Decision-Making Framework for Hospitals to Acquire Innovative High-Tech Medical Devices

by

S. Dekker

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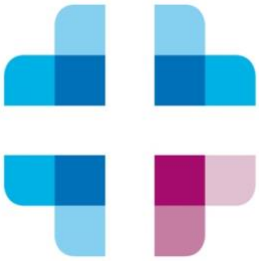

Rijnstate

Student number:	5872618
Date:	28-04-2025
Supervisors:	Annetje Guédon (NWZ)
	Bernke Papenburg (Rijnstate)
	John van den Dobbelsteen (TU Delft)

Abstract

Introduction Healthcare systems are increasingly integrating advanced technologies into daily practice, leading to a growing emphasis on the adoption of innovative high-tech medical devices. Unlike conventional device replacements, these innovations introduce new technologies that can significantly impact clinical workflows, patient outcomes, and organizational structures. However, the complexity and uncertainty surrounding their adoption present major decision-making challenges for hospitals. Despite the critical nature of these decisions, most hospitals lack a structured approach to guide them. This thesis addresses this gap by developing a decision-making framework to support hospitals in the acquisition of innovative high-tech medical devices.

Methodology This study employed a three-phase approach: analyzing the current decision-making process for acquiring innovative high-tech medical devices, developing a decision-making framework, and evaluating the framework. Semi-structured interviews with stakeholders from two hospitals were conducted to map current practices and identify challenges. Insights from the interviews and a successful case study informed the development of the framework, designed using principles from the Cynefin framework to address the complexity of innovation adoption. The framework was refined based on expert feedback and evaluated through a semi-structured questionnaire focusing on its structure, usability, and expected effectiveness.

Results The results of this study revealed several challenges in the current decision-making processes for acquiring innovative high-tech medical devices including limited exploration of broader organizational needs, premature formation of project groups and unclear early-stage leadership. The interviews and the case study highlighted the importance of iterative decision-making, early project leadership by a technically skilled project leader, and flexibility in adapting project structures as new insights emerge. Based on these findings, a decision-making framework was developed that addresses these challenges by promoting adaptive, stakeholder-driven, and strategically aligned acquisition processes. Both respondents of the evaluation questionnaire agreed that the framework is clearly structured, adds value to the hospital's decision-making process, and supports a well-informed investment decision. Nevertheless, some limitations were identified.

Discussion The developed decision-making framework approaches the acquisition of innovative high-tech medical devices as a complex, iterative process aimed at uncovering broader organizational needs behind device requests. It emphasizes early stakeholder involvement, flexible project structures, and delayed formalization of business cases to better navigate uncertainty. While the framework offers hospitals a structured but adaptable tool to professionalize decision-making and foster innovation, its development was based on interviews at only two hospitals and has not yet been tested in real-world applications. Future research should focus on validating the framework through longitudinal case studies and further refining its usability with detailed guidance and practical examples.

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1. Introduction

Healthcare systems are increasingly integrating technology in daily practice (1-4). This trend is reflected in the rising costs associated with medical technology in hospitals (3, 5-8). As technology continues to evolve, medical devices are becoming more advanced and complex (4). High-tech medical devices are characterized by their advanced technology and are used in healthcare for diagnosing, monitoring, treating or preventing medical conditions (9). Examples include robotic surgical systems, AI-powered diagnostic tools, wearable health monitors, and advanced imaging techniques. To drive continuous improvements in healthcare, new medical devices are constantly being developed. Innovative high-tech medical devices are advanced healthcare technologies that introduce new methods, systems, or functionalities beyond conventional medical equipment (10). Their ongoing development and implementation aim to improve safety, efficiency and healthcare quality (1, 11). Consequently, many hospitals are placing greater emphasis on innovation, leading to an increased adoption of high-tech medical devices in routine medical practice to enhance clinical outcomes and streamline workflows (2).

Usually, hospitals invest in a new medical device when the existing devices becomes outdated or non-functional. In such cases, the replacement device is often similar to its predecessor, facilitating a straightforward procurement process. However, unlike these conventional replacements, innovative high-tech medical devices introduce entirely new technologies to hospital environments, which can significantly impact various aspects of hospital operations, including clinical workflows, patient outcomes, and overall care delivery (12, 13). Due to their complexity and innovative nature, both the devices themselves and the decision-making processes associated with their acquisition present considerable challenges. Since these technologies are newly developed, critical information about their long-term performance, integration, and impact may still be unknown. As a result, hospital decision-makers must assess the investment's viability, identify the most suitable device, and select the right supplier, all while dealing with incomplete information (14, 15).

The decision-making process for adopting innovative high-tech medical devices in hospitals is complex and multidisciplinary. It requires careful consideration of clinical effectiveness, operational efficiency, financial viability, and compliance with regulatory, legal, and safety standards. This complexity is further aggravated by the uncertainties associated with innovative technologies, particularly during the early stages of the decision-making process when the full implications and applications of a device may not yet be fully understood (16). Additionally, innovation is inherently disruptive (17), often necessitating changes in established organizational processes and workflows (18-20). As a result, hospitals frequently encounter resistance to change (13, 21, 22), which further complicates the decision-making process. This challenge is particularly pronounced for disruptive innovations, where organizational adaptation plays a crucial role in successful implementation (23). An example of this is robot-assisted surgery, which introduces a fundamentally different way of operating and thus demands extensive training for surgeons and operating room staff, as well as adjustments to surgical workflows and infrastructure. Furthermore, hospitals often face tight time constraints and limited high-quality evidence when making these high-stakes investment decisions (24-26). Although only a fraction of hospital purchases involves innovative high-tech devices requiring complex decision-making, these acquisitions are typically time-intensive, resource-demanding, and involve significant financial investments (5).

1.1 Problem Statement

Despite the complex yet critical nature of the decisions on innovative high-tech medical devices, most hospitals do not employ objective and systematic approaches to support their decision-making (27-29). The absence of a structured framework for such decisions leads to ad-hoc and subjective decision-making processes, often driven by internal politics or personal preferences rather than objective evaluation criteria (27, 29). Additionally, misalignment among key stakeholders, including clinicians, administrators, procurement teams, and financial officers, can further hinder efficiency and lead to suboptimal investment decisions. Although the adoption of high-tech medical devices is increasing, there remains a significant gap in theoretical research on the decision-making processes for their acquisition (15). Existing studies primarily focus on the clinical and surgical outcomes of new medical technologies (30) or on their implementation (1, 31, 32), rather than on the decision-making strategies themselves. The limited research that does examine decision-making primarily address medical devices in general and do not specifically consider the complexities of acquiring innovative and high-tech medical devices (19, 33, 34). Furthermore, even within studies on medical device decision-making, the focus is largely on decision criteria and the involvement of stakeholders, while the concrete steps and actions required to reach a well-informed decision are often overlooked (24, 25, 35, 36). In other cases, decision-making is treated as a minor step within the broader procurement process, rather than a critical and complex process in itself (34, 37).

To address this gap, there is a pressing need to enhance understanding of the decision-making processes for innovative high-tech medical devices in hospitals. These technologies have the potential to transform clinical practices but may also require substantial changes in hospital workflows, infrastructure, and staff training (12). Without a systematic approach, hospitals risk adopting devices that fail to deliver intended benefits, create inefficiencies, or disrupt existing processes. Furthermore, the substantial financial implications of these acquisitions necessitate a well-justified investment strategy. A structured decision-making framework that guides the entire process, from initial consideration to the final decision, can help hospitals make well-informed investment decisions, optimize device utilization, and prevent inefficiencies.

1.2 Research Question & Objectives

This thesis aims to analyze the current decision-making process for acquiring innovative high-tech medical devices in hospitals and develop and test a decision-making framework to guide future decision-making processes.

The main research question is:
"What is a suitable decision-making framework to support hospitals in the acquisition of innovative high-tech medical devices?"

The objectives of this thesis are:

- **To analyze the current decision-making process**, focusing on key decision criteria, stakeholders, and the steps taken withing the process.
- **To identify challenges and areas for improvement** in the decision-making process to enhance decision-making and optimize added value of the device in clinical practice.
- **To develop a decision-making framework** for acquiring innovative high-tech medical devices using a retrospective case study.
- **Evaluate the decision-making framework** using an evaluation questionnaire.

2. Methodology

This section outlines the methods used to achieve the research objectives. It consists of three main parts: a description of (1) the analysis of the current decision-making process and identification of challenges, (2) the development of a decision-making framework, and (3) the evaluation of the decision-making framework.

2.1 Analysis of the Current Decision-Making Process and Identification of Challenges

Developing a decision-making framework for innovative high-tech medical devices requires a comprehensive understanding of the current procurement process. This includes identifying mandatory steps, determining the roles of involved stakeholders, and recognizing key decision criteria. Additionally, challenges and shortcomings within the decision-making process need to be identified to develop a useful framework.

2.1.1 Data Collection

To analyze the current decision-making process and identify challenges and areas for improvement, semi-structured interviews were conducted with experts directly involved in the decision-making process. Given the limited literature on how hospitals make decisions regarding the acquisition of innovative high-tech medical devices, primary data collection was necessary. Semi-structured interviews were chosen because they allow for in-depth discussions while maintaining a clear focus on key decision-making aspects. Given that hospital decision-making is often based on experiential knowledge and institutional practices rather than formalized guidelines (38), interviews provide valuable insights into the complexities of decision-making and capturing perspectives that would otherwise be difficult to obtain through secondary sources.

