

MASTER THESIS BUSINESS ADMINISTRATION

INVESTMENT DECISION-MAKING IN DUTCH HOSPITALS

EXAMINING THE DECISION-MAKING PROCESS FOR INVESTMENTS IN NEW TECHNOLOGIES
WITHIN DUTCH NON-ACADEMIC HOSPITALS AND PROPOSING A DECISION-MAKING
FRAMEWORK.

O.A.J. ROESINK

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AUTHOR(S)

O.A.J. Roesink

STUDENT NUMBER

S2606305

TELEPHONE

06-12729174

EMAIL

o.a.j.roesink@utwente.nl

WEBSITE

www.utwente.nl

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I am proud of the final result and hope you will enjoy reading my thesis.

Abstract

Dutch hospitals are facing financial constraints that threaten the quality of care, with a growing need for investments in efficient technologies and process redesigns. Due to their narrow margins, hospitals struggle to achieve these necessary transitions. Investment decisions in medical technologies are crucial, as they significantly affect both financial and medical performance. With a rising number of financially unhealthy hospitals, choosing efficient technologies is essential for improving long-term financial stability and care quality. This research explores how investment decision-making processes can be improved in Dutch hospitals, where multiple criteria are often considered.

This research is a qualitative study in which the current investment decision-making process has been identified through a combination of literature review, interviews, and follow-up verification. During the interviews and follow-up verification, issues within the process were identified, and potential solutions were proposed.

Based on the findings from the literature review, interviews, and follow-ups, an integrated process has been developed that is not only scalable for investments in medical technology but also applicable to other areas such as infrastructure and IT. A step-by-step plan is outlined, highlighting all key elements of the decision-making process. This plan includes recommendations on multidisciplinary collaboration and stakeholders that should be involved, a specific criteria selection, financial considerations, risk assessment, an evaluation cycle, and reducing both the complexity and administrative burden of the process.

The comparison of hospital investment processes reveals significant differences in structure, formality, and integration, highlighting varying levels of maturity. Hospitals with highly structured processes utilize standardized formats, multiple review stages, and comprehensive financial and risk assessments, whereas others follow a more flexible yet inconsistent approach. A striking finding is the inconsistent weighting of decision-making criteria and risk analysis, where some hospitals adopt a holistic view from the outset, while others only assess financial and strategic implications later in the process. Additionally, integration levels vary, with mature hospitals incorporating IT, infrastructure, and operational costs early on, while less mature hospitals handle these aspects separately. These differences present an opportunity to develop a shared framework that enhances decision-making consistency and fosters professionalization across hospitals.

The model that is proposed is the result of interviews, follow-ups, and input from nine different hospitals. This collaborative approach has provided a comprehensive perspective, incorporating various components into the process. Through this joint effort, a well-rounded and effective model has been developed. It includes components that every hospital should consider incorporating into their process. Hospitals or other researchers are encouraged to test this process, or its components, to assess its applicability within ‘the

field'. While a general framework has been outlined, investment decision-making processes remain highly complex, requiring hospitals to tailor their approach based on their unique characteristics and specific needs. Continuous evaluation of the process keeps very important to keep up with all the challenges that healthcare organization will face.

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1. Introduction

1.1 Background

In the dynamic landscape of Dutch healthcare, hospitals are grappling with financial constraints that threaten their ability to maintain the high quality of care. Due to increasing pressure on healthcare, deep investments in new and more efficient technologies, digitalization, and the redesign of healthcare processes are urgently needed to reduce the workload on scarce personnel and ensure the quality of care. However, due to their narrow margins, hospitals are unable to achieve the necessary transition, as stated by the IZA [1] [2]

Hospitals are the biggest purchasers and users of medical technologies. Their adoption of these technologies significantly impacts both the financial and medical performance of a country's healthcare system. Technologies often are very expensive, so investment decisions are crucial for the hospital's long-term effects on their financial stability. Therefore, understanding and enhancing the investment decision-making processes in hospitals is essential for achieving better and more affordable healthcare at both the hospital and national levels.[3] Which eventually can increase the financial health and the quality of care of hospitals. [3][1] In a recent publication that is looking at the current financial health of hospital in the Netherlands, it can be seen that the proportion of financially unhealthy hospitals increased from 11% to 40% in 2023. [4] The financial health of hospitals in the base scenario deteriorates in 2023 and 2024 to such an extent that more than 50% experience a covenant breach or liquidity problem in 2024. [4] Hospitals can only spend the money that they invest once, therefore choosing efficient new technologies is crucial. Investing in profitable and potentially cost-reducing equipment can positively impact the financial health of hospitals. According to a study by the RIVM on the acquisition and introduction of medical technology in hospitals, investment projects can be improved. More control and structure are needed to follow important steps. [5]

Hospitals are not necessarily focused on profit, which means that other aspects may also be considered in an investment decision. For this reason, it is particularly interesting to investigate how these processes take place and can be improved in Dutch hospitals, because it is possible to include multiple criteria in an investment decision.

1.2 Research objectives

The primary objective of this study is to analyze the current decision-making processes within Dutch hospitals, including the challenges they encounter and potential areas for improvement. Based on this analysis, a process will be proposed to address these challenges and establish an efficient and effective workflow.

To achieve this objective, the research will investigate the current investment practices in Dutch hospitals, identify the factors and stakeholders influencing investment decisions in their hospital, discover faced problems within the process and evaluate the efficiency of existing decision-making processes according to a model that is developed from the existing literature and empirical findings. The main research question of the research is: “How can Dutch hospitals determine investment decisions for new medical technologies?”

This study can be divided into multiple phases. The phases undertaken in this study are based on the steps of design thinking research. Normally the steps of the design thinking process are: empathize, define, ideate, prototype. [6] This study follows the steps of this theory as a guideline but will deviate from the ideal standard. For example, the empathize phase will be replaced by a literature review and corresponding interviews. Based on this, key points will be identified, allowing for the development of a structured process. While this research does not constitute a full design study, it still incorporates a significant design component. Eventually, the research is structured into four phases, with some phases of research integrating multiple steps of the design thinking process.

The study's first phase will involve a comprehensive review of existing literature, specifically focusing on the decision-making processes related to investments. There will be made of a funnel approach towards the literature review. The review will begin by examining general concepts about investment options before delving into the specific circumstances faced by hospitals in the Netherlands. The aim of this review is to identify key factors influencing investment decisions, such as cost considerations, clinical priorities, legal limitations, and the impact of technological advancements. Additionally, it will explore established frameworks and protocols for decision-making. Based on the findings, a foundational framework will be developed outlining potential steps and criteria for making investment decisions. This framework will serve as a basis for future research and refinement of the proposed process.

The second phase involves examining current practices in Dutch hospitals. This will include an in-depth exploration of how hospitals currently make investment decisions, structured by the findings from the literature research. It will involve understanding the roles of various stakeholders such as hospital administrators, medical staff, financial officers, board of directors and personnel from medical technology departments. It also focuses on identifying the diverse range of factors that influence investment decisions. These factors may include financial considerations like budget constraints and return on investment, clinical needs such as patient outcomes and healthcare demands, regulatory requirements, and technological improvements. The second area also involves evaluating the efficiency of the theoretical model that is proposed from existing literature and theories. It will involve comparing the processes with the theoretical model and theories identified in the existing literature to pinpoint gaps and areas for improvement.

The third phase is the revising of the model following the initial findings and will undergo a follow-up phase for further refinement. The updated version of the theoretical model will be discussed with respondents for feedback. This step will lay the final base for the third and last area.

The last stage concentrates on creating an organized procedure and a model or optimal practice framework that incorporates insights from the literature review, the examination of current practices, and subsequent validation. The produced process and framework provide a systematic set of steps and criteria for making investment choices that consider both theoretical concepts and practical circumstances. Its purpose is to provide hospitals with improved investment outcomes, enhance decision-making efficiency, and enhance organization. This phase marks the completion of the study, merging empirical data and theoretical insights to establish a comprehensive model. Section 3.2 provides a detailed exposition of the aims and methodologies of the research.

1.3 Contributions

BDO provides several recommendations to translate the IZA plans that have already been introduced into concrete actions. These include the flexibilization of cost and revenue structures, an integrated perspective on investments, financial support for necessary sustainability investments, and the digitalization of healthcare. [1] In this study the focus will be on creating a better understanding of an integrated perspective on investments.

In this research we will take a look of the investment-decision making in Dutch hospitals. While existing studies often focus on international or generalized contexts, this research addresses the particular needs and constraints of Dutch healthcare institutions, making the findings and recommendations directly applicable to improving the efficiency and effectiveness of hospital operations in the Netherlands. Examining the existing literature, two articles about investment-decisions in the Netherlands was found, but one of this articles has been published in 1988. [7][8] Then it can be seen as outdated, because the health industry is and has been changing rapidly in the past years. A study by the RIVM on the acquisition and introduction of medical technology in hospitals was also found. It highlights key issues regarding investments within Dutch hospitals; however, it does not provide any examples of how the processes are currently organized in their entirety or how these processes could potentially be improved. The research that will be described in this paper provides recommendations on how certain points of concern identified in both the literature, for example as stated in the RIVM paper and practices can be improved.

A guideline for new interventions in clinical practice was also established in 2013. However, this guideline primarily focuses on the introduction of medical technology and associated risks. It lacks a clear and detailed process description, and any relevant factors are only superficially addressed. [9] Follow-up research, dated from 2020, has further highlighted that the current versions of the

guidelines and the Medical Technology Covenant are outdated in certain areas and are no longer fully applicable to current practices. Additionally, the NIKP has not been fully implemented within hospitals, and many hospitals still adhere to their internal protocols. This underscores the importance of exposing the current practices and potential areas for improvement. [10]

A lot of the current research on hospital investment choices is obsolete and does not consider the current economic pressure, technological advancements, and growing healthcare demands that hospitals are experiencing today. This study aims to address this gap by gathering updated data and viewpoints from various hospitals in the Netherlands. By taking into account recent changes and modern challenges, this research provides more pertinent and practical advice for hospital decision-makers than what is currently available in the literature.

Another key differentiator of this research is its focus on the collaboration with different disciplines in the hospital regarding the decision-making, including financial experts, medical professionals, and hospital staff. It is known that the integration of stakeholders in the decision making process leads to a higher level of rationality because it integrates multiple perspectives and reduces the influence of individual biases. [11] This interdisciplinary approach ensures that investment strategies are well-rounded, and all of the possible different perspectives are taking into account.

As last, the EU is currently working on an HTA Regulation. The fact that the EU is actively working on this topic highlights its importance and the need for further research. The regulation of the EU addresses quite the same topic and at first sight looks quite familiar. [12] However, there are some limitations, making additive research, like this study, highly relevant. The HTA regulation focuses only on high-risk medical devices and will not be fully operational until 2030. [12] The collaboration is limited to reporting on the performance and safety of a medicine or medical technology compared to standard care. The European reports do not include statements about the value of interventions. Instead, these reports are used as input for national assessments, primarily concerning the effectiveness of interventions. Importantly, economic, ethical, and organizational aspects are not included in these reports, but they will be a part of this research, adding a broader perspective. [13] This inclusion of additional dimensions highlights the need for more comprehensive studies that go beyond the scope of current EU efforts.

1.4 Overview of the structure

This study will begin with an extensive literature review, which will be found in Chapter 2: Theoretical Framework. To develop this comprehensive theoretical framework for understanding investment decisions in new medical technologies within Dutch hospitals, a funnel approach will be adopted that progresses from broad concepts to more specific contexts.

First, the general theory of investment decisions will be explored, based on relevant academic literature and theoretical models. This will provide a foundational understanding of the principles and factors that influence investment choices in various sectors, which also can be applicable to hospitals. Next, the focus will narrow to the particularities of investment decisions concerning new technologies. This involves discovering the unique characteristics and challenges associated with investing in innovative technologies, for example uncertainty and rapid evolving changes. Following this, the concentration will shift to investment decisions within the hospital setting. Hospitals can have specific considerations that differentiate their investment processes from other organizations, because hospitals technologies can have more outcomes than only be cost-effective and profitable. When investing in new technologies for hospitals, also quality of care and efficiency can be important in the decision-making process. Finally, the literature will be reviewed to determine what is already known about the steps in the decision-making process with additionally a stakeholder analysis that will be mapped out, identifying the roles and influences of various parties involved, such as medical staff, hospital management, patients, and external bodies.

Based on these findings in the literature, an interview protocol will be developed, which will be used to conduct interviews in this multiple case study at various Dutch hospitals. The purpose of the interviews is to gain insight into the practical processes within Dutch hospitals. The existing literature offers limited information about how these processes are conducted, necessitating field research to uncover the details of investment decision-making in hospitals. The field research utilizes a theoretical model as a starting point, which respondents are encouraged to criticize. This approach gives valuable insights and will ensure that feedback will arise from the respondents in the field. The model serves as a foundational element throughout the research, undergoing continuous evaluation and refinement based on findings and input gathered during the interviews. After the interviews, a follow up will be organized based on the results to delve deeper into certain interesting findings for better understanding. Subsequently, the data will be analyzed using thematic analysis and coding. This will allow for the comparison of different cases, similarities and patterns in answers and provide a description of how Dutch hospitals make investment decisions. Eventually, when gaps and problems that are faced by the hospitals become clear, a model or best practice can then be proposed to potentially make these decisions more structured and efficient.

2. Theoretical framework

In this chapter, the theoretical framework will be presented. This will lay the foundation for the research through findings from existing literature. Information from the literature that is useful will be presented in a funnel shape, working from broad information to specific information relevant to this research.

First, the theory of general investment decisions will be explained, followed by an in-depth look at investment decisions for new technology and what makes these decisions unique. Then, investments within hospitals will be examined and how these differ from investment decisions in other companies. Next will be the importance of the stakeholders be analyzed. Lastly, what is already known about the steps in the investment decision-making process will be presented. All of this will provide the structure for the research in the field at a later stage. This framework will be used to propose a structured interview scheme and evaluate how hospitals currently make investment decisions.

2.1 Theory of general investing decisions

Investment decisions are critical for the growth and sustainability of any organization. These decisions involve evaluating potential investments to determine their viability, added value and expected returns. As indicated, this theoretical framework will start broadly by first examining how 'normal' investment decisions are weighed against each other. These decisions often focus primarily on profitability, which is different from hospitals, as will be further explained in section 2.3. Several methodologies have been developed to guide this process, each with its unique approach and focus. The most used methods for evaluating investment opportunities will be discussed. The methodologies that are used can be divided into static evaluation methods and dynamic evaluation methods for investment efficiency.

Static methods focus on the short-term or a specific period, without considering the entire lifespan of the investment or the effect of time on money value (i.e., time value of money). These methods are simple to compute and easy to understand, which makes them attractive for straightforward decision-making, which can be useful when quick decision-making is needed in critical moments. However, they are limited in scope because they don't consider the evolving nature of investments over time, future cash flows, or the changing risks that may arise during an investment's lifecycle. Methods that can be seen as static evaluation methods are: Payback period, accounting rate of return, cumulative cash flows and the rate of return (return on investment).

The Payback Period (PBP) measures the time required to recover the initial investment costs from the net cash flows generated by the Technology. Van Horne and Wachowich define that the payback period indicates the number of years required to repay the money that is invested.[14] In the case of hospital equipment, this is when the device has yielded as much as the device has cost, in financial

resources. The Accounting Rate of Return (ARR) represents the ratio of the average annual accounting profit to the initial investment cost. The average is all of the accounting gains and/or losses added up within the number of years. [15] Cumulative Cash Flows (CCF) represent the final sum of all future net cash flows over the investment's entire life, providing an absolute measure of the Technology's efficiency. A positive CCF represents an efficient investment, because it will be profitable a negative CCF will represent an inefficient investment. The Rate of Return (ROR), also known as Return on Investment (ROI), is the percentage of net profit after tax from investments, calculated by dividing net profit after deducting costs by the total investment cost. A higher return of investment indicates a better investment, because more profit will be made. [16] All of these four methods can be used for the decision making for new technologies, but numbers all should be estimated, because the technologies aren't active when calculating. While all these four methods are simple to compute and understand, they should not be used alone but alongside other methods for a comprehensive evaluation.

More comprehensive are the dynamic evaluation methods. Dynamic methods provide a more comprehensive and long-term view of investments by factoring in the entire investment lifecycle and the time value of money. These techniques discount future cash flows to account for risks and changing economic conditions over time. Dynamic methods are more complex and better suited for evaluating long-term investments or investments with significant uncertainties, which can be applicable in a hospital setting. They allow planners to understand the overall profitability of a project, including the impact of changing conditions over time. [14]

The Net Present Value (NPV) technique adds up all of an investment technology's future net cash flows, discounts them to their current value, and deducts the initial investment. A technology is considered efficient if its net present value (NPV) is positive, break-even if it is neutral, and inefficient if it is negative. [14] A monetary unit-based absolute measure of efficiency is provided by net present value (NPV). It might be difficult to determine the right discount rate to account for potential cash flow risks, which is one of the critics about this method.

The discount rate that brings a technology's net present value (NPV) to zero is called the internal rate of return, or IRR. A technology's efficiency is determined by whether or not the IRR is higher than the lowest allowable rate. Even though the IRR approach has benefits, it also has limitations. These include the inability to provide a monetary value, the possibility of several IRRs in intricate technologies, and difficulties figuring out the lowest acceptable rate. [14]

All of these three methods also are applicable to investment decisions for technologies in hospitals. Also with the dynamic methods, some estimating is needed for predicting the accurate numbers.

So, in conclusion, while static methods provide quick and simple answers, dynamic methods offer a more accurate and holistic view of an investment's feasibility and profitability over time. It is important to assess which methods hospitals use to evaluate investments in order to gauge how well

they consider financial costs and benefits. Understanding this will provide insight into the level of financial rigor hospitals apply when making decisions about new technologies. Therefore, this aspect will be used into the framework to ensure that hospitals' decision-making processes are adequately assessed for financial sustainability and efficiency.

As said in the beginning of this chapter, more criteria are needed to investigate for the decision-making process for new technologies in hospitals, which will be discussed next.

2.2 Theory of investing decisions in new technologies

In the previous chapter, various methods were discussed for making financial decisions regarding the acquisition of general equipment and projects. However, investment decisions for technologies, such as those found in hospitals, require consideration of additional factors. These include uncertainty, high competition, and the availability of accurate information. [17] [18]

Highly innovative technologies often come with substantial operating set-up costs, but they produce a positive externality for the broader scientific community. This is because followers in adopting the technology can benefit from the learning process of the pioneers at no additional cost. In this respect, investment in medical quality can be seen as a privately provided public good. [19] Consequently, it may be advantageous to observe and learn from others before taking the initial step with a new technology.

A previous study shows the importance of timing in investment decisions, particularly when costs are sunk and there is uncertainty over future rewards. They argue that irreversibility and uncertainty prompt firms to invest optimally only when the value of the investment exceeds the value of the option of waiting before making the irreversible decision. This approach ensures that the decision to invest is made with a clear understanding of the potential risks and benefits, reducing the likelihood of suboptimal investments. [18]

In the context of hospital technologies, this means that decision-makers must carefully weigh the potential benefits of early adoption against the risks associated with high initial costs and uncertain outcomes. By waiting until there is more information and a clearer understanding of the technology's effectiveness and cost-efficiency, hospitals can make more informed and strategically sound investment decisions. This approach not only mitigates financial risk but also ensures that the investment contributes positively to the overall healthcare system and patient outcomes. The overall healthcare system and patient outcomes are also very important factors in the decision-making process for acquiring new equipment in hospitals.

A key tool often used in investment decisions for new technologies is the technology readiness level (TRL). The purpose of the TRL is to assess technological maturity by evaluating key factors such as performance, reliability, durability, and operational experience within the anticipated environment, which

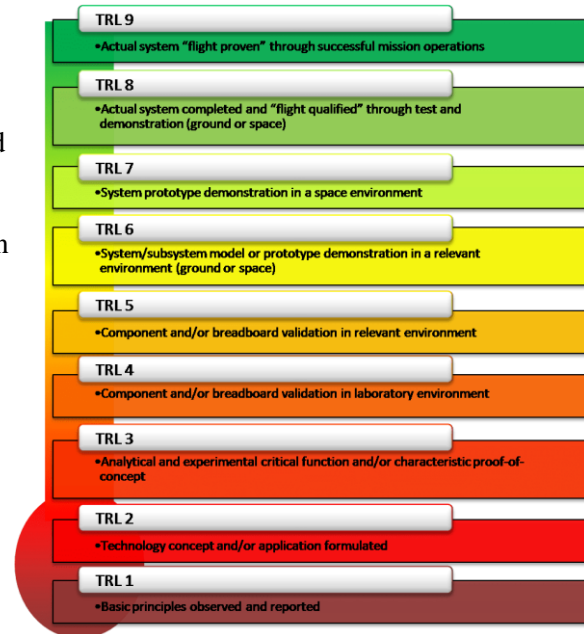


Figure 1. Technology Readiness Levels [21]

in this case is the hospitals. [20] The TRL consist out of different levels, how lower the level how lower the maturity of the technology, how riskier. Each level of the TRL has his own criteria to determine if the technology is mature enough to meet these criteria. [20] The TRL is originally developed by NASA and the different levels are shown in figure 1. [21] Although these levels are tailored to aerospace, they are also applicable to hospitals, for example by adjusting "flight qualified" to "hospital qualified." At level 9, the technology has been successfully tested on patients. To make a decision on a new technology, the TRL can be used to determine whether a technology is ready for use. Criteria for a specific level can be established to proceed with the selection of the technology.

However, there are more factors to consider as well. These will be further explained in the next chapter, 2.3.

2.3 Theory of investing decisions new technologies in hospitals

In contrast to the theory discussed in section 2.1, investment decisions in hospitals often extend beyond these criteria. In the Netherlands, the hospitals are not primarily focused on making pure profits, as the Dutch healthcare system is not designed that way. For this reason, among others, and because we are dealing with patients' lives, different criteria are considered when making investment

decisions in hospitals. To begin with, the regulations will first be outlined, as sometimes mandatory investments in new technologies are required due to changing regulations.

To begin with, all technologies used must comply with the EU Medical Device Regulation (MDR), which has been in force in the Netherlands since 2021. Medical devices must meet stricter safety and performance requirements. This regulation was implemented to enhance patient safety and ensure that innovative medical devices remain accessible to patients. [22][23] This is an example of a regulation that controls the technology, but sometimes regulations also give the needs for new investments. In 2018, the General Data Protection Regulation (GDPR) was implemented in the Netherlands as part of the AVG (Algemene Verordening Gegevensbescherming), which significantly tightened the requirements for the protection of personal data, including patient records in hospitals. [24] Many hospitals had to make adjustments to their Electronic Patient Dossier (EPD) systems to comply with these enhanced security and privacy standards. These adjustments required substantial investments, as compliance with the GDPR is mandatory for healthcare institutions.

