also unclear which actions should be taken and by whom. For example, it is not clear who, from which department, is the representative of the hospital who needs to sign the FSN response form and confirm acknowledgment of receiving and accepting the FSN. From the one hand, biomedical engineers who are usually receiving the FSNs are signing it after providing it to the protocol (administrative department) for distribution to the impacted department or after personally assessing it and informing the relevant department. On the other hand, the head of the impacted department is signing it or it can happen that nobody sign it which can raise some concerns. Or the impacted department has not been indeed informed for some reasons (e.g. the notification from the protocol did not sent to them). Or the impacted department has been informed but eventually they don't do it due to unwillingness to sign or even unawareness that they need to sign which is the result of misalignment. In both cases, this creates an uncertainty to biomedical engineers about the implementation of the recommended actions until the final technical solution from manufacturer will be implemented (if any). This uncertainty also exists in cases that biomedical engineers have signed it after receiving the protocol number which in theory ensures them that the impacted department will be informed by administrative department. This confirms the importance of monitoring the acknowledgment of the FSN by collecting signed response forms from impacted departments or by ensuring in a different way that the departments have taken necessary actions. Also, educational training or seminars to all stakeholders would raise awareness and with the combination of a clear guidance inside healthcare institution about the management of FSNs would help employees to understand their role in this process. Last but not least, managers and organizational leaders should embrace cooperation among different departments enhancing the common goal of ensuring patient safety.

Considering the above, all healthcare institutions and stakeholders should treat these notifications with the appropriate importance. All stakeholders should be aware of the scope of an FSN and give attention of the action(s) requested to be taken. This could be accomplished by creating a culture which will prioritize medical device changes with impact on patient safety within healthcare institutions though raising awareness, creating procedures with clear responsibilities for each stakeholder and embracing coordination between different departments for more efficient and effective adaptation management. In this case, the support of managers/organizational leaders would be critical for the successful implementation.

Another challenge for healthcare institutions is balancing operational continuity and at the same time reducing patient care impact mostly in case the system will be requested for safety reasons to not be used until the technical solution will be provided which has a big operation impact for them. The struggle is appearing especially when the hospital is on call for emergencies. E.g. it can happen that an emergency arises and even if the system was suggested to not be used, it will most probably be continued to be used if the risk of using the system is less than not using it. This is also related to the challenge of balancing competing objectives as for example for medical device manufacturers the goal is to ensure medical device safety which lead to patient safety but for medical staff is to do whatever it takes to keep the patient alive. This confirms the major importance of the circumstances surrounding the change (internal context) and the need of doing an assessment every time about the context of the change and to decide an adaptation plan. Also, it seems that the duration of the corrective action implementation by field

service engineers is impacting the operational continuity as depending on the change it can take a few hours or a full day the system to be corrected so system can't be operational at this period. At least in this case the date of the field safety corrective action implementation is planned after an alignment between vendor/distributor and healthcare institution. In this case, close collaboration between manufacturers and healthcare institutions would be necessary.

Staffing resources is also considered a challenge. Biomedical engineers stated that there is lack of resources which means that they can't dedicate more time for some activities such as continuous monitoring of the acknowledgement status from relevant department(s) (who have been informed and started implementing the actions needed) which is not currently done systematically or not at all. There should have been people dedicated to handle new changes immediately (with no delays) and monitor their adaptation with priority e.g. by having a schedule to check its status (the next day, next week, month etc.). Also, better allocation of staff of the involved departments potentially would help the management of changes to be more direct and efficient. Financial resources is not a challenge as the field safety corrective actions are free of charge and only in rare cases healthcare institutions need to buy something extra. Technical resources is considered for some healthcare institutions a challenge when it comes to non-safety related changes e.g. product improvements that are covered by the manufacturer only in case the system has an active maintenance contract. So, the healthcare institutions which doesn't have such contracts don't receive these updates.