The aim of the interviews was to gain insight into the decision-making process for acquiring innovative high-tech medical devices that significantly impact hospital workflows. The questions focused on the general decision-making process, stakeholder roles, and perspectives on the decision-making. Prior to the interviews, the interview questions were reviewed by a clinical physicist from Noordwest Ziekenhuisgroep and the program manager of Rijnstate Robotics. Based on their feedback, three additional questions related to the general process, along with the question, "*Are you missing any individuals or departments in the selection process?*" were included in the interview. Minor adjustments were made to the formulation of some questions, and additional follow-up questions were included. The full set of interview questions is provided in Appendix A. During the interviews, follow-up and in-depth questions focused on the process leading up to the drafting of official documents to gain a better understanding of how the final decision was made.

Selection of hospitals and stakeholders

Noordwest Ziekenhuisgroep (NWZ) in Alkmaar and Rijnstate hospital in Arnhem were selected for the interviews. Rijnstate was chosen because of its advanced adoption of high-tech medical devices and extensive experience with the decision-making process. By analyzing Rijnstate's approach, a general framework for broader application across hospitals could be developed. NWZ was chosen, because they recently experienced some dissatisfaction with some of their decision-making processes. Their experience with this can provide valuable insights in the challenges of the decision-making process.

In total, twelve interviews were conducted: five with stakeholders from Rijnstate and seven from NWZ. To ensure a diverse representation of perspectives, different stakeholders were selected based on their

involvement in the decision-making process. Stakeholders were identified in consultation with the program manager of Rijnstate Robotics, as well as with a clinical physicist and project leader from NWZ. Table 1.1 provides the professional functions of the interviewed stakeholders at both Rijnstate and NWZ. Table 1.2 provides a description of the interviewed professional functions together with an explanation of their role in the decision-making process. All interviews, except one, were conducted in person and lasted between 17 and 67 minutes.

Table 1.1: Professional functions of the interviewed stakeholders at both Rijnstate and NWZ.

Rijnstate	NWZ
Program manager Rijnstate Robotics	Policy Advisor to the Board of Directors
Clinical physicist	Clinical physicist
Information manager & advisor in the innovation and healthcare transformation department	Organizational manager operating room
Biomedical engineer	Project leader OR organization
Strategic purchaser	Purchasing department manager
	Senior medical purchaser
	Ear, nose and throat (ENT) specialist & discipline representative

Besides the semi-structured interviews, documentation related to medical device acquisition was the reviewed. This included the AdhopHTA handbook (39) the WHO procurement process resource guide (34), an example of a filled-out business case obtained from the clinical physicist of the NWZ and an empty requirement specification found online (40). The AdhopHTA handbook and the WHO procurement guide were consulted for an overview of existing frameworks; however, they were not directly incorporated into the development of the decision-making framework, as both focus on broader procurement and adoption processes, with decision-making representing only a small component. The business case and requirement specification were analyzed to gain a deeper understanding of the key considerations and requirements involved in the decision-making process.

2.1.2 Data Processing

After data collection, the interviews were transcribed and analyzed. As one interviewee did not give permission for recording, all but one of the interviews were recorded and transcribed verbatim. From the interview which was not recorded, as much as possible useful information was written down during the interview. From the transcripts, all important information has been ordered per interview, after which similarities, differences, key points, and challenges were identified. Key points were derived directly from the interviews, reflecting the primary insights and observations shared by the interviewees. The challenges were identified through analysis and reflection, including the interpretation for example conflicting responses provided during the interviews.

Table 1.2: Description of the interviewed professional functions and their role in the decision-making process.

Professional function	Description
Clinical physicist	Clinical physicists understand exactly how each medical device works and supports (the medical specialist) in the correct use of medical technology. Clinical physicists also advise on safety and quality requirements of the device. In the decision-making process the clinical physicist assesses whether the device matches the objective and contribute to the objectivity of the final choice.
Program manager Rijnstate Robotics	Develops a vision and strategy focused on innovative & robot technology to strengthen the robot surgery program and build the center of excellence. Responsible for the management of complex decision-making processes with the goal of maximizing the added value of the device.
Medical purchaser	Responsible for the researching, identifying, requisitioning, and ordering of medical/surgical supplies and diagnostic equipment for use in hospitals. Medical buyers are in contact with the suppliers with the goal of finding the most suitable device for the best price.
Project leader	Responsible for the management of the decision-making process, involving all relevant stakeholders and to draft the business case.
Organizational manager operating room	Budget manager, responsible for the budget of the department and the submission of the business case to the investment committee.
Policy advisor to the board of directors	Responsible for assessing whether the business case is complete and if the financial consequences of the investment are clear.
Information manager & advisor in the innovation and healthcare transformation department	Responsible for aligning information systems, ICT technology, and data as closely as possible with the needs of various healthcare processes. Manages some of the decision-making processes of innovative medical devices.
ENT specialist & discipline representative	Responsible for managing or delegation of the acquisition process of new medical devices for the ENT department.

2.2 Development of the Decision-Making Framework

This section describes the development process of the decision-making framework for the acquisition of high-tech innovative medical devices, including its sources of input, design choices and refinement.

Sources of Input

The decision-making framework was developed based on the insights gained from interviews and the challenges identified. In addition to the interview findings, a successful retrospective case study at Rijnstate Hospital was used to inform the framework design. This case concerned the acquisition of a 3D spine navigation system. The process stood out because it addressed not only the initial request for improved navigation during spine surgeries but also broader needs, such as reducing ergonomic strain on surgeons and lowering radiation exposure. Furthermore, the device proved to be valuable in other procedures and disciplines, extending its impact beyond the original scope. These added benefits emerged during the decision-making process through an iterative approach involving multiple stakeholders and an openness to redefine the problem and explore alternative solutions. This case exemplified a well-executed and adaptive decision-making process, making it a valuable reference for developing the framework.

Design Principles: From Complicated to Complex

The framework is designed on the premise that the acquisition of high-tech innovative medical devices is best approached as a complex rather than a merely complicated process. This distinction is based on the Cynefin framework (41), shown in figure 2.1. This framework sorts the issues faced by leaders into five contexts, each defined by the nature of the relationship between cause and effect (41). While complicated problems involve multiple variables that can be analyzed and resolved by experts, complex problems are characterized by ambiguity, emergence, and interdependence, where solutions evolve through iterative processes.

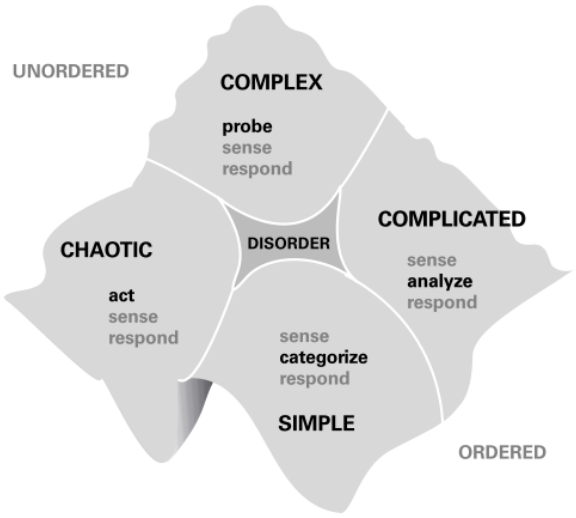

Figure 2.1: Cynefin framework. Adapted from: Snowden and Boone (2007) (41).

When decision-making is approached as a complicated process, the focus is often on choosing the device that best fits the initial request and current workflow. While this requires expertise and careful analysis, it assumes that the goals are known and fixed. However, the acquisition of high-tech innovative

devices typically involves 'unknown unknowns' and requires a reevaluation of existing workflows to unlock the full potential value of the technology. This places the process in the complex domain, where the relationship between cause and effect only becomes clear in hindsight. Recognizing this, the proposed framework emphasizes probing, sensing, and responding as foundational actions within an iterative and adaptive decision-making trajectory.

Refinement and Validation
Following the development of the initial version of the framework, it was reviewed and refined based on expert feedback. Specifically, the program manager of the Rijnstate Robotics program provided input on the wording of the steps, the logical sequence of actions, and the inclusion of iteration throughout the process. This feedback ensured that the framework was both complete and realistic in the context of actual hospital decision-making processes.

2.3 Evaluation of the Decision-Making Framework

The developed decision-making framework is evaluated by the program manager of Rijnstate Robotics and the project leader of NWZ through a questionnaire. These stakeholders were selected due to their comprehensive experience with the entire decision-making process. The evaluation aims to assess the framework's structure, expected usability, and effectiveness, providing insights into its potential value in real-world decision-making.

