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The Potential and Challenges of Extended Reality (XR) Technology in Healthcare

An Interdisciplinary Exploration of Ongoing Development Processes

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ABSTRACT

In recent years, research in extented reality (XR) technology for healthcare has shown potenital benefits for a variety of clinical applications. However, a lack of implementation in clinical settings has made it difficult to determine the true impact. Nevertheless, understanding the current status and prospects of XR for healthcare research helps map out existing challenges in addition to future directions.

This study investigates ongoing development processes and the context in which they take place in order to generate this insight. Data was generated through interviews with computer scientists, clinicians, and business developers involved in XR for healthcare. A qualitative analysis of the responses was carried out.

A total of nine interviews were conducted, and a variety of topics were discussed. Participants highlight interdisciplinary collaboration as crucial, and mention the importance of involving clinicians throughout the process. However, they make note of the challenges presented by having different perspectives and terminologies. Other challenges include ease of use not being satisfactory, and limitations in accessing data for automatic modelling. Additionally, factors such as time consuming regulatory processes for medical devices, challenges in obtaining funding, and separation between research, industry and hospitals are described as barriers.

The results indicate that while XR may have several benefits for healthcare, there are currently barriers that make it difficult to determine the added value. Efforts to resolve these challenges are necessary in order to fully understand the impact of XR in healthcare. Suggested measures include investigating how the healthcare sector can better facilitate innovation projects and engagement in research activity, evaluation of public research funding, strengthening the interactions between education, research and innovation, and investigating methods to facilitate interdisciplinary collaboration.

SAMMENDRAG

De siste årene har forskning på utvidet virkelighet(XR) vist potensielle fordeler innen flere kliniske bruksområder. Imidlertid har manglende implementasjon i klinisk praksis gjort det vanskelig å fastlå den faktiske effekten av å introdusere XR-verktøy. Ved å forstå den nåværende statusen og fremtidsutsiktene til XR innen helsesektoren, er det mulig å kartlegge de eksisterende utfordringene samt fremtidige retninger.

Denne studien utforsker pågående utviklingsprosesser og konteksten hvor de finner sted. Data ble generert gjennom intervjuer med teknologer, leger og forretningsutviklere involvert i utvikling av XR-teknologi for helsesektoren. Svarene ble analysert kvalitativt for å danne et bilde av prossessene og utfordringene.

Totalt ni intervjuer ble holdt og en rekke temaer ble diskutert. Deltakerne trekker fram tverrfaglig samarbeid som avgjørende, samt understreker viktigheten av å involvere klinikere gjennom hele prosessen. Imidlertid merker de seg utfordringene som oppstår i samarbeid på tvers av ulike bakgrunner, perspektiver og terminologier. Andre utfordringer inkluderer manglende brukervennlighet på nåværende appliaksjoner, samt begrensninger knyttet til tilgang på data for automatisk modellering. I tillegg blir faktorer som tidkrevende regulatoriske prosesser for medisinsk utstyr, utfordringer knyttet til finansiering, samt en strukturell separasjon mellom forskning, næringsliv og sykehus beskrevet som hindringer.

Resultatene indikerer at det finnes utfordinger som gjør det vanskelig å avgjøre hvilken verdi XR-teknologi kan tilføre helsevesenet. Det er nødvendig med tiltak for å løse disse utfordringene for å få en full forståelse av effekten av å anvende XR. Foreslåtte tiltak inkluderer å utforske hvordan helsevesenet bedre kan fasilitere innovasjonsprosjekter og involvering i forskningsprosjekter, evaluering av offentlig forskningsfinansiering, en styrking av samspillet mellom utdanning, forskning og innovasjon, samt å undersøke metoder for å fasilitere tverrfaglig samarbeid.

PREFACE

This thesis has been written to fulfill the requirements of the computer science master's programme at the Norwegian University of Science and Technology(NTNU). It was researched and written between January and June 2023.

I would like to thank my supervisor, Patrick Mikalef, for guidance and advice throughout the process. Our meetings could always provide reassurance and helpful feedback. A thank you to my co-supervisor, Eric Monteiro, for additional guidance and help on the interview process.

A special thank you goes out to my sister(and favorite medical doctor) Henriette, who regularly provides a simple student of computer science with explanations of medical terminology and concepts. You probably find this thesis too long and boring to read. However, if you find yourself using XR later on in your career I hope you imagine that you contributed to making that possible. An additional thank you to my father, who shared his long experience with writing research papers and made time to read through this entire thesis and provide feedback.

Finally, this work would not be possible without the help of my interview subjects who generously offered me their time, of which I am sincerely grateful. I hope the time given and resulting thesis proves to be somehow useful for you.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER

ONE

INTRODUCTION

Extended reality(XR) describes a family of technologies, including augmented reality(AR) and virtual reality(VR), in which reality is altered to various degrees with computer generated elements. XR technology for healthcare has been researched for a variety of applications, including education and training, surgical planning and guidance, and non-surgical patient care and treatment. The potential benefits include improvements in patient outcomes, communication between doctors, and cost effectiveness. However, XR technologies have not reached widespread use in medical practice. This leaves a knowledge gap related to clinical use and effect on the healthcare sector.