To conclude, except the proposals provided above for management of the existed challenges in healthcare institutions, it would be ideal if there was a separate department in healthcare institution which could manage the adaptation of medical device changes from generating the adaptation plan to monitoring its implementation (e.g. Risk management department or Quality Assurance department). This department could coordinate all relevant departments and stakeholders inside healthcare institution ensuring that all are informed about the FSN and aligned on the actions needed to be taken in order to achieve the desired objectives.

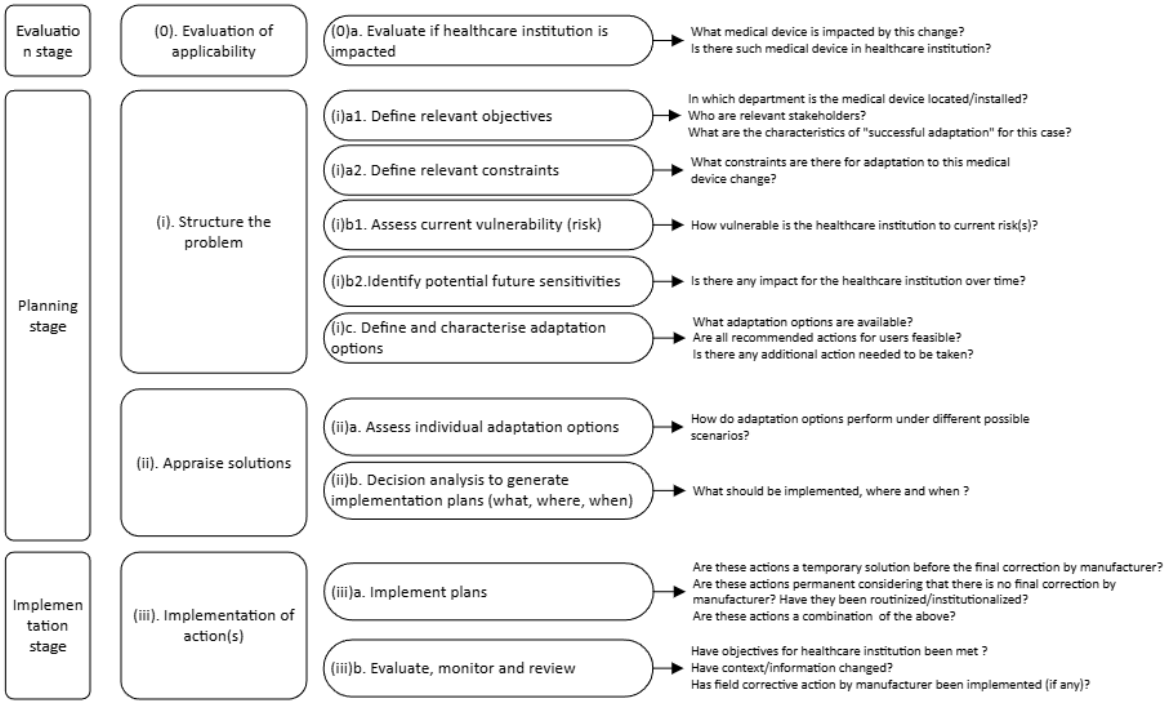

Figure 18: General framework for adaptation decision-making to medical device changes

4.2 Theoretical and practical implications

The findings of this research on the investigation of product adaptation management and more specifically the adaptation management of medical device changes in healthcare institutions have theoretical and practical implications.

This study contributes to the existing literature on product adaptation management in healthcare institutions and has focused particularly on adaptation of medical device changes initiated by manufacturers. Previous research had focused on adaptation management of planned medical device changes however this study is contributing to the adaptation management of unexpected medical device changes initiated by manufacturers. Therefore, as a result, the current research by addressing this gap is expanding the area of subject. Moreover, this study used the Decision-making Process created by Grantham Research Institute on Climate Change and the Environment in 2024 more specifically the general framework for adaptation to climate changes adjusted to medical device changes expanding its potential use partially to healthcare industry as well. However, as current research is limited on adaptation management of medical device changes in public healthcare institutions in Greece, it cannot provide any conclusive results until further research is conducted across different contexts, for example in other healthcare institutions settings and countries.

