Decision-Making Strategy for Hospitals to Implement AI Applications

Master Thesis

S. Sturkenboom

TU Delft

Decision-Making Strategy for Hospitals to Implement AI Applications

by

S. Sturkenboom

to obtain the degree of Master of Science in Biomedical Engineering
at the Delft University of Technology,
to be defended publicly on Friday November 29, 2024

Student number:	5642302	
Project duration:	February 5, 2024 – November 29, 2024	
Thesis committee:	Prof. dr. J. J. van den Dobbelsteen,	TU Delft, supervisor
	Dr. ir. R. M. Oosting	TU Delft
	A. Guédon,	NWZ, supervisor

TU Delft

Preface

One of the most valuable lessons I've learned as a Biomedical Engineering student is how to bridge the gap between the medical and technical worlds. This graduation project has been the perfect embodiment of this role, a unique opportunity to blend my engineering skills with real-world healthcare challenges, and to apply the theoretical knowledge I have gained throughout my studies in a practical and impactful way.

Throughout this project, I have grown both personally and professionally. I have learned how to manage my own research, gained insight into the inner workings of a large hospital, and had the privilege of collaborating with a diverse range of professionals within the medical field. This experience has deepened my passion for integrating technology with healthcare to improve patient outcomes and advance the healthcare sector as a whole.

I would like to thank everyone who contributed to this project. I wish to express my sincere gratitude to Annetje Guédon for giving me the chance to conduct my graduation project at Noordwest Ziekenhuis and for providing guidance and motivation throughout the process. Furthermore, I would like to thank John van den Dobbelsteen for helping me stay focused and providing a broad perspective that helped guide my work, and to Hester Scheffer for her invaluable assistance with the case study. Finally, I want to thank all the other stakeholders involved in my project for their enthusiasm and for making me feel so welcome every step of the way.

This project has been an incredible journey, and I am truly grateful for all the knowledge, experience, and support I have received along the way.

S.Sturkenboom
Delft, November 2024

Abstract

INTRODUCTION Artificial intelligence (AI) has great potential to optimise patient care and reduce the burden on healthcare. Despite numerous AI solutions being developed for hospitals, the clinical adoption rate remains low, largely due to challenges in evaluating their practical usefulness before implementation. This research addresses the gap by developing a decision-making strategy that hospitals can use to assess whether specific AI applications should be implemented. The strategy aims to ensure that AI solutions are effectively integrated, address genuine problems, and meet stakeholder needs, thereby facilitating better decision-making and more successful AI adoption in clinical settings.

METHODS The methodology involved three key phases: development, testing, and evaluation of the decision-making strategy. The strategy was initially developed through an analysis of existing guidelines, specifically the "Stappenplan Healthy AI (HAI)" document, and corresponding literature. Stakeholder evaluations, including input from hospital AI teams, medical officers, and clinical specialists, were used to refine the strategy. A practical case study was conducted in the Radiology department of the Noordwest Ziekenhuisgroep (NWZ) hospital to test the strategy's applicability, followed by stakeholder feedback through a structured questionnaire to evaluate its effectiveness and usability.

RESULTS The results showed that the iterative development process, involving multiple rounds of stakeholder feedback, substantially improved the decision-making strategy's comprehensiveness and relevance. Stakeholders highlighted that the strategy effectively captured critical aspects of AI integration, such as technical requirements, stakeholder needs, and workflow implications. Testing in the Radiology department revealed challenges in identifying responsible individuals for data collection, which initially delayed the process, but also underscored the need for well-defined roles. The feedback from stakeholders was largely positive, indicating that the strategy was clear and practical for evaluating AI solutions, though some improvements were suggested for addressing technical integration and detailing follow-up actions. Stakeholders appreciated the structured format, which facilitated effective communication and collaboration among different departments. Overall, the decision-making strategy succeeded in creating a robust framework for evaluating AI applications, helping ensure that such technologies are implemented thoughtfully and effectively.

CONCLUSION The aim of this study was to develop a decision-making strategy for hospitals to determine whether AI applications should be implemented, as well as to test and evaluate the strategy. The iterative process proved effective in creating a practical and efficient tool that helps identify potential bottlenecks and clarifies resource needs for implementation. The involvement of ICT stakeholders was crucial, highlighting the importance of technical evaluation as a key factor in decision-making. Overall, the strategy provides a focused and manageable framework that allows hospitals to evaluate AI applications effectively, supporting informed decisions to improve healthcare efficiency and patient care quality.

Contents

Abstract ii

List of Abbreviations iv

Glossary v

1 Introduction 1
- 1.1 Problem Statement . . . 1
- 1.2 Research Question and Purpose. . . . 2

2 Methods 3
- 2.1 Development of Decision-Making Strategy . . . 3
- 2.2 Testing of Decision-Making Strategy: Case Study . . . 5
- 2.3 Evaluation of Decision-Making Strategy . . . 8

3 Results 11
- 3.1 Development of Decision-Making Strategy . . . 11
- 3.2 Testing of Decision-Making Strategy: Case Study . . . 13
- 3.3 Evaluation of Developed Decision-Making Strategy. . . . 19

4 Discussion 22
- 4.1 Process of the Decision-Making Strategy . . . 22
- 4.2 Limitations and Future Research . . . 23

5 Conclusion 24

Reference List . . . 27

A Appendix
Developed Decision-Making Strategy 28

B Appendix
Decision-Making Strategy in Case Study 32

C Appendix
Additional Results Evaluation Questionnaire 44

D Appendix
Completed Evaluation Questionnaires
of Respondents 45

List of Abbreviations

Abbreviation	Definition
CT	Computed Tomography
CTA	Computed Tomography Angiography
CVA	Cerebrovascular Accident
FDA	Food and Drug Administration
IAT	Intra-Arterial Thrombectomy
ICH	Intracranial Haemorrhage
ICT	Information and Communication Technology
IR	Interventional Radiologist
IVT	Intravenous Thrombolysis
VO	Vessel Occlusion

Glossary

Term	Definition
CT	Imaging method that uses X-rays to produce detailed pictures of the inside of the body
CTA	Using an injection of contrast material into the blood vessels and CT scanning to help diagnose and evaluate blood vessel disease or related conditions
FDA's 510(k) premarket notifications documents	A premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device
IAT	IAT is the standard treatment for patients with a cerebral infarction due to a large vessel occlusion.
ICH	Type of haemorrhagic stroke that occurs within the brain tissue
ICT	The use of technology for accessing, processing, and communicating information. It encompasses tools and systems that facilitate communication, data management, and information sharing across different platforms.
IR	A radiologist who specialises in performing radiological examinations and treatments.
IVT	Treatment that uses a powerful blood thinner that dissolves the blood clot, administered through an intravenous infusion.

1

Introduction

Artificial intelligence (AI) is increasingly becoming a key element of modern society, finding applications in industries such as marketing, gaming, e-commerce, and education [1]. AI can be defined as the capability of a system to model human intelligence to accurately interpret external data, learn from it, and apply these insights to accomplish specific goals and tasks through adaptive flexibility [2][3]. With the endless opportunities it provides, AI has undoubtedly found its place in the healthcare sector as well (see Figure 1.1). To identify consistent patterns in the growing volume of data from various sources, these amounts of data need to be structured. Using these patterns can help to, for instance, a) enhance and optimise patient care and treatment, and b) support healthcare professionals in their work. These challenges involving huge amounts of data could be addressed by using AI [4][5]. Furthermore, the pressure on healthcare and the requirement for additional healthcare workers is already increasing [6][7]. To reduce this burden on the healthcare sector, AI could be helpful [8]. It is expected that by adopting AI into healthcare, this will assist and improve healthcare professionals in their work, rather than replace them [6][7].

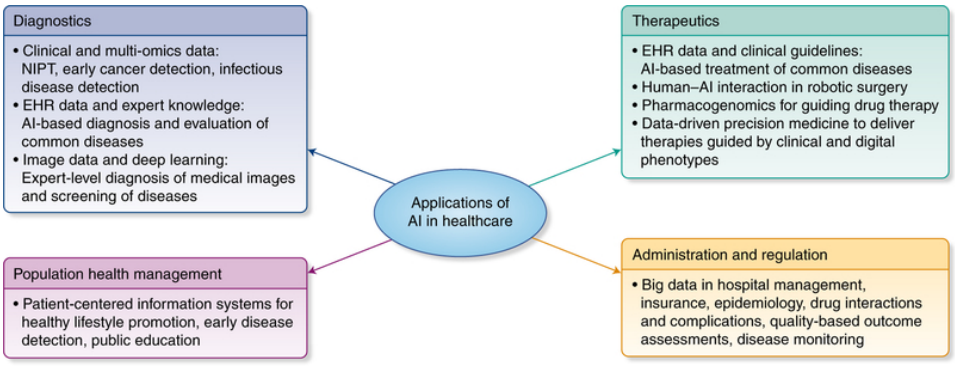


Figure 1.1: Applications of AI in healthcare. Adopted from: He et al. (2019) [9]

1.1. Problem Statement

Although many AI applications for the healthcare domain are being developed or have already been developed, few are actually used clinically within the hospital [5][10][11]. Ideally, a hospital would first explore where specific problems arise, and only then consider possible AI solutions, both commercially available and/or self-developed AI solutions. This recommendation is included in several recent guidelines on AI in healthcare, such as guidelines in the Netherlands [12], across Europe [13], and internationally [14]. These guidelines support the implementation of AI in hospitals.

In practice, however, it is often unclear what specific problem the AI application is intended to solve [15]. For example, most of the time AI vendors are the ones offering various types of AI applications to the hospital for many different solutions. Or, as another possibility, medical specialists independently conduct research via their network and introduce AI applications to their medical department. Moreover, most hospitals do

not have the ability to develop AI applications themselves and therefore rely on commercially available AI applications. These hospitals are experiencing an AI technology push from vendors. As a consequence, some AI applications are not properly evaluated before the actual implementation and thus implementation is carried out without sufficient consideration. Accordingly, certain aspects may be unknown in advance:

a) Problem
Is there actually a problem within the healthcare process, and will the AI application solve it?

b) Integration
Will the AI application be able to integrate into the healthcare process?

c) Impact
What will the impact of the AI application be on the healthcare process?

d) Requirements
What are the requirements of the stakeholders involved for the AI application?

One of the consequences of not properly evaluating these aspects, is that the AI application may not function as expected. Additionally, the application could require extra actions in the current process [15], or healthcare personnel may lack sufficient knowledge to use the application effectively [11]. This could lead to dissatisfied end-users and even complete discontinuation of using the AI application, which could further contribute to its persistently low adoption in clinical practice.

First, hospitals should investigate the impact of an AI application in order to make a suitable decision on the usefulness and necessity of the relevant AI solution, before it is being implemented [16]. Making a suitable decision will hopefully result in the effective use of AI applications and a prudent financial investment, reducing the burden on healthcare and optimising the quality of care for patients.

1.2. Research Question and Purpose

Following the problem statement, the research question is therefore:
What is a suitable decision-making strategy for a hospital to decide whether AI applications should be implemented?

The three main purposes of this research are:

1. Development of a decision-making strategy based on existing literature and evaluation by relevant stakeholders.
2. Testing of the developed decision-making strategy using a case study.
3. Evaluation of the developed decision-making strategy.

2

Methods

In this section, the methods for achieving the three main research purposes will be explained. In the first paragraph, the development of the decision-making strategy itself will be described. The second paragraph will outline how the decision-making strategy will be tested in practice. Lastly, the third paragraph will clarify how the decision-making strategy will be evaluated.

2.1. Development of Decision-Making Strategy

To examine the impact of an AI application and to achieve a suitable decision, preliminary research should be performed by following a decision-making strategy. First, literature research is done on how this preliminary research should be executed. To achieve this, an analysis of the guidance document "Stappenplan Healthy AI (HAI)"[17] and corresponding literature is performed. The decision to use this guidance document as the primary basis for analysis was informed by prior literature research, which indicated that "Stappenplan HAI" effectively consolidates existing guidance documents on healthcare technology. Moreover, this guidance document is specifically focused on AI applications. "Stappenplan HAI" is developed for hospitals and healthcare institutions to guide them through the actual implementation of AI applications within the hospital or institution. This guidance document consists of eight main steps, each with several subtopics, which are recommended to follow when implementing AI applications within a hospital. However, "Stappenplan HAI" is considerably lengthy for use solely with commercially available AI applications, making it less practical for hospitals. In addition, it specifically focuses on implementing AI applications, while the decision-making strategy will focus on making a suitable decision whether AI applications should be implemented.

To ensure comprehensive coverage, the corresponding literature related to "Stappenplan HAI" was also reviewed, allowing for the analysis of any (sub)topics not included in the guidance document and minimising the risk of missing relevant information.

The analysis of both "Stappenplan HAI" and corresponding literature will decide which relevant topics and subtopics will be incorporated into the decision-making strategy. In order to identify these relevant (sub)topics, inclusion and exclusion criteria were established for the analysis. The criteria can be seen in Table 2.1.

Table 2.1: Inclusion and exclusion criteria for identifying relevant (sub)topics in guidance document "Stappenplan HAI" and corresponding literature.

Inclusion	**Exclusion**
• (Sub)topics focused on commercial AI applications	• (Sub)topics focused on self-developed AI applications
• (Sub)topics focused on preparatory steps prior to implementation	• (Sub)topics specifically focused on performing the actual implementation
	• (Sub)topics that are overly detailed for the scope of this preliminary research

After establishing the first concept design of the decision-making strategy, stakeholders involved in AI within the hospital will be identified. These stakeholders will evaluate the (sub)topics outlined in the decision-making strategy and they may provide additional input and suggestions. Evaluation will be done one-to-one or in the form of a panel. Input of various stakeholders is crucial, since they may provide different insights on the same topics, such as on a technical or practical level. Potential stakeholders who could be included can be seen in Table 2.2. Following each evaluation, adjustments will be incorporated to develop a finalised decision-making strategy presented as a questionnaire, which will then be converted into a checklist or decision matrix.

Table 2.2: Potential stakeholders for providing input in developing the decision-making strategy.