1.1 Background

The motivation to use XR in medical settings is mainly related to the flexibility and visualizations offered by XR technologies. Head-mounted displays (HMDs) can be worn as goggles and allows the user to be emerged in the XR view they are presented with. Monitor-based systems use non-wearable displays to present the view to the user. Over the past 30 years, research in XR for healthcare has seen exponential growth, going from close to zero published articles a year to over 800 [1]. This trend is expected to continue in the coming years.

Virtual models of patient anatomy allows the doctor to "look into" organs or other structures in a completely different way than with traditional images such as Magnetic Resonance Imaging (MRI) or Computed Tomography (CT). This allows for new approaches to things like surgical planning and communication between doctors. Planning using XR tools has been reported to enhance spatial understanding in planning of liver surgery [2, 3], partial kidney removal [4], and removal of lung tumors [5].

XR training applications allow healthcare staff to practice skills, procedures, methods, and anatomical understanding. Various disciplines have different traditional training methods, although the apprenticeship model - in which the trainee learns through observation and on-the-job practical training guided by instructions from more experienced personnel - is a common form of training. However, practicing on a live patient has some ethical and safety concerns. XR training has the potential to provide pre-training before practicing on patients. XR simulator training for education of medical residents has been demonstrated to improve

performance within disciplines such as neurosurgery [6], ophthamology [7] and thoracic surgery [8].

During surgery or other medical procedures, XR allows the surgeon's field of view to be augmented with digital objects such as medical images or visualizations of patient anatomy. By providing the surgeon with this additional information, XR may allow tailoring incisions better to patient anatomy [9], reduce unintended damage to subsurface structures such as blood vessels [10], or reduce time spent in the operating room [11]. Thus, it bears the promise of improved patient outcomes. XR guided procedures has been demonstrated for applications such as laparoscopic surgery [12] and neurosurgical procedures [13].

Despite extensive research, the potential improvements of medical practice have yet to be validated. While studies demonstrate technical feasibility and/or clinical applicability, they call for future work in terms of cost-benefit analysis, further development of systems, and investigation into clinical safety and benefit. Literature searches for clinical trials of XR applications yield few relevant results. Additionally, literature indicates that the maturity level of XR technology for healthcare is moving towards, but not ready for, widespread implementation. A 2019 literature review assessed the technology readiness level(TRL) in 338 research articles on AR for medicine [14]. TRL is a scale from 1 to 9, where 1 is described as "basic principles observed" and 9 is described as "actual system proven in operational environment". The literature review showed a trend around 6 - "technology demonstrated in relevant environment" - and 7 - "system prototype demonstration in operational environment". This indicates that research is moving toward practical application. In the eyes of the Norwegian regulations of public funding (Statsstøtteregelverket), level 7 is considered the last level before mass production and implementation of the product [15]. However, only 16 of the publications had a maturity level of 8 or higher, at which a complete system is demonstrated. While additional factors such as risk classification are also important for commercialization of a medical device, this implies that XR technologies are not currently ready for widespread use in clinical settings.

1.2 Motivation and Purpose of Project

Because of the lack of implementation in clinical settings, it is difficult to determine the impact of XR technology in healthcare. Additionally, the clear trend of TRL-levels around 6 and 7 may indicate the presence of one or more bottlenecks that inhibit the technology from moving towards level 8 and 9. The potential benefits of XR in healthcare suggest a need to understand how and when the technology can be used, and which challenges must be handled in order to move XR technology forward.

This exploratory study aims to generate insight and develop a deeper understanding of the current status and prospects of XR for healthcare. This involves investigating ongoing development processes and the context in which they take place, the gaps XR tools are intended to fill and what added value they may provide, in addition to identifying potential challenges and barriers. This insight may in turn be helpful in determining how XR can be used in healthcare in a strategic manner that benefits patients and doctors, and which issues may need to

be resolved before this becomes possible. From this starting point, the following research questions were formulated:

- How do clinicians and developers collaborate throughout the process in order to ensure added value of XR technology for healthcare?
- What are the current barriers and limitations that inhibit widespread adoption of XR technology for healthcare, and how do they manifest?

The thesis is structured as follows: First, the methods for collecting and analyzing data are described. Secondly, the findings are presented and analysed. Finally, implications for research and practice are discussed, along with recommendations for future work and limitations of the study.

CHAPTER

TWO

METHODS

In order to collect qualitative data on the development process and context of XR for healthcare purposes, a series of semi-structured interviews were carried out. The goal was to explore the topic with a variety of stakeholders, and thus gain multiple perspectives. Data from the interviews were analyzed with an hermeneutic approach.