The evaluation is conducted using a semi-structured questionnaire, which combines closed-ended and open-ended questions. Closed-ended questions are formulated using a 5-point Likert scale, enabling quantitative analysis and measurable feedback. The questionnaire includes both questions and statements to maintain participant engagement and alertness. Additionally, a mix of positively and negatively worded statements is incorporated to minimize response bias, where participants might otherwise agree with all statements or provide uniform responses (41).
Open-ended questions primarily serve to provide deeper insights, allowing participants to elaborate on their previous responses. To ensure a clear and systematic structure, the questionnaire is organized into four key categories: Clarity & Structure, Effectiveness & Decision Support & Effectiveness, Usability &Practical Implementation and General Feedback & Suggestions. The full evaluation questionnaire is presented in Figure 2.2.

Evaluation Questionnaire 'Decision-Making Framework'				
Purpose: This evaluation aims to assess the clarity, usability, and expected effectiveness of the decision-making framework for innovative high-tech medical devices. Your feedback will help refine and improve the framework.				
Clarity & Structure of the Framework				
1. The overall structure of the framework is clear and easy to understand				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
2. The framework covers all essential aspects of the decision-making process				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
3. The steps in the framework are logically ordered				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
4. Each step in the framework has a clear purpose				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
5. The framework requires too much prior knowledge to understand and use effectively				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
6. The decision points add value to the framework				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
7. The decision points are correctly positioned within the framework				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
8. Are there any steps or decision points that are unclear, redundant, missing or incorrectly placed? If so, please explain.				

Decision Support & Effectiveness
9. The framework helps facilitate a well-informed investment decision ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
10. The framework supports a decision aimed at realizing the device's full potential ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
11. The iterative approach of the decision-making is clearly integrated in the framework ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
12. If you don't agree with any of the above statements, could you explain why? How could the framework be improved to better support the decision-making?
Usability & Practical Implementation
13. The framework is useful and of added value to the hospital's decision-making process ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
14. The framework will require significant adjustments to work in real-world hospital setting ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
15. The framework ensures that relevant stakeholders are involved in the decision-making process at the right moment(s) ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
16. The framework is useful for the decision-making of various types of innovative high-tech medical devices ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

17. If you believe the framework is not useful or practical to implement, please explain why. If you have any suggestions for improvement, they would be greatly appreciated.

General Feedback & Suggestions

18. Do you have any additional feedback, comments, insights or suggestions regarding the framework?

Figure 2.2: Evaluation Questionnaire

3. Results

The results section first summarizes the current decision-making process for acquiring medical devices. It then highlights key interview insights relevant to developing the decision-making framework. Finally, it outlines the main challenges identified in acquiring innovative high-tech devices. Together, these findings form the foundation for the proposed framework.

3.1 Current Decision-Making Process

For a clear overview of the current decision-making process, this result section is subdivided into three sections; (1) the required steps and documentation of the decision-making process, (2) the involved stakeholders and (3) the decision criteria that influence the final decision.

3.1.1 Required Steps and Documentation in the Decision-Making Process

The acquisition of new medical devices in hospitals follows a structured decision-making process with mandatory steps and required documentation. This section provides a global overview of the key steps and documentation involved in this process. This section does not detail how each step is carried out, as this varies between hospitals and devices. The order in which the steps are carried out is not fixed, varies with every decision-making process and depends on different factors. Figure 1 gives two examples of a possible decision-making process, more examples can be found in Appendix B.

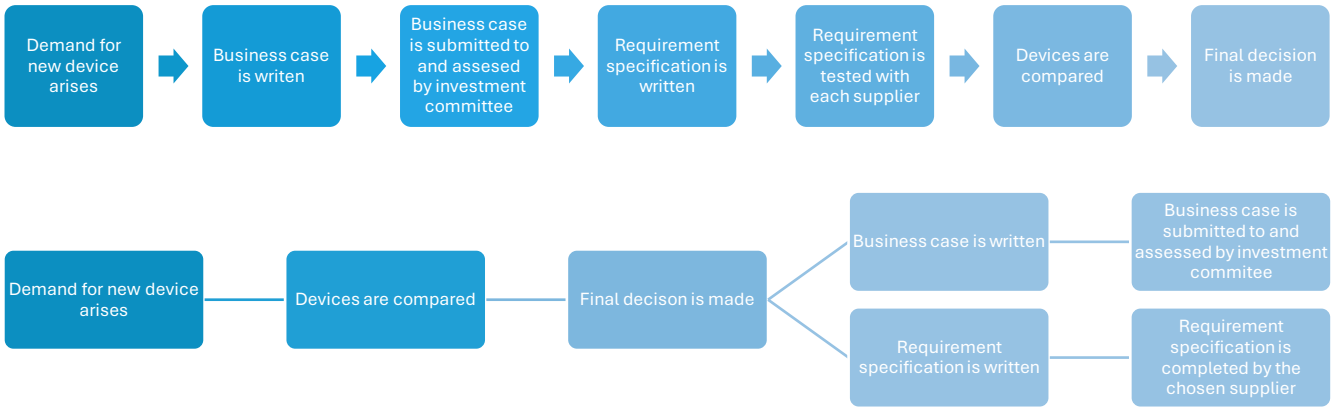

Figure 3.1: Possible orders of the decision-making process

Demand for a new device arises

All interviewees stated that the demand for an innovative high-tech medical device predominantly arises from the operational level, typically from clinicians or end users. This aligns with findings reported in the literature (27, 28, 39, 42). In some cases, the initiative may also come from a hospital division or the board of directors.

Business case is written

A business case is required for all new acquisitions. Hospitals use standardized business case forms or templates that includes key project details, a financial overview, and an assessment of potential risks. The information needed in the business case is obtained from different stakeholders and substantiated with data. When the business case is written before the final decision, the requested budget and

financial overview is an estimate. The business case serves as the foundation for evaluating the feasibility and necessity of the investment. The level of detail in the business case depends on when it is developed within the decision-making process. If the final choice has not yet been made, the business case remains broad in scope. As the decision becomes more defined, the business case becomes increasingly detailed and specific.

Business case is submitted to the investment committee
Once completed, the business case is submitted to the investment committee for review. This committee assesses the proposal and advises the board of directors on whether to allocate funding for the acquisition.

Requirement specification is written
Once the solution direction is clear, a requirement specification is drafted. It outlines the functional and technical criteria the device must meet. Stakeholders contribute their expertise, and if multiple suppliers are involved, the document should clearly separate essential requirements (knock-out criteria) from preferences (used for comparison).

Requirement specification is tested with each supplier
The requirement specification is sent to suppliers to confirm whether their devices meet the requirements and preferences. The requirement specification completed by the supplier also acts as part of the contract, outlining the terms and conditions that both the supplier and the device must meet.

Devices are compared
Devices that meet all requirements are compared based on different decision criteria, including price and preferences. Sometimes a tender process is used for structured evaluation with predefined weighting.

Final decision is made
A final choice is made based on clinical, operational, and financial considerations. Before acquiring a medical device, hospitals are required to create a procurement file in accordance with the ‘Convenant Veilige Toepassing van Medische Technologie in de medisch specialistische zorg’ (43). This file must include, at a minimum: the necessity of the acquisition, the institution's requirement specifications, a risk analysis, competency requirements with corresponding training for future users and technicians, and a periodic evaluation plan (43).

3.1.2 Involved Stakeholders

Since each medical device and its operation differ, the relevant stakeholders also vary. Not every decision-making process requires input from all hospital staff or departments, but it is essential to carefully determine who should be involved. Table 3.1 provides an overview of (potential) stakeholders identified in the interviews and explains their role in the decision-making process.

Table 3.1: Involved stakeholders and their role in the decision-making process.

Stakeholder	Role in the decision-making process
Project leader	Responsible for managing the decision-making process, involving all relevant stakeholders, and drafting the business case.
End user (clinician/ medical specialist)	Defines clinical needs, assesses usability, and provides input on whether the device meets medical requirements.
Direct colleagues of end user (OR-team)	Provide input on usability, workflow integration, and practical implications in the operating room.
Medical purchaser	Responsible for procurement, obtaining quotes, and ensuring compliance with purchasing regulations.
Medical technician	Evaluates technical compatibility, maintenance requirements, and long-term reliability.
Clinical physicist	Assesses the safety, technical specifications, and compliance of the device with regulatory standards.
ICT	Evaluates IT compatibility, integration with hospital systems, and cybersecurity risks.
Architect	Assesses spatial requirements and necessary adjustments to hospital infrastructure.
Hygiene and infection prevention	Ensures the device meets infection prevention protocols and evaluates cleaning procedures.
Business controller	Analyzes financial feasibility, cost-effectiveness, and budget impact.
Investment committee	Evaluates the business case, financial justification, and strategic alignment before approving the purchase.
Board of directors	Grants final approval, considering financial, strategic, and regulatory factors.
Organizational manager /second echelon manager/ budget manager	Responsible for the budget of the department and the submission of the business case to the investment committee.