Function	Description
AI team	Supporting individuals and teams in developing and implementing AI projects. They provide expert guidance, from advising on initial ideas to assisting with project initiation and execution, ensuring comprehensive support for AI initiatives.
Chief Medical Information Officer (CMIO)	Chairman of the medical expert group, which focuses on co-directing the strategic plan for information provision in relation to patient care, research, education, patient involvement, outcomes, e-health, and innovation, from a medical perspective.
Chief Nursing Information Officer (CNIO)	Chairman of the nursing expert group, which focuses on process improvement and optimisation within the nursing domain, specifically in electronic health dossiers, innovation, data exchange, and data-driven practices.
Clinical physicist	Responsible for thoroughly understanding the operation of each medical device, they support medical specialists in the effective and safe use of medical technology and advise on the necessary safety and quality standards for this equipment.
Data innovation manager	Responsible for leading and managing the hospital's innovation in the field of data.
ICT adviser	An ICT adviser in a hospital ensures that the technology systems supporting patient care and hospital operations function smoothly and securely. They manage and optimise healthcare ICT solutions, troubleshoot issues, and implement new digital tools to improve workflows and data management within the hospital setting.
Information manager	Responsible for aligning information systems, ICT technology, and data as closely as possible with the needs of various healthcare processes.
Medical specialist	Doctors with the specialised knowledge and expertise needed to practise a particular specialty.
Nurse	Provides medical care, support, and education to patients, helping them manage illness, recover from injury, and maintain health. They work closely with doctors and other healthcare professionals to monitor patients' conditions, administer treatments, and offer compassionate care.

2.2. Testing of Decision-Making Strategy: Case Study

The developed decision-making strategy will be tested in practice through a case study to identify any missing information and evaluate the strategy's usability. Testing will be performed by collecting all relevant information and data on an AI application as requested in the decision-making strategy. Throughout the collecting process, possible bottlenecks or difficulties can be identified. Additionally, the collecting process will help determine the appropriate individuals or sources that are responsible for providing this necessary information. The case study will be performed in the Radiology department of the Noordwest Ziekenhuisgroep (NWZ) hospital. There are several reasons the Radiology department provides opportunities to use this case study for testing the developed decision-making strategy.

First, since the decision-making strategy is focused only on AI applications commercially available, NWZ is a suitable hospital to test it, because NWZ does not have the ability to develop AI applications itself.

Second, the Radiology department has experienced 'rapid' implementation of certain AI applications in recent years. As a result, the department gained considerable experience and knowledge on AI. Nevertheless, some AI applications were implemented without adequate consideration beforehand. Consequently, end-

users were not sufficiently satisfied, performance was less than expected or adoption across healthcare staff was inconsistent. For certain AI applications, this led to their discontinuation after just a few months of use. Therefore, these past experiences, with both successes and setbacks in AI implementation, will provide an opportunity to closely examine where the decision-making strategy might enhance preparation and adoption.

Third, the Radiology department is currently considering a specific AI vendor, which is named Aidoc. This vendor came to notice by radiologists who had attended a radiology convention. Aidoc has developed many AI modules with clinical solutions for the Cardiovascular, Neuro and Radiology domains. One of the AI modules that the Radiology department is interested in, is the Stroke module. Aidoc states, among others, that the Stroke module optimises the analysis of Computed Tomography (CT) and Computed Tomography Angiography (CTA) scans, leading to faster detection (or exclusion) of stroke, resulting in a quicker start of treatment. A CT scan is an imaging method that uses X-rays to produce detailed pictures of the inside of the body [18]. CTA "uses an injection of contrast material into your blood vessels and CT scanning to help diagnose and evaluate blood vessel disease or related conditions" [19]. Moreover, the stroke module is accessible via a mobile application, enabling image review remotely, outside the hospital setting. The mobile application also facilitates direct communication with any member of the care team. In addition, NWZ hospital receives approximately 2,500 patients with suspected stroke in the emergency department annually, which is another reason they are keen on adopting the Stroke module.

Cerebro Vasculair Accident (CVA), which is the medical term for stroke, is a collective term for a transient ischaemic attack (TIA), ischaemic stroke and haemorrhagic stroke. The terms CVA and stroke are used interchangeably in this text. Around 80% of patients with stroke have a TIA or ischaemic stroke and around 20% a haemorrhagic stroke, which is divided into 15% intracranial haemorrhage (ICH) and 5% subarachnoid haemorrhage (SAH) [20]. In a stroke, part of the brain is deprived of blood and oxygen, which causes the brain cells to die and the brain may lose some of its function. In ischaemic stroke, the cause is a blood clot blocking the blood vessel. If this arterial blockage is of short-term (several minutes or hours), it is called a TIA. In haemorrhagic stroke, the blood vessel is ruptured, causing a haematoma and oedema formation [21]. In ICH, this occurs within the brain tissue, while in SAH this occurs in the space between "the brain and the surrounding membrane (subarachnoid space)" [22]. For CVA patients "Time is brain", which refers to the rapid loss of nervous tissue as stroke progresses. Therefore, time is crucial and therapeutic interventions should be started as quickly as possible [23]. Thus, the Stroke module from Aidoc appears promising for optimising the care of CVA patients at NWZ.

The Radiology department's interest in this AI application provides a supportive environment for testing the decision-making strategy. Moreover, this ensures that the testing process is a realistic, real-world case study.

Lastly, the type of software (i.e., the detection of stroke) is new to the Radiology department and the AI vendor itself is new to NWZ. Hence, this new setting is suitable to test the decision-making strategy.

Background on Aidoc Stroke module

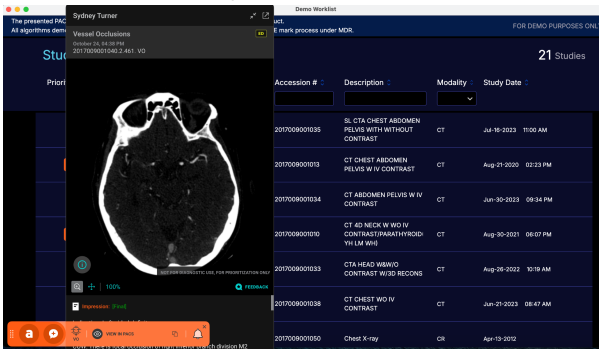
The AI application Stroke module of Aidoc consists of the following:

- Aidoc platform aiOS
- Intracranial haemorrhage detection (Aidoc algorithm)
- All vessel occlusion detection (Aidoc algorithm)
- Aidoc Mobile Application (with secure chat and call function allowing for virtual consultation)

The application is "a radiological computer aided triage and notification software indicated for use in the analysis" [24][25] of head CT and CTA images. The analysis ensures that cases with suspected positive findings of ICH and/or vessel occlusion are flagged and communicated to the designated stroke team members. In this way, the application assists hospital networks and stroke team members in workflow triage. The communication of the flagged cases is performed via pop up notifications. Since the Stroke application is connected to the Aidoc desktop application (i.e., the Aidoc platform that runs on the Windows computer) as well as to the Aidoc Mobile app, stroke notifications will be received on both applications.

The process for the desktop application is as follows: The radiologist receives an orange pop-up notification indicating a suspected positive finding (Figure 2.1a). By hovering over the notification, the radiologist can view the specific image contributing to the positive finding and directly open the case in PACS with a single click on "view in PACS" (Figure 2.1b). Additionally, the application can triage and prioritise cases based on suspected positive findings, creating a "Prioritization" column within the native radiology worklist (Figure 2.1c).

(a) Visual representation of receiving an orange pop up notification notifying of a suspected positive finding on Aidoc's desktop application.



(b) Visual representation of hovering over notification to see image which contributes to positive finding on Aidoc's desktop application.

(c) Visual representation of "Prioritization" column in the native Radiology worklist on Aidoc's desktop application.

Figure 2.1: Visual mock-up representation of the communicating process of flagged cases on an Aidoc desktop application. These screen captures are from a virtual demonstration software provided by Aidoc. The images were obtained through direct contact with Aidoc itself.

For the mobile application, the process is as follows: The radiologist receives an orange pop-up notification indicating a suspected positive finding. The user will have access to the AI results and the analysed image series. Moreover, electronic health records (EHR) of patients are also available. The user can have direct contact with the care team in a secure chat and call window. A visual representation of using the mobile application is pictured in Figure 2.2.

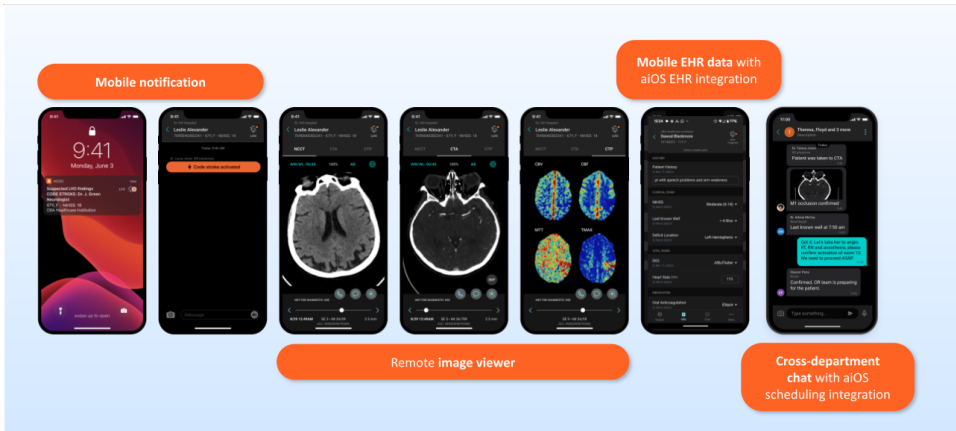


Figure 2.2: Visual mock-up representation of the communicating process of flagged cases on an Aidoc mobile application. The images were obtained through direct contact with Aidoc itself.

2.3. Evaluation of Decision-Making Strategy

The developed decision-making strategy will be evaluated by the potential involved stakeholders (see Table 2.2) through the completion of a questionnaire. This questionnaire will help provide more insight into the use of the decision-making strategy, thereby considering various aspects such as end-user satisfaction, deficiencies in the strategy and time investment per stakeholder. Eventually, this evaluation ensures that it is clear whether the decision-making strategy has been helpful in gaining a better understanding of AI applications before actual implementation. The evaluation questionnaire is presented in Figure 2.3 and 2.4.

The evaluation will include of a semi-structured questionnaire, which consists of closed and open-ended questions for the stakeholders. The closed questions are formulated based on Likert questions and statements, providing a 5-point scale with response options. The Likert 5-point scale was selected to enable quantitative analysis of the data afterward. Moreover, the combination of using questions and statements ensures that participants remain interested and alert during the questionnaire. In addition, both positive and negative formulated statements and questions were used. This can help reduce the risk of response bias, where participants tend to agree with statements or give the same answer to all questions [26]. The open questions primarily aim to allow participants to explain the answers they provided earlier.

To provide a clear structure in the evaluation questionnaire, the first part of questions and statements are focused on the main headings regarding the structure of the decision-making strategy. The last part of the questionnaire is more focused on general questions and statements regarding the overall decision-making strategy.

Evaluation Questionnaire "Decision Strategy"

1. The decision strategy provides sufficient information about the application and effectiveness of the AI application.

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

2. If information is missing, in which area(s)? (multiple options possible)

☐ *Purpose of the AI application* ☐ *Clinical applicability* ☐ *Time investment* ☐ *Ethical aspect*

☐ *Performance of the AI application* ☐ *Adaptability* ☐ *Market research* ☐ *Level of innovation* ☐ *Other, namely:*

Explanation of insufficient information:

3. Does the decision strategy provide insufficient information about the technical aspects of the AI application?

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

4. I am missing information in the area of: (multiple options possible)

☐ *User-friendliness* ☐ *Technical integration* ☐ *Data storage* ☐ *Software connection* ☐ *External integration* ☐ *Other, namely:*

Explanation of insufficient information:

5. The decision strategy provides sufficient information about the costs of the AI application.

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

6. If more information is desired, in which area(s)? (multiple options possible)

☐ *Purchase of AI application* ☐ *Licence AI application* ☐ *Other costs?* ☐ *Other, namely::*

Explanation of insufficient information:

7. Does the decision strategy provide sufficient information about the benefits of the AI application?

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

8. If information is missing, in which area(s)? (multiple options possible)

☐ *Savings* ☐ *Benefits* ☐ *Other, namely:*

Explanation of insufficient information:

1

Figure 2.3: Questionnaire regarding evaluation of the developed decision-making strategy (page one).

9. The decision strategy contains insufficient information about the sustainability aspects of the AI application.

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

10. I am missing information in the area of: (multiple options possible)

☐ *Energy* ☐ *Sustainability* ☐ *Other, namely:*

Explanation of insufficient information:

11. The decision strategy provides sufficient information about the internal validation of the AI application.

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

12. If information is missing, in which area(s)? (multiple options possible)

☐ *Performance own dataset* ☐ *User-acceptance test* ☐ *Other, namely:*

Explanation of insufficient information:

13. Were the questions in the decision strategy clear and easy to understand?

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

14. If unclear and/or not easy to understand, in which area(s)? (multiple options possible)

☐ *Application and effectiveness* ☐ *Technical aspects* ☐ *Costs* ☐ *Benefits*

☐ *Sustainability* ☐ *Internal validation* ☐ *Other, namely:*

Explanation of insufficient information:

15. How much time did it take to complete your contribution to the decision strategy?

☐ *0 – 4 hours* ☐ *4 – 8 hours* ☐ *8 – 12 hours* ☐ *12 – 16 hours*

16. Has the decision strategy helped you gain better insight into the respective AI application?

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

17. Has the decision strategy stimulated input and communication among the various stakeholders?

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

18. After using the decision strategy, is it clear what next steps should be taken?

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

19. Do you have any other feedback/comments about the decision strategy?

☐ *No* ☐ *Yes*

Explanation:

2

Figure 2.4: Questionnaire regarding evaluation of the developed decision-making strategy (page two).

3
Results

In this section, the first paragraph will address the results of developing the decision-making strategy. In the second paragraph, the results of testing the strategy in a case study will be presented. Lastly, the third paragraph outlines the results of the evaluation questionnaire on the use of the decision-making strategy.

3.1. Development of Decision-Making Strategy

The development process of the decision-making strategy started first with creating a concept design based on an analysis of literature. Thereafter, an iterative process began, in which two stages followed one another repeatedly, namely the evaluation stage and the adjustment stage. The evaluation stage consisted of presenting the decision-making strategy to the stakeholders followed by discussions and receiving feedback. This was one-to-one or in the form of a panel. The adjusting stage consisted mainly of processing feedback from the evaluation sessions and adding additional questions/(sub)topics or adjusting questions/(sub)topics. This iterative process was repeated several times with different stakeholders, until the final concept of the decision-making strategy was developed. The final concept of the decision-making strategy is presented in Appendix A.

For the first concept design of the decision-making strategy, guidance document "Stappenplan HAI"[17] provided the basis for collecting relevant information of an AI application. This guidance document consists of eight main steps, each with several subtopics, which are recommended to follow when implementing AI applications within a hospital. This document was analysed to adopt relevant (sub)topics by the author based on the predetermined criteria (see Table 2.1). The (sub)topics which were included or excluded from "Stappenplan HAI" are presented in Table 3.1.