2.1 Research Methodology

The research was conducted as a descriptive case study. As described by Briony Oates, a case study focuses on all factors, issues, processes and relationships of a phenomenon in its real life context, in order to explain why and how certain outcomes occur [16]. This pertains to understanding the context in which development of XR tools for healthcare takes place. Ultimately, this can explain how added value is ensured throughout the development process, and which factors inhibit adoption of XR tools for healthcare. Additionally it can explain how XR tools are influenced by and influence the context. Thus, the research follows an inherently interpretive approach, according to the description of interpretive research in information systems by Geoff Walsham [17].

2.2 Data Generation

Data was generated through semi-structured interviews. An interview guideline was developed prior to the interviews, providing a general plan for topics to be covered. However, questions did not need to follow a particular phrasing or order. Questions were preferably open-ended, allowing the interviewee to speak freely and follow-up questions to be formulated throughout the interview. This flexibility allowed new topics of interest to emerge and be further investigated despite not being a planned part of the interview. The contents of the interview guideline varied slightly depending on the participants(i.e. whether the interviewee was a developer, clinician, or other stakeholder). Additionally, they varied throughout the duration of the project, starting out as more explorative in order to uncover topics of interest, then becoming more focused on specific topics. An example interview guideline can be found in the appendix.

2.3 Participants

The participants were involved in the development of XR tools for medical purposes. It was important to include a variety of stakeholders in order to capture diverse factors, issues, and processes. As the development process is inherently interdisciplinary, both clinicians and developers involved in XR for healthcare were relevant groups. However, during the project it became clear that stakeholders with a perspective on commercialization were relevant for the project. Consequently, business developers of medical XR companies were included. Participants were selected in order to provide insights on various projects and application areas. Additionally, they were selected in order to provide several perspectives from similar stakeholder roles - i.e. including several clinicians, developers, and business developers.

2.3.1 Recruitment

Participants were continuously recruited. Several media were utilized in order to identify potential participants. Key people at relevant institutions were identified trough the network of the author and the supervisor. Researching relevant literature produced in Norway revealed researchers involved with the topic. Websites of relevant institutions and companies, as well as social networks such as LinkedIn, provided contact information. However, an important method was utilization of the network of existing participants. By the end of each interview, the participants were asked for suggestions of relevant stakeholders.

2.3.2 Management of Participant Data

The data collection was approved by NSD, and precautions were taken in order to protect privacy of participants. Interview recordings were deleted immediately after transcription. Participants were assigned a code and all transcriptions anonymised. The codes were stored separate from the transcriptions.

2.4 Data Analysis

Interview recordings were transcribed, and the transcriptions were used as an object for analysis. In order to identify relevant topics and participants for upcoming interviews, the interviews were partly analyzed in parallel with the data generation. However, the data generation phase was followed by a phase purely dedicated to analysis. This section describes the hermeneutic mode of analysis that was utilized, coding of interviews, and how the coded data was analyzed.

2.4.1 Mode of Analysis

The data were analyzed based on a hermeneutic approach. Hermeneutics is the underlying philosophy of interpretivism, and is concerned with making sense of a text [18]. It is based on an assumption that meaning is not necessarily inherent and objective, but is created by human interpretation. Michael Myers argues that hermeneutics helps understand the design and implementation of information

systems, and the social, cultural and organizational aspects of systems [18]. The hermeneutic circle describes the dialectic between understanding a text as a whole and the interpretation of its parts [18]. Understanding is a result of continuously orienting between the whole and its parts. In this project, the "whole" is the context in which XR development for healthcare takes place. Perspectives offered by stakeholders provide parts of that whole, in terms of factors, issues, and processes. However, they are subjective experiences in a broader context and must be interpreted as such.

2.4.2 Interview Coding

The transcribed interviews were coded in several iterations. Initial coding was mainly descriptive, in which excerpts of the texts were assigned labels, or codes, to describe the topic of their contents. Some of the codes were developed prior to the actual coding, while some emerged throughout the process. For example the code "Interaction between clinicians and developers" was developed prior to coding, while "The importance of data" emerged from studying the transcriptions. Additional rounds were carried out, sometimes leading to excerpts being assigned different codes than originally chosen.

The codes were continuously evaluated, leading to codes being renamed if found ill-fitting or insufficiently descriptive, merged if found redundant, or split if found to be overarching. For example, "Interaction between clinicians and developers" encompassed topics such as "Characteristics of interaction between clinicians and developers" and "Strategies for understanding and productive collaboration". This led to greater cohesiveness between the excerpts labeled with the same code, which enabled meaningful generalizations and conclusions to be drawn.

The codes were grouped into categories based on patterns and themes, forming a hierarchical structure. For example, the general topic "Challenges" included the codes "Technical challenges", "Regulatory challenges" and "Funding challenges". Interview data was organized in a spreadsheet based on codes and topics.