Moreover, this research provides a contribution to the adaptation management of medical device changes in healthcare institutions in practice. The findings can help the healthcare institutions, both in understanding the background of medical device changes and in adapting to them. Firstly, by bringing more awareness on the factors determining a safety related medical device change initiation by

manufacturers and the importance of effective adaptation for ensuring patient safety. Also, by providing actionable insights to enhance preparedness and streamline processes.

- Raising awareness of all potential corrective actions manufacturers can initiate
- Raising awareness of shared responsibilities for ensuring the safety and performance of medical devices and the importance of identifying all relevant stakeholders
- Providing visibility of the different ways of working across healthcare institutions and potential best practices
- Providing the general framework for adaptation management (evaluating, planning, implementing and monitoring) of medical device changes (figure 18) as a suggestion of improvement of the already existed processes
- Highlighting the challenges healthcare institutions are facing and ways to improve their handling increasing the possibilities of successful adaptation

In addition, this research provides a contribution at a public policy level as it highlights the need of an appropriate public policy as EU MDR and EOF are not currently providing guidelines for maintaining users (both public and private health care facilities) as well as lay users (estimated from the number of home-use medical device vendors) and concerned citizens groups. This could be done by raising awareness and providing information on the importance of patient safety and institutional resilience in managing medical device changes effectively through basic regulatory programs/directions. On the evolving landscape of medical device regulations healthcare institutions should be prepared to follow the technological advancements ensuring patient safety.

4.3 Direction for future research

Although the findings of this research have theoretical and practical implications, some limitations related to the methodology applied in this study were mentioned in Chapter 3. This study has revealed that there is not an established process of medical device changes adaptation in healthcare institutions which is critical for ensuring patient safety. Moreover, the adaptation management of medical device changes is not done by a specific department but it a combination of actions performed by different departments which makes it more complicated. Considering that biomedical engineering department is managing only medical devices for which maintenance activities are needed (systems), it would be interested to investigate what is happening with medical device changes for consumables (e.g. pads of defibrillators) by interviewing employees in healthcare institutions but with different roles e.g. procurement officers. Also, it would be interested to investigate the adaptation management in case of other types of field safety corrective actions except device modifications in order to understand how healthcare institutions manage these cases as well. As the findings of this research refer to a relatively small sample size and to a specific context, it is suggested that future research investigates the adaptation management of medical device changes in healthcare institutions across different countries in Europe as well as different healthcare institution settings (e.g. private healthcare institutions). It could also be extended to countries with other regulatory frameworks like U.S. FDA regulation in order to have a global perspective. In addition, a future research could explore deeper the adaptation management steps e.g. the risk assessment or tracking and monitoring of the medical device changes in healthcare institution. Also, it would be interested if it would be possible to measure the readiness of healthcare institutions as well as the successful adaptation. In addition, it could be explored the manufacturer and healthcare institution

dynamics. Moreover, this research proposed suggestion for improvements for healthcare institutions so it would be beneficial to investigate for future the effect of these factors on the medical device adaptation management, for example by applying a quantitative research method. Finally, another interesting and connected subject to safety related medical device changes would be how Greek public healthcare institutions are managing the safety or potential safety incidents related to medical devices.

PERSONAL REFLECTION

This thesis "Product Adaptation Management: The case of medical device changes in Healthcare Institutions" allowed me to explore the importance and the complexity of the intersection of the regulatory frameworks, healthcare operations and the impact of technological advancements on patient safety. More specifically, I have gained a deeper understanding of when medical device changes are being initiated by manufacturers based on the regulation and how healthcare institutions adapt to them especially those triggered by FSNs. I also learned about the importance of a comprehensive approach to adaptation management and of creating a proactive, structured system for managing and evaluating these changes over time. An effective adaptation relies on clearly defined objectives, ongoing evaluation, and the ability to adapt strategies based on feedback and emerging challenges. Therefore, even if healthcare institutions can't know what medical device change will be initiated by manufacturers they can be prepared to accept and adapt to it. The highlight of this research was the on-site interviews conducted which gave me the opportunity to contact experienced people and deep dive on the healthcare environment understanding the general process and the challenges employees are facing. From the other hand the diversity of the roles of the participants and considering of how different healthcare institutions approach these changes made it challenging for me to summarize the results of qualitative data. However, these challenges ultimately led me to discover valuable insights. This thesis has truly been a valuable learning journey as it has strengthened my critical thinking, helped me connect a variety of perspectives, and taught me to stay open to surprises and shifts in direction. In conclusion, I am proud of how this work came together and hopeful that it contributes to a better understanding of the adaptation management process and offer practical recommendations for improving the management of medical device changes in the future maintaining high standards of patient care and safety.