Furthermore, the corresponding literature of Stappenplan Healthy AI was consulted [12][16][27][28][29][30], which resulted in additional questions/(sub)topics or adjustments of questions/(sub)topics. The additional input or adjustments on certain (sub)topics from the corresponding literature is presented in Table 3.2. The 'X' indicates that the input was provided by the corresponding literature.

Thereafter, the iterative process of evaluating and adjusting started, and this process was repeated several times. Evaluation was performed by various stakeholders. The included stakeholders and the main additions and adjustments made through their input during the iterations can be seen in Table 3.3.

Table 3.1: Inclusion and exclusion criteria of (sub)topics based on "Stappenplan Healthy AI".

Inclusion (Sub)topics related to:	**Exclusion** (Sub)topics related to:
• AI software features	• AI Act
• CE classification	• Assessment frameworks
• Clinical problem	• Business Impact Assessment
• Data protection	• Classification of availability, integrity and confidentiality
• Economical validation	• Design
• Education	• Evaluating outcomes
• Effectiveness model	• Field standards
• Expected effects	• Implementation management agreements
• Human-machine interaction	• Implementation plan
• Innovation funnel	• Liability
• Local validation	• Model development process
• Market research	• Product recalls
• Product safety	• Prospective risk assessment
• Purpose	• Safe incident reporting
• Purchasing	• Self-built
• Statistical validation	• Set of requirements
• User acceptance test	

Table 3.2: (Sub)topics from corresponding literature included into first concept design of the decision-making strategy. The 'X' indicates that the input was provided by the corresponding literature.

(Sub)Topic	**Literature**					
	[12]	[29]	[27]	[16]	[28]	[30]
Added value of application use						X
Application costs		X				
Characteristics and requirements of ICT functionality, architecture and infrastructure		X	X	X		
Comprehensibility of the application				X		
Characteristics and size of datasets			X	X		
Identifying end users			X			
Effort required from the end user						X
Integration of the application within external healthcare institutions				X		
Integration of the application in the current process				X	X	
Outcome measures of clinical added value		X				
Level of application automation	X					
Manual or automatic execution of the application			X			
Medical conditions targeted by the application			X			
Provision of new information through the application			X			
Requirements for ICT architecture and infrastructure			X			
Threshold determination for optimal application usage				X	X	
Data accessibility			X			
Applicability of the application in new clinical setting					X	
Type of application function			X			

Table 3.3: Main input from the included stakeholders during the iterations which resulting in adjustments of the decision-making strategy.

Stakeholder	Input
Clinical physicist	- Rephrasing of questions - Assessing the relevance of questions - Adding questions on ethical aspects - Evaluation of the overall questionnaire
Information manager	Adding questions on: - Time commitment - Intelligence of the application - Existing or new software - Storage and processing of patient data - Software integration - Effort required to operate the software
AI team	- Evaluation of the overall questionnaire Adding questions on: - Medical device - Costs - Sustainability
ICT adviser	- Rephrasing of questions - Assessing the relevance of questions on technical aspects - Adding questions on costs
CMIO	- Evaluation of the overall questionnaire - Adding questions on collaboration with other hospitals

3.2. Testing of Decision-Making Strategy: Case Study

This section outlines the results identifying who or what source was responsible for providing the necessary information as requested in the decision-making strategy. The information is presented according to the format established in the decision-making strategy. The results of the decision-making strategy used for the case study (i.e., the information on the questions) is presented in Appendix B and contains the necessary information on the Stroke module of Aidoc. Throughout the project, many people were involved in providing the information, which was one of the reasons that the project was time-consuming. Another reason was that it was often unclear who was supposed to be responsible for providing the information. Therefore, part of the project time was spent determining the necessary information sources and identifying the responsible individuals. For each topic, a brief summary table is provided of the information source used and the person responsible for gathering the information. An explanation and details of the process regarding data and/or information collection is provided for each subtopic. Overall, the interventional radiologist (IR), ICT adviser, ICT architect and the author provided and gathered the most information needed.

Header 1. General information

General information (names of initiators of the project, name of the department, stakeholders of the project, name of the AI application, name of the vendor) was provided by the initiators. The initiators were an interventional radiologist, a clinical physicist and the author. The interventional radiologist contributed expertise knowledge in stroke and healthcare processes, while the clinical physicist provided experience from regular involvement in similar projects and healthcare processes. The author's role was specifically associated with conducting a graduation research project. Hence, these are the persons who were responsible for this project.

Header 2. Application and Effectiveness

Table 3.4: Summary of information sources used and the responsible persons for gathering the information regarding the topic Application and effectiveness of the decision-making strategy.

Information source	Information gathered by
- Aidoc's website[31]	- Author
- Additional information from Aidoc itself	- IR
- Expert knowledge of IRs	
- FDA 510(k) premarket notifications documents[24] [25]	
- Internal clinical protocols	
- Published clinical research studies	
- www.HealthAIregister.com[32][33]	

Purpose AI Application
Information on, among others, the function, the purpose and the intended use of the AI application was mainly collected through the analysis of 510(k) premarket notifications documents on the website of the U.S. Food and Drug Administration (FDA) and Aidoc's own website. "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device" [34]. The FDA is a part of the Department of Health and Human Services and regulates certain products to ensure the safety and effectiveness of those products [35]. Information was acquired by the IR and the author.

Clinical applicability
Regarding the clinical applicability of the application, information was mainly requested on the healthcare process within NWZ and the benefits of the AI application. NWZ consists of two locations that a patient with suspected CVA can visit (location Alkmaar and Den Helder). Furthermore, if a patient at location Den Helder is considered a candidate for intra-arterial thrombectomy (IAT) treatment, the patient must be transferred to location Alkmaar, as IAT treatment is exclusively provided there. IAT is the standard treatment for patients with a cerebral infarction due to a large vessel occlusion, during which doctors use a special tool to remove the blockage [36]. As a consequence, the healthcare process in NWZ regarding a suspected CVA patient is complex. Therefore, to provide a clear and concise overview of this process, it was beneficial to outline the process within a flowchart. The flowchart is presented in Appendix B of the decision-making strategy used in the case study, where it is listed in Appendix I. Additionally, in this way, the bottlenecks could be identified and illustrated. Outlining the process in a flowchart was done by using internal documents and through expert knowledge of two interventional radiologists. These internal documents were clinical protocols related to the diagnostics of CT scans regarding a suspected CVA patient who may be eligible for intravenous thrombolysis (IVT) and/or IAT treatment. IVT is a treatment using a powerful blood thinner that dissolves the blood clot, administered through an intravenous infusion [37]. The clinical protocols describe, for example, which actions are to be performed and with whom to communicate. The IRs explained provided more details on these actions and the communication process, and, in addition, offered information about the bottlenecks. In the flowchart, the process of inpatients, outpatients and emergency patients of suspected stroke can be seen, thereby presenting the steps necessary to diagnose the patient with suspected CVA. Information on the benefits of the AI application was gathered through a review of the FDAs 510(k) pre-market notification documents, Aidoc's website, and insights provided by the IR. The IR and the author provided all the requested information.

Time commitment
Information on time commitment of the Radiology department for possible implementation (regarding which persons have time and the amount of time) was provided by the IR, since the IR is the contact person of the Radiology department.

Ethical aspect
As the IR will be one of the end-users, if the application is implemented, the IR explained how disagreements between the AI application and the end-user would be managed and how the end-user would conduct an audit.

Performance AI application

Regarding the performance of an AI application, the main focus in the decision-making strategy was on the performance of certain metrics, prove of effectiveness of the AI application and setting minimal performance limits of the AI application.

For evaluating the performance of an alternative diagnostic test compared to the gold standard, the performance metrics sensitivity and specificity are the most frequently used. In this case, the alternative diagnostic test is the Stroke module and the gold standard is the medical specialist. Furthermore, time-to-notification is a process metric specifically for this AI application, since time is an important factor within the process of a suspected CVA patient. Therefore, data on the performance metrics and process metric (sensitivity, specificity, time-to-notification) was extracted from the FDA's 510(k) premarket notifications documents. Sensitivity "measures the proportion of subjects with an actual positive outcome . . . who are correctly given a positive assignment" [38]. On the other hand, specificity "measures the proportion of subjects with an actual negative outcome . . . who are correctly given a negative assignment" [38]. Time-to-notification is the time to retrieve the medical imaging exam, de-identify it, upload it to the cloud, analyse the exam and, when needed, send a notification if a suspected positive case is detected back to the desktop application [24][25]. Data gathering was done by the author.

To gather evidence of the effectiveness of the AI application, all published clinical studies that used one of the two algorithms (ICH and vessel occlusion (VO)) of Aidoc were analysed. First, Aidoc's website was consulted for published clinical studies. However, for the VO algorithm only two clinical studies were published on Aidoc's website. One of these studies was a published study which didn't contain relevant data (i.e., not related to performance or process metrics), the other study was not a published study but rather an abstract which was unavailable. Therefore, none of these clinical studies provided on Aidoc's website could be used as evidence. For the ICH algorithm, several of the clinical studies on Aidoc's website were also not published works but rather abstracts, therefore lacking relevant data. Furthermore, several published studies did not provide any data on performance or process metrics. This resulted in a total of 8 published studies with relevant data. Moreover, a PRISMA analysis was performed to find additional published studies that used one of the two algorithms of Aidoc. Studies already provided by Aidoc's website were excluded. For the VO algorithm, no published studies were found. For the ICH algorithm, the analysis resulted in 4 additional published studies with relevant data. A total of 12 studies were analysed and data on performance metrics and process metrics were structured into two tables (see Appendix B Table 1 and Table 2). Data collection was performed by the author.

Establishing the minimal values and/or limits that at least have to be achieved by the AI application, have to be determined by the IR or another medical specialist involved within the stroke process, since they will be the end-users and are experts in the field. However, no final conclusion has yet been reached on establishing a minimum value or limit.

Adaptability of AI application

Information on the intelligence of the application and the adaptability of the application to local data could not be retrieved from previously used documents or Aidoc's website. Therefore, this information was requested from the vendor itself and this was provided to the author, who retrieved the information.

Market research

Information was gathered by the IR on the existence of other potential AI vendors with similar AI applications. However, it has yet to be determined whether this potential vendor is also being considered and who is responsible for providing this information. Moreover, user experience with previous AI applications in the Radiology department was also collected. This information was provided by two IR's. Furthermore, it remains to be determined who is responsible for providing information on whether AI is the appropriate solution, or if simpler alternatives might be viable.

Level of innovation

To assess the level of innovation, information was required on whether the AI application qualifies as a medical device, whether it is CE-marked and whether it is intended for use in research or within healthcare. This information was retrieved from FDA's 510(k) premarket notifications documents and from www.HealthAIregister.com. This website offers an overview of AI-powered software options for use in clinical radiology. Retrieving of the information was done by the author.

Header 3. Technical Aspects

Table 3.5: Summary of information sources used and the responsible persons for gathering the information regarding the topic Technical aspects of the decision-making strategy.

Information source	Information gathered by
- Additional information from Aidoc itself	- Author
- Expert knowledge of IRs	- ICT adviser
- FDA 510(k) premarket notifications documents[24] [25]	- ICT architect
- Expert knowledge of ICT adviser	- IR
- Expert knowledge of ICT architect	

Usability of AI application
To provide insight in the usability of the application, information was needed to determine whether the interaction with the application was manual or automatic. The FDA's 510(k) premarket notifications documents provided this information and this was gathered by the author.

Technical integration
The ICT adviser and architect contributed details regarding the potential integration of the application within the hospital's ICT architecture. This included information on whether the hospital has the necessary ICT architecture and infrastructure and whether the AI application is new or existing software within the hospital. Both the ICT adviser and architect provided this information through expert knowledge and reviewing the FDA's 510(k) premarket notifications documents. Nevertheless, information from the FDA's 510(k) premarket notifications documents were found to be limited and provided not all answers. Therefore, additional information was requested from the vendor itself and this information was used to provide more details.

Data storage
Regarding data storage for the AI application, the query primarily focused on how and where data, including patient data, is stored and processed, as well as whether any adjustments are needed to ensure secure storage. The FDA's 510(k) premarket notifications documents did not contain enough information for the ICT adviser and architect. As a result, further information was requested directly from the vendor, who subsequently provided it. Hereafter, the ICT adviser and architect could provide the necessary information. However, additional details regarding Aidoc's mobile application are still needed and should be requested directly from Aidoc. Moreover, information on whether a data processing agreement was needed, was provided by the ICT adviser.

Software connection
The FDA's 510(k) premarket notifications documents were reviewed by the ICT adviser and architect for information whether software connections and/or additional software are needed to run the AI application. However, these documents lacked sufficient information for the ICT adviser and architect, prompting a direct request to the vendor for additional details. This new information provided further answers; however, additional details about Aidoc's mobile application are still required.

External integration
Information on whether the AI application was already being used by other healthcare institutions was first provided by the IR, through network connections. In addition, the vendor was approached to inquire whether other healthcare facilities are already using the stroke module and whether the application will be immediately applicable in the new clinical setting. This proceeded through communication with the vendor and author. Moreover, the ICT adviser made an estimation on what the required effort will be to run the software.

Header 4. Costs

Table 3.6: Summary of information sources used and the responsible persons for gathering the information regarding the topic Costs of the decision-making strategy.

Information source	Information gathered by
- Additional information from Aidoc itself	- Author
- FDA 510(k) premarket notifications documents [24] [25]	- IR
- Expert knowledge of ICT adviser	
- Expert knowledge of ICT architect	
- Expert knowledge of IR	
- Procurement	

Purchase AI application
Procurement of NWZ had contact with the vendor to gather information on the purchasing costs and to discuss the possibilities regarding the costs, such as a reduction. This information was communicated to the IR and therefore the IR could provide this information. The ICT adviser and architect provided the information on the costs of additional hardware.

Licence AI application
For licence costs of the application, the same applies: procurement of NWZ contacted the vendor and thereafter communicated the information to the IR. The ICT adviser and architect provided the information on the costs of additional hardware.

Other costs
Regarding the other costs, information on management costs of ICT and integration costs was requested from the ICT adviser and ICT finance. However, information on this still has to be received. For information on the costs of this project, i.e. project staff deployment, and costs on training/education, it is yet to be discussed where this information could be obtained from or who could provide it.

Header 5. Benefits

Table 3.7: Summary of information sources used and the responsible persons for gathering the information regarding the topic Benefits of the decision-making strategy.

Information source	Information gathered by
- IR	- IR

Savings
How the provision of information on this issue will be addressed remains to be discussed.

Benefits
Explanation of the benefits of the AI application was provided by the IR.