2.4.3 Analysis of Coded Data

The spreadsheet formed a basis for analysis within several categories. Excerpts assigned with the same code were analyzed both as a whole and grouped by profession of the participant. Viewing all interviewees as a whole allowed analysis of general themes and patterns. Grouping by profession allowed exploration of the specific groups, both with regards to consistencies and inconsistencies between the groups, as well as relationships between groups.

The findings were analyzed in light of the research objectives. Using the hermeneutic mode of analysis, interpretation was a continuous process of considering experiences and opinions of participants, and the bigger context they were part of. Meanings and implications of the patterns were interpreted in relation to the research questions. Finally, a narrative was constructed.

CHAPTER

THREE

RESULTS

3.1 Introduction

This section presents the findings from the interviews. First, the participants are presented and interviews described. This includes a description of the participant's role and background related to XR for healthcare, projects they were involved with at the time of the interview, and a short report of main topics that were covered in the interview. Secondly, emerging themes are discussed across the interviews.

3.2 Interviews

A total of nine interviews were conducted. The interviewees consisted of four developers, four clinicians, and one business developer. For simplicity, those are the categories used throughout the thesis to refer to the participant's role: developer, clinician, and business developer. "Developer" refers to participants who handle technical aspects such as software development and image processing. "Clinician" refers to participants who have a medical background (in Franklin's case, a background in neuroscience) and mainly provide a non-technical perspective in the projects discussed. All participants were male. Most of the interviews were conducted in Norwegian or Swedish. Thus, some of the quotations used are translated from their original language into English. In order not to provide a translation note for every single quotation throughout the text, the original languages are indicated in table 3.2.1.

3.2.1 Johnson

Johnson is the co-founder and business developer of a start-up company developing an AR navigation tool for laparoscopic surgery. The aim of the tool is to simplify the removal of cancerous tumours of the liver. The procedure was described as "complex" and "requires very long experience to perform", involving challenging visualization tasks. Traditionally, pre-operative 2D imaging is used during the planning phase. During surgery, a camera feed of the 3D patient anatomy is displayed on a 2D screen. This requires a challenging mental transformation between the two modalities. Additionally, he described how there are few natural

Pseudonym	Profession/Background	Language	Approximate duration
Johnson	Business developer	Swedish	60 minutes
Wollstonecraft	Clinical doctor	Norwegian	55 minutes
Ginsburg	Clinical doctor	Norwegian	75 minutes
Lovelace	Doctor	Norwegian	60 minutes
Franklin	Neuroscientist and software developer	English	35 minutes
Goodall	Computer scientist	English	45 minutes
Tubman	Computer scientist	English	50 minutes
Steinem	Computer scientist	Norwegian	60 minutes
Collett	Computer scientist	Norwegian	55 minutes

Table 3.2.1: Overview of the participants, their profession, original language of the transcription, and the approximate duration of the interview.

landmarks to localize the tumor in relation to blood vessels, bile ducts, and other anatomical features. The current practice often involves open surgery rather than laparoscopic surgery for these reasons. He described how challenges related to visualization manifested during an observed laparoscopic procedure:

> *"It happened again and again that the surgeon had to leave his - you know they sit by a robot and control - he had to leave it multiple times to go look at the images to try to understand 'OK, where am I? Where is the tumor? Where am I in relation to it?'"* - Johnson

The challenge was originally identified by two surgeons, who initiated a collaboration with two professors of mathematics in order to start developing a navigation tool. Johnson became involved with the project through his enrollment at an entrepeneurship school, at which students typically pair up with researchers for business development projects. The project resulted in further concept development and incorporation. At the point of the interview, the technology had been verified in a surgical setting on animal materials. The next steps were trials on live animals and patients. The product was described as a "software running on a very competent computer", consisting of the software itself and a single-use tracking device that is placed on the organ. The vision is for the software to be delivered as a "plug-and-play" solution that can be connected to the laparoscopy camera. The company aims to introduce the product to market in 2025 or 2026. The interview covered various topics surrounding business development of a medical technology start-up, the commercialization process of a medical device, and the various interests of parties involved in the development process.

3.2.2 Wollstonecraft

Wollstonecraft is a full time pulmonologist, working primarily with diagnosis of cancer and other conditions of the lungs. Additionally, he is involved in the development of an XR navigation tool for bronchoscopy. A bronchoscopy is a diagnostic procedure in which a flexible scope is passed down the airways, making it possible

to inspect the inside of the airways through a camera. Additionally, biopsies can be taken for tissue analysis. Prior to the procedure, patients will have CT imaging taken in order to identify and locate areas of interest. However, CT images only provide cross-sectional 2D slices, and come in addition to several other image modalities during bronchoscopy. Wollstonecraft described how CT images and the video feed from the bronchoscope camera is used for navigation, and X-ray and ultrasound imaging is used to control that the goal has been reached. This means that a total of four different modalities and sources are utilized, demanding that attention is shifted between several screens and interpretive modes. The navigation tool is aimed at relieving some of this effort, reducing the number of screens necessary, and to make navigation to the area of interest easier. From CT images, a virtual model is created, along with a guiding path to the goal. By using electromagnetic tracking on the bronchoscope, the doctor can locate its position in the virtual model. The application utilizes Microsoft HoloLens, an HMD. This allows all image modalities to be available on one screen. At the time of the interview, the tool had been tested on patients in a real environment.