This is confirmed by the Autoriteit Persoonsgegevens (Dutch Data Protection Authority), which outlines the obligations of healthcare providers under the GDPR, especially in terms of securing personal health data. Hospitals are required to ensure that their systems are robust enough to prevent data breaches and unauthorized access, leading to necessary technological upgrades and investments. [25] There are other laws and regulations as well, such as the WEGIZ (Wet elektronische gegevensuitwisseling in de zorg), which governs the electronic exchange of health data. It is possible that additional laws and regulations will be introduced in the future. Therefore, the framework must account for these potential developments and include mechanisms to adapt to new legal requirements when making investment decisions. [26]

During the literature review, a reliable and valuable source was found that can be used for building the framework. A previous study conducted by Sebastian Gurtner developed a framework outlining the key criteria for decisions regarding new equipment in hospitals.[11] In the "Evidence and Value: Impact on Decision-Making" framework, the following criteria are established: organizational impact, patient safety, budget impact, effectiveness, demand for treatment, usability, and cost-effectiveness. The definitions of these criteria can be found in appendix 10.1. [11] These criteria will be used as a guiding principle in this study and will be further elaborated in the theoretical framework. The framework proposed by Sebastian Gurtner has been established based on several pieces of literature examined in the literature review, such as those by Cicchetti et al. and Hikmet et al., that also support this framework. [27][28] The study by Cicchetti et al. is a globally conducted survey that provides extensive

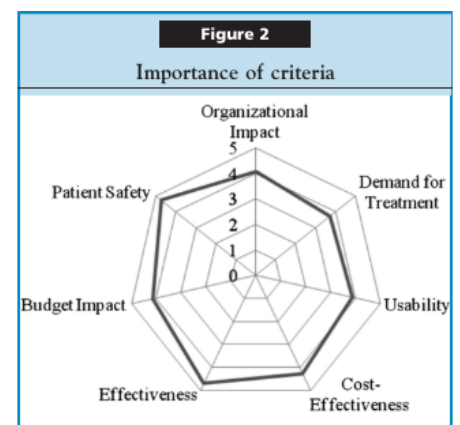


Figure 2. Results survey criteria Gurtner [11]

information and can serve as a reference for this study and has been the biggest fundament for the study of Sebastian Gurtner. [27] The study by Hikmet et al. shows that organizational aspects, such as the criteria organizational impact, must also be taken into account. [28] Gurtner's framework has been validated by his research. This study showed that the identified criteria were repeatedly mentioned in the survey responses. Scores were given for the relevance of the criteria from 1-5 on the Likert Scale. The results are shown in figure 2. In total, the survey received 220 responses from various experts. These experts came from the health technology assessment industry, universities, private companies, government agencies, and hospital staff. [11] Since these criteria are supported by multiple literary sources and have been revalidated by Gurtner, it is established that this framework is suitable as a guideline for this research on the decision-making process in Dutch hospitals. However, the theoretical framework will be further elaborated. An additional layer will be included to emphasize the importance of involving various stakeholders. This importance will be further explained in the next chapter.

2.4 Stakeholders

2.4.1 Stakeholder theory

The most widely known definition of a stakeholder has been proposed by Freeman in 1984 which states: "A stakeholder in an organization is (by definition) any group or individual who can affect, or is affected by, the achievement of the organization's objectives." [29] The stakeholder theory around decision-making emphasizes the importance of identifying and involving all relevant parties in the decision-making process to ensure their interests and concerns are considered. [29] Collaborative decision-making encourages interdisciplinary collaboration among the stakeholders to make well-rounded investment decisions, where every stakeholder is involved in this process. [30] While stakeholder analysis also addresses external stakeholders, a study conducted in 2004 by Gibson and Singer has stated that internal stakeholders, such as staff and patient representatives, are just as important in the decision-making process as these external stakeholders. [31]

In the context of healthcare, stakeholders can include a diverse array of individuals and groups such as healthcare providers, patients, healthcare administrators, regulatory bodies, insurance companies, and technology vendors. Each of these stakeholders can bring unique perspectives into the decision-making process. For instance, healthcare providers may focus on clinical effectiveness and patient safety, while administrators might prioritize cost-effectiveness and operational efficiency. So, when examining and reviewing the decision-making process, like in this study, it is important to involve those different stakeholders.

2.4.2 Stakeholder analysis

To identify the different stakeholders within an organization, the basic stakeholder analysis technique can be used. This technique is described in Bryson in 1995. [32][33] It is a easy and quick technique to identify the different stakeholders and their interests. The first step in the process begins with brainstorming a comprehensive list of the potential stakeholders. These can include internal stakeholders, such as employees and patient representatives, as well as the external stakeholders like regulatory bodies, insurance companies, technology vendors, and the broader community. It then is important to understand the criteria they would use to outline their expectations of the organization. In that way it becomes clearer what matters the most to each of the stakeholders, which is essential for the decision-making process. Once the expectations of the various stakeholders are clear, the organization can assess how well it is meeting these expectations, possibly by assigning a rating. Finally, reasonable steps can be devised to better meet the expectations of different stakeholders, if necessary. [32][33]

This technique is highly effective for several reasons. Firstly, it ensures that all relevant parties are identified, and their concerns are considered, leading to more comprehensive and balanced decision-making. Secondly, by understanding stakeholder expectations and perceptions, organizations can prioritize their efforts to address the most critical issues, thereby enhancing satisfaction and support. Thirdly, this method promotes transparency and accountability, as it requires a systematic assessment and documentation of stakeholder views and the organization's performance.

For these reasons, this technique will also be used in the study to identify and involve the relevant stakeholders. They will be incorporated into the framework presented in Chapter 2.6.

2.5 Steps of the decision making

Decision makers, individuals or groups, find it difficult to make decisions and evaluate relevant information systematically. Without a structured procedure for evaluating alternatives and priorities, there may be inconsistency, uncertainty, or lack of predictability regarding the relevance of a specific component or criterion in the choice.[34] Therefore, it adds value to know what is known about the systematic efficient steps hospitals can take in the decision-making process.

To understand these steps hospitals generally take to evaluate the mentioned criteria, we reviewed existing literature on these processes. This review revealed that there is no standardized protocol used by all hospitals, which was anticipated. In a study by Paule Poulin et al., five steps were outlined for decision support: topic selection, clinical evidence, economic evidence, societal evidence, and recommendation. [34] These steps are in line with the criteria found in chapter 2.4 and will be described below.

The first step involves identifying national health needs and technologies that could have a significant impact, guided by regional healthcare priorities. This process ensures the technologies are relevant and addresses pressing healthcare issues, with stakeholder involvement aligning objectives with national health goals. The next step is evaluating clinical evidence, which requires a thorough analysis of literature, systematic reviews, clinical trials, expert suggestions, HTA reports, and local experience to support the safety, efficacy, and effectiveness of the health technology.

Following this, the focus shifts to economic evidence, where the theoretical costs of new technologies are assessed. This involves examining organizational issues, manpower needs, compatibility with existing systems, and budget constraints. Cost analysis studies help stakeholders understand the financial and long-term implications of implementing the new technology.

The subsequent step addresses societal evidence, which includes ethical and regulatory concerns, as well as local access challenges, values, and priorities. This step ensures that the technology meets societal standards, legal requirements, and is socially acceptable and accessible.

Finally, the technology is evaluated, and a recommendation is made based on the gathered evidence. This decision incorporates clinical, economic, and societal factors to determine whether the technology should be adopted, ensuring it provides real benefits to the healthcare system and patients while being economically viable and socially responsible. [34]

Praveen Thokala et al. present a more detailed method, breaking down the decision-making process into eight separate parts. [35] However, it is fundamentally consistent with the technique stated above. These procedures will also be included in the framework for this research since they connect to the previously described criteria: taking into account important requirements, including stakeholders, and using a structured decision-making process. The steps proposed by Praveen Thokala et al. can be summarized as follows. [35] The process starts with defining the decision problem, which includes determining the decision aim, stakeholders, alternatives, and intended output. Stakeholders can include patients, professionals, payers, regulators, and the general public.

Decision challenges can range from one-time issues, such as deciding between treatment alternatives, to ongoing ones, such as determining reimbursement decisions at HTA agencies.

Once the decision problem has been identified, the following stage is to choose and structure the criteria for comparing alternatives. Criteria are identified using techniques such as reviewing prior judgments, focus groups, and workshops. These criteria should be thorough, non-redundant, and independent. They are frequently organized using "value trees," which visually break down the overall value into multiple criteria and sub criteria.

After criteria are set, the performance of each alternative is evaluated. This entails obtaining data through systematic reviews, meta-analyses, or expert opinions, then presenting it in a "performance

matrix." This matrix allows decision-makers to evaluate and compare the performance of several solutions across the defined criteria.

Following performance measurement, alternatives are ranked according to stakeholder preferences within each criterion. Scoring converts performance data into a standard scale while also taking into account stakeholders' priorities for performance modifications. Scoring systems might be compositional, evaluating each criterion separately, or decompositional, taking into account the whole value of alternatives.

Weighting criteria entails assessing stakeholders' preferences for different criteria, which represents trade-offs. Weights are used to integrate scores across multiple criteria into a single measure of "total value." Weighting methods include "swing weighting" as well as approaches like discrete choice experiments (DCEs) and conjoint analysis.

The approach calculates aggregate scores using an additive model. Each alternative's scores on the criteria are multiplied by the relevant weights, and the weighted scores are added together to get a "total value" for each choice. This total value is used to rank and compare the options.

Uncertainty in the process is addressed using several strategies. Parameter uncertainty, such as fluctuations in performance data, can be investigated using probabilistic sensitivity analysis. Structural uncertainty, such as the selection of criteria, is investigated via scenario analysis. The effect of ambiguity on decision outcomes is evaluated to ensure robustness.

Finally, the data is displayed in tabular or graphical format. Aggregate scores can be used to rank options or assess their value. Outputs help decision-makers comprehend the relative qualities of each alternative, allowing them to make more informed decisions. This model is intended to guide decision-makers rather than make decisions for them, allowing for the study of many scenarios and outcomes.[35]

2.6 Framework

Based on the reviewed literature, it has become clear what is important regarding investment decisions, investment decisions for new devices/technologies, and also in the context of hospitals. By consolidating this information, a framework has been established that provides an overview of how investment decisions for new technologies in hospitals could look according to the theory. This framework is shown in figure 3. In the appendix 10.2 the Dutch version is shown, this version of the framework was shown to the respondents during the interviews.

The figure illustrates all the steps of the decision-making process, including the critical requirements identified by Gurtner, the regulations, the TRL, the importance of financial decisions as discussed in the first chapter of this section, the involvement of various stakeholders, and the consideration of early adoption versus waiting and the associated uncertainty. [11] All these mentioned variables and steps will serve as the foundation for structuring the interviews, by creating themes according to these

variables and steps. Additionally, the model as shown in figure 3, will be evaluated to determine the extent to which it aligns with reality. This evaluation will also reveal which aspects of the framework are incorrect, unfeasible, or particularly effective. Therefore, this framework can be considered the foundation upon which the design of a final model is built. It serves as the starting point and will be refined based on the findings from the interviews. Ultimately, this will result in a model that reflects reality and incorporates improvements. Further details on the design process will be explained in the methodology.

The central thread in the framework consists of the steps in the decision-making process, around which all the key influencing factors are organized. Regulations and laws play a crucial role in the first step, as they can shape or redefine the decision problem by creating the need for adjustments or compliance measures that need to be addressed. This makes regulatory requirements a fundamental starting point in the decision-making process, which definitely needs to be taken into account. In the next step, Gurtner's criteria are used when selecting the criteria, as they help to define the most important elements that need to be taken into consideration by fundamental earlier research. These criteria are further reinforced by the Technology Readiness Level (TRL), which provides a structured approach to assess the maturity of the technologies involved. For financial criteria, it's important to look at the distinction between static and dynamic evaluation methods, which helps in making more informed and accurate financial assessments of different options.

In the second step, it's critical to ensure that all necessary stakeholders are involved in the decision-making process, which is revisited in the fifth step. This involvement ensures that everyone has a say in defining and weighing the criteria, leading to a more inclusive and transparent decision. When addressing uncertainty in the decision-making process, particularly in the "address uncertainty" step, it's important to carefully weigh the trade-offs between early adoption of new technologies and the associated risks, such as high costs and unpredictability. This step requires a delicate balance, as early adoption can offer competitive advantages but also comes with increased exposure to unknowns and potential failures. Taking this uncertainty into account effectively ensures that the organization can make strategic decisions without being overly risk-averse or reckless.

By structuring the decision-making process and incorporating critical elements such as regulations, financial assessments, stakeholder involvement, and risk considerations, the framework serves as a comprehensive guide for analyzing hospital investment decisions and will serve as the basis for further research in the next step. This theoretical model ensures that the interviews are structured around relevant themes, allowing for a systematic exploration of how hospitals make investment decisions in practice. Through these interviews, the framework will be evaluated and refined by the respondents and later by the researcher, to better reflect real-world challenges, ultimately contributing to the development of a more effective and applicable decision-making model. Therefore, this framework

will serve as the basis for the next phase, such as the interviews and research questions, in this research that can be found in Chapter 3: the methodology.

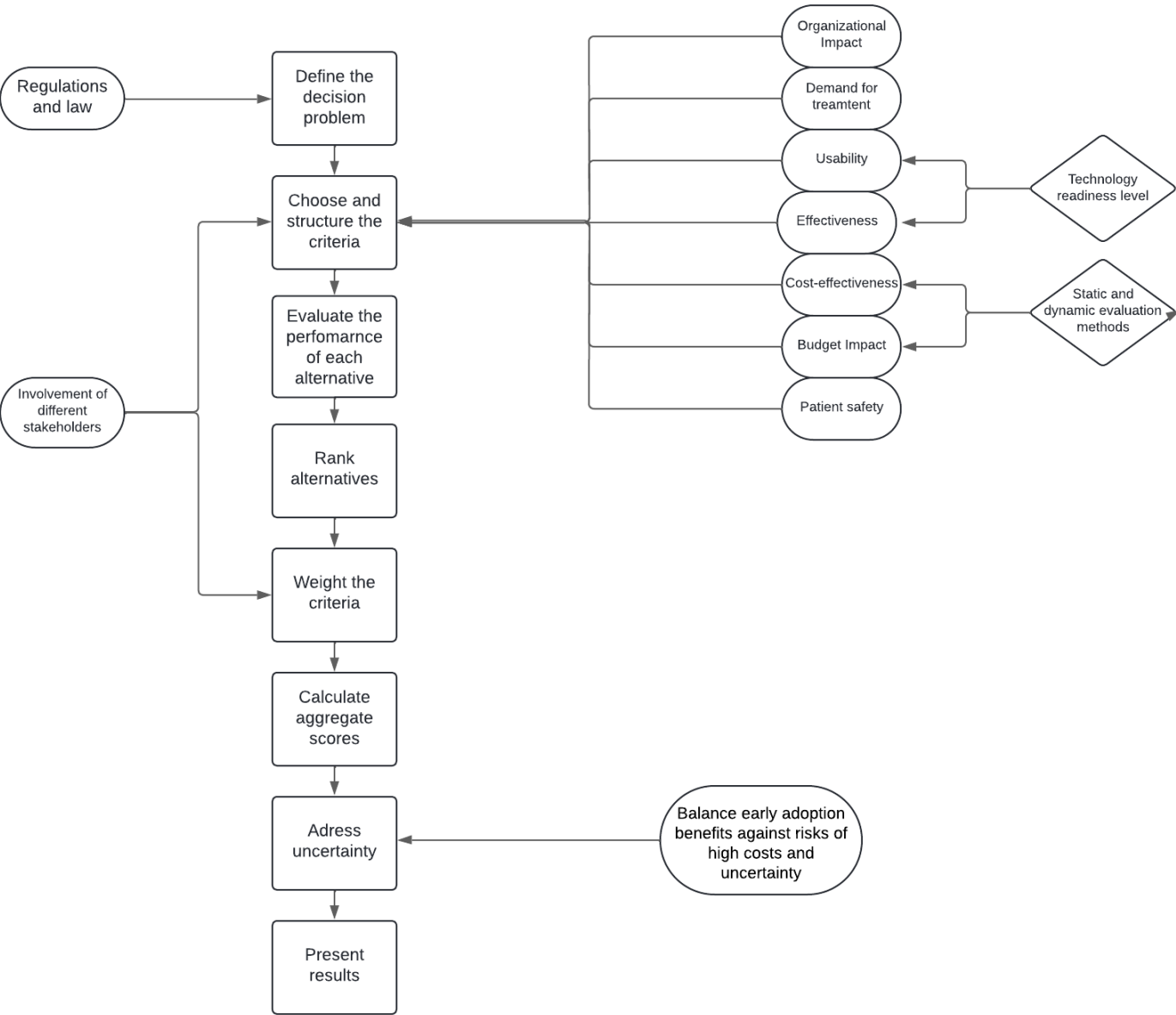


Figure 3. Framework decision-making in hospitals version 1

3 Methodology

3.1 Overview of methodology

In this research the following research question will be studied: “How can Dutch hospitals determine investment decisions for new medical technologies?” To understand how Dutch hospitals determine investment decisions for new medical technologies, several sub questions are formulated to explore different aspects of the decision-making process and to give structure to this study. The theoretical framework, as presented in Figure 3, serves as the foundation for these sub questions by structuring the analysis of investment decision-making processes in Dutch hospitals. This framework is directly integrated into the study by guiding the formulation of interview questions, ensuring that each sub questions will be answered at the end of this research. These sub questions help to provide a comprehensive understanding of the factors, processes, and criteria involved in the practices of the process. The following sub questions are identified:

- “Which steps are taken in the investment decision-making process in Dutch hospitals?”
- “Which criteria are used in the investment decision-making process in Dutch hospitals?”
- “How do regulations and law determine the need for investment decisions?”
- “How do hospitals cope with risks and uncertainty of the new technologies?”
- “Which stakeholders are involved in the investment decision-making process in Dutch hospitals?”
- “In which areas can the investment decision-making process in hospitals be improved?”

Answers to these questions will give a deeper insight in the involvement of practical process used and the important factors for the decision-making process, as found in the theoretical framework.

It is expected that no structured and consistent approach will be found in Dutch hospitals. This is based on outdated or foreign literature, which often reaches the same conclusion, contrasting negatively with the recommendations found in the literature. There is little to no information available about the working methods in Dutch hospitals on this subject.

This study will follow a qualitative approach, which is suitable for this research as it enables an in-depth investigation into the specific decision-making practices of Dutch hospitals. The qualitative data will be extracted through interviews and follow-ups. Throughout the research, the theoretical framework as shown in figure 3 is not only used to analyze existing processes and form the interviews but is also validated by respondents on its usability and completeness. During the interviews, participants assess whether the framework accurately represents their decision-making process and highlight any missing elements or impractical aspects. Through this iterative validation, the final

framework will be adjusted to better align with the realities of Dutch hospitals, incorporating key improvements based on real-world insights.

This research is a multiple case study that incorporates a design aspect to ultimately develop a practical process model for hospitals. To achieve this, four steps of design thinking research are followed as structure for this research. [6] The first phase involves understanding the needs and behaviors of the hospitals. The focus is to gain an in-depth understanding of the process, problems and efficient steps. This step is essential as it allows to identify the process and to oversee possible problems and improvements for the process. The second phase and third phase will be taking in one in the field research. Their purpose is to first, define the process with a clear and actionable improvements and struggles and second to generate creative ideas which could address the user's needs, this will be evaluated in this research in form of a follow-up. This phase is crucial as it sets the foundation for the design thinking process to follow. The fourth and last phase, prototyping, involves the creation of a physical or digital representation of the chosen idea. Where a final idea will be presented, which can be tested by the hospitals for their efficiency and effectiveness. [6]

Therefore, the initial stage of this research involves identifying a group of Dutch hospitals which can be included in this study, more detailed in part 3.2. Data will be collected primarily through interviews but will be complemented with follow-ups with different stakeholders involved in the decision-making process.

The collected data will be analyzed using thematic analysis, using an inductive approach. Initial steps include data familiarization, transcription, and cleaning to ensure data validity. This study is a multiple case study, so coding and analysis are conducted at the hospital level, allowing for the identification of both the most significant similarities and differences between hospitals. This approach highlights the varying degrees of maturity and structure in the decision-making process. The analysis aims to provide a nuanced understanding of how the Dutch hospitals make their investments decisions and where several points of improvement lay, which aligned with the research question.

Based on the findings and the literature, a refinement of the theoretical framework will take place. This will either present a best practice that can be found or a more developed framework than figure 3 with the results from this research improving the framework.

3.2 Research object

The study will primarily focus on Dutch hospitals, that are included as non-academic hospitals in the BDO benchmark, each chosen based on their size and financial health. [1] These hospitals will include both financially stable and struggling institutions to provide a comprehensive view of the decision-

making landscape. In this study we will achieve this to include hospitals from different trend rating scales from the BDO benchmark, to ensure the diversity and to increase the external validity. Also, picking the hospitals from the BDO benchmark, gives room to use information from the benchmark to evaluate possible differences. [1] Only non-academic hospitals will be included. This choice was made because academic hospitals often have more resources to spend due to government investments they receive. There will be a consistent focus on non-academic hospitals to ensure that the model is applicable to hospitals with roughly the same financial means, so it becomes applicable to majority of the Dutch hospitals, which increases the external validity.

Within the hospital the inclusion of different stakeholders, such as financial experts, medical professionals, and patient representatives, ensures that the study captures a holistic view of the investment process because the issue is approached from different angles. [33]

As mentioned before, this study implements a part of the design thinking research theories. Where problems are discovered, findings are defined and solutions are developed and eventually tested. [6] Therefore the field research will focus on the three key areas that remain after the initial literature review: analyzing current hospital practices, proposing and evaluating a model developed from theory and practical findings, and refining the definitive model based on empirical findings that will be suitable for testing and usage. This study is both descriptive and evaluative. On one hand, it aims to map out the existing practices within hospitals, and on the other, it tests the applicability of a model and identifies areas for improvement. Mapping out the current processes is also highly relevant because there is so little published on this subject in the existing literature and therefore it is unknown how efficient processes are at the moment. By documenting these practices, transparency is provided, which can serve as a foundation for identifying areas that need improvement. This will not only help pinpoint inefficiencies but will also contribute to enhancing the overall quality of healthcare.