Information and medical technology department (IMT)	Provides input on integration with existing medical technology and IT systems.
Central sterile department (CSA)	Ensures sterilization requirements are met and assesses compatibility with hospital sterilization processes.
Expert sterile medical devices (DSMH)	Evaluates sterilization protocols and regulatory compliance.
Biomedical engineer	Assesses device safety, reliability, and technical compatibility with existing equipment.
Safety expert advisor	Evaluates workplace safety and potential hazards associated with the device.
Housing	Assesses infrastructure needs and ensures facility adaptations are feasible.
Facility	Ensures logistical feasibility and maintenance capabilities for the new device.
Security	Assesses data security and access control for the device, especially for IT-connected devices.
Quality department	Ensures compliance with hospital policies and regulatory requirements concerning the quality of care.
Occupational health and safety (ARBO)	Assesses ergonomic impact and workplace safety concerns.
(OR) capacity manager	Evaluates impact on OR scheduling and workflow efficiency.
OR department manager	Ensures device fits within operational workflows and staffing requirements.
Assortment coordinator	Ensures alignment with hospital procurement policies and existing device portfolio.
Nuclear department/ radiation protection	Evaluates compliance with radiation safety standards.
Radiology	Assesses imaging compatibility and clinical usefulness.
Functional management	Ensures system usability and integration with clinical workflows.

Healthcare contracting	Evaluates reimbursement options and contractual considerations.
The division	Ensures alignment with broader departmental strategies and objectives.
CMIO (Chief Medical Information Officer)	Ensures alignment with hospital-wide digital health strategy.
CNIO (Chief Nursing Information Officer)	Ensures usability and workflow integration from a nursing perspective.
Supporting departments, such as pharmacy, lab, team managers OR	Provide input on specific use cases and ensure cross-departmental compatibility.

3.1.3 Decision Criteria

The key decision criteria in the decision-making process can be categorized into two groups: factors influencing budget allocation and factors guiding the comparison between suppliers and device types. The criteria influencing budget allocation can be categorized under five sub-categories: Financial and Economic Considerations, Clinical and Operational Feasibility, Medical and Patient Benefits, Strategic and Competitive Positioning and Regulatory and Practical Considerations. The decision criteria that influence the choice between different devices can be categorized into four different categories: Technical and Infrastructure Compatibility, Clinical and User Preferences, Supplier and Purchasing Considerations and Financial and Long-Term Cost Considerations. The decision criteria that influence the final decision can be found in Figure 3.2.

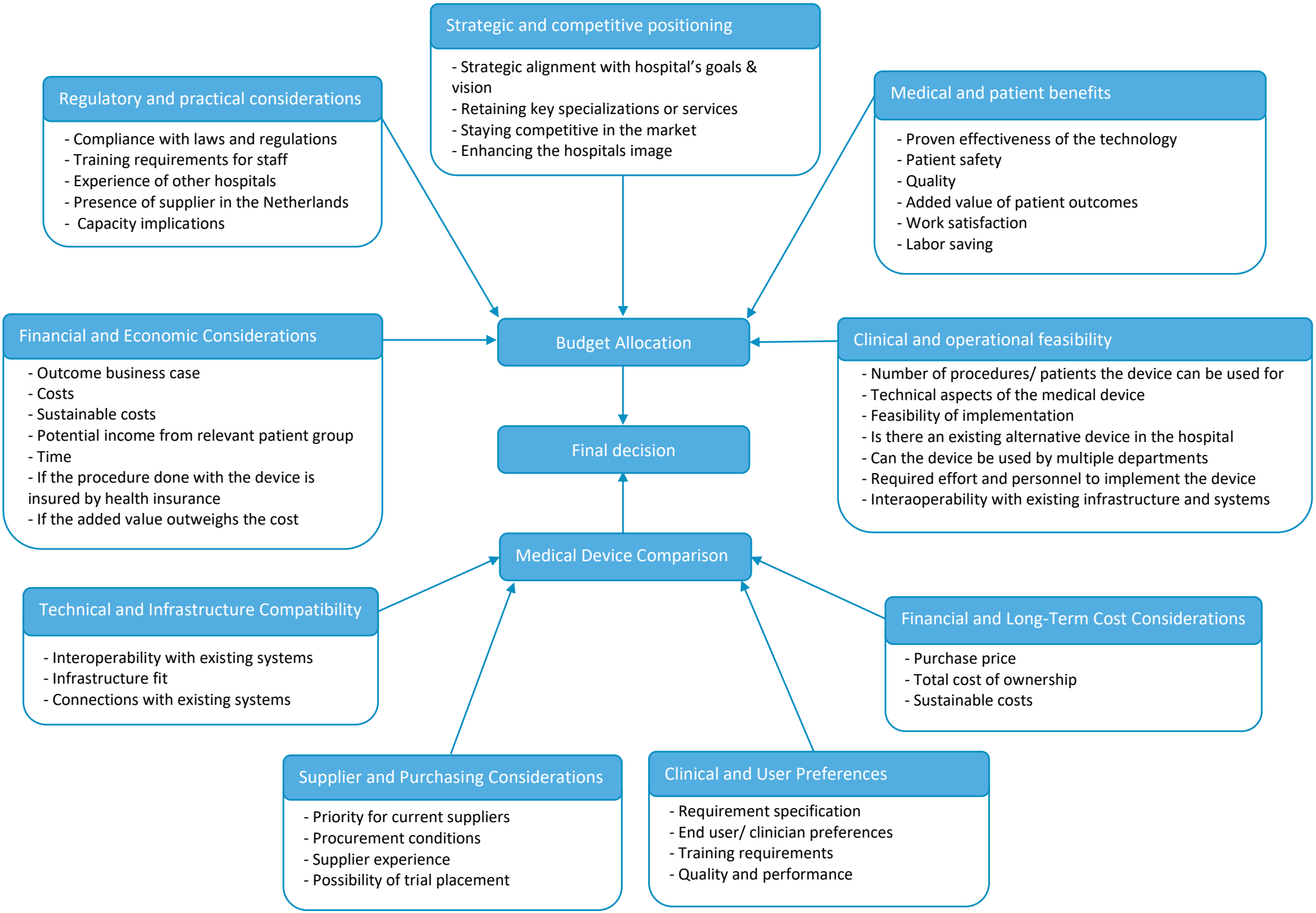

Figure 3.2: Decision criteria that influence the final decision

3.2 Key points from the interviews

This results section provides an overview of ten key insights obtained from the interviews regarding the decision-making process specifically for innovative high-tech medical devices.

3.2.1 Deviation from Established Processes in Innovation Projects

All interviews revealed that the regular acquisition process of medical devices is well-structured and typically delivers the desired outcomes. However, a distinct and clearly defined process for acquiring innovative high-tech medical devices is lacking. While many steps from the regular acquisition process are also relevant for these devices, past acquisitions of innovative high-tech medical devices often deviated from the established procedures for general acquisitions and/or failed to achieve the intended outcomes. These deviations have led to frustrations and dissatisfaction among multiple interviewees.

One possible explanation for these deviations is that the general decision-making process is not well-suited for innovative high-tech medical devices. 60% of the interviewees from Rijnstate described the general process as too bureaucratic and rigid to accommodate the decision-making for innovative high-tech medical devices. Additionally, they and three interviewees from the NWZ emphasized that the preliminary phase of decision-making, prior to budget allocation, is far more critical for innovative high-tech medical devices than for general acquisitions. Unlike regular acquisitions, where key information is often already available, innovative devices require in-depth research and broad stakeholder involvement to build a solid business case.

3.2.2 Early Stakeholder Involvement

Early stakeholder involvement was the most emphasized aspect in the interviews, with over 80% of participants highlighting its critical importance, especially for innovative high-tech medical devices. Lack of early engagement was seen as a primary cause of past inefficiencies, as important issues often emerged too late, delaying implementation or limiting effective use.

Moreover, all interviewees not leading the decision-making process expressed a preference to be involved earlier in the process, as they find it frustrating to be included merely for formality when the decision has essentially already been made. They emphasized that early involvement would not only improve decision quality but also reduce resistance, as understanding the rationale behind choices fosters acceptance. While initiators initially viewed broad involvement as a slowdown, Rijnstate's experience showed that early engagement actually speeds up adoption and implementation in the long run.

3.2.3 Variability of the Decision-Making Process

Both project leaders emphasized that each decision-making process for innovative high-tech medical devices is unique, with significant variability between processes. This uniqueness affects the logical sequence of steps within the decision-making process. While all necessary steps must be completed, their order often depends on the specific context, and a different sequence may be more appropriate for each case.

For instance, if only one supplier offers the desired device, it makes little sense to submit an investment request before evaluating that option. Similarly, the importance of factors like cost, quality, or clinical effectiveness varies by case and must be tailored accordingly. This variability highlights the need for a flexible, context-specific approach to decision-making.

3.2.4 Iterative Process

Due to the high variability in the decision-making processes for innovative high-tech medical devices and the uncertainty of every step and its following step, the program manager of Rijnstate Robotics indicated that it is crucial to adopt an iterative approach. Rather than following a rigid, predefined sequence of steps, the process is dynamic, allowing for adjustments at each stage. Every step taken should therefore be reassessed as new information becomes available or slightly changes are made. It is a repeated process of questioning, investigating, testing, evaluating.

3.2.5 Buyer Supplier Interaction

In both hospitals, the purchasing departments prefer to handle all direct contact with suppliers to strengthen their negotiation position and limit supplier influence. All interviewed buyers noted that suppliers often bypass them, targeting clinicians and other stakeholders early on with aggressive sales tactics. Three other interviewees also indicated that only the purchasing team should manage discussions about quotes and requirements to keep the process clear and efficient. For this to work, it's essential to involve a buyer early in the decision-making process.