Wollstonecraft discussed the dynamics of clinicians and engineers collaborating. He described a difference in perspective due to different backgrounds, placing high demands on communication. Several strategies aimed at facilitating mutual understanding and collaboration were described, as well as the importance of personal relationships. Overall, he emphasized the importance of involving clinicians, especially with regards to "practical elements that we simply know better".

3.2.3 Ginsburg

Ginsburg is a pediatric surgeon specializing in congenital heart disease. He has a combined position, dividing his time between clinical practice and a research and development(R&D) centre at a Norwegian university hospital. At the research centre, he is involved with development of an XR visualization tool of medical images, using the Microsoft HoloLens to achieve what he describes as "surgical planning in real 3D". The tool is aimed at the most difficult cases, involving rare and complex heart defects - so rare that only two surgeons in Norway perform surgeries to correct them. This was emphasized by saying:

> *"Rare diseases like this - there may be 5 years until the next time you see a heart like the one you operated on yesterday. Maybe you see that particular defect 3-4 times throughout your career"* - Ginsburg

Traditional planning of these surgeries utilizes MR imaging, requiring a mental mapping from 2D images to 3D structures. Ginsburg highlighted that visuospatial skills and thus ability to perform this mapping is unevenly distributed among people. To combat this, 3D printing has been applied at the research centre, but even this method has its limitations - which prompted the use of VR.

The project has resulted in a start-up company that owns the software for the visualization platform, with applications for visualization for both cardiology and hepathology purposes - in addition to coming orthopaedic visualization. At the time of the interview, the platform was a research tool with validation studies upcoming, in preparation for FDA approval. Future studies will be aimed at identifying the specifics of how the holograms may impact surgical planning and

what added value it may provide. Ginsburg gives some examples of the specifics they will investigate:

> *"Was it useful to you to see that structure? Can you tell me exactly what you gained from opening the hologram? Can you specify in detail what you couldn't see previously?"* - Ginsburg

The interview covered various elements of the process from idea towards a finished product, including topics like intellectual property, medical technology regulations, and the dynamics of competition and collaboration with other researchers. Ginsburg discussed challenges related to commercialization of an idea, options for facilitation of this process, and how the current model of doing this is lacking when it comes to incentivizing clinicians to continue contributing to the development.

3.2.4 Lovelace

Lovelace is a medical doctor and became involved in XR for healthcare through a PhD project at the same R&D centre as Ginsburg. The project was part of the basis for the start-up company described by Ginsburg in section 3.2.3, investigating visualization methods for surgical purposes. Lovelace has upon completion of the PhD continued working with method development at the R&D centre and as an industry consultant for the start-up. He emphasized the value of having 3D visualization, as the patient and the surgical task is three-dimensional. Additionally, he mentions the potential for better communication and understanding between doctors, commenting that "the communication is not always the greatest" in surgical settings he has partaken in. Lovelace expressed a strong technological interest, especially with regards to minimally invasive procedures, and described the potential of utilizing technologies to improve current processes as a driving factor for his involvement.

He described his role as the "glue" between the different entities involved in development, translating problems between clinicians and developers as well as handling communication between the hospital and the start-up company. He described how clinical problems will have to be explained differently to a computer scientist compared to a doctor, and a doctor may lack the technological terminology to effectively do this. Similarly, the company lacks the medical resources to continue developing the tool on their own. In both cases, Lovelace serves as an intermediary to facilitate the process.

The interview covered several aspects of XR development for medical purposes, including regulatory challenges, challenges and mechanisms related to commercialization, and current bottlenecks. Lovelace described a lack of resources for implementation, creating a gap between specialized research and practical application, which must be bridged in order to determine the added value of XR for healthcare.

3.2.5 Franklin

Franklin has a background both from computer science and as a neuroscientist. He was involved in the development of a VR application for assessment of Alzheimer's patients. His role in the project was as an advisor on the neuroscience related

elements of the application rather than as a programmer. In previous development projects related to Alzheimer's disease he has contributed as a programmer. The project was at an early stage, with the initial goal of implementing the Montreal Cognitive Assesment test in VR and evaluate its reliability and correlation to traditional neuropsychological tests. In the longer term, the aim is to create rehabilitation tools for Alzheimer's patients.