The first phase of the field research will involve a detailed exploration of current practices in hospital decision-making. This is essential to determine whether hospitals are already using structured methods for investment decisions, such as predefined criteria or decision-making frameworks. Interviews will be used to gather data, with questions carefully designed around key components from the literature as designed in the framework, such as financial analysis, stakeholder involvement, and technology assessment. Creating the questions around the literature will provide structure to the interview. This phase will not only describe these practices but will also identify gaps or inconsistencies that might exist between theory and practice. For instance, hospitals currently may rely on informal or ad-hoc processes rather than formalized models, which could lead to inefficiencies in decision-making. But otherwise, maybe a hospital is making use of a model that is efficient and effective. It is also important to measure the extent to which laws and regulations influence the investment behavior of hospitals. As

described in the theoretical framework, these can sometimes create a necessity for making investments. Therefore, it is relevant to understand their current practices.

First, the respondent will be asked to briefly explain what their decision-making process currently looks like. They will also be asked to provide examples, such as recent investment decisions. This approach allows the respondent to share their own narrative without being influenced by the questions that follow, which are based on the theoretical model.

The next step in the research process will be to inquire about the exact steps hospitals take when arriving at an investment decision. This will allow for a thorough understanding of the decision-making process, enabling us to identify commonalities and variations across different institutions. Questions will focus on how hospitals assess and prioritize potential investments and the key actions taken from proposal to final decision.

Next, the research will explore which stakeholders are involved in the decision-making process for each investment. This aspect will examine whether there are differences between decisions—whether some involve a broader array of stakeholders while others are confined to a smaller group of decision-makers. Hospitals may include a variety of professionals in the process, such as financial managers, clinical staff, and even patient representatives, depending on the scope and impact of the investment. Identifying whether hospitals engage multiple stakeholders or restrict decisions to a smaller group will help gauge the level of inclusivity in these decisions.

The requirements from Gurtner's framework, which are further elaborated in appendix 10.1, will also be assessed. This is expanded with also investigating whether hospitals use a Technology Readiness Level (TRL) scale to assess the maturity and viability of new technologies before making an investment. The TRL scale helps in determining whether the technology is in the early stages of development or ready for immediate implementation.

Additionally, financial analyses employed in the investment decision process will be examined. The goal is to identify whether hospitals use specific methods like Net Present Value (NPV), Internal Rate of Return (IRR), or other financial metrics to evaluate the long-term financial impact of their investments.

Lastly, the research will address how hospitals manage risks associated with investment decisions. Hospital investments often carry significant financial, technological, and operational risks, especially when dealing with advanced medical technologies. Investigating how hospitals handle these risks, whether through risk assessments, mitigation strategies, or contingency planning, will provide insight into their ability to navigate complex investment landscapes.

This detailed examination will form the foundation for evaluating and improving the theoretical investment decision-making framework, ensuring that it not only reflects theoretical best practices but

also resonates with the realities faced by hospitals in their day-to-day operations. After this first step, efforts will also be made to persuade hospitals to collaborate on the follow-up, by asking whether they are interested in evaluating the developed model.

Subsequently, the theoretical model can be adjusted based on the findings from the field. The interviews provide valuable insights to determine the limitations of the theoretical model and identify its strengths. Theory and practice will then be combined into an improved model, which will proceed to the second round of evaluation. Next, this evaluation of the theoretical model will involve working closely with hospital stakeholders to assess how applicable the proposed model is to real-world hospital operations. This will be done through follow-up research, which are particularly valuable for facilitating in-depth information and surfacing diverse viewpoints.

The ideal situation would involve an ongoing case where the model could be applied and tested in a real-world context, therefore it is asked in the prior interview if there is a casus going on. By integrating the model into the actual decision-making or operational process, it would be possible to observe how effectively it functions under real-life conditions. This would not only provide insights into the model's strengths but also help identify any weaknesses or areas for improvement. Such a hands-on application would be invaluable in refining the model further and ensuring it is robust and reliable for broader implementation. Since it is not certain that there will be any cases and hospitals that are willing to cooperate with testing the model, it will mainly consist of the previously mentioned interviews and follow-ups.

In the final phase, the study will turn toward refining and developing the final framework. The data collected during the earlier phases will guide the adjustments needed to make the theoretical model more practical and usable for hospitals. The goal is to create a flexible, yet structured decision-making model that can be adapted to a variety of hospital environments, including those with differing financial health or levels of technological sophistication. The improved model will focus on optimizing decision-making by balancing financial considerations, regulatory requirements, and technological innovations with the input from stakeholders across different levels of the hospital. This refined framework will offer Dutch hospitals a clear roadmap for making efficient, informed investment decisions, thereby improving long-term sustainability.

In appendix 10.3 and 10.4, the interview scheme is outlined. This framework ensures that enough information will be gathered to answer the various areas, sub-questions, and the main research question. It covers all relevant components and provides a well-structured approach for this study, helping to ensure that the investigation is thorough and systematic.

3.3 Data collection

The study will be a descriptive research. Finding a collection of related instances that can be included into the study is the initial stage in this research. These instances will be Dutch hospitals as explained in part 3.2. The hospitals will be contacted through email, phone calls and LinkedIn. There is no universally required number of interviews for qualitative research, as the appropriate sample size depends heavily on factors such as the type of study and the homogeneity or heterogeneity of the target group. Saturation has, in fact, become the gold standard for determining purposive sample sizes in qualitative research. [36] Therefore, the aim is to get information saturation. Previous studies have shown that data saturation is often reached after 8–12 interviews when respondents share relatively homogeneous characteristics. [36] [37]

Qualitative data will be collected primarily through interviews with relevant stakeholders and additionally supported by follow-up evaluations. Interviews offer deep insights into decision-making processes that are not easily captured by these quantitative methods. This method allows participants to elaborate on their experiences and perspectives, leading to richer data collection.

The interviews will be conducted either in person or online, depending on the availability and preferences of the participants. Each interview is expected to last between approximately 30 minutes and will be audio-recorded for accuracy and analyzing, with prior consent obtained from the participants. The recordings will be deleted when transcribed and analyzed.

After completing the interviews, the researcher may opt to conduct follow-up evaluation to delve deeper into topics that diverge from existing literature and to evaluate the framework from step 2. These follow-ups will be structured, which will create a follow-up that primarily focuses on the questions that remain unanswered in the research. A preliminary guide for these follow-ups has been developed after conducting the interviews and is shown in appendices 10.6 and 10.7.

When a case is available for observation, the data will be collected by the researcher present at the case. The model will then be implemented, and its strengths and weaknesses will be noted so that they can be incorporated into the analysis. This will be done in a structured manner in a document.

3.4 Data analysis

When analyzing the interviews and follow-ups, thematic analysis will be used. This will provide concise description and interpretation in terms of themes and patterns from the data received, even if the data is very varied. [38]

The first step will be general exploring of the data and cleaning the data. This involves transcribing all interviews and follow-up discussions. [38] The researcher will also review relevant documents and record any initial ideas or patterns that emerge. The first step is crucial for developing a deep understanding of the data set as a whole and establishing a foundation for more detailed analysis, because when the researcher doesn't work with clean, valid and reliable data in the first step, it can get worse in the upcoming analyzing.

Next, the researcher will generate categories where initial codes are hung to the answers from the transcribes of the interviews and follow-ups. This process involves systematically identifying segments of the data that are relevant to the research question or topic of interest. Each code captures a specific idea, concept, or phenomenon present in the data. This process helps in organizing the data into meaningful groups, which can then be further analyzed. [38][39]

When the data has been coded, themes will be made that include similar codes. The goal of creating themes is to identify important relations and factors within the decision-making process. [39]

Finally, the researcher will create an overview of the decision-making process in the different hospitals, based on the results from the interviews. The overview will be checked for similarities and differences between the different hospitals, by using the codes that emerged from the data. In this way, the researcher will gain a clear understanding of how investment decisions are currently made in hospitals. Are these decisions made in a similar manner across different hospitals, or is there no consistent structure, with each institution following its own process?

Subsequently, each aspect derived from the findings of the literature review, incorporated into the initial theoretical model (Model 1), will be critically examined. This analysis will focus on identifying key factors, pinpointing areas where challenges arise, and highlighting opportunities for improvement within hospital decision-making processes. Each topic will be analyzed in detail, emphasizing notable aspects that should be considered. Ultimately, this approach will yield insights that are deemed relevant by the respondents during the interviews and are supported by existing literature. These insights will form the basis for creating Version 2 of the model, which will be evaluated during a follow-up phase.

Following the follow-up phase, the findings will be thoroughly analyzed and coded to create a final model that could be tested and implemented in Dutch hospitals. This final model will provide a structured framework, including the essential criteria, requirements, and steps necessary for making effective and efficient investment decisions.

The final model will not only incorporate insights gained from practical fieldwork but will also be substantiated by evidence from the literature. This dual foundation ensures that the model is both

theoretically sound and practically applicable, offering Dutch hospitals a reliable and validated tool to improve their investment decision-making processes.

4 Results

A total of 11 respondents were interviewed, distributed across 9 non-academic Dutch hospitals. This number aligns with the required number of interviews described in the methodology, as information saturation was achieved. As the number of interviews increased, little new or groundbreaking information was uncovered, therefore this number of respondents is considered sufficient by the researcher. In total, there are 61 non-academic hospitals in the Netherlands, meaning the sample size represents approximately 15% of the population. Saturation occurs when new data no longer reveal additional insights or themes, indicating that the sample size adequately represents the population under study. [37] These hospitals have various characteristics, such as size, geography, and financial health. Two additional interviews were conducted at two hospitals because the first respondent was unable to answer all the questions. By interviewing a second respondent, a complete picture of the investment process at the respective hospital was still obtained. The respondents held different positions within the hospitals and were all involved in the investment process. The following roles were interviewed: Head of OR (Operating Room), business controller, strategic buyer, medical technology manager, clinical physicist, purchasing manager, board member, and financial controller. In addition to the interviews, formats from six hospitals related to the investment process, criteria, risks, and/or financial aspects were collected. This approach provided a clearer and more reliable understanding of the subject matter. The results below will be shown as the results of the 9 hospitals, this means that the answers from the two double interviews from the same organization will be combined in the results.

4.1 Overview of the differences per hospital

This chapter outlines the differences in policies and approaches to the investment process within the hospitals. First, a summary is provided for each organization, giving a clear and concise overview of how they operate and the extent to which their processes are either highly detailed and structured or more streamlined. This highlights the differences in process maturity between the hospitals.

4.1.1 Organisation 1

This organization has made two distinct routes in its investment process: replacement requests and purchase requests. Replacement requests follow an ‘fast track’ route, bypassing the investment committee and being reviewed by two individuals. This helps accelerate the decision-making process. In contrast, their expansion requests follow a more comprehensive trajectory.

The process begins with submitting a request, which can be done throughout the year using a standardized format. These requests are filled in by the organization’s business managers. The format for new acquisitions includes sections on the device, its impact on the organization, and stakeholder involvement. For replacement investments under €100,000, a simplified format is used, which lowers the administrative burden.

Each purchase request is reviewed by a financial advisor, who drafts a financial assessment that is then forwarded to the investment committee. The investment committee meets every six weeks and exists out of a finance manager, procurement manager, ICT and technology manager, clinical physicist, business manager, facilities manager, and two medical specialists. Additional members, such as infection prevention experts, may be included depending on the request.

For financial evaluation, a business case is generally required for innovative or non-standard investments that have a higher impact on the budget of the hospital. Each proposal is assessed based on its total cost of ownership (TCO), including both the initial costs and operational expenses over the lifespan of the investment, which ranges from five to ten years depending on the asset type. Procurement is involved to ensure fair supplier comparisons and cost-effectiveness within the process. While projected financial benefits for the hospital (e.g., through Diagnosis-Related Groups or DBC's in dutch) are also considered, these are often harder to quantify.

The hospital incorporates risk analysis into its investment decision-making process, focusing on two areas primarily: patient safety and financial risks. For patient-related risks, a prospective risk analysis is conducted to ensure that the equipment or technology can be safely integrated into healthcare practices. This analysis aims to identify potential issues and establish measures to guarantee the quality and safety of patient care. These findings are documented in a separate report that is added in the investment proposal. Financial risks are also assessed as part of the application process. Applicants must outline potential financial uncertainties in the structured form, such as the possibility of a new technology failing to attract the anticipated patient group and therefore not meeting revenue expectations.

There is no formal prioritization system for investment requests because the organization's strong financial position and investment capacity make it unnecessary. However, ICT capacity for implementation is prioritized, because the pressure on this department is high.

Once an investment is approved, it becomes a decision for the board of directors. Before purchasing unfamiliar technologies, trial placements are mandatory to document and evaluate the technology's effectiveness.

The organization highlights the importance of distinguishing between new investments and replacement requests to maintain process efficiency. Additionally, they stress the need to evaluate device management and maintenance, alignment with the hospital's strategic priorities, and a multidisciplinary approach to decision-making.

4.1.2 Organisation 2

The organization uses a single integrated process for investment requests, where all aspects, such as construction and IT components, are considered from in an integral way. Their hospital has a detailed process overview. Requests are submitted through a very detailed factsheet containing all essential information needed by the investment committee to make a decision. These requests can be submitted throughout the year by department managers, representatives of care or staff departments, or process team owners.

Initially, the request is assessed based on strategic alignment to determine whether it fits within the hospital's key priorities. This assessment is carried out by a strategic committee. If the request aligns with the strategic objectives, it can be further developed, including the exploration of alternatives, suppliers, and potential solutions for the need of investment.

The request is then reviewed by the investment committee, which consists of three medical specialists, a care manager, a purchaser, a financial manager, a manager for housing, services, and technology, and a controller. The composition of the committee is fixed and does not change. The committee evaluates the request based on the criteria outlined in Table X.

Each request must include a financial section in which the total cost of ownership (TCO) is calculated. Additionally, cost savings compared to alternatives are considered. The applicant assigns scores from 1 to 10 to various criteria, which are validated by the committee. This scoring system enables prioritization when the budget is limited, although this is not currently the case due to their strong financial position.

The technological maturity of the request is assessed by a specialized committee, which evaluates aspects such as privacy, security, and information safety. This process is conducted in collaboration with the medical technology covenant, which includes a checklist that is carefully reviewed. Decisions are made by the board of directors, and for very large investments amounting to several million, by the supervisory board. These decisions are published on the intranet to ensure transparency for all employees.

According to the organization, their strong financial position can be attributed to the initial screening of strategic alignment and their commitment to pursuing aligned objectives. They also emphasize the importance of balancing administrative tasks, such as prioritization, with the practical benefits they provide. The organization reports significant advantages from their integrated approach to requests, as it helps prevent issues related to building management and specific equipment. They highlight the importance of treating operations and investments as a unified whole.

4.1.3 Organisation 3

The hospital uses a one track process for regular and more urgent requests such as replacements. The hospital works in an 1 year cycle, so continuous requests aren't possible. Urgent requests, such as those addressing immediate improvements or critical needs, are prioritized but must include a strong justification for the urgency and they still follow the same path as the other requests. They go through the process in a faster pace. Regular requests are treated equally and processed according to their submission date.

The investment decision-making process at this organization follows a structured pathway. When a new piece of medical technology or equipment is identified by a department or physician, a business case must be prepared. This is done using an established internal format, which includes detailed information and justification for the request. Once the business case is complete, it must be approved by the department's business manager before being submitted to the investment committee. It then will be controlled by a medic, medical technician and financial if the stated advantages are really reachable.

The investment committee evaluates the business case on various aspects, that are shown in table X. Financial benefits will be fitted in a TCO and expected DBC's will be checked. If further clarification is needed, the committee may request revisions or additional meetings with the requesting department. Final decisions are communicated formally, and if approved, a budget is allocated for the purchase. The committee maintains a repository of all business cases, approvals, and policy documents. The investment committee is composed of a business manager, a clinical physicist, a manager finance, and representatives from medical technology and clinical departments. While the group remains fixed, the focus may shift depending on the specifics of a request.

Technological maturity and risks are assessed using a risk classification framework that categorizes equipment as low, medium, or high risk. This evaluation is conducted by the clinical physics department and medical technology experts. Risk management tools are also applied to assess patient safety, usability, and operational risks. The organization mentioned that they are never a first adopter of a technology.

Final approval is typically given by the board of directors.

The respondent highlighted challenges, including delays in decision-making due to long processing times by the investment committee. This inefficiency can lead to issues such as price changes or missed budgetary deadlines. The respondent suggested that more efficient timelines would improve the overall process. Additionally, they emphasized the importance of accounting for all costs, including consumables, and ensuring alignment with patient and clinician needs to create a comprehensive and effective investment framework.

4.1.4 Organisation 4

Investment requests are initiated by business managers, who are the only individuals authorized to submit proposals. These requests are prepared using a standardized form, submitted via the hospital's financial system. The form includes essential details such as the functional need, risk assessment, technical specifications, financial analysis, and any supporting documents. Replacement investments follow a simpler pathway, as their necessity is generally already established according to the organization. New or innovative proposals require more in-depth justification, including an exploration of alternatives and a detailed business case.

The investment process in this hospital also is structured around an investment committee, which advises the board of directors on decisions. On the forehand of the investment committee, an other committee will check the request for necessary parts. Both of the committees are multidisciplinary. The investment committee includes representatives from finance, procurement, technology, and other key areas, that were not mentioned all in a clear way. The committee checks for criteria as stated in table x. Financial evaluations are based on total cost of ownership (TCO), which incorporates initial investment costs, operational expenses, and maintenance.

The investment committee reviews submissions approximately every six weeks, allowing for a continuous submission process throughout the year. This continuous approach enables greater flexibility and reduces bottlenecks in decision-making according to the respondent.

Technological readiness is not assessed using a specific standardized scale but is evaluated based on the hospital's experience with the technology and its proven reliability in other healthcare settings. For highly innovative technologies, additional acceptance criteria are established to ensure compatibility and performance. Risks are assessed in two main categories: patient safety, evaluated through a prospective risk analysis, and financial risks, which are described in the application but lack a formalized framework.

After the committee evaluates a proposal, it submits its recommendation to the board of directors, which makes the final decision. Approved investments and decisions are communicated via the hospital's intranet and directly to the managers who submitted the requests.

While the respondent expressed overall satisfaction with the investment process, they highlighted areas for improvement, particularly in the assessment of long-term maintenance and management requirements for new equipment. They also emphasized the importance of involving a multidisciplinary team early in the process to avoid issues during implementation. The hospital's flexibility in its investment budget allows for decisions to be made without strict prioritization, except in cases where limited ICT capacity requires a ranking of projects.

4.1.5 Organisation 5

Requests can be submitted to this hospital once per year. After submission, the hospital unit managers assess whether the request aligns with the hospital's strategy. A strategic review is conducted, which is reviewed by the board of directors. Ideally, this is followed by a procurement process that includes a market survey, the creation of a specification document, and an invitation to suppliers.

Once suppliers have been selected and contacted, a formal review is carried out by the investment committee, which examines all aspects, with a particular focus on the financials. The total cost of ownership (TCO) is carefully considered, including upfront investments, maintenance components, consumables, training costs.

Regarding the financial benefits, the hospital evaluates the Diagnosis Treatment Combinations (DBC), though this proves to be a complex issue. Further criteria are documented in figure 5. The organization mentioned that it currently lacks a prioritization system but is considering implementing one, as this remains an unresolved issue within the organization.

The hospital is not a first adopter and does not purchase any technology that is not proven. A multidisciplinary approach is used for risk analysis, where input is gathered from different disciplines, though no formal model is currently applied for this risk analysis.

The investment committee and pre-review team consists of representatives from building management, IT, control, procurement, medical technology, finance, and medical staff. Stakeholders remain consistent regardless of the investment size, but medical specialists are invited when their expertise or knowledge is required for specific devices in their field.

The process begins with an alignment check against the strategy, followed by the procurement phase, and all of this is reviewed by the investment committee. The board of directors makes the final decision, which is then communicated to the requester.

The organization stated that the current process is not running smoothly and sometimes faces challenges. One point of concern is the lack of evaluation. The process does not include checks to verify whether the expected outcomes are achieved, and the organization acknowledges that this needs to be addressed moving forward.

4.1.6 Organisation 6

The hospital has a structured investment process that begins with an annual review conducted by the care technology department and clinical physics team. This review involves equipment owners, primarily department managers, and evaluates the condition and replacement needs of existing equipment. The hospital uses a centralized system to register all equipment and track technical

conditions and replacement recommendations. Department managers are also asked to identify any expansion needs or requests for new technologies. These discussions result in a prioritized list of investment needs, which is submitted to the board of directors for budget approval.

Once the budget is approved, the investment process moves to the application phase, where department managers submit detailed requests in a system. These requests include justifications for the proposed investment, technical specifications, quality criteria, and any associated costs, such as integration with electronic patient records (EPRs) or maintenance. The application is reviewed by the preparation group that goes before the investment committee, a multidisciplinary team that ensures all submissions meet the hospital's requirements, including compliance with regulatory standards and the inclusion of a complete product dossier. If the application is incomplete, it is sent back to the requester for revisions.

After this initial review, the application proceeds to the investment committee, which evaluates requests exceeding €10,000 and provides recommendations to the board of directors. The board has the final decision-making authority for investments above this threshold. For smaller investments under €10,000, the preparation group can approve the request.

The hospital uses a comprehensive set of criteria for evaluating investment requests, these criteria are visible in figure 5. A significant focus is placed on ensuring compatibility with existing hospital infrastructure and uniformity in equipment to minimize operational risks and errors. Above investments of €100,000 a business case needs to be made. Financial evaluations include total cost of ownership (TCO) calculations, incorporating investment, operational, and personnel costs. While return on investment is considered, the hospital emphasizes that investments in safety and quality do not always need to be financially profitable.

New interventions or technologies are assessed using the NIKP framework, which focuses on safety and risk management. Risk management is a key component of the process, with all medium- and high-risk investments undergoing a multidisciplinary risk assessment. These assessments evaluate functional, technical, and operational risks and are conducted collaboratively by expert teams, including representatives from clinical departments, technology, and sterilization services.

Although prioritization is generally unnecessary due to sufficient budget availability, a scoring system is in place to rank requests if needed.

The respondent noted areas for improvement, including the integration of investment streams (e.g., ICT and medical equipment) into a unified process. They also highlighted the importance of periodically updating evaluation criteria to reflect organizational needs and technological advancements. Lastly, they stressed the necessity of maintaining a strict adherence to the established process to prevent bypassing procedures, which could undermine its effectiveness.

4.1.7 Organisation 7

The hospital's investment process revolves around a structured approach involving distinct budgets for maintenance, replacement, and new investments. Four key budget areas are managed: medical technology, IT, imaging technology, and other inventory. A new category for construction will be added in the upcoming budget cycle in 2026. These budgets are primarily used for maintaining existing assets. New investments are evaluated separately and submitted to the investment committee, which includes representatives from these budget areas, medical specialists, and a finance manager. The hospital works with two routes, for new investments and replacement investments.