Header 6. Sustainability

Table 3.8: Summary of information sources used and the responsible persons for gathering the information regarding the topic Sustainability of the decision-making strategy.

Information source	Information gathered by
- Additional information from Aidoc itself	- Author
- Expert knowledge of sustainability programme manager	

Energy
No information was found regarding the sustainability of energy on Aidoc's website. Therefore a query was made to the vendor regarding what type of energy is being consumed, which was provided. The sustainability programme manager briefly reviewed this information and recommended involving the procurement team to assess it further. This also applies to information on the consequences of energy consumption for NWZ for using this AI application. This information has yet to be discussed with procurement.

Vendor
To gain insight into the sustainability of the vendor itself and the working/labour conditions of the employees of the company, Aidoc was contacted to gather this information, which they provided. For this subtopic the sustainability programme manager also briefly reviewed this information and recommended involving the procurement team to assess it further. This also applies to information on whether NWZ agrees with the sustainability and conditions. This information has yet to be discussed with procurement.

Header 7. Internal Validation

Table 3.9: Summary of information sources used and the responsible persons for gathering the information regarding the topic Internal validation of the decision-making strategy.

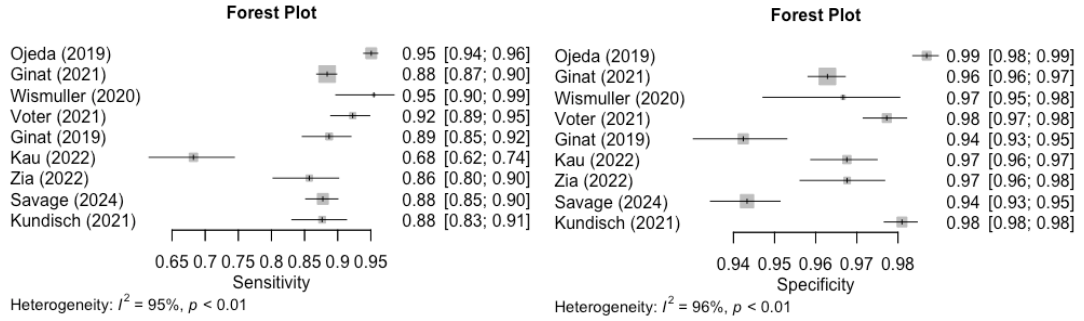
Information source	Information gathered by
- Published clinical research studies	- Author
- RStudio (version AGPL v3)	
- CTCue (version v4.11.1)	

Performance own data
To locally validate the performance of the AI application on data of NWZ and to determine whether this performance is sufficient enough, the application should be implemented. However, without starting an actual pilot period, this was not possible according to the vendor.

Performance metrics
Therefore, to obtain a form of local validation for performance metrics, a request was made to send the vendor a small dataset of pseudonymised, CT/CTA head images, enabling the vendor to run the AI application on the dataset. However, this was not possible according to the vendor.

Hence, to still obtain an initial impression of the potential performance metrics, a meta-analysis was conducted with published studies using algorithms of the Stroke module. As mentioned above, only published studies using the ICH algorithm were available. Study characteristics of the included studies is presented in Table 2 in the completed decision-making strategy for the case study (Appendix B). The meta-analysis was performed by using the statistical programme RStudio. To examine the heterogeneity of the included studies, a graphical presentation of the distributions of sensitivity and specificity from the included studies was displayed in a forest plot (Figure 3.1). Figure 3.1a shows a forest plot for sensitivity and figure 3.1b shows a forest plot for specificity. The grey box represents the point estimate of the sensitivity or specificity, and it illustrates the size of the study. A larger box indicates a greater number of participants in the study. The horizontal line represents the 95% confidence intervals of the included studies, where each end marks the limits of the confidence interval. As can be seen from the forest plots and the statistical measurements ($p<0.01$ for both sensitivity and specificity, and I^2 is 95% and 96% for sensitivity and specificity, respectively), heterogeneity exists [39]. A threshold effect was assumed to be absent, as all included studies used the same AI application

to classify cases as either positive or negative, meaning a consistent threshold was applied across all studies. Therefore, it was chosen to perform a Bivariate random effects model analysis to get the pooled estimate of sensitivity and specificity [40]. These results are presented in Table 3 in the completed decision-making strategy for the case study (Appendix B. The meta-analysis was performed by the author.



(a) Sensitivity

(b) Specificity

Figure 3.1: Forest plots of included studies for the ICH algorithm.

Process metrics

Additionally, to gain an impression of the potential process metrics, particularly the time savings in the process, it was decided to collect relevant data on key time points in the process for suspected CVA patients within the hospital. This data could then be analysed and used to compare with the process metrics from published studies, providing an estimate of how the AI application might perform in the NWZ setting. Moreover, the data could offer an overview of the number of suspected CVA patients at NWZ and how many received treatment. The data extraction of suspected CVA patients was performed by using CTcue (version v4.11.1). This is a medical search platform designed to help healthcare professionals retrieve relevant patient data from electronic health records. After retrieving the data, calculating the key time points and data analysis were performed using Microsoft Excel (version 16.89.1). These results are presented in Table 4 in Appendix B. The calculations and analysis of the process metrics was executed by the author. It is yet to be determined by the IR whether these results may be sufficient enough.

User-acceptance test

For the testing of the decision-making strategy, the testing of user-acceptance was not possible, since the AI application could not be tested by end-users.

3.3. Evaluation of Developed Decision-Making Strategy

The decision-making strategy was evaluated by the clinical physicist and three members of the AI team. The results of the evaluation on whether the decision-making strategy included sufficient information on certain (sub)topics, and the time commitment required to provide information for the decision-making strategy are presented in Figure 3.2. Findings regarding which (sub)topics lacked specific information and which (sub)topics were unclear or difficult to understand are presented in Figure C.1 in Appendix C.

As can be seen in the results (Subfigure A), all the respondents generally agreed that the decision-making strategy provided sufficient information about the application and effectiveness of the AI application. However, one respondent indicated a need for further details on the ICT components, while another suggested placing more emphasis on a time-efficient plan to ensure the department's optimal use of the application, particularly concerning time commitment.

On the contrary, the responses were diverged regarding the question whether the technical aspects of the AI application contained insufficient information (Subfigure B), where the respondents either agreed or disagreed. One of the respondents noted the need for more detailed information on technical integration and data storage, emphasizing the importance of involving the ICT department's expertise to address these aspects.

For the question regarding the costs of the AI application (Subfigure C), the majority of respondents agreed that sufficient information was provided. Nonetheless, one respondent suggested that it might be

useful to specify, within this topic, the types of staff or functions required other than the initiators, and their estimated hours needed for the process.

Most of the respondents agreed that the decision-making strategy included adequate details regarding the benefits of an AI application, with one respondent being neutral (Subfigure D). An additional comment on this subtopic was that the benefits should be written in one's own words, rather than simply copying text from sources such as the vendor's website.

All but one respondent felt that the decision-making strategy included sufficient information on sustainability aspects (Subfigure E). The remaining respondent was neutral, noting that further input from the sustainability programme manager is still needed.

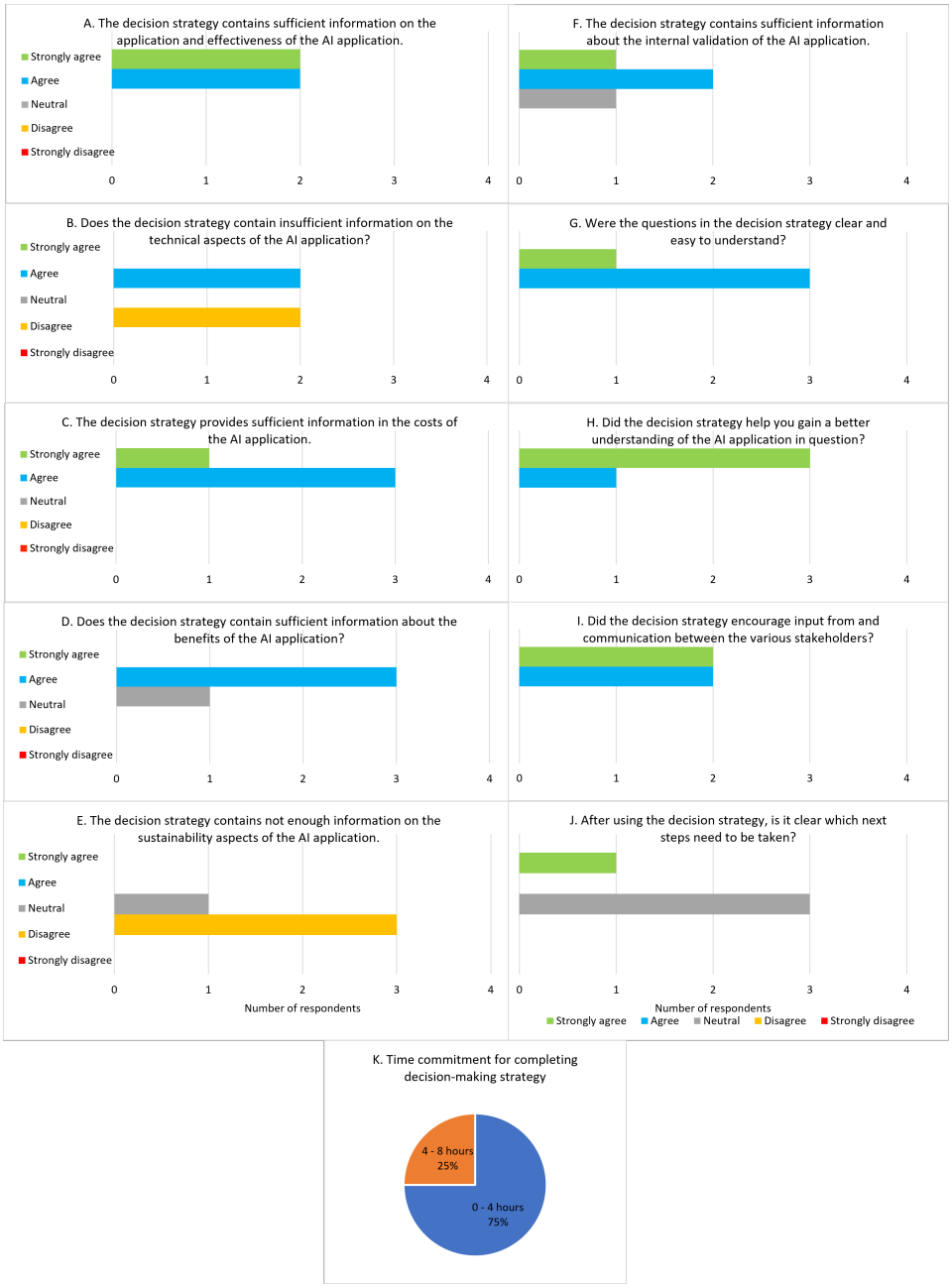


Figure 3.2: Evaluation results of respondents' ratings on the sufficiency of information provided in various aspects of the AI application decision-making strategy.

The results regarding whether the topic of internal validation provided sufficient information are more mixed, with responses ranging from strongly agree to neutral (Subfigure F). One respondent commented that

the decision-making strategy appears complete but suggested that it may still need to address the subtopic of the retraining of the AI application over time. Another respondent noted the shortage of a clear method or standard measure for internal validation.

Furthermore, all respondents agreed that the questions in the decision-making strategy were clear and easy to understand (Subfigure G). In addition, the decision-making strategy was found to improve understanding of the AI application among all respondents, as they collectively acknowledged this benefit (Subfigure H). Respondents also mutually agreed that using the decision-making strategy encouraged the input from and communication between various stakeholders (Subfigure I).

Nevertheless, even after using the decision-making strategy, it remained unclear to the majority of respondents which steps needed to be taken, as most expressed a neutral stance (Subfigure J). One respondent noted, however, that the subsequent steps to be taken after using the decision-making strategy will be outlined in a separate document. In the respondent's view, it is therefore unnecessary to include these steps within the decision-making strategy itself. Another suggestion was that the next step should involve trying to make the decision-making strategy even more user-friendly to complete. Furthermore, another comment was made with suggestions which subsequent steps could be taken after the use of the decision-making strategy.

Lastly, with regard to the time commitment from respondents for using the decision-making strategy, the majority dedicated between 0 to 4 hours.

4
Discussion

This section will discuss the process of the decision-making strategy, consisting of the development, testing by using a case study and the evaluation. Furthermore, the limitations of the study will be addressed and future research will be recommended.

4.1. Process of the Decision-Making Strategy

To achieve the finalised decision-making strategy, the iterative process ensured that stakeholders provided substantial input, as illustrated in Table 3.3. The stakeholders who provided input during this process are typically involved in implementing AI applications within the hospital. Therefore, their insights were highly valuable, as they identified bottlenecks they frequently encounter. They also suggested ways the decision-making strategy could address these challenges in advance. These suggestions were included into the decision-making strategy, with the expectation that they will help avoid these bottlenecks in the future and ensure a more streamlined process for deciding whether an AI application should be implemented.

Identifying the most relevant (sub)topics at the preliminary stage of evaluating an AI application can be challenging. This is because the decision-making strategy needs to remain straightforward and user-friendly, avoiding excessive complexity or the depth of a full business case. Such complexity would require substantial time and resources and could potentially demotivate initiators from using the decision-making strategy. Therefore, the decision-making strategy is designed to be both manageable and focused, ensuring it remains practical and directly applicable in real-world settings. Besides that, most guidance documents, such as Stappenplan HAI and other literature ([12], [13][14]), are often considerably lengthy documents and therefore less practical and appealing to use from the outset. However, the developed decision-making strategy only comprises a concise two and a half pages and is clear and easy to understand, as evidenced by the results of the evaluation (Figure 3.2, Subfigure G).

Furthermore, as Table 3.2 shows, Stappenplan HAI didn't include several (sub)topics from their corresponding literature, mostly regarding ICT and technical aspects. Nevertheless, this decision-making strategy did incorporate those (sub)topics, since the ICT adviser and information manager confirmed the importance of including these (sub)topics. In addition, they both contributed a great amount of input in providing additional (sub)topics for the decision-making strategy (see Table 3.3). This also shows that Stappenplan HAI lacks of sufficient ICT and/or technical aspects related (sub)topics. By including these (sub)topics, ICT components are considered from the outset, ensuring the department's involvement from the beginning. Thus, the required commitment from the ICT department is clearly defined in advance, which is beneficial given that ICT department is often in high demand, potentially causing bottlenecks in the process. As a result, potential challenges can be identified earlier, and opportunities can be explored more promptly, enabling a well-informed decision on potential implementation. Moreover, the case study (see Results section 3.2) confirmed the crucial role of ICT in the planning and preparation stages in order to make a suitable decision. This is in line with several studies ([5][10][11][16]) that underline the necessity of ICT and technical factors as key evaluation components to guide decision-making for AI deployment.