Based on experience in interdisciplinary development projects prior to being trained in neuroscience, Franklin discussed the challenge of programmers in understanding the research question. He emphasized how important that understanding is in order to create applications that are useful.

> *"Everyone now can develop the apps(...), they can learn how to develop the apps in, in YouTube, probably - it's very simple, but yeah, to see the question itself in AD [Alzheimer's disease] for example or in another disease, it's something else"*

Thus, he described the involvement of and communication with experts within the clinical areas as crucial.

3.2.6 Goodall

Goodall is an associate professor and senior engineer, coming from a computer science background. He is involved in several projects involving XR for healthcare, mainly related to education and training. One example that was described is an application aimed at practicing Doppler ultrasound, which is used to measure flow through blood vessels. Another example is aimed at practicing measurement of the head of a fetus using ultrasound. The applications aid the task of mentally transforming a 2D ultrasound image to a 3D structure, as the 3D visualization can be displayed simultaneously with the 2D image. However, intra-procedural applications were also described, such as an AR navigation tool for bronchoscopy as well as intra-operative ultrasound visualisations. Microsoft HoloLens was indicated as the main hardware for deployment. The applications were described as working prototypes.

The interview covered the development process of an XR tool. Goodall described how healthcare professionals are involved in order to allow adaptation to their needs. Furthermore, he discussed how interactions between the developer and medical staff influence the end product, and how workflow considerations are taken into account.

3.2.7 Tubman

Tubman is a post-doctorate of computer science. At the time of the interview he had been involved in XR development for six years, and XR for healthcare for six months. Through an XR research lab and network, he is involved in several projects. Applications described include an application for midwives, aimed at training of Doppler ultrasound for measuring blood flow in the umbilical cord; a training application for monitoring the brain activity of premature babies using Doppler ultrasound; rehabilitation of stroke patients with XR visualization of phantom limbs, using a method called mirror therapy; and an XR version of

an assessment tool to measure the cognitive impairment of Alzheimer's patients. Readiness of the applications was not explicitly covered.

The interview went in-depth about the development process and research methodology. It covered recruitment of clinicians, the dynamics and relationship between the developers and clinicians involved, as well as challenges with regards to differences in terminology and perspective on the development process. Strategies to improve communication and collaboration between the two camps were presented. Further, Tubman discussed bias in the context of XR research, and methods to reduce the effect of bias.

3.2.8 Steinem

Steinem is a chief scientist at a medical technology research center. He had been involved in XR development for five to six years. The main topic of the discussion was an intra-procedural navigation tool for bronchoscopy. This is the same project as described by Wollstonecraft in section 3.2.2. Steinem emphasized the complexity of navigating in the lungs, as the bronchi diverge multiple times, resulting in an extensive network of branching structures. XR was described to be the natural choice for visualization of medical images. He highlighted the flexibility offered by having a mobile screen that can be controlled by gestures.

Steinem discussed how improvements in XR technology - regarding both user comfort and performance - have made it more feasible for use in healthcare. He emphasized the importance of interdisciplinary collaboration to solve practical problems in the medical field. However, he described how the separation between academia, industry and the healthcare sector is a challenge for the development. Further, he described the challenges related to obtaining funding as a scientist, with high competition and much time spent on the application process. Steinem emphasized that the main challenges are not necessarily on an interpersonal level between developers and clinicians during the development process, but structural and related to policy making.

3.2.9 Collett

Collett had been involved in medical technology development at a Norwegian research institute for over 10 years. He was involved with segmentation and visualization of structures for the bronchoscopy navigation tool described in section 3.2.2. In describing the motivation for the tool, he used the analogy of driving without a map, only using the road for navigation, compared to having a map and a GPS for support. In the application, the "map" is constructed from CT images, and the directions given by the "GPS" is a path leading to a virtual location representing the area of interest for biopsy.

Collett discussed a variety of topics regarding the dynamics of interdisciplinary collaboration and the various priorities, trade-offs and considerations. He described how clinicians typically have limited time dedicated to research, which can be especially challenging with regards to time consuming tasks such as data labeling. Additionally, he described how research interests may sometimes interfere with what has the most practical applications. A similar challenge of competing interests is related to sharing of data. Collett noted that the research institute has

a close relationship with clinicians, creating a productive environment for research and development.

3.3 Analysis of Themes

Six main topics were identified from the interview data: development processes, interdisciplinary collaboration, added value, commercialization and intellectual property, and bottlenecks and barriers. While these topics are treated as separate, they do in fact have overlapping elements. Certain characteristics of interdisciplinary collaboration are also discussed as a barrier in section 3.3.5, and likewise, elements of the development process are discussed with regards to how value is identified in section 3.3.3. As these topics are closely intertwined parts of XR development for medical purposes, a certain degree of overlapping is inevitable. An overview of the themes and their related subtopics are presented in table 3.3.1.