The hospital employs a formalized process where requests are submitted two weeks before the bi-monthly investment committee meetings. Only complete applications are reviewed, and these are shared with committee members one week in advance for preparation. Compliance with laws and regulations is a critical aspect, and investments required to meet regulatory standards are typically approved without financial objections.

Requests for new investments must be submitted with recommendations from both the medical technology and finance departments. The investment committee evaluates these proposals based on qualitative benefits, financial viability, and compliance with safety and quality standards. Requests that demonstrate a positive business case are generally approved, provided the equipment is deemed safe and effective. For investments that do not meet these criteria, the request may be rejected, or the applicant may appeal directly to the board of directors. In such cases, qualitative improvements, such as enhanced patient care, must be emphasized to justify the investment, despite the absence of financial returns. If approved by the board, adjustments may be required in the hospital's long-term financial planning to accommodate the decision.

The criteria for evaluating investment proposals include financial feasibility, patient safety, quality of care, and alignment with the hospital's strategic priorities. The hospital works with business cases that factor in the total cost of ownership (TCO), which includes acquisition costs, maintenance, and consumables. Expected savings, such as reduced personnel costs or more affordable disposables, are also considered in these evaluations.

While investments are not formally prioritized, the hospital recognizes the growing need to cluster requests to improve prioritization and better manage the limited capacity of the medical technology department. The respondent also highlighted challenges, such as applicants frequently specifying a particular device or brand without first identifying the functional requirements, limiting the evaluation of alternatives.

Innovation is approached cautiously, with pioneering work conducted by a dedicated innovation department before proposals are brought to the investment committee. This ensures that only technologies with proven potential are considered for integration into the hospital's operations. Further risk management tools weren't mentioned by the organization. The department of medical technology check a list of potential risks, but don't use a certain model or format.

The respondent emphasized the importance of aligning investments with the hospital's overall strategy, which could vary between being a specialized care center or a general hospital, as this influences the prioritization and relevance of specific investments. The respondent concluded that a successful investment model must include financial feasibility, prioritization mechanisms, and adherence to safety and regulatory standards. Additionally, they noted that financial constraints in less well-resourced hospitals might necessitate stricter prioritization and decision-making processes.

4.1.8 Organisation 8

The hospital has recently implemented changes to its investment process, which is now in a pilot phase. The process begins with committee on forehand of the investment committee tasked with evaluating initial requests and ideas from various departments. This team conducts a preliminary assessment of feasibility, both technologically and financially, as well as alignment with the hospital's strategic priorities. If a request pertains to replacement or continuity, it follows a "fast track" route within the established investment process, ensuring all stakeholders are involved. These requests are reviewed for completeness and compliance before being sent to the investment committee for final advice to the board of directors.

For innovative requests, a more complex trajectory is followed, often requiring a preliminary investigation to define financial, technical, and organizational impacts. This investigation may involve multiple stages and determine whether the investment is viable. The advisory team plays a central role in this process, conducting operational checks that include infrastructure, cooling systems, floor load, and compliance with maintenance requirements.

The investment committee evaluates proposals based on the organization's budget, strategic goals, and other ongoing initiatives. The committee makes recommendations to the board of directors, which holds final decision-making authority. Each year, the hospital prepares its budget, allowing departments to submit anticipated initiatives, primarily for replacements or innovation projects tied to major strategies like digital transformation or facility upgrades. Throughout the year, the committee ensures that requests align with this budget and makes adjustments as necessary.

The hospital uses a flowchart and digital application system to guide the investment process. Stakeholders access the system to review, comment on, or supplement applications. Decisions and outcomes are communicated via the system, ensuring transparency and traceability.

Key criteria for evaluation include strategic alignment, financial impact, patient safety, and compliance with regulations, they are further discussed in table x. Financial analyses rely on total cost of ownership (TCO), including upfront costs, operational expenses, and maintenance. While the hospital avoids rigid scoring systems for prioritization, qualitative assessments are conducted by the investment committee. Requests for innovative projects often require a benefit-tracking system to evaluate long-term organizational and financial impacts.

Risk management is embedded within the process, utilizing a risk classification model to categorize investments as low, medium, or high risk. Additional analyses, such as failure mode effect analysis, are conducted for higher-risk projects. Challenges include balancing simplicity and thoroughness, ensuring that the process remains accessible while effectively mitigating risks.

The respondent emphasized the importance of creating a learning cycle, where outcomes from previous investments inform future decisions. Evaluating long-term impacts, such as the actual benefits realized versus initial assumptions, was highlighted as a key area for development. The hospital also aims to maintain flexibility in prioritization, particularly for unforeseen expenses or regulatory requirements, while managing capacity constraints effectively.

4.1.9 Organisation 9

The hospital's investment decision-making process for medical technologies and equipment revolves around a framework embedded in their planning and control cycle. They maintain a multi-year budget covering operational and investment expenses. Investments are categorized into four clusters: ICT, buildings and facilities, eldercare, and the hospital itself. Each cluster has a dedicated manager responsible for planning and expenditures.

Monthly investment committee meetings are held where cluster managers present their investment requests. A format ensures that every request includes a business case, technical evaluation, and alignment with organizational needs, though informal and pragmatic elements still influence decisions. Large-scale investments (multiple millions) are treated separately, with dedicated project teams and budgets.

Decisions are documented within regular planning and communication cycles, with large projects also involving centralized updates and internal communications teams. Legal regulations, such as sustainability mandates or sector-specific requirements, also influence investment decisions.

Criteria for investments include alignment with the hospital's multi-year strategy, quality of care, employee well-being, and financial feasibility, which are stated in table x. Many decisions focus on replacing outdated equipment, with minimal emphasis on business cases in these instances. When

evaluating new technologies, the hospital avoids early adoption, preferring proven solutions used by other organizations.

Risk assessments are typically conducted for larger or more complex projects, with smaller replacements often bypassing such formalities. Stakeholders include the board of directors, the supervisory board for investments over €1M, and the investment committee, which comprises finance, facility management, ICT, and medical representatives.

The respondent emphasizes the need for improved long-term investment planning and a more formalized approach to criteria and documentation, as the current process is considered informal and organic. While individual investment decisions are well-supported, prioritizing competing large-scale projects remains challenging.

4.1.10 Summary and most important differences

The comparison of hospital investment processes reveals interesting differences in their level of maturity. The level of maturity can be based on different aspects of the investment process, such as the:

- Initial screening and application forms
- Standardized formats and criteria list
- Documentation
- Integration
- Multiple routes
- Review and approval bodies and stages

Some hospitals display a highly structured and methodical approach while others rely on a more flexible, yet often inconsistent, system. It is remarkable that while some hospitals have extensive frameworks in place, complete with multiple committees, uniform formats, and rigorous risk and financial assessments, others operate with a surprising level of informality. This lack of structure may provide agility but also introduces risks, as financial evaluations are sometimes treated as an afterthought or risk analyses are only performed for major investments.

One particularly striking observation is the inconsistent weighting of decision-making criteria. Some hospitals apply a holistic view from the outset, meticulously balancing costs, benefits, and risks, while others seem to take a more reactive stance, addressing financial implications only in later stages. It is surprising that in certain hospitals, strategic priorities are not always well-defined, leading to a more ad hoc decision-making process. This can raise concerns about whether investments are truly aligned with long-term goals or simply driven by immediate needs within the hospital.

An even more pronounced difference emerges in how well-integrated these processes are. Hospitals with a high level of maturity ensure that elements such as IT, infrastructure, and operational costs are considered from day one, resulting in smoother implementation and fewer unforeseen complications. In contrast, hospitals with less mature processes tend to handle these aspects separately, which can lead to bottlenecks, inefficiencies, and delays. There are strong indications that this fragmented approach can hinder hospitals from embracing innovative technologies proactively. Instead of leading in innovation, these hospitals often wait for others to take the first step, limiting their ability to be at the forefront of medical advancements. This also often is in line with their strategic view, by stating that the hospital don't want to be first adopters.

These findings demonstrate that there is room for improvement in some hospitals decision-making process by introducing greater structure, integration, and uniformity into their processes. This research presents an opportunity to develop a shared framework that hospitals can use to learn from each other and further professionalize their processes.

Ultimately, the differences on the categories per hospital can be displayed, as shown in figure 4. For the BDO rating presented, the BDO rating score from 2024 has been used. Pass is a grade of 6 or higher and fail is a grade of 5 or lower. [40] This gives an brief indication of the financial situation of the hospital.

	<i>Org1</i>	<i>Org2</i>	<i>Org3</i>	<i>Org4</i>	<i>Org5</i>	<i>Org6</i>	<i>Org7</i>	<i>Org8</i>	<i>Org9</i>
<i>BDO Grade 2024</i>	Pass	Pass	Fail	Fail	Fail	Pass	Pass	Fail	Fail
<i>Documents of process available</i>	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes
<i>Number of committees/control stops</i>	1	2	1	2	2	2	2	2	1
<i>Application availability</i>	Year-round	Year-round	Once a year	Once a year	Once a year	Once a year	Year-round	Year-round	Year-round
<i>Prioritization option</i>	No	Yes	Yes	No	No*	Yes	No*	No	No
<i>Financial assessment</i>	TCO	TCO	TCO	TCO	TCO	TCO	TCO	TCO	TCO
<i>First adopters</i>	Yes	No	No	Yes	No	Yes	No	Yes	No
<i>Risk analysis Number of criteria</i>	PRI 6	MC 8	PRI 7	PRI 5	MTA 3	NIKP 10	MTA 5	PRI 14	PRI 9

Figure 4. Summary differences per hospital

*= Thinking of a prioritization option

PRI= Prospective risk inventarisation

MC= Medical covenant

MTA= Medical technology analysis

NIKP = Nieuwe interventies in de klinische praktijk (Dutch form)

The number of criteria are displayed in the table above. Below, in figure 5, the criteria are further elaborated. They are grouped into fairly similar categories, and the exact names used by the organizations have been standardized as much as possible. As a result, there may be minimal differences. The criteria listed below are found in the hospital documents or are stated in the interviews. Therefore it can be a mixture of quantitative and qualitative data.

Organisation Criteria

<i>Org1</i>	<ol style="list-style-type: none"> 1. Organizational consequences (impact on personnel, ICT (project plan or management), facilities, GBMS, work satisfaction, quality and safety, learning and development, or medical care) 2. Business-economic consequences (financial, financing, and capacity/planning) 3. Necessity and urgency 4. Compliance with laws and regulations 5. Alignment with strategic priorities 6. Quality of care/value added for the patient
<i>Org2</i>	<ol style="list-style-type: none"> 1. Alignment with strategic priorities 2. Changes in length of stay and other medical KPIs 3. Safety (patient, staff, information, privacy, equipment, building) 4. Financial 5. Impact on personnel 6. Feasibility 7. Quality of patient care 8. Network strategy
<i>Org3</i>	<p>Impact on:</p> <ol style="list-style-type: none"> 1. Patients 2. Safety and quality 3. Staff 4. Production 5. Finances and efficiency 6. Logistics 7. Strategic objectives
<i>Org4</i>	<ol style="list-style-type: none"> 1. Compliance with laws and regulations 2. Continuity of operations 3. Patient safety 4. Staff safety 5. Financial
<i>Org5</i>	<ol style="list-style-type: none"> 1. Financial 2. Quality of care

<i>Org6</i>	<ol style="list-style-type: none"> 3. Strategic alignment 1. Motivation 2. Volumes 3. Competency requirements for users 4. Compliance with laws and regulations 5. Quality of patient care 6. Physical aspects for users 7. Strategic priorities of the hospital 8. Financial 9. Demand for the device 10. Whether the device is already available in the hospital
<i>Org7</i>	<ol style="list-style-type: none"> 1. Financial 2. Necessity and urgency 3. Quality of care 4. Competency requirements for users 5. Compliance with laws and regulations
<i>Org8</i>	<ol style="list-style-type: none"> 1. Service 2. Implementation and training 3. Documentation 4. Interoperability 5. Infrastructure 6. Information security 7. Technology 8. Quality and safety 9. Cleaning and disinfection 10. Functionality 11. Ergonomics 12. Financial 13. Alignment with strategic priorities 14. Quality of care
<i>Org9</i>	<ol style="list-style-type: none"> 1. ICT alignment 2. Motivation 3. Financial 4. Quantitative benefits 5. Qualitative benefits 6. Risks of not investing 7. Risks of investing 8. Compliance with laws and regulations 9. Impact on personnel

Figure 5. Criteria table per hospital

Looking at the criteria hospitals use to evaluate investments, it is striking how much variation exists. It shows that the number of requirements ranges from a minimum of 3 to a maximum of 14. This variation can partly be explained by the way hospitals approach the process in terms of style. Hospitals with fewer criteria generally have a less structured process, allowing for flexibility and individual input, for example, from the investment committee. In contrast, hospitals with a larger number of

criteria operate with structured lists, application forms, and a well-defined process. According to them they thought of every detail and individual input is less needed. Therefore some organizations have highly detailed frameworks that consider everything from patient impact to interoperability and cleaning protocols, while others focus primarily on finances, strategic alignment, and quality of care. The fact that some hospitals place little emphasis on operational consequences—such as how investments affect staff and logistics—is concerning, as this oversight could lead to implementation challenges down the line.

Another curious observation is the diversion in the use of the law and regulation as a criteria, the extent to which it shapes investment decisions varies significantly. Some hospitals embed legal and ethical considerations deeply into their decision-making processes, while others seem to treat compliance as a checkbox exercise rather than a guiding principle. This divergence raises questions about how consistently hospitals prioritize regulatory adherence and whether some may be exposing themselves to unnecessary risks.

While financial and strategic criteria are universally applied, the differences in detail and focal points demonstrate how organizations tailor their evaluation processes to fit their unique needs, objectives, and levels of maturity. These contrasts provide opportunities for organizations to learn from each other's approaches and enhance their investment processes. The frequency of the given criteria will be further discussed in 4.3.

4.2 Process

4.2.1 *Global process*

This section outlines the various steps, that were discovered during the interviews, involved in the decision-making process within Dutch hospitals. In doing so, it provides an answer to the first sub-question: "Which steps are taken in the investment decision-making process in Dutch hospitals?" In section the answer to the third sub-question will be given, stated: "How do regulations and law determine the need for investment decisions?"

The investment decision-making process in Dutch non-academic hospitals is characterized by various steps and levels of decision-making. While some steps, committees, or details may differ, there is largely a clear pattern that can be described for how the process works within the gross of these hospitals.

The allocation of investments for new equipment varies between hospitals. Four hospitals indicated that they work with different categories when it comes to investments, such as ICT, buildings, equipment, and other inventory. Other hospitals stated that they have combined all investments or are considering doing so to promote the integration of processes. In 7 out of the 9 hospitals, it has been

indicated that there are two or even three different routes within the process of the investment decisions. These differences relate to replacement requests, new purchases, or innovations. It is observed that replacement requests follow a faster track. In such cases, the decision might bypass certain committees or even the board of directors in order to speed up the process. This approach has been chosen by hospitals to ensure continuity of care. Replacement requests are submitted when existing equipment or materials have either broken down or reached the end of their expected depreciation period. This typically happens when it is anticipated that the item can no longer function reliably or cost-effectively. According to the interviews, the standard depreciation periods vary, with most equipment being depreciated over 8 to 10 years, while IT assets, including software and hardware, generally have a shorter lifespan of around 5 years.

The process for expansion purchases is a more extensive one, often involving the full trajectory, unless the investment falls below a certain threshold, with variations mentioned between €5,000 and €50,000. Investments above this amount follow the full process. For innovations, there is sometimes an even more comprehensive path. In these cases, additional information, such as a business case, may be requested, or a more detailed risk analysis might be conducted.

Every investment begins with a application request. In hospitals, there are differences regarding who is authorized to submit such a request. In some cases, anyone may submit a request, while in others, only the business unit manager is permitted to do so. Additionally, some requests must be endorsed by a financial, technological, or business advisor before submission. All nine hospitals use at least one committee, generally called the investment committee, to oversee the investment process. In most cases, this committee is responsible for reviewing and approving investment requests. However, in six hospitals, there are additional steps that take place before an application is submitted to the investment committee. These preliminary processes ensure that each proposal is thoroughly reviewed and aligned with the hospital's strategic objectives and budget.

In two of the hospitals, it is required for an application to be submitted with advice from a financial advisor and/or a medical technology consultant. The financial advisor assesses the economic viability of the proposed investment, looking at factors such as return on investment, long-term costs, and whether the proposal fits within the available budget. The medical technology consultant, on the other hand, evaluates whether the proposed equipment or technology is technically feasible, safe to use, and compatible with existing systems in the hospital. Additionally, in four hospitals, a smaller committee conducts a preliminary check to determine whether the investment aligns with the hospital's overall goals, strategies, and budgetary limits. This smaller committee typically includes representatives from various departments, and they review whether the proposed investment fits within the hospital's broader priorities before it proceeds to the formal investment committee.

The frequency of the investment committee meetings also varies between hospitals. At 5 out of the 9 hospitals, it is possible to submit requests throughout the year, and the committee meets more frequently during the year to review these requests. At the other 4 hospitals, a yearly cycle is used. In these cases, requests are collected and submitted once a year, often aligned with the hospital's planning and control cycle. When looking at the overall flow of the process, it can be schematically represented as shown in figure 6. While this representation lacks detail and may vary slightly between hospitals, it serves as a general guide to better illustrate and comprehend the red line of the process. It is a basic model and not complete with all additions. It can be seen as the skeleton of the investment process when leaving behind differences and some exceptions in and between the hospitals.

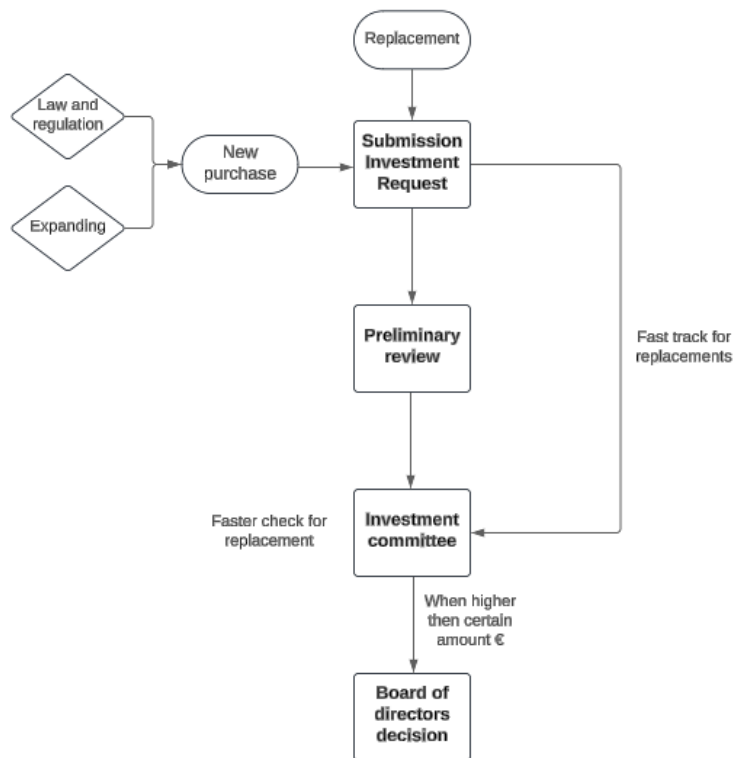


Figure 6. Global summary of the process

However, this represents the absolute foundation of how the process typically looks. It varies from hospital to hospital in terms of how closely this model aligns with their specific realities, but overall, this overview can be generalized across the respondents. The biggest deviations from this overview across the hospitals concern the following aspects:

- Preliminary review: Some hospitals have additional review steps before the application is submitted to the investment committee. These steps are designed to ensure the alignment of proposals with the hospital's strategic goals and financial parameters.
- Timing of alternative solutions: In certain cases, alternatives to the proposed investment are evaluated at different stages of the process, either during the initial request or after initial reviews. The timing and depth of this evaluation can vary between hospitals.

- Decision-making authority: The authority to make final decisions on investments varies among hospitals. In some cases, the investment committee has the final say, while in others, the board of directors or higher-level management might have the ultimate decision-making power, particularly for large-scale investments.
- Risk and technology assessment: The extent and timing to which investments are assessed for risks, particularly in terms of technological compatibility, safety, and long-term viability, differs across hospitals. Some hospitals have specialized personnel to evaluate these aspects, while others rely more on internal committees without a specific check. Some hospitals do a risk assessment before screening by the investment committee, other do it afterwards.
- Different routes: Hospitals tend to have distinct approval routes based on the nature of the investment. While replacement requests may follow a faster track, new purchases or innovations often undergo a more extensive review process. Some hospitals have clearly defined routes for different types of investments, while others may have a more flexible or uniform approach.
- Formality, speed, and structure of the process: The formality and speed of the investment decision-making process differ widely. Some hospitals have a highly structured process with multiple stages and strict documentation requirements, while others follow a more informal or flexible approach that allows for quicker decision-making, especially for replacements or smaller investments.

4.1.2 Documentation, communication and decisions

In all nine hospitals, the Board of Directors has the final say when it comes to investment decisions. For high-value or exceptional investments, approval is often required from the Supervisory Board as well. For lower amounts, investment committees are typically authorized to grant approval, and the decision does not need to go through the Board of Directors. Similarly, certain replacement investments, as described earlier in this chapter, may also bypass the Board of Directors. How these decisions are made and by whom is partly determined by what falls within the mandate of the board of directors.

The documentation and communication of investment decisions in hospitals vary by institution. Recommendations from the investment committee and other stakeholders are typically prepared in writing and submitted to the Board of Directors (RvB) if the type of investment requires it. Some hospitals have systems in place where applications can be submitted and processed. Decisions by the Board of Directors (RvB), as described above, are generally formally recorded and published via

designated systems or intranet, making them accessible to all hospital employees. In many cases, submitted documents such as business cases are stored on central drives or in specific systems managed by the investment committees. Decisions are subsequently not only published on the intranet or other platforms but also directly communicated to the relevant departments or individuals. This approach ensures that all relevant stakeholders are informed about the progress and outcomes of the investment process.

4.1.3 Law and regulations

Opinions about the influence of laws and regulations on the need to invest in, for example, new equipment differ. Five hospitals report experiencing little to some influence from laws and regulations, while the other four hospitals indicate that they are required to make regular investments due to changes in legislation. In some cases, legal and regulatory requirements directly mandate investments, particularly in areas related to patient safety, medical technology, and IT security. For example, hospitals may need to upgrade equipment to comply with CE certification or other regulatory frameworks. Additionally, audits, inspections, and accreditation processes sometimes reveal deficiencies that necessitate urgent investments to meet compliance standards.