However, while the decision-making strategy is tested with a case study, the AI application itself is not implemented, whether successfully or not. Therefore, it is not possible to determine whether the decision-making strategy is complete or if its use has been successful. Besides, the results showed that the subsequent

steps to be taken after using the decision-making strategy were not entirely clear for the respondents. Exposing issues and identifying required information may not be sufficient, therefore the decision-making strategy still requires action.

The decision-making strategy provides overall insight into the process regarding an AI application. It ensures a better understanding of the AI application itself and it encourages input from and communication between various stakeholders, both demonstrated by the results. Furthermore, the decision-making strategy helps to identify potential bottlenecks and clarifies the time and resources required to reach a suitable decision and support potential implementation. This was especially seen in the case study, where the clinical physicist and the author collaborated with the interventional radiologist to take on the role as initiator of this specific AI application project. However, it is important to consider that, under normal circumstances (i.e., in which the clinical physicist and the author are not co-initiators), other individuals would need to allocate time and resources to take on that contribution and complete this information-gathering process. Therefore, this insight into available capacity and necessary support by using the decision-making strategy provides a solid foundation for making well-informed decisions.

4.2. Limitations and Future Research

The decision-making strategy does not establish a prioritisation of the questions and information essential for making a well-substantiated decision. This makes it challenging to clearly and consistently explain why certain applications may be suitable for implementation in the hospital, while others may not be. Therefore, future research should convert the decision-making strategy into a decision-making matrix, allowing for prioritising.

Furthermore, the questions within the decision-making strategy currently focuses primarily on medical AI applications and commercially available applications. Future research could broaden its scope to encompass a wider range of AI applications, such as those related to logistics, to create a more versatile tool applicable across various domains. Moreover, an increasing number of hospitals are starting to develop their own AI applications, and therefore, future research could also include self-developed AI applications into the decision-making strategy.

In addition, the developed decision-making strategy was tested using only a single case study within the Radiology department. Future research should aim to test the strategy with multiple case studies, ideally involving other departments, to ensure a more diverse and comprehensive evaluation. Besides, this will allow for a comparison of the case studies in their decision-making processes and help identify the subsequent steps that need to be taken after using the strategy. In addition, the AI application used in the case study is not yet ready for a decision on its implementation. Once an AI application is implemented – whether successfully or not – it will be possible to evaluate the effectiveness of the decision-making strategy. This could be determined through retrospective research.

Lastly, the decision-making strategy was not reviewed by a privacy expert to identify information that might require special attention in relation to privacy. Furthermore, the sustainability programme manager advised to include procurement to review information related to sustainability. Future research should involve a privacy expert and procurement. Their expertise would help ensure that relevant considerations are addressed and that no essential information related to privacy and sustainability aspects is overlooked.

5 Conclusion

The aim of this study was to develop a suitable decision-making strategy for hospitals to decide whether AI applications should be implemented, as well as to test and evaluate the strategy. This study highlighted the usefulness of the iterative process to develop a decision-making strategy that is both efficient and practical applicable. Moreover, by testing the strategy through a case study, the strategy helped to identify potential bottlenecks and clarified the time and resources required to reach a suitable decision and support potential implementation. The contribution of ICT in developing the strategy and providing the required information on ICT components and technical aspects was of great importance. This emphasises the need for ICT as a key evaluation factor to guide decision-making for AI deployment. Overall, the decision-making strategy provides insight into the process regarding an AI application, while the strategy itself remains both manageable and focused. This allows medical professionals to properly evaluate AI applications before potential implementation in the future. Furthermore, despite the numerous new AI applications being commercially offered to hospitals, the decision-making strategy helps them in making a suitable decision on the usefulness and necessity of these AI applications. This, in turn, facilitates the efficient use of AI applications, reduces the burden on healthcare, and enhances the quality of patient care.

Bibliography

[1] Omar Ali, Wiem Abdelbaki, Anup Shrestha, Ersin Elbasi, Mohammad Abdallah Ali Alryalat, and Yogesh K Dwivedi. A systematic literature review of artificial intelligence in the healthcare sector: Benefits, challenges, methodologies, and functionalities. Journal of Innovation Knowledge, 8(1):100333, 2023. ISSN 2444-569X.

[2] Nederlandse AI Coalitie. Wat houdt ai in? https://nlaic.com/faq/.

[3] Hadi Salehi and Rigoberto Burgueño. Emerging artificial intelligence methods in structural engineering. Engineering structures, 171:170–189, 2018.

[4] V. M. Pashkov, A. O. Harkusha, and Y. O. Harkusha. Artificial intelligence in medical practice: regulative issues and perspectives. Wiadomosci lekarskie (Warsaw, Poland : 1960), 73(12 cz 2):2722–2727, 2020. doi: 10.36740/wlek202012204. URL https://www.scopus.com/inward/record.uri?eid=2-s2.0-85102218296&doi=10.36740%2fwlek202012204&partnerID=40&md5=01d0e400158c7cade031f3a138532245.

[5] R Beckers, Z Kwade, and F Zanca. The eu medical device regulation: Implications for artificial intelligence-based medical device software in medical physics. Physica Medica, 83:1–8, 2021. ISSN 1120-1797.

[6] Adam Bohr and Kaveh Memarzadeh. The rise of artificial intelligence in healthcare applications, pages 25–60. Elsevier, 2020.

[7] Kavitha Palaniappan, Elaine Yan Ting Lin, and Silke Vogel. Global regulatory frameworks for the use of artificial intelligence (ai) in the healthcare services sector. In Healthcare, volume 12, page 562. MDPI, 2024.

[8] Guoguang Rong, Arnaldo Mendez, Elie Bou Assi, Bo Zhao, and Mohamad Sawan. Artificial intelligence in healthcare: review and prediction case studies. Engineering, 6(3):291–301, 2020. ISSN 2095-8099.

[9] Jianxing He, Sally L Baxter, Jie Xu, Jiming Xu, Xingtao Zhou, and Kang Zhang. The practical implementation of artificial intelligence technologies in medicine. Nature medicine, 25(1):30–36, 2019.

[10] Karim Lekadir, Gianluca Quaglio, A Tselioudis Garmendia, and Catherine Gallin. Artificial intelligence in healthcare applications, risks, and ethical and societal impacts. European Parliament, 2022.

[11] Christopher J Kelly, Alan Karthikesalingam, Mustafa Suleyman, Greg Corrado, and Dominic King. Key challenges for delivering clinical impact with artificial intelligence. BMC medicine, 17:1–9, 2019.

[12] M. Van Smeden, L. Hooft, N. H. Chavannes, H. J. van Os, and I. Kant. Leidraad voor kwalitatieve diagnostische en prognostische toepassingen van AI in de zorg. Unknown Publisher, 2023. URL https://doi.org/10.17605/OSF.IO/TNRJZ. DOI: 10.17605/OSF.IO/TNRJZ.

[13] Unknown Author. MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 MDR and Regulation (EU) 2017/746 IVDR. Medical Device Coordination Group (MDCG), 2019. URL https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf.

[14] Unknown Author. Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations. International Medical Device Regulators Forum (IMDRF), 2014. URL https://www.imdrf.org/documents/software-medical-device-possible-framework-risk-categorization-and-corresponding-considerations

[15] Henk Hutink, Thomas Dolman, Laura Weijenberg, and Leone Flikweert. Rapport Op weg naar een health data infrastructuur en afsprakenstelsel. Nederlandse AI Coalitie, 2020. URL https://nlaic.com/download/rapport-op-weg-naar-een-health-data-infrastructuur-en-afsprakenstelsel-2/.

[16] Sandeep Reddy, Wendy Rogers, Ville-Petteri Makinen, Enrico Coiera, Pieta Brown, Markus Wenzel, Eva Weicken, Saba Ansari, Piyush Mathur, Aaron Casey, et al. Evaluation framework to guide implementation of ai systems into healthcare settings. BMJ health & care informatics, 28(1), 2021.

[17] Sade Faneyte. Stappenplan Healthy AI (HAI). Nederlandse Vereniging voor Klinische Informatica, 2022. URL https://www.nvki.nl/community/threads/stappenplan-healthy-ai.471/.

[18] Radiological Society of North America (RSNA) and American College of Radiology (ACR). Body ct. https://www.radiologyinfo.org/en/info/bodyct,.

[19] Radiological Society of North America (RSNA) and American College of Radiology (ACR). CT Angiography (CTA). https://www.radiologyinfo.org/en/info/angioct#:~:text=Computed%20tomography%20angiography%20(CTA)%20uses,or%20an%20outpatient%20imaging%20center.,.

[20] VZinfo RIVM. Beroerte | Oorzaken en gevolgen. https://www.vzinfo.nl/beroerte/oorzaken-en-gevolgen.

[21] UMC Utrecht. Beroerte (CVA) - UMC Utrecht. https://www.umcutrecht.nl/nl/ziekte/beroerte-cva.

[22] Mayo Clinic. Subarachnoid hemorrhage - Symptoms and causes. https://www.mayoclinic.org/diseases-conditions/subarachnoid-hemorrhage/symptoms-causes/syc-20361009, 2022.

[23] Jeffrey L Saver. Time is brainquantified. Stroke, 37(1):263–266, 2006.

[24] U.S. Food and Drug Administration. 510(k) Premarket Notification Radiological Computer-Assisted Triage And Notification Software. Technical Report K203508, U.S. Food and Drug Administration, 2020. URL https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203508.pdf.

[25] U.S. Food and Drug Administration. 510(k) Premarket Notification Radiological Computer-Assisted Triage And Notification Software. Technical Report K220709, U.S. Food and Drug Administration, 2022. URL https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220709.pdf.

[26] Janice Rattray and Martyn C Jones. Essential elements of questionnaire design and development. Journal of clinical nursing, 16(2):234–243, 2007.

[27] Patrick Omoumi, Alexis Ducarouge, Antoine Tournier, Hugh Harvey, Charles E Kahn, Fanny Louvet-de Verchère, Daniel Pinto Dos Santos, Tobias Kober, and Jonas Richiardi. To buy or not to buyevaluating commercial ai solutions in radiology (the eclair guidelines). European radiology, 31:3786–3796, 2021.

[28] Ian Scott, Stacey Carter, and Enrico Coiera. Clinician checklist for assessing suitability of machine learning applications in healthcare. BMJ Health and Care Informatics, 28(1):1–8, 2021.

[29] Leidraad NIKP (Nieuwe Interventies in de Klinische Praktijk) — zorginstituutnederland.nl. https://www.zorginstituutnederland.nl/publicaties/publicatie/2014/10/15/leidraad-nikp-nieuwe-interventies-in-de-klinische-praktijk.

[30] Toolkaart Waardevolle AI voor gezondheid — nlaic.com. https://nlaic.com/wp-content/uploads/2022/06/04a.-Hulpmiddel-Handelingsruimte-Waardevolle-AI-voor-gezondheid-en-zorg.pdf.

[31] Aidoc | Clinical AI Company | Rapid Responses, Smarter Care — aidoc.com. https://www.aidoc.com/eu/.

[32] Ischemic Stroke, Aidoc — radiology.healthairegister.com. https://radiology.healthairegister.com/products/aidoc-lvo/,.

[33] Intracranial Hemorrhage (ICH), Aidoc — radiology.healthairegister.com. https://radiology.healthairegister.com/products/aidoc-ich/, .

[34] Premarket Notification 510(k) — fda.gov. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k, .

[35] About FDA — fda.gov. https://www.fda.gov/about-fda, .

[36] Amsterdam UMC, locatie AMC. Opzet studie - ai-stroke studie, 2024. URL https://www.amc.nl/web/research/trials-collaborations/ai-stroke-studie-1/ai-stroke-studie/opzet-studie-1.htm.

[37] St. Antonius Ziekenhuis. Behandeling herseninfarct, 2024. URL https://www.antoniusziekenhuis.nl/beroerte-cva/behandeling-beroerte/behandeling-herseninfarct.

[38] Thomas F Monaghan, Syed N Rahman, Christina W Agudelo, Alan J Wein, Jason M Lazar, Karel Everaert, and Roger R Dmochowski. Foundational statistical principles in medical research: sensitivity, specificity, positive predictive value, and negative predictive value. Medicina, 57(5):503, 2021.

[39] Jacqueline Chandler, Miranda Cumpston, Tianjing Li, Matthew J Page, and VJHW Welch. Cochrane handbook for systematic reviews of interventions. Hoboken: Wiley, 2019.

[40] EUnetHTA Guideline. Meta-analysis of diagnostic test accuracy studies. European Network for Health Technology Assessment, 2014.

A

Appendix
Developed Decision-Making Strategy

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

1. General information	Registration number: ...
Initiator(s)	*Hester Scheffer, Annetje Guédon, Sophie Sturkenboom*
Team/Department	*Radiology*
Stakeholders	*SEH, Neuro*
AI application	*Stroke module (consisting of ICH & VO algorithm)*
Vendor	*Aidoc* *Eleonore Parsley*
mProve	*Is the AI application already known within mProve?* Yes *: Is it the intention to carry out a joint and/or independent pilot?* Still to be discussed

To complete the form, please contact the AI team. The initiator can already provide block 2 with information (with the exception of 'Market research' and 'Adaptability').