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APPENDIX 1: PROFILE OF HEALTHCARE INSTITUTIONS

Healthcare institution	Location	Size	Scope	Services
H1	Athens	~700 beds	Quaternary care (extension of tertiary care)	Clinics vascular surgery clinic, orthopedic clinic, cardiology clinic, anesthesiology clinic, venereal and skin diseases clinic, neurological clinic, neurosurgery and neurotrauma clinic, intensive care clinic, urology clinic, pulmonology clinic, pre-educational pathology clinic, psychiatric clinic, otolaryngology clinic, ophthalmology clinic, obstetrics-gynecology clinic, oral and maxillofacial surgery clinic, pediatric clinic, surgical clinic, pathology clinic, thoracic surgery clinic, cardiac surgery clinic, pediatric surgery clinic, emergency clinic Laboratories Hematology lab - Blood Donation Unit, Radiology lab, Diagnostic Cytology lab, Clinical Microbiology lab, Clinical Biochemistry lab, Pathological Anatomy lab
H2	Athens	~250 beds	Quaternary care (extension of tertiary care)	Clinics anesthesia clinic, surgical clinic (eg vascular surgery), obstetrics-gynecology clinic, neonatology clinic, nephrology clinic Laboratories radiology lab, biopathology lab, hematological lab -blood donation service , pathology lab, cytological lab, hormonal lab
H3	Athens	~200 beds	Tertiary care	Hemodynamic department, cardiology department, neurological department, pathological department (pacemaker clinic, gastroenterology clinic, diabetic clinic, endocrinology clinic, hepatology clinic, heart failure clinic & hemodynamic clinic, infectious medicine, cardiology clinic, lipidemic clinic (pathological, cardiology), metabolic diseases, neurological department, pathological clinic, fatigue test, heart triplex, hypertension medicine
H4	Athens	~630 beds	Tertiary care (general hospital with trauma orientation)	Pathological sector (Pathology clinic, rheumatology clinic, cardiology clinic, neurology clinic, physical & medical rehabilitation clinic, pediatric clinic, dermatology clinic, psoriasis clinic, nail disease clinic), A' surgical field (orthopedic clinic, university orthopedic clinic, pediatric orthopedic clinic, scoliosis & spine clinic, hand-microsurgery clinic of the upper extremity, sports injuries clinic), B' surgical field (general surgery clinic, neurosurgery clinic, plastic surgery clinic & burns unit, oral & maxillofacial surgery clinic, vascular surgery clinic, thoracic surgery clinic, dental clinic, ophthalmology clinic), Interdisciplinary departments (ICU, Emergency Department, anesthesiology, sleep assessment and treatment clinic)

APPENDIX 2: PROFILE OF PARTICIPANTS INTERVIEWED

Healthcare institution	Participant	Role	Years of experience	Department	Department size (no. of employees)
H1	P1	Biomedical engineer	19	Biomedical engineering department	5
	P2	Technologist	23	Department of Imaging/Department of Magnetic Tomography	27/4
	P3	X-ray physicist	17	Radiology department	~50
H2	P1	Head of Biomedical Engineering department	23	Biomedical engineering department	2 (+2 students)
	P2	MRI Technologist	20	Magnetic tomography department	2
	P3	Head of diagnostic radiology department & CT technologist	36	Diagnostic radiology department /Computed tomography department	20/4
H3	P1	Biomedical engineer (clinical)	10	Biomedical engineering department	1 permanent +1 auxiliary staff
	P2	Interventional doctor	2,5	Cardiology department	8 supervisors + 10 residents
	P3	Technologist	18	Radiology department	14
H4	P1	Deputy director of technical services & Head of biomedical engineering department	32	Technical services department & Biomedical engineering department	Biomedical engineers (4) , Engineers (15 permanent + 35 contractors)
	P2	Technologist	30	Radiology department	32
	P3	Technologist	28	Computed and Magnetic tomography department	10