However, in practice, most investment decisions are driven by economic and technological factors rather than strict regulatory obligations. Many investments are made because equipment has reached the end of its depreciation period, is no longer supported by manufacturers, or can no longer be properly maintained. In such cases, while legal requirements might be cited as an argument, they are not usually the primary driver of the decision. Instead, hospitals focus on ensuring continuity of care and operational efficiency.

Regulations do play a role in specific domains, such as IT security, where laws dictate minimum standards for data exchange and system integration. Similarly, sustainability laws sometimes compel hospitals to make investments, such as replacing conventional lighting with LED solutions. Additionally, certain medical specialties are subject to specific rules, with clinical physicists and medical professionals monitoring regulatory compliance in areas like intensive care.

Overall, while regulations and laws influence investment decisions, they are rarely the sole determining factor. Instead, they interact with financial, technological, and strategic considerations, guiding investment priorities but not always directly mandating them.

4.3 Criteria

This section in combination with chapter 4.4 will address the second sub-question of the research methodology: "What criteria are used in the investment decision-making process in Dutch hospitals?" The key criteria influencing investment decisions were surveyed, revealing a wide variety of criteria,

as expected. However, several criteria emerged as commonly regarded as important by most hospitals and are therefore taken into account in the investment process. The criteria identified were derived from both interviews and the formats that were provided by six hospitals. For three hospitals, it was not possible to provide these formats, or the hospital did not have a structured list of criteria in place. In these cases, only the criteria mentioned during the interviews were noted.

As shown in figure 7, a wide range of criteria was mentioned. Hospitals sometimes use different terms for the same criteria. Through coding, these were categorized under the criteria presented in the table. All nine hospitals consider the impact on the quality of patient care and the financial aspects of the investment. The financial aspects will be discussed in more detail in the next chapter. Notably, six hospitals assess whether the proposed investment aligns with the hospital's strategic priorities.

In comparison with the theoretical model and the definitions of the criteria described in appendix 10.1, all elements are reflected in some form in the respondents' answers. However, the demand for treatment was mentioned as a criterion in the investment decision-making process by only one hospital.

<i>Criteria</i>	<i>Frequency</i>	<i>Description</i>
<i>Quality of patient care</i>	9	Impact of the proposal on the quality of care for patients, including effects on treatment outcomes and patient satisfaction.
<i>Financial</i>	9	Financial implications, including initial investment, structural and one-time costs, revenues (direct and indirect), and required funding sources.
<i>Impact on personnel</i>	7	Impact on personnel, such as required hours, workload, job satisfaction, and any training or competency requirements.
<i>Alignment with strategic priorities</i>	6	Alignment of the proposal with strategic goals and organizational priorities, such as value-driven care and focus on specific target groups.
<i>Safety</i>	5	Safety of patients and staff, protection of privacy and information security, and technical safety of equipment.
<i>Laws and regulations</i>	5	Compliance with laws and regulations, including adherence to legal frameworks and guidelines.
<i>Necessity and rationale</i>	4	The necessity and rationale for the proposal, including justification based on laws and regulations, strategic goals, and expected improvements.
<i>Impact on IT</i>	3	Impact on IT, such as required infrastructure, interoperability with existing systems, and technical support.
<i>Impact on continuity of care processes</i>	3	Effect of the proposal on the continuity and efficiency of care processes.
<i>Impact on capacity</i>	2	Effect of the proposal on the hospital's available capacity.

<i>Impact on facilities</i>	1	Impact on facilities, such as space utilization, maintenance, and availability of resources.
<i>Network strategy</i>	1	Alignment of the proposal with the network strategy, such as collaboration with other healthcare institutions and partners.
<i>Impact on logistics</i>	1	Effect on logistical processes, such as transportation, storage, and availability of materials.
<i>Quantities</i>	1	Required or expected quantities of equipment.
<i>Demand for equipment</i>	1	The demand for the equipment or system within the organization, including an estimate of future needs.
<i>Availability of alternatives</i>	1	Availability of similar devices or alternatives within the organization that can fulfill the same function or role.
<i>Desinfection</i>	1	Requirements for cleaning and disinfection, including practical feasibility and impact on hygiene standards.
<i>Technical specifications</i>	1	Technical requirements, such as specifications for service, maintenance, and necessary infrastructure.
<i>Consequences of not investing</i>	1	Risks and consequences of not proceeding with the investment, such as the impact on quality of care, safety, or costs.

Figure 7. Criteria frequency table

The hospitals were asked how investments are ultimately evaluated and whether any form of prioritization is in place. Six hospitals indicated that they do not use a prioritization system. The reasons mentioned include the difficulty of agreeing on a point-based system, the belief that one criterion is not more important than another, or that operating on a first-come, first-served basis works better. However, two hospitals acknowledged that this is an ongoing issue within their organization. They expressed a desire to implement prioritization, especially in cases of budgetary constraints.

Three organizations stated that they have a mechanism for prioritization, but it is only used when budgetary limitations arise. Examples of prioritization methods include assigning a numerical score to each criterion by the applicant or using a point-based system.

4.4 Financial evaluation

As shown in figure 7, which outlines all the mentioned criteria, every hospital makes a financial consideration before making an investment. The approach to these financial considerations varies, but all nine hospitals interviewed emphasized the importance of having a comprehensive financial overview. To achieve this, a Total Cost of Ownership (TCO) analysis is often conducted. This analysis takes into account the initial investment required to purchase the equipment, as well as costs for maintenance, consumables (disposables), sterilization, and potential training expenses for employees. The focus is then placed on identifying potential savings compared to the equipment currently in use within the hospital.

A TCO calculation is often incorporated into the application process by requiring applicants to complete a business case form. A business case is not always mandatory for smaller replacement

investments but is required for larger acquisitions of new equipment or replacements that involve a significant amount of money. A business case includes specific financial components that applicants must complete, reducing the likelihood of financial aspects being overlooked in the TCO analysis. The content, format, and complexity of business cases vary by organization. In some hospitals, they are relatively basic and loosely structured, while in others, applicants must fill in concrete figures and answer specific questions.

Financial depreciation periods are also taken into account. The stated periods vary, with equipment typically depreciated over 8 to 10 years and ICT-related investments over 5 years. These depreciation periods are factored into cost analyses for new investments.

Estimating the financial benefits is considered more challenging by the respondents. A quote from one of the interviews illustrates this: *“The benefits, that’s much more guesswork.”* Three hospitals indicated that they assess the number of DBCs (Diagnosis Treatment Combinations) involved in the treatment. For instance, if it is expected that a new patient group can be attracted, they examine how many DBCs this could potentially generate for the hospital.

There is also a trade-off for the hospital: if a device enables a patient to be discharged earlier, it improves the quality of care. However, it also results in the hospital receiving a lower reimbursement from the health insurer, as the patient stays, for example, one day less. As a result, financial benefits are often primarily compared to the current equipment and the savings that can be achieved by using a new device. The cost reduction is the main aspect analyzed in these cases.

4.5 Technology assessment

Chapter 4.5 and chapter 4.6 will assess the risks and uncertainty that come with investing in technology. Therefore these chapter will answer the fourth sub-question: “How do hospitals cope with risks and uncertainty of the new technologies?”

Hospitals do not explicitly use a single structured model to assess the maturity of a technology, such as the TRL (Technology Readiness Level) scale. Instead, an evaluation is conducted by staff from medical technology and clinical physics departments, who assess the maturity of the technology. This often includes a prospective risk analysis, which is further discussed in Chapter 4.5.

For five hospitals, assessing technological maturity is less of a priority. During the interviews, they explicitly stated that they do not wish to be early adopters and therefore only use proven technology. The devices they adopt are already in use in other hospitals and have demonstrated their reliability. Additionally, medical equipment must comply with strict laws and regulations, ensuring that these technologies are thoroughly tested and inspected.

Two hospitals, on the other hand, indicated that they are particularly interested in devices with a high degree of innovation. When a device is highly innovative, it undergoes a more extensive process. This includes trial placements, where the device can be tested within the hospital's environment. Only after this phase is it determined whether the technology is ready for practical application.

4.6 Risk analysis

Risks are assessed with more flexibility compared to the structured approach seen with criteria. The applicant, along with the medical technology or clinical physics departments, is responsible for identifying the risks associated with the implementation of the equipment. Efforts are made to conduct a comprehensive risk analysis. This involves addressing risks across various categories, including patient safety, ICT infrastructure, data privacy, financial implications, and employee safety.

It was noted that "risk" is a very broad concept, making it challenging to always rely on a standardized checklist. The nature and scope of risks can vary significantly depending on the device or application in question. For example, a diagnostic imaging device may present risks related to radiation exposure, while a new software system might involve concerns around cybersecurity or data integration.

Hospitals were asked whether they use specific risk management tools or frameworks to assess risks. Five hospitals mentioned conducting a prospective risk inventory to evaluate risks. [41] A Risk Assessment Matrix framework, as shown in figure 8, is often used for this purpose. Risks are assessed based on their severity and the likelihood of their occurrence. These assessments are typically conducted by the medical technology and/or clinical physics departments.

Additionally, one hospital mentioned the "Medical Covenant on the Safe Application of Medical Technology" as a guideline for risk management. [42] The Inspectorate considers this covenant an important field standard in Dutch healthcare. Another hospital stated that they use questions from the NIKP (National Instrument for Clinical Physics) to perform a risk analysis and to determine any necessary control measures to ensure safe implementation. [9]

Two hospitals did not mention a specific framework, model, or document in use; they rely on advice from the medical technology department. It is possible, however, that medical technology departments are using a framework internally.

		Risk Assessment Matrix			
		Severity			
		Catastrophic - 4	Critical - 3	Marginal - 2	Negligible - 1
Probability	Frequent - 4	High (16)	High (12)	Serious (8)	Medium (4)
	Probable - 3	High (12)	Serious (9)	Serious (6)	Medium (3)
	Remote - 2	Serious (8)	Serious (6)	Medium (4)	Low (2)
	Improbable - 1	Medium (4)	Medium (3)	Low (2)	Low (1)

Figure 8. Risk Assessment Matrix

4.7 Stakeholders

The last sub-question that investigates the current process is: “Which stakeholders are involved in the investment decision-making process in Dutch hospitals?” The answer to this question is discussed in this chapter.

As previously mentioned in the results, every hospital has an investment committee responsible for handling investment decisions. However, the composition of this committee varies across hospitals, and some hospitals also have a smaller subcommittee to preliminarily review applications for alignment with the hospital's strategic priorities. Four hospitals have such a smaller subcommittee, while five hospitals operate with only an investment committee.

The composition of these committees also differs, but the underlying structure of the composition of the committees remains the same, and all of them are multidisciplinary in nature. The following roles were mentioned as being involved in the investment process: business manager, clinical physicist, care manager, finance manager, procurement, facilities manager, head of medical technology, board member, business controller, ICT manager, facilities management, medical specialists, building management, head of healthcare technology, infection prevention, occupational health and safety, and technical services. In total, 17 distinct roles were broadly identified as being involved in hospital investment processes.

The composition of the committees is often determined by the hospital’s governance framework, which is typically established as a board decision made some time ago.

In principle, the stakeholders do not vary significantly by the type of investment, except for the involvement of medical specialists. When a device is intended for a specific specialty, medical specialists from that department may be included, although this is not always the case. Stakeholder involvement can also vary by the scale of the investment. For example, decisions involving smaller

amounts may be made by the department or the investment committee without board involvement. For larger investments, more stakeholders are typically engaged in the process, such as the supervisory board or additional medical specialists.

Hospitals were asked to what extent they involve external experts and/or patient representatives in investment decisions. Five hospitals stated that they do not use either option. The remaining four hospitals indicated that they occasionally seek advice from external experts, with one hospital also involving the client council and patient council in major decisions.

External experts are primarily consulted to provide advice on areas where the hospital lacks sufficient in-house expertise. In some cases, other medical specialists, who are not typically part of the decision-making process, may also be involved. However, patient representatives are generally not included, except during the initial stages of the investment process. For instance, it is possible that a particular device is considered for acquisition because a patient initiated the request.

4.8 Key conclusions for improvement of the theoretical model

Based on the findings from the interviews, several critical improvements were identified to enhance the theoretical investment model. These points were established based on the frequency of respondents' answers, the expected added value, and the feasibility of change.. These improvements focus on optimizing the investment decision-making process in hospitals by addressing key areas such as strategic alignment, cost evaluation, and operational efficiency. The proposed changes aim to ensure a more comprehensive, dynamic, and collaborative approach to investments. Key conclusions include:

1. Repositioning laws and regulations: Laws and regulations should be considered as a criterion rather than a driving force in the investment process.
2. Strategic alignment: Aligning investments with the hospital's strategic priorities is crucial, with an emphasis on evaluating innovation potential early in the process.
3. Total Cost of Ownership (TCO): Incorporating a holistic financial perspective, including TCO, is essential for informed decision-making.
4. Distinct pathways: Establishing specific pathways for urgent and replacement requests will streamline decision-making while maintaining the integrity of the process.
5. Capacity constraints: Addressing administrative and resource limitations within hospitals is key to improving decision-making speed and efficiency.
6. Defining functionality needs: Focusing on the functionality needs rather than specific devices helps reduce conflicts of interest.

7. Integrated approach: Adopting a more integrated approach to investment planning that includes all relevant disciplines will promote a more unified process.
8. Post-Investment evaluation: Implementing a cyclical evaluation process to measure the effectiveness of investments and identify areas for improvement.

These improvements are aimed at refining the model to better meet the dynamic needs of hospitals while ensuring investments contribute to long-term success.

4.9 Process model version 2

4.9.1 Improvements to the theoretical model

By analyzing the data, certain issues were identified that were mentioned by multiple respondents. Based on the problems and remarks of the respondents, several improvements have been identified for the theoretical model, along with the requirements for its successful implementation in hospitals. Some improvements or changes were mentioned multiple times by the respondents and, for this reason, caught the attention of the researcher. Other improvements have been made by the researcher according to the found problems. Additional research was conducted on these findings to determine whether they could contribute to improving the process.

1. Law and regulation

When examining the theoretical model, it was initially assumed that laws and regulations would drive certain investments. However, in practice, their influence is relatively limited. Instead, the focus is primarily on ensuring that equipment meets regulatory requirements rather than regulations directly prompting investments. For this reason, the regulatory factor can be repositioned as a criterion rather than a driving force at the forefront of the model.

2. Strategic alignment

One critical improvement is the incorporation of alignment with the hospital's strategic priorities as a formal criterion. Research by Kaplan et al. from the Harvard Business School emphasizes the importance of a clear and strong strategy within an organization. A good strategy helps the organization add valuable assets that can truly benefit critical processes such as operations management, customer management, and innovation. The strategy is the source of competitive advantage and financial success.[43] Therefore, it is important for a hospital to look ahead, as some hospitals are currently doing, in terms of how a new acquisition will contribute to the hospital's key focus areas. Another suggested enhancement is prioritizing the evaluation of innovation potential earlier in the process. This adjustment ensures that hospitals can strategically decide whether to pursue innovations and confirm their fit with the hospital's overarching goals before significant effort and

resources are invested. This step can be combined with aligning the strategy by making it one of the strategy points.

3. Total Cost of Ownership evaluation

Additionally, the model should incorporate a holistic financial perspective, considering all aspects of costs and benefits. The importance of this was also emphasized by multiple respondents. Contrary to the financial evaluation methods, that were presented in the theoretical model, all respondents reported using a TCO (Total Cost of Ownership) calculation. While there is limited literature on the use of TCO calculations specifically within the hospital setting, extensive research exists on TCO as a concept. For instance, Panjaitan et al. describe TCO as an excellent method for understanding the true costs of acquiring goods and services. This approach not only considers the initial purchase costs but also accounts for expenses incurred during the operation and disposal phases of an equipment's lifecycle. Therefore, integrating the Total Cost of Ownership into supplier selection, negotiation, and evaluation processes is essential for making well-informed investment decisions. [44] A TCO is a dynamic evaluation method, as was discussed in the theoretical framework.

4. Multiple pathways

Respondents also emphasized the need to establish distinct pathways within the model, such as expedited routes for urgent or replacement requests, to streamline decision-making processes. Distinct pathways are made according to the organizations to improve efficiency, reduce delays, and ensure that critical medical technologies are available when needed. They support this with the argument that, in the case of replacement investments, the technology has already proven its alignment with key priorities, as well as its necessity and usefulness. However, it remains important to continuously evaluate alternative options, as advancements in medical technology occur rapidly and may offer improved solutions. Therefore replacement request shouldn't be 'holy', and still need an examination for their added value and criteria match. Respondents emphasized the need to avoid creating alternative routes that allow bypassing the established process, as this undermines the integrity of the model. When making a definitive process, there should be kept in mind that there are no ways to avoid the process route and close an investment without having to go through the whole process.

5. Capacity constraints

Respondents highlighted several overarching factors that a successful model must address. A recurring theme was the need for a balance between administrative burden and the utility of the process steps. This balance directly affects the speed of the decision-making process, particularly for replacement requests, which must be handled promptly. This also has influence of the suggestions to incorporate a prioritization mechanism, especially for hospitals facing financial difficulties. Such a mechanism could help allocate limited resources more effectively. The administrative constraints are not the only

capacity constraints. So were capacity constraints frequently mentioned. Respondents highlighted that departments like ICT and medical technology are increasingly burdened by the growing demand for implementing new technologies. Most healthcare systems have to operate with constrained capacity, which includes limited availability of hospital beds, doctors, nurses, medicines, and other resources required to deliver care to patients. [45] This was often underscored by the respondents with the importance of considering hospital capacity when prioritizing investments. This can be combined with the need for prioritizing when budget constraints are applicable in an organization. Therefore in a applicant request here needs to be a mechanism build in that gives the option for prioritization, but that it needs to be voluntary for each organization.

6. Functionality need

Furthermore, the importance of defining needs rather than proposing specific devices was stressed. This approach helps prevent conflicts of interest, such as physicians favoring specific suppliers due to external agreements. The issue of conflicts of interest held by physicians and other caregivers has drawn increased attention in recent years. In response, some commentators and institutions have proposed policies intended to protect patients' rights, including disclosure of relationships with for-profit companies. Checking different suppliers and alternatives will ensure conflict reduction. [46]

7. Integrated approach

Some respondents suggested adopting an integrated approach to investment planning, involving all relevant disciplines in a collaborative manner. This refers to combining investments in areas such as housing, medical technology, and ICT into a unified approach. The importance of a multidisciplinary approach was already highlighted in the theoretical framework. However, multidisciplinary collaboration extends beyond just having a diverse team within the investment committee. It can also be applied at a strategic level, involving a dedicated committee that integrates various domains, including facilities management, ICT, and other key areas. [17] However, it was noted that not all hospitals operate this way. While some employ an integral approach, others divide investments into three or four distinct categories, leading to a less unified process.

8. Evaluation

Lastly, three respondents mentioned the need for an evaluation after the purchase of an investment. Currently, after an investment, there is no evaluation to determine whether certain goals have actually been achieved with the new investment. One respondent suggested creating a cyclical model for the same reason, which would integrate this evaluation. Evaluation not only provides insight into the effectiveness of the investment but also contributes to the continuous improvement of the investment process. By measuring and analyzing KPIs, hospitals can assess whether the expected benefits, such as cost savings, efficiency improvements, or better patient care, are actually being realized. [47]

Furthermore, it enables organizations to take corrective actions when big mistakes are made in the decision-making process and to optimize future investment decisions based on actual data rather than assumptions. This evaluation does not have to be done after each investment, this can be chosen on the capacity of the investment committee or other personnel. A study by the RIVM also confirms that the closure of such investment projects needs improvement within Dutch hospitals. According to the RIVM, the responsibilities for the release for use, the completion of the procurement project, and the management of medical technology should be better defined. [5] This effect can be realised by implementing an evaluation cyclus at the end of each investment process.

4.9.2 Improved model for follow-up

To verify the responses of the respondents, a follow-up model has been created that integrated the improvements in the chapter above. This follow-up model is the improved version of the theoretical model, incorporating elements from the theory that have been adjusted based on practical findings. This is therefore version 2 of the model. In this model, the responses of the respondents that are deemed important have been included and processed. Suggestions and key points, as mentioned above, have been incorporated into the model shown in figure 9 on the next page. The steps are explained in 10.5.

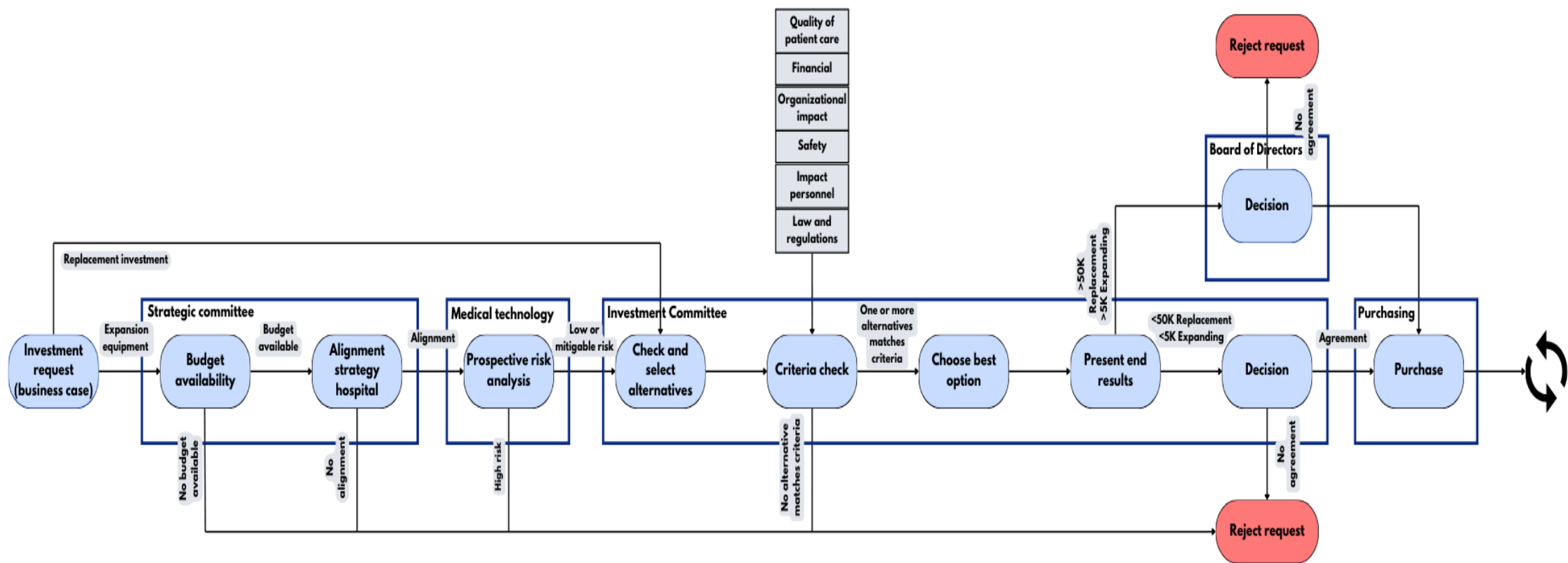


Figure 9. Model version 2

The evaluation cycle, which is shown at the end of the model, is a separate cycle. It is displayed in figure 10 , which is shown below. This cycle has been added based on the findings from the interviews. Respondents expressed outrage that investments are rarely evaluated afterwards. An investment is made, but later there is no follow-up to see if the intended improvements are actually achieved. When structural errors are made in the decision-making process for an investment, they are likely to go unnoticed. By adding an evaluation cycle at the end of the investment process, the likelihood of this happening is reduced. Errors are identified earlier, and the investment process can be better assessed for accuracy and efficiency.