3.2.6 Definition of the Underlying Objective

Interviewees involved in the early stages of decision-making, along with the policy advisor, stressed the importance of clearly defining the objective or motivation before exploring solutions. A well-defined objective ensures the actual needs are understood and helps avoid solutions that miss the core issue. It serves as the foundation for identifying suitable options and prevents misdirection and inefficiencies. Once the goal is clear, potential solutions can be evaluated based on how well they address the main objective and additional challenges.

Taking a broad view before settling on a specific solution is crucial, especially when there's an early preference for a particular device. Exploring alternatives ensures the chosen solution not only meets the main goal but also offers added value where possible. This step-back approach reduces the risk of overlooking better options and leads to stronger outcomes. In addition, a clear objective also guides the development of a solid requirement specification.

3.2.7 Leveraging Trial Placements and Insights from Reference Hospitals

When introducing innovative high-tech medical devices, hospitals often lack internal experience. To reduce uncertainty, ten interviewees recommended consulting reference hospitals and/or conducting trial placements or demos.

Reference hospitals that already implemented the technology can support the decision-making at different stages:

1. **Before budget approval**: They can share insights on budget criteria and whether they found the investment worthwhile.
2. **Device comparison**: They can offer firsthand feedback on device performance, usability, and reliability.
3. **Post-selection**: They can advise on implementation and highlight valuable features or accessories.

An example from the NWZ highlighted the benefits of consulting Rijnstate hospital about their experiences with the da Vinci robot. During this visit, NWZ discovered the need for an additional device to make the da Vinci robot fully operational, which influenced their planning and budgeting.

Trial placements or demos are another effective strategy to address uncertainties before committing to a purchase. These trials typically occur after budget approval and allow hospitals to assess whether a device fits their needs, compare options, and identify practical issues. A practical example from Rijnstate demonstrates the value of trial placements. During a trial of self-measuring kiosks, they realized that privacy screens were essential for successful implementation, an insight that might have been overlooked otherwise.

3.2.8 Maximizing the Added Value of Innovative High-Tech Medical Devices

Most interviewees were unsure whether and how a device's potential is fully explored. However, three interviewees emphasized the value of proactively identifying broader applications of innovative high-tech devices. Often, such devices are initially requested by a single clinician or specialty, and alternative applications or additional users are only considered if the device fails to be cost-effective. This reactive approach risks underutilizing the device's capabilities and limiting its impact. To maximize a device's value, hospitals should examine all possible uses and assess how it could improve workflows beyond its initial purpose. This requires closely analyzing the work process, involving end users, and discussing each feature's potential benefits.

At Rijnstate, initial skepticism about involving broader users shifted after several successful cases. This evolving perspective built upon an earlier change where the hospital transitioned from solely evaluating the requested device to also considering similar devices from other suppliers. From the interviews at the NWZ it became clear that they are they are currently experiencing a similar shift in perspective, increasingly recognizing the benefits of looking beyond the initially requested device.

3.2.9 Importance of Reevaluating Changes in the Decision-Making Process

All interviewees noted that deciding on high-tech medical devices is time-consuming, during which circumstances or device features may change. These changes are often overlooked or not reassessed within the context of the entire decision-making process. As a result, decisions may be made based on outdated information, leading to the selection of a device that is no longer the most suitable option. Even minor changes can impact workflow or compatibility. For example, at NWZ, a change to a larger screen rendered the device unsuitable for certain types of interventions. To avoid such issues, three interviewees stressed the importance of evaluating every change, no matter how small, within the full decision-making context.

3.2.10 Current Work Process and Infrastructure

Six interviewees identified the current work process as a key factor in decision-making. Implementation is easier when a device aligns with existing workflows, infrastructure and ICT links without requiring major adjustments. However, since a perfect fit is rare, one interviewee described it as a balance between selecting the device that best matches the current process and determining how to adapt workflows to accommodate it. Another interviewee emphasized that adapting the entire workflow is not necessarily an issue, unless the changes are solely to make the device function. Adjustments are acceptable if they enhance the device's added value and optimize overall processes.

3.3 Identified challenges in the decision-making of innovative high-tech medical devices

This section provides a comprehensive overview of the five key challenges identified in the decision-making process for high-tech medical devices. These challenges highlight the complexities and difficulties faced by hospitals when acquiring innovative technologies.

3.3.1 'Open' Business Case

Both the investment committee and the purchasing department have expressed a preference for an 'open' investment request. This entails that the investment request, and consequently the business case, is directed toward achieving a specific goal rather than a specific device from a preselected supplier. The model and supplier thus remain open. This offers the advantage of allowing consultation with multiple suppliers once the budget is approved, thereby strengthening the hospital's negotiation position. Additionally, an 'open' business case allows for a more objective evaluation of the various suppliers. An 'open' business case also ensures that budget is allocated before significant time and effort are invested in determining which device from which supplier best suits the hospital's needs.

Practical experience, however, demonstrates that budgets are often allocated more quickly when the business case is as complete and well substantiated as possible, reducing the likelihood of unforeseen costs or challenges after approval. In contrast, an 'open' investment request inherently involves an estimated budget of multiple quotations, as the final total costs are not yet determined. This uncertainty increases the likelihood of deviations from the allocated budget, which may necessitate requesting additional funds later, a scenario that is generally considered undesirable.

This duality highlights a challenge: balancing the flexibility and negotiation leverage of an 'open' investment request against the certainty and efficiency of a detailed and specific business case.

3.3.2 Formation of a Project Group

As discussed earlier, experience has shown that early stakeholder involvement is beneficial in the decision-making process. To ensure the right people are involved and aligned, project groups are typically formed. However, determining the ideal timing for establishing a project group remains a challenge. While early involvement leverages expertise and fosters alignment, forming a structured group before budget approval can lead to wasted time and resources if the project does not proceed.

Ideally, stakeholders should be involved soon after the need for a new device is identified to help define requirements and explore solutions. Assigning a project leader early on can improve coordination and efficiency. However, a fully established project group comes with rigid structures, fixed meetings, and limited flexibility which can cause the process to slow down. If changes arise during the process, reconfiguring the group can also slow down progress rather than accelerate it.

Thus, while forming a project group ensures the right stakeholders are involved it can slow down the process. This highlights the challenge whether and when a project group should be established.

3.3.3 Origin of the Need for Innovative Medical Devices

The decision-making process for acquiring medical devices is typically based on the assumption that the need arises internally, from a specific problem or shortcoming in existing devices. This internal demand prompts a search for solutions to a clearly defined issue. However, with innovative high-tech medical devices, the need often originates externally, for instance when clinicians encounter new technologies at conferences or hear about them from peers in other hospitals.

This external origin presents a challenge: instead of starting with a defined problem and then seeking a solution, the process may shift toward finding a problem that fits the proposed solution. This risks compromising objectivity, as requirements might be shaped to justify a specific device rather than reflecting broader organizational needs.

When clinicians express a preference early in the process, initial steps like needs assessment and requirement specification can feel redundant. Some may assume the decision is already made, which can hinder a thorough evaluation of possible devices. Nonetheless, these steps remain essential to ensure the chosen device truly meets hospital needs and delivers maximum value.

3.3.4 Pre-Process Leadership

When there is no designated person or standard workgroup responsible for overseeing the initial steps of the decision-making process, clinicians often face uncertainty about where to direct their requests. This lack of clarity is a key factor contributing to deviations from the general acquisition process. Some hospitals have addressed this issue by establishing a permanent workgroup or committee, such as an innovation or robotics group, to handle these initial steps. Another approach is to assign a project manager early on to structure the process and initiate the formation of a project group. While both options offer potential solutions, they also present challenges.

Assigning a project manager before the project has officially started can be unnecessarily costly, especially if the project does not progress. Additionally, the availability of project managers may already be limited, even when a budget is allocated, making it an even greater challenge before funding is secured. A standard workgroup dedicated to innovation or high-tech acquisitions could resolve this issue by providing a clear point of contact and ensuring a structured start to the process. However, as requests for innovative high-tech medical devices typically occur only once every few years, the question remains if it is advisable and efficient for hospitals who do not have these standard workgroups to assemble them.

3.3.5 Technical Project Manager

To fully maximize the added value of an innovative medical device, it is crucial to thoroughly explore its capabilities and evaluate whether its application can be extended to other areas. This process requires the project leader to have a deep understanding of the workflow in which the device will be implemented, combined with sufficient technical expertise to identify how additional features of the device could optimize that workflow. While an understanding of the workflow can be developed through careful observation of current processes, a lack of technical expertise among project leaders often presents a significant challenge. Without the technical knowledge to recognize the potential added value of a device or its features, the opportunity to fully exploit its capabilities may be overlooked.

3.4 Decision-Making Framework

The final concept of the developed decision-making framework for innovative high-tech medical devices is presented in Figure 3.3.

3.4.1 Evaluation of the Decision-Making Framework

The decision-making framework was evaluated by the project leader of NWZ and the program manager of the Rijnstate Robotics program. The results of the closed-ended questions are presented in Figure 3.4, and the completed evaluation questionnaires are included in Appendix C. Overall, the evaluation results were positive. Both respondents agreed that the framework is clearly structured, adds value to the hospital's decision-making process, and supports a well-informed investment decision.