APPENDIX 3: INTERVIEW GUIDELINE

PRESENTATION OF THE TOPIC

Explanation of the purpose of the study and interview structure

PARTICIPANT BACKGROUND AND HOSPITAL CONTEXT

Presentation of the organization and the participant

Q1: Can you provide a brief overview of the size, scope and services of the healthcare institution?

Q2: Can you describe your role within the healthcare institution, your department, its size and for how long you have been working in this position?

FAMILIARITY WITH MEDICAL DEVICE CHANGES AND EU MDR

Q3: On average how many medical device changes do you receive per month?

	Never	Max 5 per month	Max 10 per month	Max 15 per month	Max 20 per month	Max 25 per month	Above 25 per month
Frequency of medical devices changes							

Q4: Based on your experience, which of the following different types of medical device changes do you experience mostly? (When 1 means "Not at all" & 7 means "All the time")

		1	2	3	4	5	6	7
Medical device change type	Intended purpose changes							
	Device Design and performance specifications changes							
	Software (embedded or standalone) changes							
	Material or substance changes							
	Sterilization changes including packaging design that impacts sterility							
	Other changes (which?)							

Q5: How much of your time would you say that managing medical device changes takes in your daily activities? (When 1 means "0%" & 7 means "100%")

	1	2	3	4	5	6	7
Time allocation							

Q6: To what extent are you familiar with EU Medical Device Regulation which took effect in May 2021? (When 1 means "Not familiar at all" & 7 means "Extremely familiar")

	1	2	3	4	5	6	7
Familiarity of EU MDR							

ADAPTATION MANAGEMENT PROCESS OF MEDICAL DEVICE CHANGES

Q7: How are medical device changes from manufacturers communicated to the healthcare institution/you? (When 1 means "Not at all" & 7 means "All the time")

		1	2	3	4	5	6	7
Method of communication	Telephone call							
	In person							
	Email							
	Courier							
	Other (which?)							

PLANNING STAGE

Q8: When your healthcare institution becomes aware of the medical device change, do you plan the adaptation process before the implementation?

	YES	NO
Assessment of medical device change		

If Q8 is positive (YES), go to Q9.

If Q8 is negative (NO), go to implementation stage.

Q9: Are there established procedures in the healthcare institution for assessing adaptation to medical device changes? If yes, could you please describe it?

	Yes	No

Existence of established procedures		

Q10: During the planning stage of the adaptation of the medical device change, to what extent are the following steps being done? Is there any other step you are following? (When 1 means "Not at all" & 7 means "All the time")

			1	2	3	4	5	6	7
Planning stage	(i)Structuring the problem	(i)a1.Defining adaptation objectives							
		(i)a2.Defining adaptation constraints							
		(i)b1.Assessing current vulnerability (risk)							
		(i)b2.Identifying potential future sensitivities							
		(i)c.Defining and characterizing adaptation options							
	(ii)Appraising solutions	(ii)a.Assessing individual adaptation options							
		(ii)b.Decision analysis to generate implementation plan							
		Other (which?)							

IMPLEMENTATION STAGE

Q11: When the adaptation plan has been finalized/decided, are there established procedures in the healthcare institution for implementing it? If yes, could you please describe it?

	YES	NO
Existence of established procedures		

Q12: During the implementation stage of the adaptation of the medical device change, to what extent are the following steps being taken? Is there any other step you are following? (When 1 means "Not at all" & 7 means "All the time")

		1	2	3	4	5	6	7
Implementat	(iii)a. Implementing plans							

	(iii)b. Monitoring, evaluating and reviewing adaptation plans							
	Other (which?)							