The KPIs (Key Performance Indicators) are typically defined by the departments and teams responsible for the implementation of the device or investment. This may include the Medical Technology department, operational departments, or project teams, depending on the nature of the investment. The departments determine which performance indicators best align with the goals of the investment. Examples include efficiency, cost savings, or improved patient care. Monitoring of the KPIs is usually carried out at the operational level, with line management playing a crucial role. They are responsible for periodically measuring and tracking the KPIs to ensure that the investment achieves its intended effects. This can be done through tracking performance using automated systems or manual reports.

Ultimately, any significant positive or negative outcomes can be reported back to the investment committee. If there are outliers, the committee can examine whether they are due to the process, overlooked risks, missing criteria, or unforeseen circumstances. The process can be changed based on the findings at the end of the evaluation.

The step of the evaluation cycle is further explained in the appendix 6.4 in step 7.

Evaluation Cyclcus

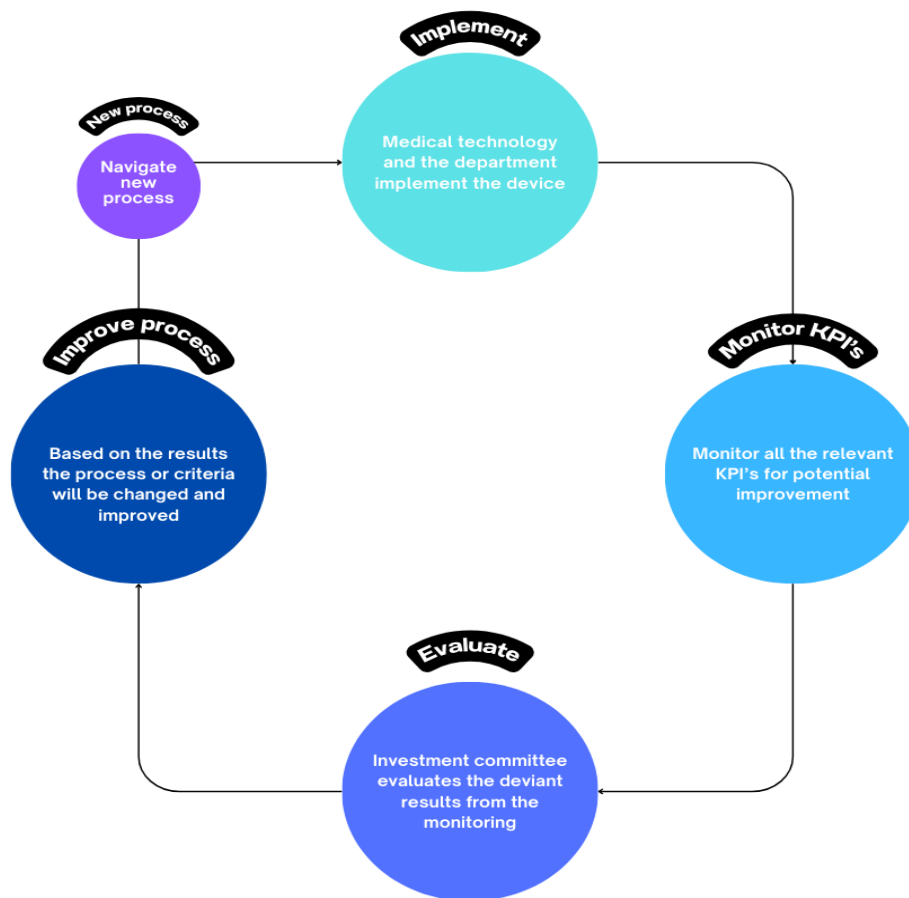


Figure 10. Evaluation cyclcus

These two images together form the process shown in the follow-up to verify the previously given responses and to gain new insights, which will lead to the creation of the final model. To structure this follow-up process, a questionnaire has been created to be used. It can be found in appendices 10.6 and 10.7.

4.10 Follow-up model version 2

To verify and further improve version 2 of the model, a follow-up study was conducted in the form of a questionnaire, where changes to the theoretical model and existing questions from the researcher were addressed. The questionnaire can be found in appendix 10.6 and 10.7, along with the explanation in 10.5.

A total of 6 individuals, representing various roles from 6 different organizations, completed the follow-up questionnaire. These participants had also taken part in the interview. According to the respondents, the model and the explanation were well understood (5/6). The main strengths identified included the evaluation cycle (6/6), the possibility to halt the process early if certain requirements are not met (3/6), and the addition of the right expertise at the right place (2/6). It was recommended to incorporate capacity into the evaluation process and to use KPI monitoring to assess whether future

replacement investments should be made. This would allow hospitals to track key performance indicators related to previously approved investments, ensuring that expected benefits, efficiency gains, and financial impacts align with initial projections. By continuously monitoring these KPIs, hospitals can make data-driven decisions on whether future replacement investments are necessary or whether adjustments to the investment process should be made. According to 5 respondents, the model is feasible within their organization, with two respondents indicating that it represents an improvement over their existing process. One respondent stated that the model is not yet applicable within their organization and saw no advantages over the current process.

The weak points of the process were also addressed. Firstly, three respondents indicated that the threshold for involving the executive board (RvB) in decision-making is too low, which leads to an excessive workload for the board. However, these suggestions varied depending on hospital size. To create a universal process, it would be necessary to consider proposals that are adaptable to different sizes, possibly using percentages. Additionally, the investment committee in the proposed process plays too substantive a role, leading to an overburdened committee. More work should be done in the preparation phase, with the committee taking on a more evaluative role. Another issue identified is the lack of a connection with the hospital's budgeting process, which should be taken into account according to three respondents. One respondent suggested adding a decision point for a risk inventory (PRI), where it could be determined whether a risk assessment is necessary. A final key point is that the proposed process currently focuses solely on investment decisions for medical technology. Three respondents suggested looking into the possibility of combining or scaling the process to include investments in areas such as ICT and construction. This is in line with the importance of integration, which all six respondents agreed is essential.

Regarding the consideration of two separate routes for replacement investments and new equipment, two main arguments were identified. Creating two routes was seen as beneficial by all respondents, as it positively impacts continuity and the speed of the process. However, it is important to continually assess whether certain replacement investments are still necessary. Due to rapid changes in equipment, ICT, and construction, it is often no longer feasible to replace items on a one-to-one basis or with the best option. Therefore, there should always be a broader evaluation than simply replacing existing equipment one-for-one.

One respondent mentioned that a bottleneck in the process could be the administrative burden, due to the need for filling out business cases and other formats. The follow-up study asked for suggestions to reduce this administrative load. Digitalization and automation, using standardized templates that are well known within the organization, were identified as potential solutions (4/6). Additionally, it helps if the business case is complete in advance, reducing the need for constant back-and-forth

communication. The respondents also suggested that an ongoing evaluation could help reduce administrative burden by continuously refining the process.

Finally, the proposed method for prioritization was deemed feasible by the respondents (5/6). However, according to the respondents it could lead to a bureaucratic process, potentially causing long discussions over scoring then evaluating the process. It is possible to establish strict agreements on scoring, which can help prevent these discussions in advance. There appeared to be a slight demand for prioritization mechanisms. Therefore, it may be beneficial to keep the scoring informal and to clarify how prioritization should be handled, especially in situations like financial crises, as suggested.

With all of these insights, the definitive model will be created and shown in the next chapter.

4.11 Definitive proces and model

4.11.1 *Improvements to model version 2*

Based on the feedback received and the frequency and added value of the responses, the following key elements have been modified in process model version 2: the threshold for the Board of Directors' decision-making, the substantive role of the investment committee, integration with the budgeting process, the addition of a risk assessment decision point, the implementation of a replacement investment check, the degree of prioritization, and scalability across multiple disciplines.

1. Role of the investment committee

Regarding the role of the investment committee, the current process assigns too much responsibility for the selection of equipment to the committee, despite limited expertise in this area. Instead, the committee should focus on reviewing applications that have been substantively prepared by the requesting party, rather than engaging in content-heavy evaluations themselves. The key questions should be: has everything been considered, is the application complete, have all criteria been realistically filled in or are there extreme outliers, and has the correct option been appropriately chosen.

To facilitate this, the application form submitted at the beginning of the process must include all critical criteria, with later endorsements from the medical technology and finance departments. These reviewing parties can also add comments for the investment committee if necessary. This endorsement ensures that the application is complete before being assessed by the committee, reducing the administrative burden of the process. Additionally, the functional necessity must be justified in the application to verify that the requested equipment provides real added value and addresses capacity gaps, rather than being an unnecessary addition. The final process description will include a template application form to provide structure, responding to multiple respondents' requests for standardization, which could further reduce administrative workload.

2. Threshold of the Board of Directors

To alleviate the pressure on the Board of Directors caused by the low threshold for decision-making, an alternative approach should be implemented. As discussed previously, threshold values vary between organizations, influenced by factors such as organizational size or financial position. Instead of a fixed threshold, such as 50,000 euros for replacements and 5,000 euros for expansions, it can be set as a percentage of the hospital's total annual investment budget. Applying a percentage allows the process to adjust to fluctuations in the investment budget and overall financial scope. This ensures that the workload on the Board of Directors remains proportionate, even when investment activity increases or decreases. Since investment budgets, current thresholds, and governance workloads are not publicly available, each hospital must determine its policy regarding the threshold value.

3. Integration with planning and control

Process model version 2 currently lacks a direct connection with the hospital's planning and control cycle. Some hospitals allow investment requests to be submitted throughout the year, providing departments with flexibility to respond to urgent needs or unexpected changes. This can be essential for replacing equipment that suddenly fails or for addressing unforeseen investment needs. These hospitals operate with a continuous approval process, without strict submission deadlines. Other hospitals follow an annual cycle for investment applications, requiring departments to prepare and submit requests during a specific period, often in the second half of the year, for the following year. This approach centralizes requests, allowing for a structured evaluation based on priorities and a comprehensive budget allocation for the upcoming year. While this method may be more efficient at an organizational level, it limits flexibility for submitting requests outside the designated cycle.

A hybrid model can be introduced to combine the advantages of both approaches. Based on the hospital's budgeting system, periodic rounds can be conducted annually, semi-annually, or quarterly in a rolling forecast structure to assess replacement investments and collect expansion requests. Certain systems allow hospitals to track equipment and IT components, providing an overview of when replacements are expected. This enhances planning and preparedness. Based on this list, a budget request can be submitted to the Board of Directors, including a reserve for unforeseen urgent investments. These investments may involve medical devices, IT, or other essential assets requiring immediate action. If the budget is approved, applications can be submitted periodically, for example, every six weeks. This distribution of requests throughout the year reduces the workload and administrative burden on the investment committee. Other budgets for investments in areas such as ICT and facility management can be allocated and planned separately. However, the overall process can still follow the same integrated framework. This will be further explained later in this chapter.

4. Risk assessment

A comprehensive risk assessment for every investment was identified as time-consuming and administratively burdensome, even when unnecessary. Therefore, an initial risk estimation should be conducted by the applicant, medical technology, and healthcare professionals, when relevant. A full prospective risk analysis should only be required if a medium or high risk with significant consequences is expected. Otherwise, a more concise risk assessment will suffice. Conducting a risk analysis before reaching the investment committee is a valuable step, as the findings can be incorporated into the committee's considerations. The stakeholders involved in the risk assessment may vary by investment and could include medical specialists, facility management, IT, and medical technology experts. While the NIKP guideline from 2020 was found to be outdated, it still provides a detailed framework for conducting a thorough risk assessment in hospitals and can serve as a reference for the proposed process. [9][10]

5. Scalability

The process must be scalable to multiple disciplines, such as IT and infrastructure investments. Respondents indicated that this would enhance clarity and uniformity in applications. Having multiple formats, processes, and differing agreements can create confusion within the organization, ultimately reducing process efficiency. Minimal modifications are needed to make the process broadly applicable, as the established criteria are already generalizable across disciplines. However this research focuses on medical technology investments, these changes can be done without harming the investment process for the technology. Additional stakeholders, such as IT and facility management, must be involved in the risk analysis. Representatives from these departments should also participate in the strategic and investment committees, as originally proposed, to ensure an integrated approach.

6. Replacement investment check

A verification step should be included to determine whether replacement investments are truly necessary. During the initial assessment phase, which identifies potential replacements, a critical evaluation should be conducted to assess the actual need for investment. Continuous evaluation is necessary to ensure that the organization is making the right decisions. Without this, there is a risk that technology will continue to be added without removing outdated assets, leading to increased healthcare costs. Therefore, the application must include a clear functional justification explaining why the replacement is required. Later in the process, alternative solutions should be considered. Data from interviews and follow-up discussions revealed that one-to-one replacements are often inefficient, as technological advancements over the years frequently present better, more cost-effective alternatives. A full strategic review by the strategic committee is unnecessary if the demand, need, and justification are already clearly established during the initial assessment and application phase.

7. Prioritizing

Follow-up discussions confirmed that the proposed prioritization mechanism for evaluating investments against each other appears feasible. However, respondents also indicated that prioritization is typically unnecessary in hospitals with a strong financial position. Therefore, a prioritization mechanism should be reserved for times of financial distress. If an organization is facing financial difficulties, prioritization can be integrated into the process to assess which investments provide the most immediate value. This evaluation can be based on key criteria such as a quick return on investment, low upfront costs, or a strong potential to attract new patient groups. In the final process, prioritization will be added by assigning scores from 0-10, as seen in one of the hospitals. This option adds little administrative burden, and it can be decided not to fill in the scores, but rather to provide an explanation of the added value within the criteria when the hospital is in a good financial position

8. Administrative burden

The administrative burden can be further reduced through standardization, digitalization, and automation of the process. Investment management systems or shared workspaces can facilitate this by enabling structured tracking of all applications, formats, comments, and decisions in one central location. Centralized communication and documentation streamline workflows, making the process more efficient.

4.11.2 Definitive process description

In this chapter, the proposed, optimized process according to this research will be described. A schematic representation of this process is provided in Chapter 4.9.3.

1. Investment request

An investment request may arise from replacement needs or expansion desires. In relation to the planning and control cycle, departments periodically assess their needs. This includes required replacements and desired expansions. A systematic list is also maintained with expected replacements, allowing an estimation of the required budget by the Board of Directors. Additionally, a budget should be allocated for unforeseen urgent investments. These are necessary to ensure the continuity of the hospital but are not anticipated in the replacement investment budget. Budgets for other investments, such as ICT and facility management, must also be requested separately.

Once the budgets have been allocated, the integrated investment process can commence. Investment requests can be submitted throughout the year by the business managers of the departments in a designated system, such as Ultimo or a shared workspace. A project is opened in this shared workspace, ensuring that each investment has its own dedicated space. This structure provides clarity and oversight for every request. Organization-wide awareness of the use of this workspace or system

is essential, as it contains all required templates, and all completed templates along with related comments are consolidated in one place.

Each investment request starts with a structured application form, submitted by manager of the requesting department. It is up to the applicant to initially assess whether they have sufficient knowledge to complete the application or if additional knowledge is required. In that case, the applicant can involve appropriate stakeholders to correctly and completely fill out the application. A proposal for this form is provided in appendix 10.8.

This form includes all essential criteria, such as strategic relevance, impact on patient care, financial feasibility, and organizational consequences. An explanation of the added value per criteria is asked in the application form. There is an option to give a scoring on some of the criteria from a range of 0 (no added value / no alignment) tot 10 (maximum added value / perfect alignment). When applicants fill in a scoring, a prioritizing mechanism can be used to prioritize investments when the financial health of the hospital is low. A prioritizing mechanism like this also can help to lay the focus on the best investments when capacity is low in the organization. Investments with a high added-value can be implemented first. It can be chosen by the hospital to let out the grading and only ask for an explanation for each criteria.

Additionally, the functional necessity must be explicitly justified to confirm that the investment truly adds value and is not merely an enhancement without a clear necessity. This also encourages early consideration of whether a replacement investment is genuinely needed or if the current equipment still meets functional requirements.

2. Screening and completion of request

Once the investment request has been fully completed by the applicant, it is reviewed by a financial officer and a clinical physicist or another medical technology staff member. They perform a preliminary screening to check if the request is complete. The financial officer collaborates with procurement to refine the Total Cost of Ownership (TCO) calculation, enhancing its reliability for the later stages of the process. Procurement is involved to provide an initial estimate of the investment amount, allowing the financial officer to assess whether all components, as indicated by the applicant, have been accounted for and assigned the correct values.

Additionally, the clinical physicist or medical technology staff member conducts a preliminary risk assessment for investments related to medical equipment. They evaluate whether the chosen alternative is justifiable for review in the process and, in the case of a replacement investment, whether replacement is warranted. If the investment concerns facility management or ICT, the respective teams will be involved in the initial risk assessment.

This process is designed to be low-threshold but provides a foundation for later stages. Based on the risk assessment, it is determined whether a formal prospective risk inventory needs to be conducted. The risk assessment is plotted on a matrix as shown in figure 11.

		Risk Assessment Matrix			
		Severity			
		Catastrophic - 4	Critical - 3	Marginal - 2	Negligible - 1
Probability	Frequent - 4	High (16)	High (12)	Serious (8)	Medium (4)
	Probable - 3	High (12)	Serious (9)	Serious (6)	Medium (3)
	Remote - 2	Serious (8)	Serious (6)	Medium (4)	Low (2)
	Improbable - 1	Medium (4)	Medium (3)	Low (2)	Low (1)

Figure 11. Risk assessment matrix

When it appears that multiple alternatives could potentially be successful for the hospital, the clinical physicist may consider, together with the applicant and the financial officer, evaluating multiple alternatives before selecting the best option based on the assessment. If the replacement investment is no longer available at all, requiring an entirely new alternative that is unfamiliar within the organization, the same representatives and the applicant may decide to follow the full process for an expansion investment.

If it becomes evident that the investment is financially unfeasible or presents unavoidable extreme risks from the outset, the applicant and the reviewing team may decide to reject the investment early in the process. If the investment request is found to be incomplete, it will be returned to the applicant for further completion, after which it can re-enter the process.

3. Budget availability

If the investment concerns an expansion investment and has received a sufficiently positive evaluation in the previous step, the process moves to the budget assessment by the strategic committee. This committee reviews whether there is available budget within the financial plan to accommodate the investment. If there is no budget, this is determined early in the process, preventing unnecessary effort. Additionally, the budget impact is assessed to ensure the investment remains within the hospital’s financial framework. If the budget is insufficient, the investment is rejected; if the budget is available, the investment proceeds to the next step within the strategic committee.

4. Alignment strategy hospital

In this step, the strategic committee evaluates whether the request aligns with the hospital's strategic objectives. A strategic committee must exist out of representatives from different disciplines. It is recommended to include finance, housing, ICT, medical technology and if possible someone from the board of directors. Other wished representatives also can be included. The committee assesses whether the investment fits within the organization's long-term vision and key focus areas. These focus areas may vary per hospital. Important strategy focus areas include:

- Alignment with hospital specialization – Some hospitals aim to specialize in certain areas due to high patient inflow for these specialties.
- Level of innovation – Some hospitals prioritize innovation, while others prefer not to be early adopters.
- Sustainability – The extent to which the investment contributes to environmental and social responsibility.
- Collegiality – The degree to which the investment alleviates employees' workload.
- Financial health of the hospital – If the hospital is in poor financial condition, a prioritization mechanism may be implemented, requiring the investment committee to conduct a brief informal scoring of the criteria later in the process.

This final consideration may lead to the implementation of a prioritization mechanism in cases of poor financial health. Later in the process, the investment committee may be asked to conduct a brief informal scoring of the criteria. This provides hospitals with better insight into which investment should take precedence over another. Depending on the outcome, the request will either be approved for further evaluation or rejected.

5. Prospective risk analysis

In collaboration with Medical Technology and relevant healthcare professionals, Facility Management, or ICT, a prospective risk analysis is conducted in this step. The involved stakeholders depend on the type of investment. A comprehensive prospective risk analysis is only carried out if the risk is classified as medium or high in Step 4.

If Step 4 identified low-complexity and low-volume risks, a smaller-scale risk assessment can be conducted. This prevents unnecessary administrative burden and ensures that only investments with potentially significant risks undergo an in-depth analysis. The different pathways are based on proposals from the NIKP and are categorized into two levels: low risk and medium/high risk. [9] The corresponding pathways are outlined below in figure 12 and 13.



Figure 13. Risk route medium/high risk



Figure 12. Risk route low risk

According to the NIKP, there are various methods to conduct a proper prospective risk assessment. One example of a standardized approach for an effective PRA is the Healthcare Failure Mode and Effect Analysis (HFMEA) method. [48] [9] The HFMEA method systematically maps out all the steps for a prospective risk assessment (PRA), after which they are evaluated. Key questions addressed include how the process may fail and what effects this could have on patient outcomes. Based on this analysis, measures can be taken to prevent failures, and solutions can be identified in case a process step does fail. In the Netherlands, HFMEA became known as SAFER (Scenario Analysis of Failure Modes, Effects, and Risks).

The disciplines involved vary depending on the type of investment. At the beginning of the process, it is determined which representatives need to be involved. In the case of medical equipment, this will always include medical technology specialists and end users. During the PRA, potential risks are extensively mapped and mitigated where possible. The results of the risk analysis are incorporated into the further evaluation by the investment committee. However, if highly complex risks with high occurrence rates are identified and are found to be difficult to prevent, the investment may be rejected early in the process.

6. Investment request judgement

The request then reaches the investment committee. The investment committee consists of representatives from various key disciplines within the hospital. To ensure a comprehensive evaluation, it is recommended to include the following stakeholders:

- Finance
- Procurement
- Medical specialists
- Facility Management
- ICT
- Medical Technology / Clinical Physics
- General Services

Additionally, other stakeholders may be included depending on the type of investment, such as Infection Prevention, additional medical specialists, or the applicant.