Theme	**Subtopics**
Development processes	- Phases and methods - Project initiation - Understanding the clinical problem - Understanding the technical solution - Testing and evaluation - Patient safety
Interdisciplinary collaboration	- Involvement of clinicians: how, when and why - Terminologies and understanding - Perspectives and priorities - Communication and personal relationships
Added Value	- Strategies to ensure and identify added value - Perceptions of added value - Challenges in identifying added value - The effect of technology acceptance
Commercialization and intellectual property	- The process of commercializing a product - Regulations - Facilitation of commercialization processes - Intellectual property and ownership
Bottlenecks and barriers	- Usability challenges - User preference - Scepticism and enthusiasm - Performance challenges - Bottlenecks in AI modelling - Competing interests - Financial challenges - Structural challenges

Table 3.3.1: Overview of main themes and related subtopics.

3.3.1 Development Processes

Understanding the development process is part of understanding how added value is ensured. Various aspects of the process is covered in this section. First, an overall description of the development process and its phases. Second, the manners in which projects are initiated - by whom and under which circumstances. Third, how the parties develop an understanding of a clinical problem and potential solutions. Fourth, the role of testing and evaluation. Finally, the ways in which patient safety is maintained throughout the development process.

3.3.1.1 Description of development process

Overall, the development process is described by participants as iterative. Evaluations and feedback from end users serve as a basis from which the application is adapted to suit their needs and requirements. Tubman explicitly describes the methodology as "Design Science". Based on his description of the process, figure 3.3.1 was created. The figure is meant for visualization as it was constructed based on input from only one participant. While other interviewees mentioned similar aspects - especially the iterative nature of the development phase - they did not describe the process in similar detail, nor were they asked to validate the illustration in the context of their own processes. The first phase consists of defining the problem space, in which challenges or gaps are identified through approaches from clinicians and/or by conducting a literature review. Through interviews with clinicians, the problem and potential solutions are defined. The next phase is the design process, in which the requirements for the resulting application are defined through case studies and/or interviews with clinicians. Based on the requirements, a prototype is developed and evaluated in a manner suitable for the current stage and type of application. Using the feedback from the evaluation, the requirements are refined, followed by a new round of development. This cycle is repeated any number of times, producing some sort of artifact. This may be in the form of a research article or a marketable product.

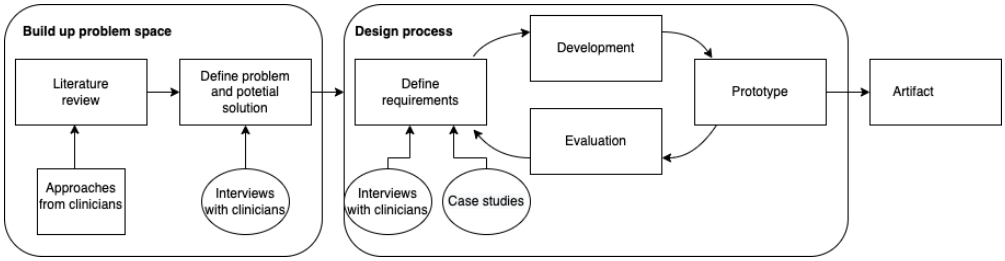

Figure 3.3.1: Diagram visualizing an iterative development process. Developed based on descriptions provided by Tubman

3.3.1.2 Initiation of projects

Various mechanisms for initiation of new projects are described by the interviewees. Developers Steinem and Collett decribe how ongoing collaboration with clinicians leads to new ideas and new problems being uncovered. For the project regarding XR for bronchoscopy, Steinem describes this to be the case:

> *"It simply started with us testing out a navigation system, and we became aware of that problem [multiple screens being used]. And then we had meetings with them afterwards, and we discussed 'how can we approach this problem and solve it?' And in that setting, XR emerged"* - Steinem

They both note that the emphasis is on having an underlying clinical problem, and that clinicians typically will have to express a need or gap. On the other hand, Wollstonecraft, who is involved in the same bronchoscopy project, perceived the technology to have been the driver rather than the clinical problem.

> *"On the developer side it's like 'OK, we have this, let's see if we can use it'. (...) The technology has come to us first, and then you look for what to do with was is available"* - Wollstonecraft

Thus, there may be different perspectives on the underlying mechanisms.

Developers Goodall and Tubman both describe cases of the developers initiating projects. Tubman describes how identification of a gap in literature may lead to an idea, using the example of him and another postdoc "on a normal day like literally hiking and just talking about this thing and just came up with this [idea of using XR for an Alzheimer's assessment tool]". Goodall described how sometimes "I have an idea that 'OK this could be really useful' and then I actually make a prototype that I show to one clinician that I think it could be useful for". He goes on to describe that this would typically be a simple prototype that allows the clinicians to "see the potential of the technology, right, because this is really unknown technology to them". This suggests that a lack of familiarity with XR makes it challenging for a clinician to devise or imagine ideas for XR solutions. Several of the interviewees described how it is often necessary to see and experience the possibilities of XR in order for ideas to develop.