Nevertheless, some limitations were identified. Both experts noted that the framework does not clearly specify when and which stakeholders should be involved. Additionally, they indicated that effective use of the framework requires familiarity with the hospital's internal processes. Finally, both respondents suggested adding a step related to the implementation or evaluation phase following the final decision.

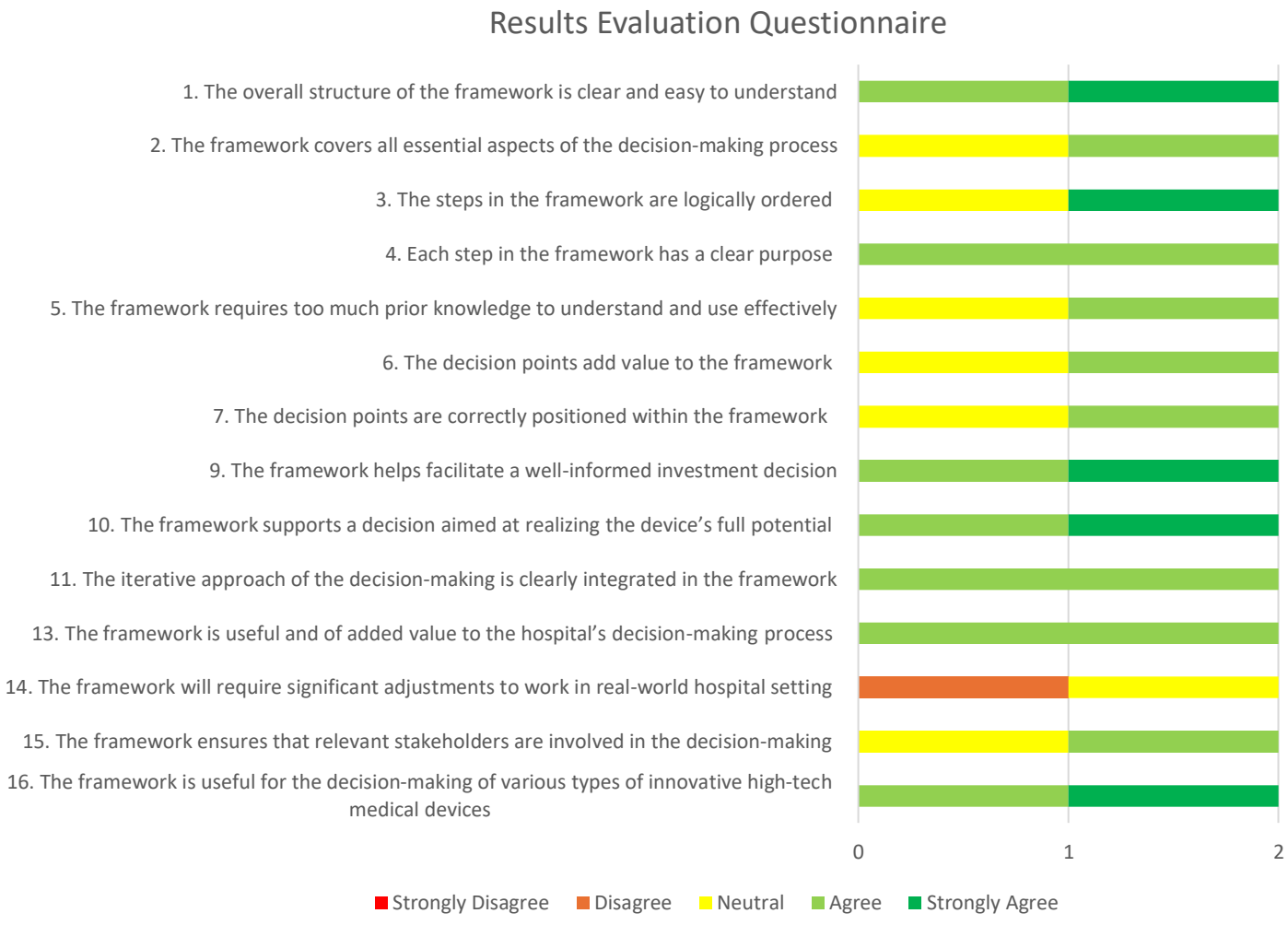

Figure 3.4: Results Evaluation Questionnaire

Decision-Making Framework for Innovative High-Tech Medical Devices

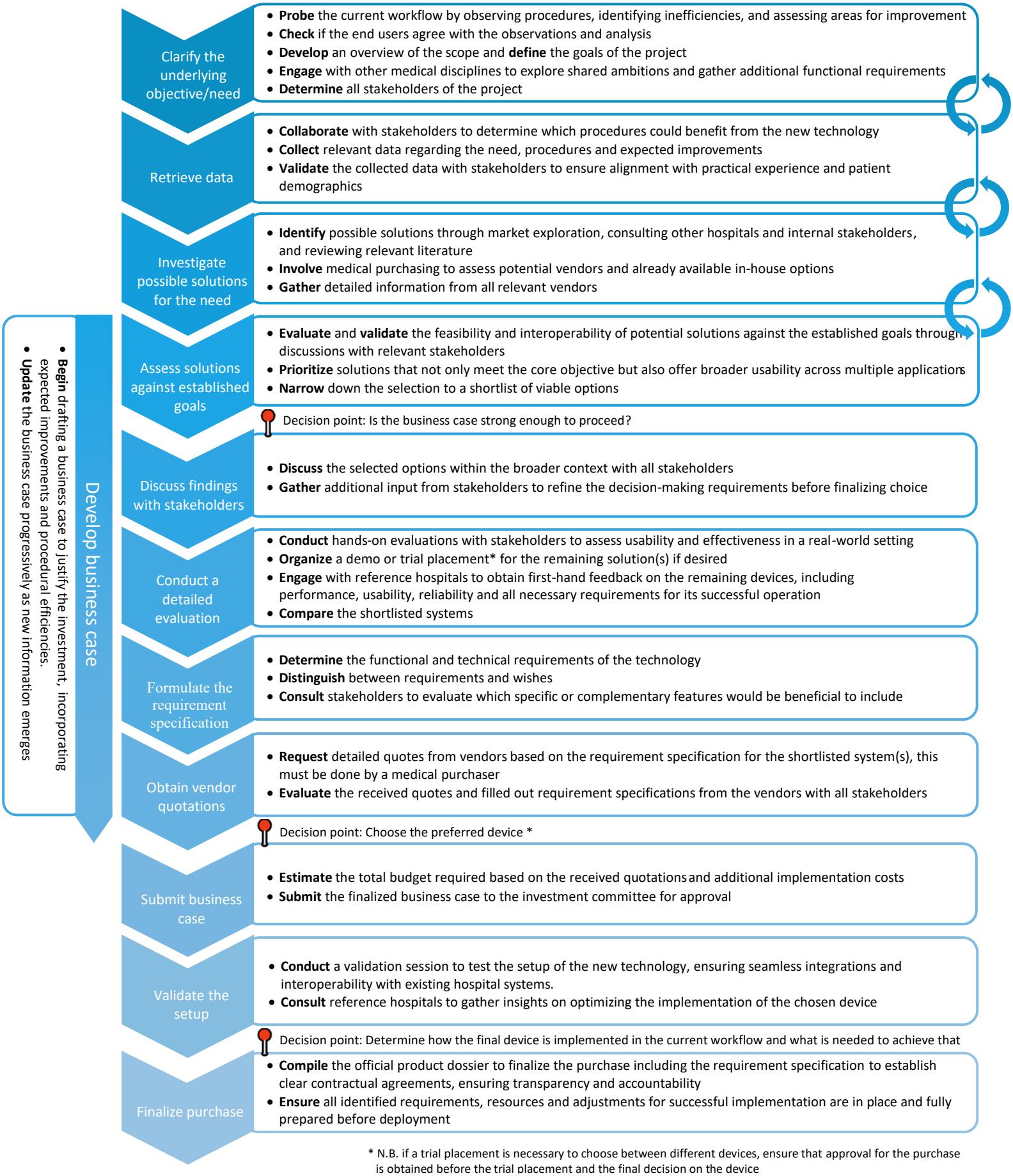

Figure 3.3: Decision-making framework

4. Discussion

This thesis aimed to develop a decision-making framework to support the acquisition of innovative high-tech medical devices in hospitals. In this section, the framework and its design choices are discussed, along with its limitations and implications for both practice and future research.

4.1 Decision-Making Framework

The developed framework approaches the acquisition of innovative high-tech medical devices as a complex decision-making process. This design choice was made to ensure that device acquisitions not only address the initial request but also maximize added value for the broader organization. Rather than treating incoming device requests as fixed demands, the framework interprets them as signals of underlying, broader needs for change. This approach prompts a comprehensive assessment of the objectives behind a request, helping to prevent reactive or impulsive decisions and ensuring alignment with the hospital's strategic goals.

To operationalize this complexity, the framework calls for the early appointment of a technically proficient project manager. Assuming this role is established early in the process, the framework deliberately avoids imposing a rigid project group structure in the initial stages. This flexible setup allows the project to adapt as new insights emerge. Furthermore, recognizing the high degree of uncertainty in early-stage decisions, the framework postpones formalizing a detailed business case until the device and its specific applications have been clearly defined.