This committee evaluates the request based on completeness, feasibility, and consistency. The selection of specific equipment remains the responsibility of the requesting department, while the committee focuses on the following key questions:

- Is the request complete?
- Are there any extreme outliers in the evaluation criteria?
- Is the chosen option the right one?

The previously conducted risk assessment is also considered during this evaluation. If necessary, the committee may request additional information or clarification from stakeholders involved earlier in the process. This ensures that only well-substantiated investments, aligned with all criteria and the hospital's strategic objectives, proceed to the final decision-making stage.

7. Present end results

If the investment committee gives a positive assessment, the final results are compiled. A brief summary of the justification for the decision is created, allowing for future reference to the reasoning behind the investment. This summary is also useful during later evaluations.

If the investment exceeds a certain percentage of the investment budget, it must be submitted to the Board of Directors for an official decision. If it falls below this threshold, the investment committee can make the decision independently.

By using a percentage-based threshold, the decision-making process automatically adjusts to the hospital's financial situation. This approach ensures a balanced distribution of decision-making pressure between the Board of Directors and the investment committee.

8. Decision

Depending on the financial size of the investment, a decision is made by either the investment committee or the Board of Directors. The threshold is set as a percentage of the total annual investment budget. This ensures that the threshold adjusts according to the financial position and investment capacity of the hospital. If necessary, the request is forwarded to the Supervisory Board for a final decision, which occurs in the case of a very high investment amount, the exact threshold of which may vary per hospital. The decision is the final point at which an investment can be rejected; after this, the procurement process is initiated.

9. Purchase

Upon approval, the request is transferred to the procurement department. Here, the best supplier is selected, and cost optimization and contractual terms are considered. This process may also involve collaboration with the applicant, ICT department, or facility management, depending on the type of investment. The procurement phase ensures that the best value for money is achieved and that the investment meets all the specified requirements.

10. Evaluation cycle

This final part of the process forms a separate cycle that is distinct from the initial process model. It can be chosen to conduct this cycle after every purchase, but also periodically for certain investments. After the acquisition of the device, the implementation phase begins, where the Medical Technology department, in collaboration with the involved department, ICT and infection prevention, ensures the device is put into use and that staff are trained to properly operate the device.

After implementation, the responsible department is tasked with periodically monitoring the established Key Performance Indicators (KPIs). These KPIs are set up to systematically track the effects and performance of the new device. Monitoring these KPIs provides insight into how well the device meets the initially set expectations and goals. The capacity for the deployment and implementation of the device is also monitored here.

The collected data is evaluated after a certain period by the investment committee. During this evaluation, important questions are answered, such as: “Has the device brought about the expected changes?” and “Were there any aspects overlooked that affected the success or failure of the investment?”

Based on the evaluation, a final judgment is made. This judgment can be recorded informally or formally, for example, in the form of a final report. The findings and conclusions from this evaluation are then used to further improve the process. Specific steps in the process model can be refined, or the evaluation criteria can be adjusted to assess future requests even more effectively. By monitoring the impact on capacity, better estimates can be made regarding the capacity impact. It is also possible to reflect on the KPIs to determine whether certain replacement investments were beneficial or whether they no longer need to be replaced in the future, as they are not used often enough.

This reflective approach helps draw valuable lessons from any mistakes made, so they can be prevented in the future. It contributes to a continuous improvement process and strengthens the organization as a whole.

4.11.3 Definitive model

Below, in figure 14, is the model shown, which schematically represents the process described earlier. The various stakeholders are highlighted using color coding, and the description of the color legend is provided for clarification. The process flows from left to right. When necessary, a step can always be revisited in the process if, for example, additional information is required.

A two-route system has been established, in which a distinction is made early on, as described in Chapter 4.9.2, between replacement and expansion investments. If it becomes clear that a replacement investment can no longer be directly replaced on a 1:1 basis, it may be decided to follow the expansion investment pathway instead.

This model visually supports the stepwise approach to decision-making, ensuring that all necessary evaluations are conducted at each stage. By utilizing this schematic, stakeholders can easily identify their role in the process, and the color-coding provides a clear understanding of each department's involvement. This system allows for transparency and ensures that every step is properly accounted for in the decision-making process. If adjustments or additional steps are needed, they can be incorporated seamlessly into the workflow, allowing the hospital to respond flexibly to changing circumstances.

Legend of stakeholders

- Applicant
- Investment committee
- Procurement, Medical Technology/housing/ICT, finance
- Board of Directors
- Strategic Committee
- Procurement
- End-user delegation and medical Technology/housing/ICT

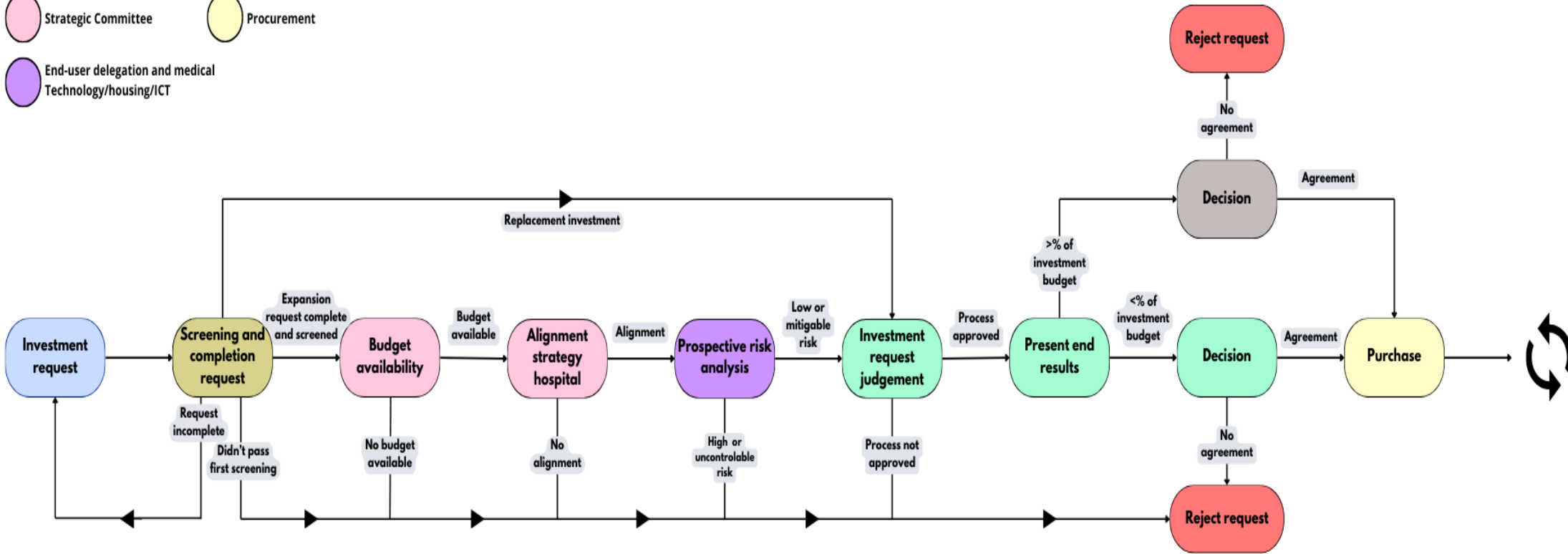


Figure 14. Definitive decision flowchart

The evaluation cycle has remained virtually the same. However, the option to include ICT, infection prevention, or housing in the implementation has been added to ensure the required integration. Additionally, monitoring the impact on capacity has been incorporated into the evaluation process. This allows for better future assessments of capacity needs.

The colors have been divided into two categories. The lighter blue represents all stakeholders involved in the implementation, who are also responsible for monitoring or must be available to provide advice on monitoring. The dark blue represents the investment committee.

Evaluation Cyclus

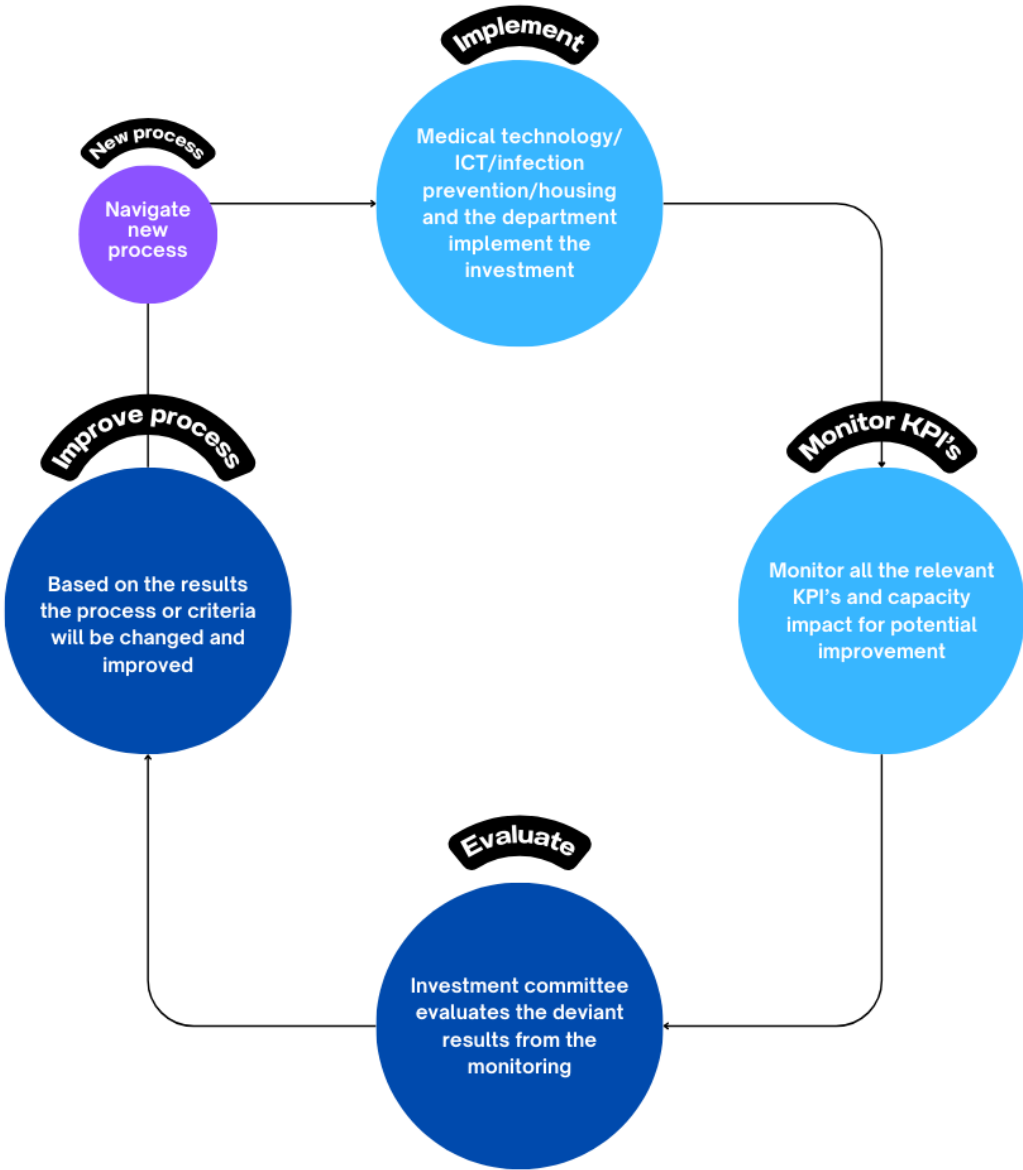


Figure 15. Definitive evaluation cyclus

5. Discussion

After conducting the research, it is essential to reflect on both the methodology and the achieved results. Initially, the interview findings deviated from the theoretical framework that had been developed. Due to the limited availability and accessibility of literature on investment decision-making, the original model may have been somewhat simplistic. Nevertheless, it included all the essential elements necessary to form a solid foundation for the interviews. In hindsight, additional literature was available that could have contributed to a more robust theoretical framework, specifically tailored to Dutch hospitals. The NIKP guideline could have played a valuable role in this regard. [9] Although research from 2020 suggests that this guideline is outdated and primarily focuses on risk management, it might still have provided a strong basis for this study. [10] A broader research design, explicitly incorporating this guideline and possibly involving interviews with its authors, could have further strengthened the research. Despite this, the theoretical framework proved to be a solid starting point, and the necessary results were ultimately obtained. Had more accurate sources been identified earlier in the research process, it is likely that the study could have proceeded more efficiently, and key insights might have been obtained sooner.

The methodology used in this research ultimately proved to be successful. In terms of validity, it can be concluded that the study measured what it intended to measure. The interviews were carefully structured and provided sufficient room for in-depth questions. This led to detailed and valuable insights, with respondents indicating that all relevant aspects of the investment process had been covered. The reliability of the collected data was further reinforced by the fact that all respondents were closely involved in investment decision-making within their respective hospitals.

In the methodology it was described to perform an observation within one or multiple hospitals. This seemed a practical challenge during the interviews. Several respondents were asked whether it would be possible to observe an investment request in practice. However, this proved to be difficult, as investment applications typically span multiple stages over extended periods. As an external researcher, it was challenging to follow the entire process comprehensively. This limitation may have influenced the depth of the analysis, particularly concerning informal dynamics within the decision-making process. Future research could attempt to overcome this limitation by conducting longitudinal studies, tracking investment decisions over a longer period or involving internal hospital researchers who can access decision-making processes in real time.

Nevertheless, the inclusion of follow-up discussions was of great value. During these follow-ups, recurring comments and improvement suggestions emerged, leading to further refinement of the final model. As a result, the process could be better aligned with real-world practice, increasing its applicability and effectiveness.

The study revealed that the level of maturity and structure of investment decision-making processes varies significantly among hospitals. Some hospitals have well-organized, structured formats and documented processes, making investment decisions in a clear and systematic manner. Others, however, partly due to this research, became aware that their process is relatively informal and unstructured, potentially requiring improvement. This finding highlights the importance of a standardized investment framework that hospitals can adopt to ensure more transparent, efficient, and well-founded decision-making.

The research question, "How can Dutch hospitals determine investment decisions for new medical technologies?" was successfully answered. Although the research question focused solely on investments in medical technology, the importance of an integrated process applicable to multiple types of investments became clear. Therefore, the process has been designed in a way that it can also be used for investments in areas such as ICT and housing, without compromising the quality of the process. A structured process and corresponding model were developed, which are further elaborated in chapter 4.11. The initial theoretical model contained elements from real-world practices but, in its original form, was not practically feasible. Insights gathered from interviews, follow-ups, and further literature analysis allowed for the creation of a more functional process. This process provides solutions to the challenges faced by nine different non-academic hospitals across the Netherlands.

The final model is grounded in current practices and has been refined through the identification of key bottlenecks and opportunities for improvement. These insights were drawn from literature reviews, interviews, and follow-up studies. As a result, the model aligns closely with real-world hospital environments, reducing the need for drastic and costly changes. This practical applicability increases the likelihood of successful implementation and acceptance within hospitals.

6. Limitations

6.1 Methodological limitations

One limitation of this study is that the full design thinking process was not completed. The final step of this process is the testing phase. Conducting this testing phase would have completed the design thinking cycle and could have provided even more reliable results, as they would have been tested in the field. Due to the time constraints of a master's thesis, it was unfortunately not possible to include this step in the research. Testing the process requires a significant amount of time, and to obtain reliable results, it would need to be tested across multiple hospitals. Given the time limitations and the number of available respondents, the researcher deemed this infeasible for this study.

An other possible methodological limitation of this study is the complexity and scale of the investment decision-making process in hospitals. Due to the extensive nature of these processes, it is possible that certain aspects were overlooked or not mentioned during the interviews or follow-ups. Decision-making in hospitals involves multiple stakeholders, informal discussions, and unwritten rules that may not have been fully captured in this research. Additionally, respondents may have unconsciously omitted details they considered self-evident or irrelevant, leading to potential gaps in the collected data. While efforts were made to mitigate this limitation by conducting follow-up interviews and analyzing multiple perspectives, the possibility remains that certain nuances of the investment process were not fully explored.

6.2 Data and theoretical limitations

Version 2 of the model was verified by the same respondents who participated in the theoretical model development and interview phase. This could introduce a form of bias, as certain responses may be automatically validated based on prior input from these respondents. However, the verification process also involved cross-validation by other respondents who had not initially considered specific solutions, factors, or process steps but later recognized them as valuable additions. Ultimately, the verification step of Version 2 proved to be a meaningful addition, significantly contributing to the development of the final model and process.

Even though efforts were made to develop a process that is generalizable to all non-academic hospitals, the characteristics of individual hospitals remain different. The recommended criteria and strategic priorities may therefore vary per hospital. This depends, among other factors, on the norms and values that a hospital upholds. Additionally, the applicability of certain steps and stakeholders may differ. Some hospitals have the capacity to follow all steps in detail, whereas others struggle with staff shortages and must prioritize ensuring continuous patient care over extensive investment evaluations. Therefore, it remains crucial for hospitals to assess to what extent the model is applicable and useful for their specific organization.

7. Recommendations

7.1 Theoretical recommendations for future research

As a follow-up study, the final phase of the Design Thinking cycle, the test phase, could be implemented and researched in hospitals. This phase would involve applying the proposed investment model within hospital organizations and systematically analyzing the resulting changes. By doing so, the researcher can assess whether the recommended improvements outlined in this research truly lead to a more efficient decision-making process and, ideally, to better financial outcomes.

During the test phase, it is crucial to closely monitor the added factors that were integrated into the model. This will help determine their impact on investment decisions and overall hospital operations. However, it is equally important to maintain flexibility and openness to further refinements. Given the highly dynamic nature of the healthcare sector, where technological advancements, regulatory requirements, and patient needs are constantly evolving, no investment process can ever be fully optimized in a static manner.

Continuous evaluation and improvement should therefore be embedded within the hospital's investment framework. Future research could explore long-term monitoring of investment outcomes, allowing organizations to track whether financial and operational benefits are sustained over time. Additionally, comparative studies across multiple hospitals could provide deeper insights into best practices and adaptable strategies for different institutional contexts.

When reflecting on the existing literature, it is clear that there are similarities with previous studies. For example, the criteria identified by Gurtner were deemed relevant by the respondents, and later, similarities were found with studies from Zorginstituut Nederland. [11] [9] Furthermore, as noted in the theoretical framework, there is a limited number of studies addressing investment decisions specifically in Dutch non-academic hospitals. For further research, it is recommended to closely examine the "Leidraad NIKP" and subsequent research conducted in this area done by RadboudUMC. [10][9] Special attention should be given to the key points related to the implementation of the findings from the study of RadboudUMC, particularly regarding the integration of these insights into the investment decision-making process. Together with this research, will form a big understanding of the investment decision-making process and important points within implementing.

Ultimately, implementing and testing this model in practice will not only validate its effectiveness but will also serve as a foundation for ongoing enhancements, ensuring that hospitals remain adaptable and well-equipped to make informed, strategic investment decisions in a rapidly changing environment.

7.2 Practical recommendations

It is recommended that Dutch non-academic hospitals compare their investment decision-making processes with the findings of this study. The findings from this study should serve as a valuable benchmark, offering hospitals an opportunity to reflect on their own practices. Each hospital must take into account its unique context, available resources, and organizational culture when evaluating whether adopting these findings will be beneficial for their practices. Each hospital should critically evaluate its investment process, considering the rationale behind the steps it follows. If certain steps are used without well-founded arguments, hospitals should reflect on whether these steps or factors should be adjusted, refined, or even eliminated to enhance efficiency and effectiveness.

Furthermore, it is advisable to conduct follow-up research before implementing any significant changes. This follow-up study should focus on the final phase of the Design Thinking methodology, specifically the testing phase, as outlined in section 5.4. Through this phase, hospitals can systematically assess the feasibility and impact of proposed modifications, ensuring that any changes lead to tangible improvements in the decision-making process. It also offers an opportunity for hospitals to engage their staff and key decision-makers in a collaborative dialogue about the proposed changes. This engagement can help foster a sense of ownership and commitment to the changes, increasing the likelihood of successful implementation and sustained improvement in the investment decision-making process.

8 Conclusion

Investment processes within Dutch non-academic hospitals are inherently complex, involving numerous steps, criteria, legal frameworks, technologies, and stakeholders. Developing an optimized model that remains universally applicable to every hospital is challenging due to the unique characteristics and operational differences between institutions. However, a structured, overarching process has been established that effectively captures all critical aspects of investment decision-making while being adapted to challenge that healthcare faces today.

The proposed process, as outlined in chapter X and X, provides a comprehensive framework encompassing the essential steps and key influencing factors. While hospitals may need to tailor certain elements to align with their specific organizational structure, capacity, and strategic priorities, the model serves as a robust foundation for an efficient and structured investment process. It offers a standardized approach that enhances transparency, consistency, and informed decision-making.

Continuous evaluation is very important, as also evidenced by this research. Hospitals must consistently engage in this practice and incorporate the investment process into their evaluations. This will allow the process to evolve in line with the future needs of hospitals.