2. Application and Effectiveness		
Purpose AI application	*What is the function?* *What is the purpose?* *What is the intended use?* *What information does the AI application offer that was previously unavailable?* *Is the AI application used in patient care?*	
Clinical applicability	*Is there a clear picture of the current care process and its bottlenecks?* *Where in the clinical process is the AI application applied?* *Does this fit within the intended use of the supplier?* *What does the AI application improve?* *Who does this apply to (patients, caregivers, hospital)?* *Who can access the new information?* *How many employees will use the application?*	
Time commitment	*Who will be deployed from your department for this project/implementation of the AI application?* *How many hours per week can you dedicate to the implementation of the AI application?*	
Ethical aspect	*If the AI application gives a result that the end user does not agree with, how will this be resolved?* *Is a check on the AI application carried out from the end users? If so, how?*	
Performance AI application	*How well does the AI application perform according to the vendor?* *What kind of patient data is the AI application developed on and is it representative of the hospital?* *What evidence is there that shows the effectiveness of the application?* *Has thought been given to which value/limit is good enough so that the application can be used optimally clinically?* *Does it still need to be validated within NWZ?*	
Adaptability	*Will the application become more intelligent?* *Does the application adapt to the local data over time or through updates?*	
Market research	*Are there any potential other vendors that offer a similar AI application?* *Are these being considered?* *What are the experiences of end users with previously used AI applications?* *Is AI the best solution to this problem, or is a simpler solution possible?*	
Level of innovation	*Medical device?*	Yes/No
	CE-markering?	Yes/No
	Is it used in science or healthcare?	Yes/No

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

3. Technical aspects	
User-friendliness	*Is manual interaction necessary, or automatic running in the background?*
Technical integration	*Does the desired AI application fit within the ICT architecture?* *Does the hospital have the necessary ICT architecture and infrastructure?* *Is the AI application a plug-in to existing software? Or is it completely new software?*
Data storage	*How is data stored (e.g. Cloud or local server) and do adjustments need to be made?* *Is patient data stored and where is it processed?* *When data is stored in the Cloud: is it inside or outside Europe?* *Is a GDPR data processing agreement required?* *How is the data secured?* *Will our data be used to train the model outside NWZ?*
Software connection	*Which connection/additional software is needed to run the software?*
External Integration	*Is the AI application already being used in other hospitals or healthcare institutions?* *Is the application immediately applicable in new clinical settings?* *(Or the application can be retuned or recalibrated using local data to account for differences in population characteristics, type or reporting format of imaging equipment, or care protocols.)* *What kind of effort do you have to put in to get the software running?*

4. Costs	
Purchase of AI application	*What are the costs for purchasing the AI application/hardware?*
License AI application	*What are the license costs per year for the AI application?*
Other costs?	- *ICT management costs. (Expansion of management capacity may be required)* - *Integration costs* - *Project costs* *(Project deployment of employees)* - *Training/education costs* *(How will the training on the application be provided after implementation?)*

5. Benefits	
Savings	*Does it save costs?*
Benefits	*What are the benefits?*

6. Sustainability	
Energy	*What kind of energy is used (e.g. solar energy)?* *What are the energy consumption implications of NWZ?*
Vendor	*How sustainable is the supplier?* *What are the working conditions of the employees like?*

7. Internal validation	
Performance own dataset	*Is the performance of the AI application locally validated?* *Is performance AI application good enough such that end-users are satisfied?*

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

User Acceptance Test	*Has the integration into the workflow been tested (both technically and clinically)? Have the functionalities of the AI software been tested? Also with extreme or deviating cases?*

6. Final verdict *(to be completed by AI team)*	
Final Verdict	Click or tap to enter text.
Signature	

B

Appendix
Decision-Making Strategy in Case Study

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

1. General information	Registration number: ...
Initiator(s)	*Hester Scheffer, Annetje Guédon, Sophie Sturkenboom*
Team/Department	*Radiology*
Stakeholders	*SEH, Neuro*
AI application	*Stroke module (consisting of ICH & VO algorithm)*
Vendor	*Aidoc* *Eleonore Parsley*
mProve	*Is the AI application already known within mProve?* Yes *: Is it the intention to carry out a joint and/or independent pilot?* Still to be discussed

To complete the form, please contact the AI team. The initiator can already provide block 2 with information (with the exception of 'Market research' and 'Adaptability').

2. Application and Effectiveness	
Purpose AI application	*Function:* Analyse CT and CTA head cervical vessels and immediately notify treatment team (medical specialists) in case of suspected findings of Intracranial Occlusion (ICH), Large Vessel Occlusion (LVO) and Medium Vessel Occlusion (MeVO) for triage by sending pop up notifications. This is done by sending pop-up notifications via both the desktop application and the mobile application. In the case of the desktop application: a compressed preview image can be shown by means of notification and the suspicious case can be opened directly in PACS via the preview image. In the case of the mobile application: images can be viewed in a remote image viewer and direct communication between the entire treatment team is possible via the mobile application. *Purpose:* To make images of patients with a possible LVO or MeVO who may be eligible for IAT available more quickly and direct communication options between practitioners, for the purpose of shortening door-to-needle time. *Intended use algorithms:* The AI ICH algorithm is a triage tool for analysing non-enhanced head CT images to assist in identifying potential ICH. The AI vessel occlusion (VO) algorithm is a triage tool for analysing head CTA images to assist in identifying potential Large Vessel Occlusion (MCA-M1, PCA-P1, ACA-A1, ICA, Basilar) and Medium Vessel Occlusion (MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4). Both algorithms provide notifications for suspected cases for healthcare professionals, presenting them with preview images for informational purposes, allowing them to prioritize cases without altering the standard diagnostic process. While both algorithms aid in prioritizing workflow, it is not intended to replace diagnostic interpretation or alter the original medical images.

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

	What information does the AI application offer that was previously unavailable? The new information offered by the AI application: sending a notification in case of suspicion or a finding; the possibility to view images directly via your phone and have direct contact with the treatment team for the next steps (immediate treatment). *Is the AI application used in patient care?* Yes
Clinical applicability	*Is there a clear picture of the current care process and its bottlenecks?* The current process surrounding a patient with suspected stroke has been mapped out by means of a flowchart (see Appendix I). The red box indicates where the bottlenecks are in the process. This mainly concerns the delay due to communication within the treatment team, in particular the back and forth calls (interventional radiologist on duty, radiology resident, neurology resident and neurologist) and waiting for a call to consult. When IR is on duty during the weekend (Friday evening to Monday morning) the IR is not always located near a PC, which makes viewing images longer and causes delays. In addition, it takes at least 10 minutes to start up the home office to view the images, which leads to further delay in the decision whether or not to start treatment. *Where in the clinical process is the AI application applied?* The application is applied to all CT cerebrum (blank/non-contrast) and CTA head and neck vessels with suspected bleeding (ICH)/LVO and MeVO. This is about 2500 patients per year. *Does this fit within the intended use of the supplier?* Yes. *What does the AI application improve?* The application ensures that in the case of patients with a possible finding, the images are viewed more quickly, regardless of the location of the resident or person on duty (especially during the shifts). Communication between the treatment team is also improved, because it is possible to communicate directly via the communication system with all specialists involved. As a result, patients are treated faster and staff workflow is improved. *Who does this apply to (patients, caregivers, hospital)?* Patients and caregivers. *Who can access the new information?* The new information is accessible to all doctors in the patient's treatment team (Radiology and Neuro). *How many employees will use the application?*
Time commitment	*Who will be deployed from your department for this project/implementation of the AI application?* IR (Hester Scheffer), AI team and a technical physician (starts from the new year). *How many hours per week can you dedicate to the implementation of the AI application?* No fixed number of hours
Ethical aspect	*If the AI application gives a result that the end user does not agree with, how will this be resolved?* The AIOS/(possibly)IR still has to check all images and always gives the final result.

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

	In the event that the application gives a positive result, and this is false positive: Then only an incorrect notification has been sent and the patient does not need to be treated. In the event that the application gives a negative result, and this is a false negative: because AIOS/(possibly)IR always checks the images, just like with any other AI application, there is little chance that he/she will miss the finding. So if a positive finding is found, the patient can be treated if necessary. *Is a check on the AI application carried out from the end users? If so, how?* A check is carried out from the end users, by the resident and (possibly) by IR.
Performance AI application	***ICH algorithm*** Sensitivity = 93.6% Specificity = 92.3% Time-to-notification of application for true positive cases = 4.5 minutes *What kind of patient data is the AI application developed on and is it representative of the hospital?* Blank CT head images with ICH positive. This is representative of the hospital. *What evidence is there that shows the effectiveness of the application?* Tables 1 and 2 show the published studies that have done research with the ICH algorithm. As can be seen in Table 1, the algorithm reduces the length of stay. In addition, the algorithm can also reduce the other process metrics, but these are difficult to measure time points, so the results are different. The question is how representative these results are. Table 2 shows that the algorithm is performing well. Also, some studies have compared the algorithm with the performance of a medical specialist or the performance of a medical specialist who uses the algorithm. These results show that in those cases, performance is better than the algorithm alone.

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

Table 1 Proof effectiveness of process metrics ICH algorithm (Aidoc stroke module). For each 'Metric' it is about the difference between 'before use AI' and 'with use AI', unless otherwise stated. NR: not reported
** Statistically significant*

Metric	Study	Study size (No. of scans)	Patient groups	
LOS	Petry et al. (ref) Mean difference time	NR	ICH+ Decrease of 1.30 days* (11.9%)	ICH- Decrease of 0.46 days* (5.0%)
LOS	Davis et al. (ref) Mean difference time	NR	ICH+ inpatient Decrease of 2.3 days*	ICH- inpatient Decrease of 2.6 days*
LOS	Davis et al. (ref) Mean difference time	Pre-AI: 18,549; Post-AI: 18,325	ICH+ ED Decrease of 36 min	ICH- ED Decrease of 46 min*
Wait time	O'neill et al. (ref) Mean difference time	Pre-AI: 2296; Post-AI: 2546	ICH+ Decrease of 3.74 min*	ICH- Decrease of 0.3 min
Reading time	O'neill et al. (ref) Mean difference time	Pre-AI: 2296; Post-AI: 2546	ICH+ Increase of 1.39 min	ICH- Increase of 0.75 min
Report TAT	Davis et al. (ref) Mean difference time	Pre-AI: 25,658; Post-AI: 24,996	Entire health system Decrease of 5.7 min*	Entire ED Decrease of 4.8 min*
Report TAT	Zia et al. (ref) Mean difference time	Pre-AI: 1628; Post-AI: 1446	ICH+ Increase of 13.3 min*	ICH- Increase of 42.3 min*
Report TAT	Zia et al. (ref) Mean difference time	Pre-AI: 967; Post-AI: 884	ICH+ ED Decrease of 3.7 min	ICH- ED Increase of 9.7 min
Report TAT	Zia et al. (ref) Mean difference time	Pre-AI: 134; Post-AI: 97	ICH+ outpatient Decrease of 9.9 min	ICH- outpatient Increase of 584.6 min
Report TAT	Zia et al. (ref) Mean difference time	Pre-AI: 527; Post-AI: 465	ICH+ inpatient Increase of 22.6 min*	ICH- inpatient Increase of 7.8 min*
Study TAT	Wismuller et al. (ref) Mean difference time between flagged and non-flagged	Flagged: 66; Non-flagged: 56	ICH + Decrease of 59 min*	

Table 2 Proof of effectiveness of performance metrics ICH algorithm (Aidoc stroke module). NR: not reported

Study	Year	Study size (No. of scans)	Sensitivity Aidoc	Sensitivity by		Specificity Aidoc	Specificity by	
Ojeda	2019	7112	95.1%	NR	NR	98.7%	NR	NR
Ginat	2021	8723	88.4%	NR	NR	96.1%	NR	NR
Wismüller	2020	620	95.0%	NR	NR	96.7%	NR	NR
Ginat	2019	3605	88.7%	NR	NR	94.2%	NR	NR
Zia	2022	2011	85.7%	NR	NR	96.8%	NR	NR
Voter	2021	2188	92.3%	98.30%	Neuroradiologist	97.7%	99.90%	Neuroradiologist
Kau	2022	1446	68.2%	94.9% & 95.8%	Resident & Radiologist	96.8%	99.2% & 99.7%	Resident& Radiologist
Savage	2024	3716	87.8%	98.6% & 98.9%	Radiologist & Radiologist with AI	94.3%	99.8% & 99.3%	Radiologist & Radiologist with AI
Kundisch	2021	4946	87.6%	89.10%	RR (radiology report)	98.1%	99.80%	RR (radiology report)

Has thought been given to which value/limit is good enough so that the application can be used optimally clinically?
To be determined...

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

	VO algorithm Sensitivity = 91.3% Specificity = 85.6% Time-to-notification of application for true positive cases = 2.23 minutes *What kind of patient data is the AI application developed on and is it representative of the hospital?* CTA head images with full brain VO. This is representative of the hospital. *What evidence is there that shows the effectiveness of the application?* There are no published studies for this algorithm yet. *Has thought been given to which value/limit is good enough so that the application can be used optimally clinically?* To be determined... *Does it still need to be validated within NWZ?* Application still needs to be validated in its entirety within NWZ.	
Adaptability	*Will the application become more intelligent?* No. Algorithms are regulated and static from the moment they are approved. They don't actively learn from patient data or feedback. *Does the application adapt to the local data over time or through updates?* No. Aidoc does retrain the algorithms (usually once every 18-24 months), which then have to be resubmitted for regulatory approval.	
Market research	*Are there any potential other vendors that offer a similar AI application?* Stroke viewer (NicoLab). *Are these being considered?* To be determined... *What are the experiences of end users with previously used AI applications?* Previously used AI applications performed less well or as well as the radiologist. When performing as well as the radiologist, the question was raised whether the AI application was worth the money. Not everyone used the AI application. *Is AI the best solution to this problem, or is a simpler solution possible?* To be determined...	
Level of innovation	*Medical device?*	Yes
	CE-markering?	Yes, FDA (Class II) and CE (Class I)
	Is it used in science or healthcare?	Healthcare

3. Technical aspects	
User-friendliness	*Is manual interaction necessary, or automatic running in the background?* The analysis of the blank CT and CTA images is done automatically.
Technical integration	*Does the desired AI application fit within the ICT architecture?* Purchase of Microsoft Windows server 2022 64bit is required. Aidoc Desktop App can be installed on PC with Windows 10 and above, which NWZ already has. *Does the hospital have the necessary ICT architecture and infrastructure?* Yes

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

	Is the AI application a plug-in to existing software? Or is it completely new software? New software
Data storage	*How is data stored (e.g. Cloud or local server) and do adjustments need to be made?* *Is patient data stored and where is it processed?* All data is temporarily stored and processed on the server in NWZ running Aidoc OS and in the Aidoc Cloud environment, after which it is deleted. If you are also going to work with the mobile application, you can ask Aidoc about it: - How does security work? - How does the mobile application know which radiologist is working? - How long is data temporarily stored for mobile application? - How long can the mobile application be used to view images etc? *When data is stored in the Cloud: is it inside or outside Europe?* Within Europe. *Is a GDPR data processing agreement required?* Yes, it has to be closed because of working with patient data. *How is the data secured?* Data is fully encrypted. *Will our data be used to train the model outside NWZ?* No, Aidoc does not use patient data to train their algorithms.
Software connection	*Which connection/additional software is needed to run the software?* A link with DICOM is required, this only needs to be checked and approved. If use of mobile application is desired and to access the EPD from mobile application: link HL7/FHIR is required. For this, more information will have to be requested from Aidoc. - How far back does retrieving data from the EHR go (same day/10 years?)?
External Integration	*Is the AI application already being used in other hospitals or healthcare institutions?* The application is used in UMC Utrecht, Isala, OLVG and Bravis. *Is the application immediately applicable in new clinical settings?* *(Or the application can be retuned or recalibrated using local data to account for differences in population characteristics, type or reporting format of imaging equipment, or care protocols.)* Yes, can be applied equally. *What kind of effort do you have to put in to get the software running?* *A week of ICT effort. In addition, requesting the server takes 1 – 2 weeks.*

4. Costs	
Purchase of AI application	*What are the costs for purchasing the AI application/hardware?* There are only license costs associated with the AI application and the Windows server.
License AI application	*What are the license costs per year for the AI application?* License costs for only Stroke module are approximately €45,000 per year.