The developed framework emphasizes early stakeholder involvement, iterative decision-making, and a focus on uncovering the underlying needs behind a device request. It offers hospitals a structured, yet flexible approach designed to enhance both the legitimacy and efficiency of the acquisition process.

For successful implementation, several preconditions are critical. First, hospitals should establish a dedicated point of contact, either a person or department, to manage and guide new device requests. This ensures that initiators have a clear starting point and that early steps in the process are properly supported. Second, appointing a technically knowledgeable project leader at an early stage is essential. Ideally, this individual should have a deep understanding of the hospital's internal dynamics and be capable of navigating different stakeholder perspectives, making informed judgments, and articulating decisions clearly.

Moreover, hospitals must be willing to invest sufficient time, resources, and organizational flexibility to allow the exploratory phases of the framework to unfold effectively. This requires a cultural shift from favoring "fast and cheap" decisions toward prioritizing "right and valuable" investments. Previous studies have shown that pressuring innovation processes into short-term decision cycles often undermines their long-term sustainability (44). Additionally, overly rigid bureaucratic structures may need to be loosened to foster an environment that supports adaptive and innovation-friendly decision-making.

Compared to existing approaches, this framework stands out by focusing explicitly on the decision-making process itself, rather than treating it as a minor part of the procurement. The framework can be used by hospitals with similar organizational characteristics as that of NWZ and Rijnstate although some adaptation to local circumstances may be necessary.

The practical relevance of the framework lies in its potential to professionalize decision-making practices, reduce costly errors or mis investments, and promote broader organizational engagement with innovation initiatives.

4.2 Limitations and Future Research

Some limitations of this study may have influenced the design of the framework. First, only stakeholders from two hospitals were interviewed, which limits the generalizability of the findings. As each hospital, department, and decision context is unique, the framework may require tailoring to fit specific circumstances. Second, the framework was not tested or validated in an ongoing decision-making process. To assess the practical value of the framework, future research should focus on testing it in real-world decision-making processes. Longitudinal case studies could help evaluate its impact on process efficiency, stakeholder satisfaction, and outcome quality.

In addition to these research limitations, the framework itself also contains some limitations. It does not prescribe exact stakeholder involvement at every step; it remains the responsibility of the user to determine which stakeholders should be engaged. Furthermore, the framework does not perform the actual device comparison but instead defines when and how such steps should be taken.
To improve the usability of the framework, it should be accompanied by a more detailed description of the steps, clearly explaining the meaning and purpose of each phase, potentially supplemented with successful examples. This would help less experienced users better understand the concept of the framework and how to apply it to create true added value.

5. Conclusion

This thesis highlights the complexity of decision-making processes for the acquisition of innovative high-tech medical devices in hospitals. Through an analysis of current practices and challenges, a structured, iterative decision-making framework was developed. The framework supports hospitals in aligning technology acquisitions with broader organizational goals and clinical needs, while navigating uncertainties inherent to high-tech innovations. Evaluations confirm its relevance and usability, offering a valuable foundation for more strategic and informed investment decisions in hospitals.

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Appendix A: Interview set-up

A.1 Interview opzet Nederlandse versie

INTRODUCTIE

- **Doel:** Het doel van het onderzoek is inzicht krijgen in het keuzeproces van de aanschaf van nieuwe (innovatieve) hightech medische apparaten die een grote invloed hebben op de werkprocessen in het ziekenhuis. Denk daarbij aan de da Vinci operatierobot of het 3D-navigatiesysteem op de OK. In dit interview zal met het keuzeproces van medisch apparaat dit soort nieuwe hightech medische apparaten worden bedoeld. Eerst zal ik wat algemene vragen stellen over het keuzeproces en daarna meer specifieke vragen over uw rol binnen en kijk op het keuzeproces.

- **Vertrouwelijkheid:** De gegeven antwoorden zullen vertrouwelijk blijven en de inzichten worden alleen voor academische doeleinden worden gebruikt.

- **Duur:** Het interview zal ongeveer 30 minuten duren.

- **Toestemming:** Vindt u het goed als ik het interview opneem?

DEELNEMER

- Wat is uw officiële professionele functie in het ziekenhuis?
- Bij de aanschaf van welke medische hulpmiddelen bent u betrokken?

PROCES ALGEMEEN

- Kunt u mij (kort) meenemen in de stappen van het keuzeproces voor nieuwe medische apparaten in dit ziekenhuis?
- Waar komt de behoefte voor een nieuw medisch apparaat vandaan?
- Hoe wordt het keuzeproces voor een nieuw medisch apparaat geïnitieerd? En door wie?
- Welke factoren spelen een (grote) rol bij het goedkeuren of afwijzen van een nieuw apparaat?
    - Waar in het keuzeproces wordt er naar deze factoren gekeken?
- Welke factoren spelen een (grote) rol bij de keuze tussen verschillende leveranciers en modellen/type apparaat?
    - Waar in het keuzeproces wordt er naar deze factoren gekeken?
- In hoeverre wordt het uiteindelijke werkproces waarin het apparaat gebruikt gaat worden meegenomen in het keuzeproces?
    - Hoe wordt er gezorgd dat het apparaat wordt geïntegreerd in dat uiteindelijke werkproces?
- In hoeverre wordt er in het keuzeproces gekeken naar hoe het apparaat maximaal benut kan worden?
- Op welke manier wordt het beheer (onderhoud, ICT, CSA) meegenomen in het keuzeproces?

- Wanneer in het keuzeproces wordt er bepaalt hoe jullie gaan meten of jullie tevreden zijn met het nieuwe apparaat?

UW ROL BINNEN HET KEUZEPROCES

- Bij welke stap of stappen van het keuzeproces bent u betrokken?
- Wat is uw rol binnen deze stap/stappen?
- Wat zorgt ervoor dat u ervan op de hoogte dat deze stap/onderdeel uitgevoerd moet worden?
- Wat is de grootste uitdaging binnen uw rol van het keuzeproces?
- Wanneer is uw rol in het keuzeproces voldaan?
- Wat is uw voornaamste doel bij de keuze voor een nieuw medisch apparaat?
- Met welke wet-/regelgeving heeft u te maken in het keuzeproces?

BETROKKENEN

- Welke andere personen en/of afdelingen zijn betrokken in het keuzeproces?
- Welke rol vervullen deze personen of afdelingen in het keuzeproces? of hoe dragen deze personen/ afdelingen bij aan het keuzeproces?
- Mist u sommige personen en/of afdelingen in het keuzeproces?
- Wie maakt of is verantwoordelijk voor de uiteindelijke keuze? En wat vindt u hiervan?

UW KIJK OP HET KEUZEPROCES

- Over welke elementen/ stappen in het keuzeproces bent u tevreden, en wilt u graag zo houden?
- Hoe is en wordt ervoor gezorgd dat het huidige proces op deze manier verloopt?
- Waar zijn jullie tegen aan gelopen tijdens vorige keuzeprocessen, waar in het keuzeproces is het wel eens stroef gelopen?
    - Hoe is dit opgelost?
- Welke stappen of elementen van het keuzeproces kunnen worden verbeterd of mis je in het huidige keuzeproces?
- Hoe kunnen deze stappen van het keuzeproces volgens u verbeterd worden?
- In hoeverre staat het hele team achter de gemaakte keuze? Hoe wordt dit gerealiseerd?

OVERIG

- Zijn er nog andere dingen over het keuzeproces die nuttig of interessant zijn voor mij om te weten die nog niet naar voren zijn gekomen?

A.2 Interview set-up English version

INTRODUCTION

- **Objective**: The aim of this research is to gain insight into the decision-making process for acquiring new (innovative) high-tech medical devices that significantly impact hospital workflows. Examples include the da Vinci surgical robot or the 3D navigation system in the OR. In this interview, the term "medical device decision-making process" refers specifically to these types of high-tech medical devices. I will begin with some general questions about the decision-making process, followed by more specific questions about your role and perspective.

- **Confidentiality**: All responses will remain confidential and will be used solely for academic purposes.

- **Duration**: The interview will last approximately 30 minutes.

- **Consent**: Do I have your permission to record this interview?

PARTICIPANT

- What is your official professional role within the hospital?
- Which medical devices have you been involved in acquiring?

GENERAL PROCESS

- Could you briefly walk me through the steps involved in the decision-making process for new medical devices in this hospital?
- Where does the need for a new medical device originate?
- How is the decision-making process for a new medical device initiated, and by whom?
- What factors play a significant role in approving or rejecting a new device?
    - At what stage in the process are these factors considered?
- What factors are critical when choosing between different suppliers and models/types of devices?
    - At what stage in the process are these factors considered?
- To what extent is the final workflow, where the device will be used, considered during the decision-making process?
    - How is it ensured that the device is integrated into this workflow?
- To what extent is the potential for maximum utilization of the device considered during the decision-making process?
- How is maintenance (e.g., ICT, technical support, sterilization) factored into the decision-making process?
- At what stage is it decided how to measure satisfaction with the new device?