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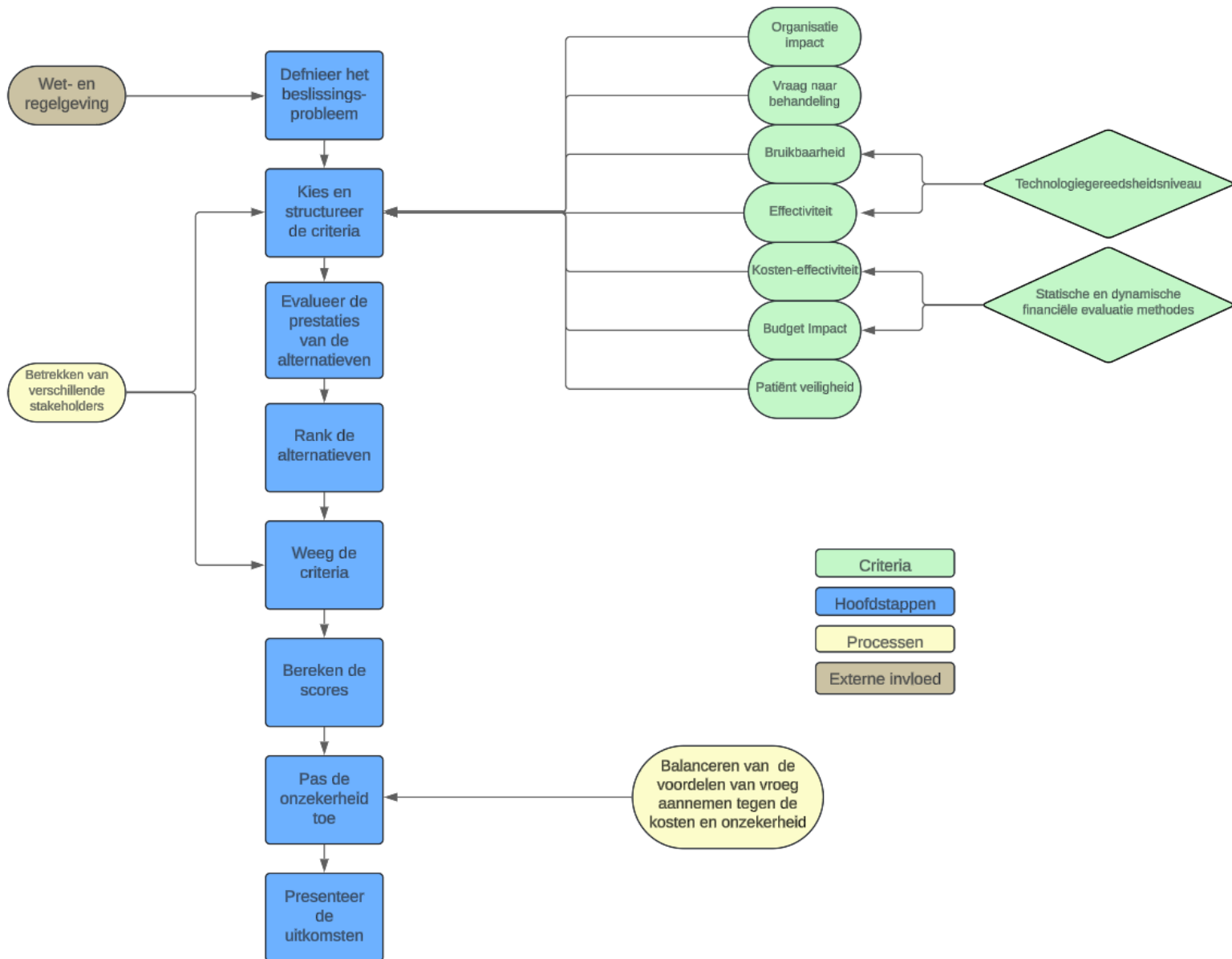
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10 Appendix

10.1 Definitions of the criteria in the "Evidence and Value: Impact on Decision-Making" framework [11]

<i>Criteria</i>	<i>Definition</i>
<i>Organizational impact</i>	The effect that the adoption of new equipment has on the hospital's operations, including workflow, staff productivity, and overall organizational efficiency.
<i>Patient safety</i>	The extent to which the new equipment improves or ensures the safety of patients, minimizing risks and potential harm during medical procedures.
<i>Budget impact</i>	The financial implications of acquiring, implementing, and maintaining the new equipment on the hospital's budget.
<i>Effectiveness</i>	The ability of the new equipment to achieve the desired medical outcomes and improve patient health conditions.
<i>Demand for treatment</i>	The extent to which the new equipment meets existing or anticipated patient needs and demand for specific medical treatments.
<i>Usability</i>	The ease of use, user-friendliness, and learning curve associated with the new equipment for healthcare professionals.
<i>Cost-effectiveness</i>	The balance between the costs incurred and the benefits gained from using the new equipment, considering both economic and health outcomes.

10.2 Dutch version of the theoretical model



10.3 Interview scheme (Dutch)

Interview Schema

Introductie

1. Inleiding:

- Bedanken van de deelnemer voor hun tijd en bereidheid om mee te doen aan het onderzoek.
- Uitleggen van het onderzoeksdoel en het interview
- Korte uitleg over het opnameproces en toestemming vragen voor het opnemen en opslaan van het interview.
- Kunt u kort wat vertellen over uw functie binnen het ziekenhuis?

Deel 1: Huidig besluitvormingsproces

1. Proces van investeringsbeslissingen

- Kunt u het proces beschrijven dat uw ziekenhuis volgt bij het nemen van een investeringsbeslissing voor nieuwe technologie of medische apparatuur?
- Kunt u een voorbeeld geven van een recente investeringsbeslissing die genomen is?
- Is er een formele structuur, framework of besluitvormingskader dat hierbij wordt gebruikt?
- Hoe worden deze beslissingen gedocumenteerd en gecommuniceerd binnen de organisatie?
- Welke invloed hebben wet- en regelgeving op uw ziekenhuis investeringsgedrag?
- Heeft uw ziekenhuis afgelopen tijd investeringen moeten doen vanwege wet- en regelgeving?

2. Belangrijke criteria in de besluitvorming

- Wat zijn de belangrijkste factoren die invloed hebben op investeringsbeslissingen? (Bijvoorbeeld: financiële aspecten, technologische rijpheid, uitkomsten voor patiënten)
- Hoe worden investeringen beoordeeld en geprioriteerd?
- Zijn er specifieke criteria die u gebruikt om de haalbaarheid van een technologie te evalueren?

3. Stakeholders in het besluitvormingsproces

- Welke stakeholders zijn betrokken bij het besluitvormingsproces en hoe wordt dit bepaald?
- Verschillen deze stakeholders per type investering of omvang van de investering (bijvoorbeeld medische staf, financiële experts, IT-specialisten)?
- In hoeverre worden externe deskundigen of patiëntenvertegenwoordigers geraadpleegd bij deze beslissingen?
- Wie heeft het laatste woord bij investeringsbeslissingen?

4. Financiële evaluatiemethoden

- Welke financiële criteria gebruikt uw ziekenhuis om potentiële investeringen te evalueren (bijvoorbeeld: Netto contante waarde (NPV), Interne Opbrengstvoet Terugverdientijd (IRR)?
- Gebruikt u specifieke financiële modellen om de langetermijnrentabiliteit of haalbaarheid te beoordelen?
- Hoe worden toekomstige kosten en baten ingeschat voorafgaand aan een investeringsbeslissing?

5. Technologiebeoordeling

Technology Readiness Level (TRL)

- Uitleggen en laten zien van TRL
- Gebruikt uw ziekenhuis een TRL-schaal om de rijpheid van nieuwe technologieën te evalueren voordat een investering wordt gedaan?
 - Zo ja, hoe ervaart u het werken met deze schaal?
 - Zo nee, hoe beoordeelt u of een technologie klaar is voor klinische toepassing of verdere ontwikkeling nodig heeft?

6. Risicobeheer

- Welke soorten risico's worden doorgaans overwogen voordat een investeringsbeslissing wordt genomen? (Bijvoorbeeld: financieel, operationeel, technologisch)
- Gebruikt uw ziekenhuis specifieke risicomanagementtools of -kaders om deze risico's te beoordelen en te beheersen?

Deel 2: Evaluatie en aanbevelingen voor het model

7. Evaluatie van het huidige model:

- Uitleggen en laten zien van het model dat is ontstaan vanuit de literatuur.
- Op basis van uw ervaring, hoe relevant en praktisch vindt u het voorgestelde theoretische model zoals beschreven in dit onderzoek?
- Zijn er componenten die bijzonder nuttig of juist moeilijk te implementeren zijn in de praktijk?

8. Aanbevelingen van het huidige model:

- Welke veranderingen of toevoegingen zou u suggereren om het model meer toepasbaar te maken op ziekenhuisomgevingen?
- Hoe flexibel moet het model zijn om aan de behoeften van uw ziekenhuis te voldoen?
- Wat zou een investeringsmodel voor ziekenhuizen succesvol maken, volgens u?

9. Slotvragen:

- Op basis van wat we hebben besproken, vindt u dat er veranderingen moeten worden doorgevoerd in het huidige besluitvormingsproces van uw ziekenhuis en wat?
- Is er op dit moment een investeringsbeslissingen proces in werking? Zoja, is het mogelijk om hierbij eens mee te kijken?
- Heeft u verder nog opmerkingen of suggesties met betrekking tot het besluitvormingsproces of dit onderzoek?
- Bedanken voor het deelnemen en het verwerkingsproces van de informatie toelichten

10.4 Interview scheme (English)

Interview Scheme

Introduction

1. Introduction:

- Thank the participant for their time and willingness to participate in the research.
- Explain the purpose of the research and the interview.
- Provide a brief explanation of the recording process and ask for permission to record and save the interview.
- Can you briefly tell us about your role within the hospital?

Part 1: Current decision-making process

1. Investment decision process

- Can you describe the process your hospital follows when making an investment decision for new technology or medical equipment?
- Can you provide an example of a recent investment decision that has been made?
- Is there a formal structure, framework, or decision-making framework that is used?
- How are these decisions documented and communicated within the organization?
- What influence do laws and regulations have on your hospital's investment behavior?
- Has your hospital had to make investments recently due to laws and regulations?

2. Key criteria in decision making.

- What are the key factors that influence investment decisions? (For example: financial aspects, technological readiness, patient outcomes)
- How are investments assessed and prioritized?
- Are there specific criteria you use to evaluate the feasibility of a technology?

3. Stakeholders in the decision-making process

- Which stakeholders are involved in the decision-making process and how is this determined?
- Do these stakeholders differ based on the type or size of the investment (for example: medical staff, financial experts, IT specialists)?
- To what extent are external experts or patient representatives consulted in these decisions?
- Who has the final say in investment decisions?

4. **Financial evaluation methods**

- What financial criteria does your hospital use to evaluate potential investments (for example: Net Present Value (NPV), Internal Rate of Return (IRR), Payback Period)?
- Do you use specific financial models to assess long-term profitability or feasibility?
- How are future costs and benefits estimated prior to an investment decision?

5. **Technology assessment (Technology Readiness Level - TRL)**

- Explanation of TRL
- Does your hospital use a TRL scale to evaluate the readiness of new technologies before making an investment?
 - If yes, how do you find working with this scale?
 - If no, how do you assess whether a technology is ready for clinical application or needs further development?

6. **Risk management**

- What types of risks are typically considered before making an investment decision? (For example: financial, operational, technological)
- Does your hospital use specific risk management tools or frameworks to assess and manage these risks?

Part 2: Evaluation and recommendations for the model

7. **Evaluation of the current model:**

- Explain and present the model that has emerged from the literature.
- Based on your experience, how relevant and practical do you find the proposed theoretical model as described in this research?
- Are there components that are particularly useful or challenging to implement in practice?

8. **Recommendations for the current model:**

- What changes or additions would you suggest to make the model more applicable to hospital environments?
- How flexible should the model be to meet the needs of your hospital?

- What do you believe would make an investment model for hospitals successful?

Conclusion

9. Closing questions:

- Based on what we have discussed, do you believe changes should be made to the current decision-making process of your hospital, and if so, what?
- Is there currently an investment decision process underway? If so, is it possible to observe or participate in it?
- Do you have any further comments or suggestions regarding the decision-making process or this research?
- Thanking the participant for their participation and explanation of the process for handling the information collected.

10.5 Steps of the decision-making process model version 2

1. Investment Request

The first step in the process is the submission of the investment request. In this phase, the applicant must prepare a comprehensive and well-supported 'business case'. This business case contains all relevant information regarding the intended investment and the equipment for which funding is requested.

The business case is structured around key criteria. The following aspects play a central role:

<i>Criteria</i>	<i>Explanation</i>
<i>Quality of Patient Care</i>	The contribution of the equipment to improving patient care, such as better diagnostic capabilities or improved treatment outcomes. Efficiency and effectiveness are also considered here.
<i>Organizational Impact</i>	The effect that the introduction of new equipment has on the operational side of the hospital, including workflows, logistical and facility changes, and overall efficiency of the organization.
<i>Safety</i>	The extent to which the equipment is proven to be safe. This concerns patient safety, staff safety, privacy protection, information security, and technical safety.
<i>Impact on Staff</i>	Changes in work hours, workload, job satisfaction, necessary training, required skills, and work intensity. It also includes the capacity of IT and medical technology.

<i>Legislation and Regulations</i>	Compliance with current laws and regulations.
<i>Financial</i>	Financial impact, including the initial investment, ongoing and one-off costs, revenues (direct and indirect), and the necessary sources of funding. A full TCO is important here.

Additionally, the business case addresses potential risks associated with the investment. If these risks are considered severe, it is detailed how these risks will be mitigated.

Any alternative devices are also mentioned, explaining why the requested device is the most suitable choice for the hospital, with an emphasis on the advantages over other options.

It is also clearly stated whether the investment concerns a replacement investment or the purchase of entirely new equipment. Replacement investments have a streamlined procedure ('fast track') built in, as the need for such equipment is usually already proven.

2. Strategic Committee

When an investment request for new equipment is submitted, it is forwarded to the strategic committee. This committee plays a crucial role in assessing the feasibility and desirability of the proposed investment. It is an integrated committee, meaning it includes members from various disciplines.

In the first phase of the assessment, it is determined whether there is budgetary space available to realize the investment. If no financial resources are available, the process is halted, as continuing the request without the necessary funds would be futile.

If, however, budget is available, the strategic committee evaluates how the investment aligns with the hospital's strategic priorities, as well as the need and urgency of the proposed acquisition. Many hospitals have strategic priorities that guide their policies and investments. If an investment significantly deviates from these priorities, the strategic committee makes a well-informed decision whether to proceed with the request.

A brief but focused review of the investment's utility and necessity is also carried out, identifying the potential benefits the investment could bring to the hospital and how urgent the purchase is for the organization.

If the strategic committee concludes that the investment is both necessary and aligns with the strategic priorities, the request is forwarded to the next phase in the decision-making process.

3. Medical Technology

After the submission of the business case, the Medical Technology department carries out a comprehensive risk assessment concerning the requested device. This assessment includes both an analysis of the risks mentioned in the business case and an independent evaluation based on the department's expertise. The goal is to gain a full understanding of the potential risks associated with the use of the device.

For this risk assessment, a prospective risk inventory is performed, following guidelines set out in, among others, the Medical Covenant and the NIKP (National Inventory of Quality Standards for Practice Operations). Adhering to these guidelines ensures that all relevant risks are identified and assessed, leading to a comprehensive picture.

Based on the risk assessment, a risk classification is created, as shown in figure 8. This classification ranks the identified risks into categories, ranging from low to high. If a risk is classified as high, serious, or medium, the application must describe how these risks will be mitigated.

If adequate measures to control the risks are not possible, the recommendation is to reject the request, ensuring that safety and quality within the organization are always guaranteed.

4. Investment Committee

The investment committee is responsible for an in-depth review of the investment request. This committee is multidisciplinary and integrative, ensuring that all relevant areas of expertise are represented. This setup guarantees a comprehensive and balanced view of the request.

Upon receiving the request, the first assessment is made regarding the presence of alternatives. The investment committee determines whether the mentioned alternatives should be considered and, if applicable, included in the further decision-making process.

In the next phase, the equipment is assessed based on the criteria outlined in figure 3. If the device, or one of the alternatives, does not meet one or more of these criteria, the process may be halted.

However, if the device meets all criteria, the request continues in the process. The committee then selects the most suitable option, and all findings and conclusions are compiled into a final report.

The final decision is then made. For replacement investments under €50,000 and expansion investments under €5,000 (amounts may vary per hospital), the investment committee can make a decision. For higher amounts, the request moves forward.

If a positive decision is made, the acquisition of the device is transferred to the Purchasing department.

5. Board of Directors

When the amount exceeds the thresholds of €50,000 for replacements or €5,000 for expansions, the decision is forwarded to the board of directors. For even higher amounts, it may be decided or required to also involve the supervisory board in the decision-making process. The board of directors communicates the decision back within the organization.

6. Purchasing

If a positive decision is made, the acquisition of the device is transferred to the Purchasing department, which is responsible for handling the remainder of the process. Here, the best suppliers and options are considered, aiming to secure the best deal and price.

7. Evaluation Cycle

The final part of the process forms a separate cycle that stands apart from the initial process model. It can be chosen to conduct this cycle after each purchase or periodically for certain investments. After the equipment is acquired, the implementation phase begins, with the Medical Technology department working alongside the relevant department to ensure the equipment is put into use.

After implementation, the responsible department is tasked with periodically monitoring the established Key Performance Indicators (KPIs). These KPIs are set up to systematically track the impact and performance of the new device. Monitoring these KPIs provides insight into the extent to which the device meets the previously set expectations and goals.

The collected data is evaluated by the investment committee after a certain period in comparison with the investment request. During this evaluation, key questions are addressed, such as: “Has the device brought about the expected changes?” and “Were there any overlooked aspects that influenced the success or failure of the investment?”

Based on the evaluation, a final judgment is formed. This judgment can be recorded informally or formally, for example, in the form of a final report. The findings and conclusions from this evaluation are then used to improve the process further. Specific steps in the process model may be refined, or assessment criteria may be adjusted to better evaluate future requests.

Through this reflective approach, valuable lessons are learned from any mistakes made, ensuring they are avoided in the future. This contributes to a continuous improvement process and strengthens the organization as a whole.

10.6 Follow-up questions (Dutch)

Hieronder staan de vragen met betrekking op het verbeterde procesmodel. Probeer op elke vraag een onderbouwing te geven in een paar zinnen waarom u dit vindt. Hierdoor wordt het voor de onderzoeker inzichtelijker waarom dingen veranderd dienen te worden.

1. Wat zijn de sterke punten van dit proces?
2. Wat zijn de zwakke punten van dit proces?
3. Wat zouden knelpunten kunnen zijn waardoor dit model lastig toe te passen is?
4. Is het model eenvoudig uitgelegd en te begrijpen?

5. In hoeverre vindt u het van belang dat er onderscheid wordt gemaakt tussen nieuwe investeringen en vervangingsinvesteringen in het proces?
6. In welke mate is de integraliteit van het investeringsproces belangrijk en haalbaar? (betrekken van huisvesting en gebouwbeheer, medici, ICT etc.)
7. Wat is uw mening over de voorgestelde evaluatiecyclus aan het einde van het proces?
8. Wat is uw mening over het prioriteringsmechanisme dat beschreven wordt in paragraaf 4 investment committee? Denkt u dat dit haalbaar is of heeft u een ander voorstel voor een mechanisme? Onderbouw waarom.
9. In welke mate ziet u uw organisatie dit proces volgen? Onderbouw waarom.
10. Op welke vlakken liggen er kansen voor het verbeteren van de administratieve last binnen dit investeringsproces?
11. Verdere toevoegingen of algemene opmerkingen:

10.7 Follow-up questions (English)

Here are the questions regarding the improved process model. Try to provide a justification for each question in a few sentences to explain why you think this. This will give the researcher more insight into why certain changes should be made.

1. What are the strengths of this process?
2. What are the weaknesses of this process?
3. What potential bottlenecks could make this model difficult to apply?
4. Is the model explained simply and easy to understand?
5. To what extent do you think it is important to distinguish between new investments and replacement investments in the process?
6. How important and feasible do you think the integration of the investment process is? (Involving facilities and building management, medical staff, IT, etc.)
7. What is your opinion on the proposed evaluation cycle at the end of the process?
8. What is your opinion on the prioritization mechanism described in section 4 (investment committee)? Do you think this is feasible, or do you have an alternative suggestion for a mechanism? Please justify why.
9. To what extent do you see your organization following this process? Justify why.
10. In which areas do you see opportunities for reducing administrative burdens within this investment process?
11. Additional comments or general feedback:

10.8 Application form investment request

Name:
Department:
Phone number:
Email:
Date:

Investment regarding: Medical technology / Housing/ ICT / Other:
Type of investment: Replacement / Expansion

1. Functionality need

Describe the reason for the request with the following questions in mind:

- Why is this investment necessary?
- What problem will be solved by implementing this request?
- Has it been investigated whether an existing solution in the hospital can address the problem?

2. Chosen investment and alternatives

Describe the chosen investment and the alternatives to this investment, including existing solutions within the hospital that could potentially be used. Provide a justification for why this is the best solution to meet the hospital's functional needs.

3. Strategy

Describe the extent to which this investment aligns with the hospital's key focus areas and strategic objectives. Provide a score from 0 (no contribution) to 10 (full contribution) and justify this rating. Keep the following key focus areas in mind:

Strategic objective	Grade	Explanation
Alignment with hospital specialization		
Level of innovation		
Sustainability responsibility.		
Collegiality		
Financial state of the hospital		

4. Criteria

Describe the extent to which this investment contributes to an improvement per criterion. Think about the improvements that occur per criterion. Assign a score to each criterion based on how much improvement occurs compared to the current situation. A score of 0 indicates no improvement, and a score of 10 indicates maximum improvement.

Criteria	Explanation	Grade	Explanation
Quality of Patient Care	The contribution of the equipment to improving patient care, such as better diagnostic capabilities, reduced length of stay or improved treatment outcomes. Effectiveness is also considered here.		
Organizational Impact	The effect that the introduction of new equipment has on the operational side of the hospital, including efficiency, workflows, logistical and facility changes, and overall efficiency of the organization.		

Safety	The extent to which the equipment is proven to be safe. This concerns patient safety, staff safety, privacy protection, information security, and technical safety.		
Impact on Staff	Changes in work hours, workload, job satisfaction, necessary training, required skills, and work intensity. It also includes the capacity of IT and medical technology for implementation, but also for maintenance.		
Legislation and Regulations	Compliance with current laws and regulations.		
Financial	Financial impact, including the initial investment, ongoing and one-off costs, revenues (direct and indirect), and the necessary sources of funding. A full TCO is important here.		

5. Total cost analysis

Indicate the financial impact of this investment by estimating the total cost of ownership. This includes a complete overview of all costs and potential benefits associated with the investment. Conduct the financial assessment in collaboration with a financial officer of the hospital.

Cost Component	Amount	Explanation
Initial Investment		
One-time Operating Costs		
Annual Operating Costs		
Savings from Current Situation		
Expected Additional Revenue		
Financing Costs		

6. Risk

Describe the potential risks associated with the implementation and use of this investment. Consider risks in the broadest sense, including financial risks, risks for staff or patients, technical risks, etc. Conduct an initial risk assessment together with Medical Technology. Provide a brief estimation of the impact rating for each component.

Risk	Score (0-10)	Explanation
Financial Risk		
Patient Safety Risk		
Employee Safety Risk		
Technical Risk		
Operational Disruption		
Compliance & Regulatory Risk		

Based on the table above, the estimated risk classification is: Low / Medium / High

7. Stakeholders

Describe which stakeholders should be involved in the evaluation, in addition to those included in the regular process for investment decisions. Also think about the impact on the capacity on ICT and MT and describe how this can be minimized.

10.9 Transcripts and coding

The transcripts and coding of the interviews are available from the researcher. They have not been included in the appendix, as they would amount to approximately 250 pages, which would significantly imbalance the ratio between the main thesis and the appendix. If there is interest in the transcripts and coding files, they can be requested from the researcher.