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

	License costs for the Windows server are about €363 per month (incl. 21% VAT), so about €4356 per year.
Other costs?	- *ICT management costs. (Expansion of management capacity may be required)* To be determined... *A license must be purchased for the Windows server.* - *Integration costs* *To be determined...* - *Project costs* *(Project deployment of employees)* *To be determined...* - *Training/education costs* *(How will the training on the application be provided after implementation?)* *To be determined...*

5. Benefits	
Savings	*Does it save costs?* To be determined...
Benefits	*What are the benefits?* Faster diagnosis in patient during shifts, resulting in better outcome for the patient through shorter door-to-needle time. More pleasant service structure for IR with already high service load.

6. Sustainability	
Energy	*What kind of energy is used (e.g. solar energy)?* Reactie Aidoc: "Our SaaS platform operates predominantly on AWS infrastructure. We run on several AWS regions including London and Ireland attributable to 100% renewable energy (See AWS sustainability initiatives and regions list). This also saves the need to deploy and operate hardware on our customer's premises and avoids the CO2 emissions from our customers' data centers. Running on AWS saves some 30 MTCO2e per month in scope 1 and 2 emissions as per AWS calculations." Procurement has yet to assess this. *What are the energy consumption implications of NWZ?* Procurement has yet to assess this.
Vendor	*How sustainable is the supplier?* Procurement still has to assess this on the basis of Aidoc documents. *What are the working conditions of the employees like?* Procurement still has to assess this on the basis of Aidoc documents.

7. Internal validation	
Performance own dataset	The performance of the application cannot be validated by the supplier in advance. In order to get an indication of the performance metrics and what this application could mean for NWZ, it was decided to conduct a meta-analysis with published studies that use the application. In addition, different time moments of the process have been mapped out, in order to get an

Decision-Making Strategy AI

Noordwest Ziekenhuisgroep

indication of where time could possibly be saved.

Table 2 Pooled performance metrics

Performance metric	
Pooled sensitivity	88.8% (82.9 - 92.8%)
Pooled specificity	96.7% (95.4 - 97.7%)

IR response:
These values are pretty good, especially since there are few false positives.

Table 3 Process metrics emergency department (general, location Alkmaar, location Den Helder)

IAT pt'en totaal spoed NWZ	
Aantal pt'en	82
Mean LOS	100.73 min
IAT pt'en Alkmaar	
Aantal pt'en	60
Mean LOS	76.42 min
IAT pt'en Den Helder (overplaatsing naar Alkmaar)	
Aantal pt'en	22
Mean LOS	167.05 min

This is a total number of patients who received a CT scan via the ED (where discharge date/time was also known).
Comparison with studies from Table 1 that have done research in the emergency department, this could mean for IAT NWZ patients when using the Stroke module:
- Reduction of LOS of 36 min, or;
- Reduction of LOS by 3.7 min

It remains to be determined whether these values meet the requirements.

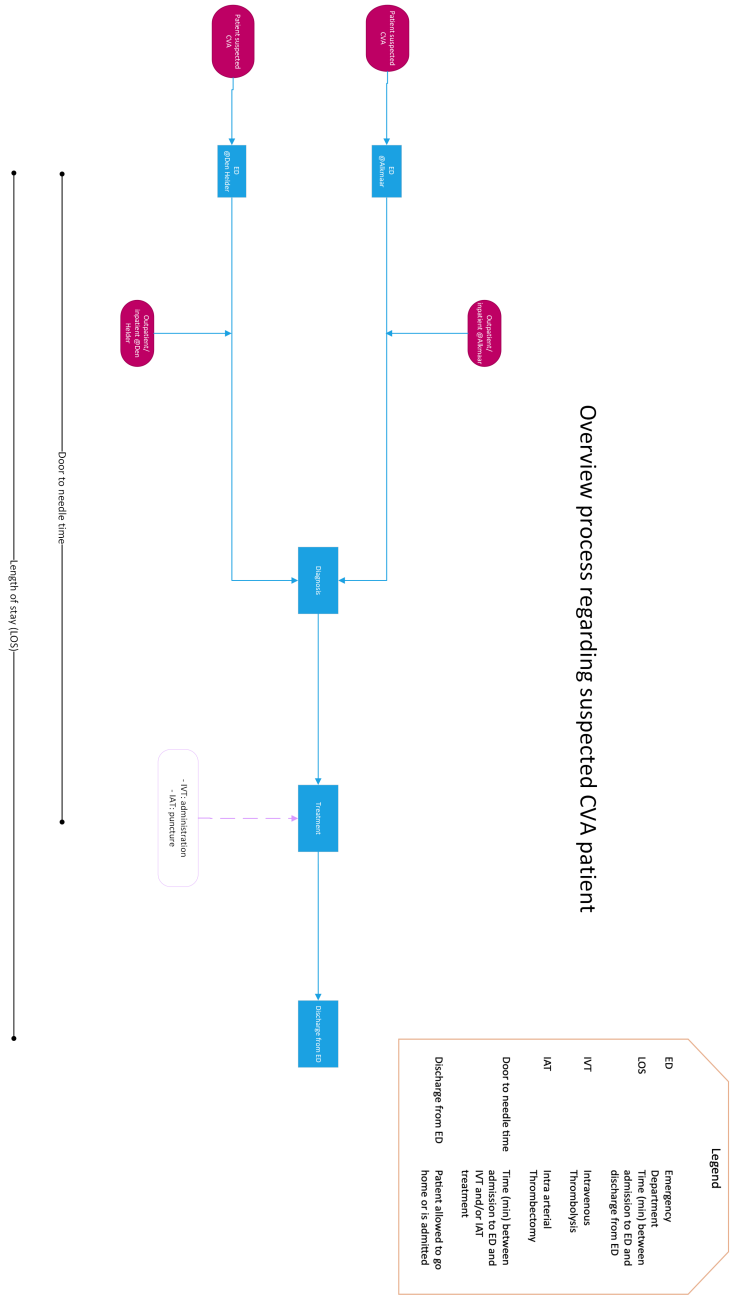
User Acceptance Test	*Has the integration into the workflow been tested (both technically and clinically)? Have the functionalities of the AI software been tested? Also with extreme or deviating cases?* This is not possible for testing.

6. Final verdict *(to be completed by AI team)*	
Final Verdict	Click or tap to enter text.
Signature	

Decision-Making Strategy AI

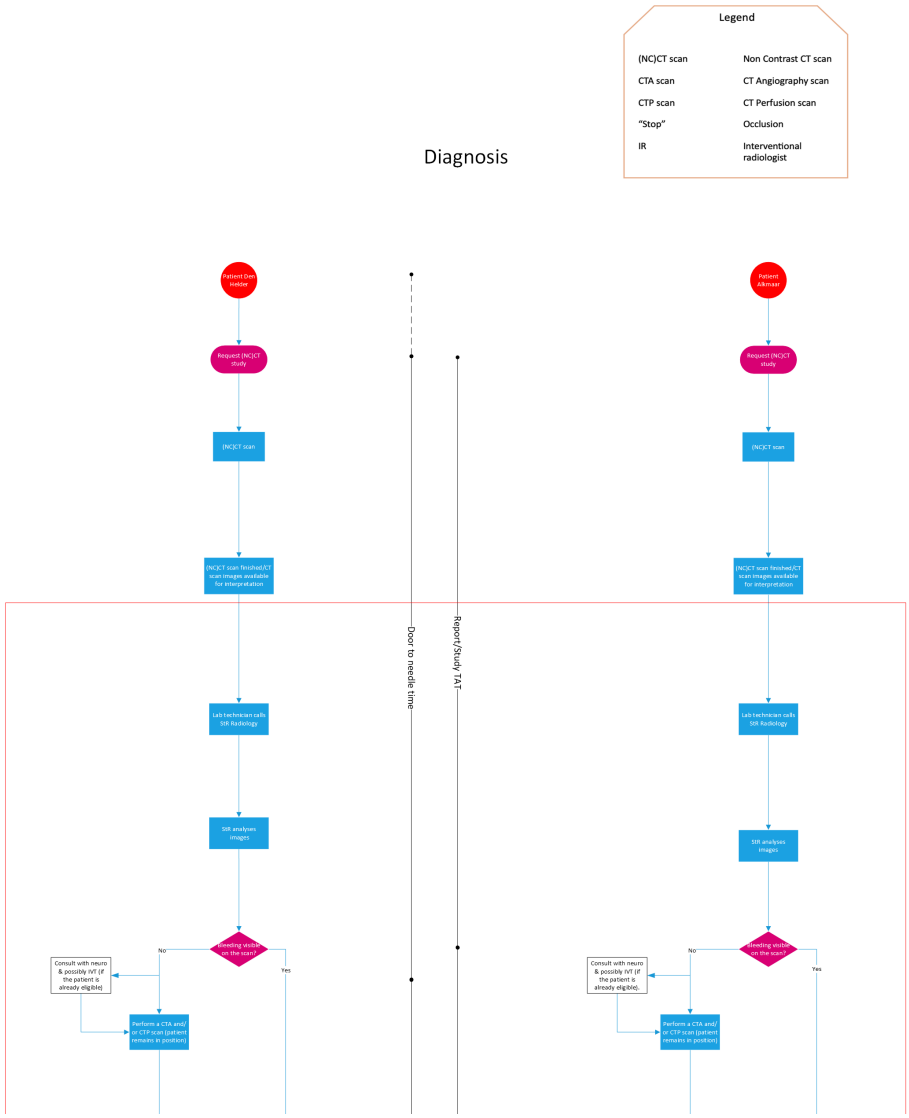
Noordwest Ziekenhuisgroep

Annex I



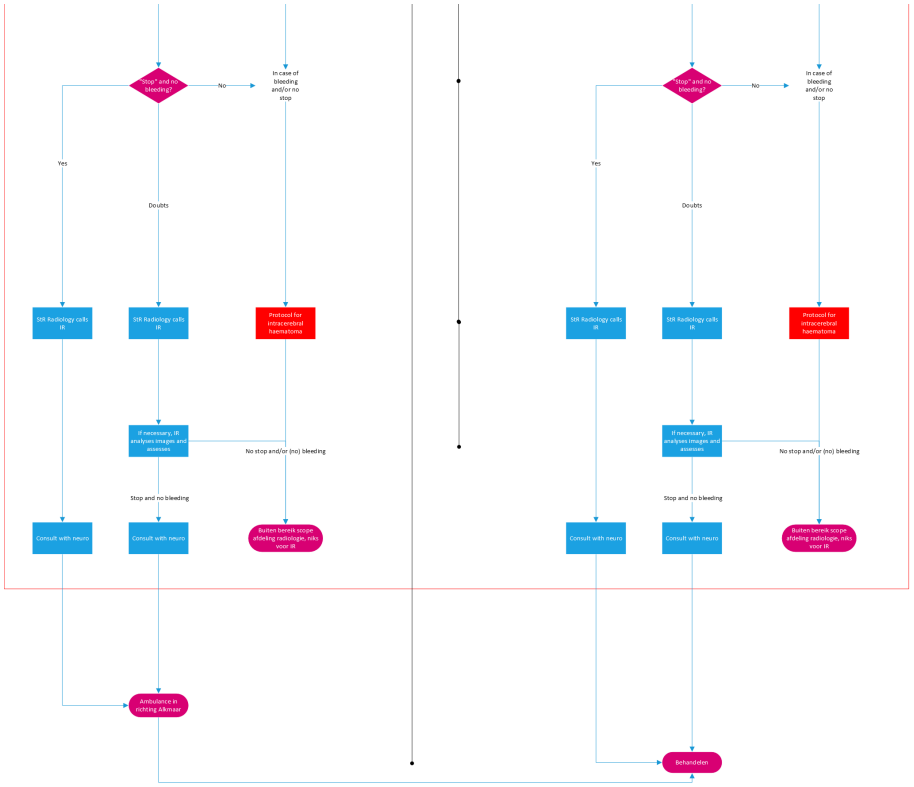
Decision-Making Strategy AI

Noordwest Ziekenhuisgroep



Decision-Making Strategy AI

Noordwest Ziekenhuisgroep



C

Appendix
Additional Results Evaluation Questionnaire

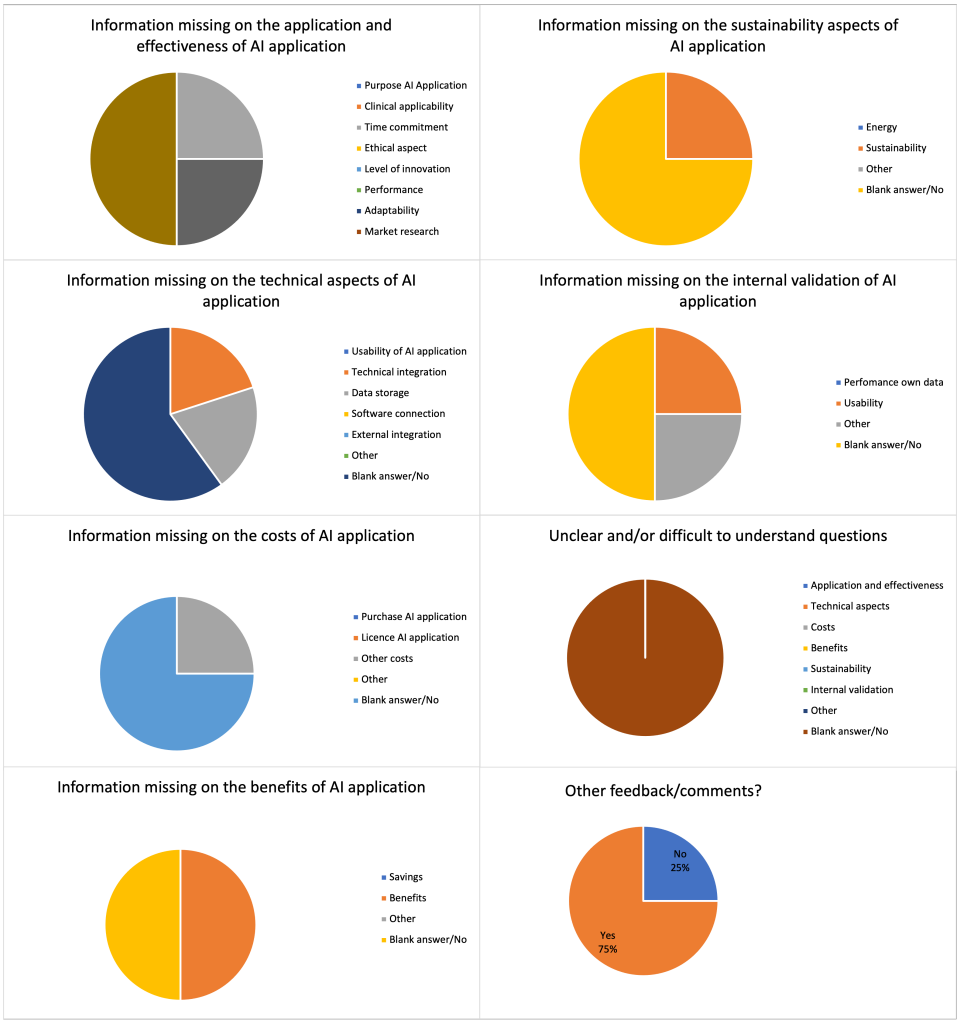


Figure C.1: Additional evaluation results of respondents' from the questionnaire.