YOUR ROLE IN THE DECISION-MAKING PROCESS

- At which steps in the decision-making process are you involved?
- What is your role in these steps?
- How do you ensure you are aware of the need to perform this step/task?
- What is the biggest challenge in your role within the decision-making process?
- When is your role in the decision-making process considered complete?
- What is your primary objective when choosing a new medical device?
- Which laws or regulations do you encounter during the decision-making process?

STAKEHOLDERS

- Which other individuals or departments are involved in the decision-making process?
- What roles do these individuals or departments play, or how do they contribute to the decision-making process?
- Do you feel certain individuals or departments are missing from the process?
- Who is responsible for or makes the final decision? What are your thoughts on this?

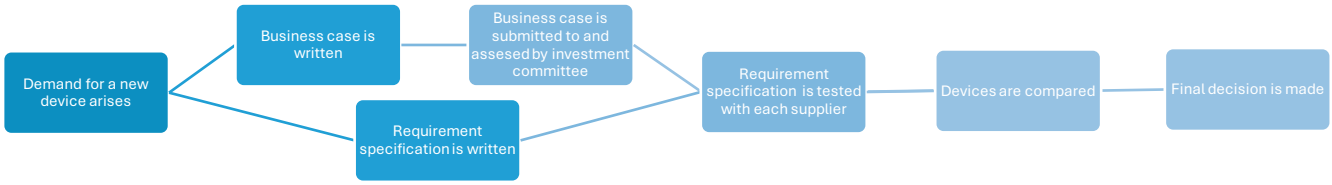
YOUR PERSPECTIVE ON THE DECISION-MAKING PROCESS

- Which elements or steps in the process are you satisfied with and would like to maintain as they are?
- How is it ensured that the current process operates in this way?
- What challenges have you faced in previous decision-making processes? Where has the process encountered difficulties?
    - How were these issues resolved?
- Which steps or elements of the decision-making process could be improved, or which do you feel are missing?
- How do you think these steps could be improved?
- To what extent does the entire team support the final decision? How is this achieved?

ADDITIONAL QUESTIONS

- Are there any other aspects of the decision-making process that you think would be useful or interesting for me to know but have not yet been discussed?

Appendix B: possible decision-making processes



Appendix C: Completed Evaluation Questionnaires

Evaluation Questionnaire 'Decision-Making Framework'				
Purpose: This evaluation aims to assess the clarity, usability, and expected effectiveness of the decision-making framework for innovative high-tech medical devices. Your feedback will help refine and improve the framework.				
Clarity & Structure of the Framework				
1. The overall structure of the framework is clear and easy to understand				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☒ Agree	☐ Strongly agree
2. The framework covers all essential aspects of the decision-making process				
☐ Strongly Disagree	☐ Disagree	☒ Neutral	☐ Agree	☐ Strongly agree
3. The steps in the framework are logically ordered				
☐ Strongly disagree	☐ Disagree	☒ Neutral	☐ Agree	☐ Strongly agree
4. Each step in the framework has a clear purpose				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☒ Agree	☐ Strongly agree
5. The framework requires too much prior knowledge to understand and use effectively				
☐ Strongly disagree	☐ Disagree	☐ Neutral	☒ Agree	☐ Strongly agree
(Ja, je moet goed de weg in het ziekenhuis weten. Dan goed te doen)				
6. The decision points add value to the framework				
☐ Strongly disagree	☐ Disagree	☒ Neutral	☐ Agree	☐ Strongly agree
7. The decision points are correctly positioned within the framework				
☐ Strongly disagree	☐ Disagree	☒ Neutral	☐ Agree	☐ Strongly agree

8. Are there any steps or decision points that are unclear, redundant, missing or incorrectly placed? If so, please explain.

Ik zou het opstellen van het pve met onderscheid tussen vereisten en wensen eerder in het proces plaats laten vinden. Vlak voordat inkoop offertes op gaat vragen. Ook zou ik het duidelijker benoemen dat er een implementatieplan geschreven moet worden.

Decision Support & Effectiveness

9. The framework helps facilitate a well-informed investment decision

☐ Strongly disagree ☐ Disagree ☐ Neutral ☒ Agree ☐ Strongly agree

(Hierdoor is pionieren niet nodig)

10. The framework supports a decision aimed at realizing the device's full potential

☐ Strongly disagree ☐ Disagree ☐ Neutral ☒ Agree ☐ Strongly agree

(Het zorgt ervoor dat je bewust die opties bekijkt en andere vakgroepen erbij betrekt)

11. The iterative approach of the decision-making is clearly integrated in the framework

☐ Strongly disagree ☐ Disagree ☐ Neutral ☒ Agree ☐ Strongly agree

12. If you don't agree with any of the above statements, could you explain why? How could the framework be improved to better support the decision-making?

Usability & Practical Implementation

13. The framework is useful and of added value to the hospital's decision-making process

☐ Strongly disagree ☐ Disagree ☐ Neutral ☒ Agree ☐ Strongly agree

14. The framework will require significant adjustments to work in real-world hospital setting

(Nee, ik denk dat het framework goed geintegreerd kan worden in Noordwest zonder (grote) wijzigingen)

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

15. The framework ensures that relevant stakeholders are involved in the decision-making process at the right moment(s) (Alleen moet je zelf nog steeds bepalen wie relevant is)

☐ Strongly disagree ☐ Disagree ☐ Neutral ☒ Agree ☐ Strongly agree

16. The framework is useful for the decision-making of various types of innovative high-tech medical devices

☐ Strongly disagree ☐ Disagree ☐ Neutral ☒ Agree ☐ Strongly agree

17. If you believe the framework is not useful or practical to implement, please explain why. If you have any suggestions for improvement, they would be greatly appreciated.

General Feedback & Suggestions

18. Do you have any additional feedback, comments, insights or suggestions regarding the framework?

- Eerder duidelijk pve opstellen
- Bij punt 1 benoemen met wie. Als ik het zo lees denk ik aan projectteam eigen afdeling
- Andere stakeholders erbij betrekken is een risico. Hoe moet je bv weten dat een bepaalde vakgroep voor een bepaalde ingreep ook gebaat kan zijn bij deze innovatie. Berust soms op toevallige kennis. Is geen duidelijke checklist.
- Punt 'estimate the total budget required based on the received offertes' → zijn niet alleen offertes. Denk hierbij ook aan huisvestingskosten (aanpassingen gebouw), scholingskosten, andere extra die gepaard gaan met de innovatie.

Evaluation Questionnaire 'Decision-Making Framework'

Purpose: This evaluation aims to assess the clarity, usability, and expected effectiveness of the decision-making framework for innovative high-tech medical devices. Your feedback will help refine and improve the framework.

Clarity & Structure of the Framework

1. The overall structure of the framework is clear and easy to understand

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

2. The framework covers all essential aspects of the decision-making process

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

3. The steps in the framework are logically ordered

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

4. Each step in the framework has a clear purpose

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

5. The framework requires too much prior knowledge to understand and use effectively

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

6. The decision points add value to the framework

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

7. The decision points are correctly positioned within the framework

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

8. Are there any steps or decision points that are unclear, redundant, missing or incorrectly placed? If so, please explain.

a. In the framework, interoperability is only mentioned in the pre-final step. This should be an integral part of the process and specifically be part of the prioritizing of solutions as part of the feasibility (step 4). However, in that phase it should be more general, and further down the process colored with more detail.

b. I'm missing the Evaluation step after implementation. Innovative high tech medical devices require a change of work procedures (if done correctly), and this doesn't stop upon implementation but should be followed up and monitored during the first months of use. In that phase, the innovation will have to become the new normal way of working – this takes time and commitment to truly sink in and transform the process.

Decision Support & Effectiveness

9. The framework helps facilitate a well-informed investment decision

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

10. The framework supports a decision aimed at realizing the device's full potential

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

11. The iterative approach of the decision-making is clearly integrated in the framework

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

12. If you don't agree with any of the above statements, could you explain why? How could the framework be improved to better support the decision-making?

Usability & Practical Implementation

13. The framework is useful and of added value to the hospital's decision-making process

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

14. The framework will require significant adjustments to work in real-world hospital setting

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

15. The framework ensures that relevant stakeholders are involved in the decision-making process at the right moment(s)

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

16. The framework is useful for the decision-making of various types of innovative high-tech medical devices

☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree

17. If you believe the framework is not useful or practical to implement, please explain why. If you have any suggestions for improvement, they would be greatly appreciated.

Comment to 13.: I agree the framework brings value, but only if truly used as intended and the iterative part of the framework is lived up to.
Comment to 14: that fully depends on the current methods employed within the specific hospital.
Comment to 15: again, that is determined by how the framework is put into practice. The framework does mention that all stakeholders should be involved in the various steps – however, it's up to who uses the framework how they implement this, and whether they actually involve 'alle stakeholders' or only the most obvious ones (purchase, ICT, clinical physicians, end user).

General Feedback & Suggestions

18. Do you have any additional feedback, comments, insights or suggestions regarding the framework?

The frameworks should be part of a more elaborate description of the steps truly explaining the meaning and purpose of each step – potentially with successful examples for each step. This way, less experienced users of the framework will better understand the concept of the framework, and how to use it to bring true added value.