Q13: To what extent are the following key stakeholders involved in the implementation stage of adaptation to medical device changes? Can you think of anyone else? (When 1 means "Not at all" & 7 means "All the time")

		1	2	3	4	5	6	7
Key stakeholders	Administrative officers							
	Biomedical engineers							
	Doctors							
	Management							
	Procurement officers							
	Manufacturers/ Vendor/Distributor							
	Physicists							
	Technologists							
	Nurses							
	Respiratory therapist							
	Patient							
	Other external partners (which?)							
	Other hospital staff (which?)							

CHALLENGES

Q14: Which of the following different challenges when planning and implementing plans for adaptation to medical device changes do you experience mostly experience? (When 1 means "Not at all" & 7 means "All the time")

	1	**2**	**3**	**4**	**5**	**6**	**7**
Balancing operational continuity							
Balancing competing objectives							
Coordinating across departments							
Managing uncertainty							
Financial resources							
Staffing resources							

Technical resources							
Internal communication							
External communication							
Conflicts between stakeholders							
Staff readiness for changes							
Resistance to change							
Accuracy of information from manufacturers							
Patient care impact							
Bureaucracy							
Time							
Other (which?)							

Q15: What are the most significant challenges the healthcare institution faces when planning and implementing plans for adaptation to medical device changes?

SUCCESSFUL ADAPTATION

Q16: To what extent are the following success factors prioritized when managing adaptation of medical device changes? Do you consider anything else? (When 1 means "Not at all" & 7 means "All the time")

		1	2	3	4	5	6	7
Success criteria	Effectiveness							
	Efficiency							
	Equity							
	Legitimacy							
	Other (which?)							

Q17: Can you share an example of a medical device change that was successfully adopted in your healthcare institution?

SUGGESTIONS FOR IMPROVEMENT

Q18: In your opinion, what could be improved in your hospital's approach to managing the adaptation of medical device changes?

HELPING GUIDE

Examples for better understanding

Medical Device Change Type	
Intended purpose changes	Expanding/Reducing the intended purpose
	Introducing a new user or patient population
	Modifying the clinical application, such as change in anatomical site, change in delivery or clinical deployment method
	Labeling changes, such as updates to contraindications or warnings affecting the intended use
Device Design and performance specifications changes	Alterations in operating principles
	Modifications that could impact safety or performance, affecting the device's benefit-risk balance
	Changes to built-in control mechanisms, energy sources, or alarm systems.
Software (embedded or standalone) changes	New or major updates to the operating system or any component, architecture or database structure.
	Algorithm modifications or replacement of user input with closed-loop algorithms.
	New ways of presenting medical data, such as format, dimension, or measurement unit.
	Any software change that may negatively affect the benefit/risk ratio of the device.
	Changes affecting interoperability, adding new features or functionality or adding new user interface (for non-IVDs)
Material or Substance changes	Addition of new or change to materials of human or animal origin.
	Modifications to medicinal substances or their excipients.
	Changes to materials or substances in contact with the patient's tissue or fluids for extended periods (more than 30 days) or that are part of surgically invasive, absorbable devices.
	Changes that affects safety or performance and negatively affects the benefit/risk ratio of the device.
Sterilization Changes including packaging design that impacts sterility	Switching terminal sterilization methods. Alterations that compromise sterility assurance levels (per the corresponding international standards).
	Packaging changes impacting sterility or microbiological stability including seal integrity.
	Shelf-life extensions not validated through approved by the Notified Body protocols.

Success criteria	
Effectiveness	achieving the desired objectives, such as improved safety or compliance
Efficiency	minimal disruption to ongoing operations like resource allocations (e.g., staffing, budget, reduce the time taken to implement changes.
Equity	changes are implemented in a way that benefits all departments and patient groups equally
Legitimacy	transparency, building trust and legitimacy among staff, involved in decision-making processes