D

Appendix
Completed Evaluation Questionnaires of Respondents

Evaluation Questionnaire "Decision Strategy"
1. The decision strategy provides sufficient information about the application and effectiveness of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☐ *Agree* ☒ *Strongly agree*
2. If information is missing, in which area(s)? (multiple options possible) ☐ *Purpose of the AI application* ☐ *Clinical applicability* ☐ *Time investment* ☐ *Ethical aspect* ☐ *Performance of the AI application* ☐ *Adaptability* ☐ *Market research* ☐ *Level of innovation* ☐ *Other, namely:*
Explanation of insufficient information:
3. Does the decision strategy provide insufficient information about the technical aspects of the AI application? ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
4. I am missing information in the area of: (multiple options possible) ☐ *User-friendliness* ☐ *Technical integration* ☐ *Data storage* ☐ *Software connection* ☐ *External integration* ☐ *Other, namely:*
Explanation of insufficient information: It seems complete, but I am less able to judge this.
5. The decision strategy provides sufficient information about the costs of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
6. If more information is desired, in which area(s)? (multiple options possible) ☐ *Purchase of AI application* ☐ *Licence AI application* ☒ *Other costs?* ☐ *Other, namely::*
Explanation of insufficient information: Perhaps it could already be addressed here what type of staff/roles and how many hours are needed in the process.
7. Does the decision strategy provide sufficient information about the benefits of the AI application? ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
8. If information is missing, in which area(s)? (multiple options possible) ☐ *Savings* ☐ *Benefits* ☐ *Other, namely:*
Explanation of insufficient information:

9. The decision strategy contains insufficient information about the sustainability aspects of the AI application.

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

10. I am missing information in the area of: (multiple options possible)

☐ *Energy* ☐ *Sustainability* ☐ *Other, namely:*

Explanation of insufficient information:
I find it difficult to assess, as I have too little knowledge about this.

11. The decision strategy provides sufficient information about the internal validation of the AI application.

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

12. If information is missing, in which area(s)? (multiple options possible)

☐ *Performance own dataset* ☐ *User-acceptance test* ☐ *Other, namely:*

Explanation of insufficient information:

13. Were the questions in the decision strategy clear and easy to understand?

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

14. If unclear and/or not easy to understand, in which area(s)? (multiple options possible)

☐ *Application and effectiveness* ☐ *Technical aspects* ☐ *Costs* ☐ *Benefits*

☐ *Sustainability* ☐ *Internal validation* ☐ *Other, namely:*

Explanation of insufficient information:

15. How much time did it take to complete your contribution to the decision strategy?

☐ *0 – 4 hours* ☒ *4 – 8 hours* ☐ *8 – 12 hours* ☐ *12 – 16 hours*

16. Has the decision strategy helped you gain better insight into the respective AI application?

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

17. Has the decision strategy stimulated input and communication among the various stakeholders?

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

18. After using the decision strategy, is it clear what next steps should be taken?

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

19. Do you have any other feedback/comments about the decision strategy?

☐ *No* ☐ *Yes*

Explanation:
Question 18 made me think. It does include the final assessment by the AI team, but it might be useful to write it down. If yes: draft and submit a business case; plan implementation with ICT and other staff, etc.

Evaluation Questionnaire "Decision Strategy"
1. The decision strategy provides sufficient information about the application and effectiveness of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
2. If information is missing, in which area(s)? (multiple options possible) ☐ *Purpose of the AI application* ☐ *Clinical applicability* ☒ *Time investment* ☐ *Ethical aspect* ☐ *Performance of the AI application* ☐ *Adaptability* ☐ *Market research* ☐ *Level of innovation* ☐ *Other, namely:*
Explanation of insufficient information: The implementation among staff is an important aspect. How does the stakeholder ensure that the team makes optimal use of the application? It is very important to request a plan for this, even if it is brief.
3. Does the decision strategy provide insufficient information about the technical aspects of the AI application? ☐ *Strongly disagree* ☒ *Disagree* ☐ *Neutral* ☐ *Agree* ☐ *Strongly agree*
4. I am missing information in the area of: (multiple options possible) ☐ *User-friendliness* ☐ *Technical integration* ☐ *Data storage* ☐ *Software connection* ☐ *External integration* ☐ *Other, namely:*
Explanation of insufficient information: In my opinion, everything has been considered.
5. The decision strategy provides sufficient information about the costs of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
6. If more information is desired, in which area(s)? (multiple options possible) ☐ *Purchase of AI application* ☐ *Licence AI application* ☒ *Other costs?* ☐ *Other, namely::*
Explanation of insufficient information: No explanation provided.
7. Does the decision strategy provide sufficient information about the benefits of the AI application? ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
8. If information is missing, in which area(s)? (multiple options possible) ☐ *Savings* ☒ *Benefits* ☐ *Other, namely:*
Explanation of insufficient information: Have the benefits described in their own words rather than copied text from the provider's website.
9. The decision strategy contains insufficient information about the sustainability aspects of the AI application. ☐ *Strongly disagree* ☒ *Disagree* ☐ *Neutral* ☐ *Agree* ☐ *Strongly agree*
10. I am missing information in the area of: (multiple options possible) ☐ *Energy* ☐ *Sustainability* ☐ *Other, namely:*

Explanation of insufficient information:
In my view, sufficient attention is given to sustainability.

11. The decision strategy provides sufficient information about the internal validation of the AI application.

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

12. If information is missing, in which area(s)? (multiple options possible)

☐ *Performance own dataset* ☒ *User-acceptance test* ☐ *Other, namely:*

Explanation of insufficient information:
Validation is crucial, requiring clarity on testing methods, stakeholder responsibilities, and metrics, alongside the development of a standardised checklist to ensure alignment and integration into the broader decision-making strategy.

13. Were the questions in the decision strategy clear and easy to understand?

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

14. If unclear and/or not easy to understand, in which area(s)? (multiple options possible)

☐ *Application and effectiveness* ☐ *Technical aspects* ☐ *Costs* ☐ *Benefits*

☐ *Sustainability* ☐ *Internal validation* ☐ *Other, namely:*

Explanation of insufficient information:
No explanation.

15. How much time did it take to complete your contribution to the decision strategy?

☒ *0 – 4 hours* ☐ *4 – 8 hours* ☐ *8 – 12 hours* ☐ *12 – 16 hours*

16. Has the decision strategy helped you gain better insight into the respective AI application?

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

17. Has the decision strategy stimulated input and communication among the various stakeholders?

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

18. After using the decision strategy, is it clear what next steps should be taken?

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

19. Do you have any other feedback/comments about the decision strategy?

☒ *No* ☐ *Yes*

Explanation:
There are many questions, which require a significant amount of time for meetings with stakeholders and independent research. However, it is important to understand what is needed to achieve this, so I support it.

Evaluation Questionnaire "Decision Strategy"
1. The decision strategy provides sufficient information about the application and effectiveness of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☐ *Agree* ☒ *Strongly agree*
2. If information is missing, in which area(s)? (multiple options possible) ☐ *Purpose of the AI application* ☐ *Clinical applicability* ☐ *Time investment* ☐ *Ethical aspect* ☐ *Performance of the AI application* ☐ *Adaptability* ☐ *Market research* ☐ *Level of innovation* ☒ *Other, namely:*
Explanation of insufficient information: *The ICT components need to be further enhanced.*
3. Does the decision strategy provide insufficient information about the technical aspects of the AI application? ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
4. I am missing information in the area of: (multiple options possible) ☐ *User-friendliness* ☒ *Technical integration* ☒ *Data storage* ☐ *Software connection* ☐ *External integration* ☐ *Other, namely:*
Explanation of insufficient information: We still require some input from our ICT department to complete this.
5. The decision strategy provides sufficient information about the costs of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☐ *Agree* ☒ *Strongly agree*
6. If more information is desired, in which area(s)? (multiple options possible) ☐ *Purchase of AI application* ☐ *Licence AI application* ☒ *Other costs?* ☐ *Other, namely::*
Explanation of insufficient information: Sufficient
7. Does the decision strategy provide sufficient information about the benefits of the AI application? ☐ *Strongly disagree* ☐ *Disagree* ☒ *Neutral* ☐ *Agree* ☐ *Strongly agree*
8. If information is missing, in which area(s)? (multiple options possible) ☐ *Savings* ☒ *Benefits* ☐ *Other, namely:*
Explanation of insufficient information: *Benefits are always challenging, but as AI team we need to help to make a proper assessment.*
9. The decision strategy contains insufficient information about the sustainability aspects of the AI application. ☐ *Strongly disagree* ☒ *Disagree* ☐ *Neutral* ☐ *Agree* ☐ *Strongly agree*
10. I am missing information in the area of: (multiple options possible) ☐ *Energy* ☒ *Sustainability* ☐ *Other, namely:*

Explanation of insufficient information:
It's included, but we need to supplement it further with input from the sustainability programme manager.

11. The decision strategy provides sufficient information about the internal validation of the AI application.

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

12. If information is missing, in which area(s)? (multiple options possible)

☐ *Performance own dataset* ☐ *User-acceptance test* ☐ *Other, namely:*

Explanation of insufficient information:
Sufficient

13. Were the questions in the decision strategy clear and easy to understand?

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

14. If unclear and/or not easy to understand, in which area(s)? (multiple options possible)

☐ *Application and effectiveness* ☐ *Technical aspects* ☐ *Costs* ☐ *Benefits*

☐ *Sustainability* ☐ *Internal validation* ☐ *Other, namely:*

Explanation of insufficient information:
Questions are clear

15. How much time did it take to complete your contribution to the decision strategy?

☒ *0 – 4 hours* ☐ *4 – 8 hours* ☐ *8 – 12 hours* ☐ *12 – 16 hours*

16. Has the decision strategy helped you gain better insight into the respective AI application?

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

17. Has the decision strategy stimulated input and communication among the various stakeholders?

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

18. After using the decision strategy, is it clear what next steps should be taken?

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

19. Do you have any other feedback/comments about the decision strategy?

☐ *No* ☒ *Yes*

Explanation:
Interesting to take another step to make it more user-friendly to complete, though the content is beautifully presented.

Evaluation Questionnaire "Decision Strategy"
1. The decision strategy provides sufficient information about the application and effectiveness of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☒ *Strongly agree*
2. If information is missing, in which area(s)? (multiple options possible) ☐ *Purpose of the AI application* ☐ *Clinical applicability* ☐ *Time investment* ☐ *Ethical aspect* ☐ *Performance of the AI application* ☐ *Adaptability* ☐ *Market research* ☐ *Level of innovation* ☒ *Other, namely:*
Explanation of insufficient information: *It seems to me to be a fairly complete document.*
3. Does the decision strategy provide insufficient information about the technical aspects of the AI application? ☐ *Strongly disagree* ☒ *Disagree* ☐ *Neutral* ☐ *Agree* ☐ *Strongly agree*
4. I am missing information in the area of: (multiple options possible) ☐ *User-friendliness* ☐ *Technical integration* ☐ *Data storage* ☐ *Software connection* ☐ *External integration* ☒ *Other, namely:*
Explanation of insufficient information: No
5. The decision strategy provides sufficient information about the costs of the AI application. ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
6. If more information is desired, in which area(s)? (multiple options possible) ☐ *Purchase of AI application* ☐ *Licence AI application* ☒ *Other costs?* ☒ *Other, namely::*
Explanation of insufficient information: Potential costs have been detailed.
7. Does the decision strategy provide sufficient information about the benefits of the AI application? ☐ *Strongly disagree* ☐ *Disagree* ☐ *Neutral* ☒ *Agree* ☐ *Strongly agree*
8. If information is missing, in which area(s)? (multiple options possible) ☐ *Savings* ☐ *Benefits* ☒ *Other, namely:*
Explanation of insufficient information: *Saving and benefits are described.*
9. The decision strategy contains insufficient information about the sustainability aspects of the AI application. ☐ *Strongly disagree* ☒ *Disagree* ☐ *Neutral* ☐ *Agree* ☐ *Strongly agree*
10. I am missing information in the area of: (multiple options possible) ☐ *Energy* ☐ *Sustainability* ☐ *Other, namely:*

Explanation of insufficient information:
It's powerful that, in addition to energy, employee working conditions are also considered.

11. The decision strategy provides sufficient information about the internal validation of the AI application.

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

12. If information is missing, in which area(s)? (multiple options possible)

☐ *Performance own dataset* ☐ *User-acceptance test* ☒ *Other, namely:*

Explanation of insufficient information:
It looks comprehensive, though perhaps some mention of retraining over time could be included?

13. Were the questions in the decision strategy clear and easy to understand?

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

14. If unclear and/or not easy to understand, in which area(s)? (multiple options possible)

☐ *Application and effectiveness* ☐ *Technical aspects* ☐ *Costs* ☐ *Benefits*

☐ *Sustainability* ☐ *Internal validation* ☒ *Other, namely:*

Explanation of insufficient information:
The descriptions are clear and easy to understand.

15. How much time did it take to complete your contribution to the decision strategy?

☒ *0 – 4 hours* ☐ *4 – 8 hours* ☐ *8 – 12 hours* ☐ *12 – 16 hours*

16. Has the decision strategy helped you gain better insight into the respective AI application?

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

17. Has the decision strategy stimulated input and communication among the various stakeholders?

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

18. After using the decision strategy, is it clear what next steps should be taken?

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

19. Do you have any other feedback/comments about the decision strategy?

☐ *No* ☒ *Yes*

Explanation:
In response to question 18: the next steps will be outlined in another document, so in my view, it's not relevant to include them here.
I see the final result as highly valuable for Noordwest, and the document will be applied in practice.