Doctors initiating problems is the most common method explicitly described by participants. Approaches from clinicians are mentioned by Steinem, Tubman, Collett and Ginsburg. Johnson describes how two surgeons identified the problem of visualization during liver surgery in their day-to-day work:

> *"They thought it would be nice to do something regarding this [problem] and they had the idea specifically about AR and that you can use AR in some kind of way"* - Johnson

This led them to contact two professors of mathematics and initiate a collaboration. In this example, the surgeons have identified a persistent problem that has not been mitigated by increased experience in any satisfactory way, and the problem is cumbersome enough for them to dedicate significant time and effort to solving it. Thus, there may be a significant demand for a device that helps solve the problem. It is difficult to imagine that engineers would have been able to identify that same gap on their own. As a matter of fact, Goodall expresses a preference for doctors initiating a project, describing that "those are the most successful ones". While it was most commonly mentioned, it is difficult to determine whether it is the most common one in practice.

Clinicians approaching developers outside of existing research collaborations require knowledge of their work. Word of mouth is described as an important

mechanism - clinicians hearing about the work at the research institute and expressing interest. Developer Collett gives an example of this:

> *"Someone speaks to some clinicians and say 'oh, you need that? In that case you should talk to people at [name of research institute]'"* - Collett

Similarly, deliberate exposure such as presentations can help spread knowledge and spark interest – as developer Steinem describes it:

> *"Sometimes we have a presentation, right, and a clinician we have never spoken to hears about our work and thinks 'wow, this is exactly what I need'"* - Steinem

Clinician Ginsburg describes similar mechanisms - the work at the R&D centre has become well known in the clinic, and surgeons come to them to have holograms created. He also describes the effect of exposure:

> *"I'm having a meeting with the entire hospital on Friday where I will talk about it, and I imagine there will be a few inquiries after that"* - Ginsburg

As many clinicians are not familiar with XR technology and may need exposure in order to see potential solutions. For this reason, deliberate exposure may be useful in order to open up for new ideas and clinical challenges.

3.3.1.3 Understanding the Problem and Potential Solutions

Clinician Franklin emphasizes the importance of developing a thorough understanding of the clinical problem, saying that "the difficulty is to create an app that is - not just looks good - that is reliable, useful". Various strategies are described in order for the developers to understand the clinical problem. Developer Tubman notes that a literature review is important to ground the project in a scientific context and define the gap in a scientific manner. Johnson recounts having two rounds of interviews with surgeons performing laparoscopic surgeries on livers. The initial round was aimed at developing a good understanding of the problem itself, and the second round at developing the product concept - asking "what is must have, what is nice to have, and so forth". Developer Collett describes how sometimes external product designers will be brought in to help map out the needs and requirements for larger systems. Overall, there are several methods that may be combined in different ways depending on the current needs of the project.

The key component described for understanding the problem and solution is to have conversations and discussions between clinicians and technicians. As developer Steinem puts it:

> *"You have to put clinicians and technicians in the same room, and you have to discuss possibilities based on the problem. They [the clinicians] describe it to the developers, and the developers can suggest solutions and which technologies exist"* - Steinem

Similarly, developer Collett emphasizes "talking and understanding". He describes close collaboration with clinicians and explains how frequent meetings that allow open discussions are key. Clinician Ginsburg emphasises that the process in interdisciplinary throughout:

> *"The way we're sitting here now [in the interview setting] across the table, that's how we work. A doctor and an engineer all the way"* Ginsburg

Because the two parties come from different perspectives, there is a mutual process of understanding the other. The clinical problem has to be described in technical requirements, suitable for the software and/or hardware development process. In order to formulate a technical solution, the developers need to understand the clinical problem in a way that allows them to translate it to such technical requirements. However, in order for the clinicians to effectively communicate with the developers, they will also have to develop an understanding for the technology that is used as a medium. It is noted that the understanding will develop and improve throughout the process, through discussions, evaluation and feedback. Developer Steinem describes that this can manifest through minor eureka moments:

> *"You start in one place and they see that 'Oh, this is actually not the solution to the problem, but it works well for another problem we have', and quite often it happens that they see that 'Wow, this technology can do that?'. And sometimes we see that 'Oh, so **that's** what you're looking for, **that's** the clinical problem'"* - Steinem

This emphasizes how involvement of clinicians is necessary at all stages of the development process. Only including them in early or late stages is not sufficient.

3.3.1.4 Testing and evaluation

Testing and evaluation are key elements in the iterative process, as described by all participants. It is also illustrated in figure 3.3.1. Developer Tubman states that "you find these things throughout the process - what works and what [does] not" and that the only way to do so is "getting very first hand feedback, like taking the application to the person". He emphasizes how the different perspectives mean that clinicians identify challenges and limitations the developers are not able to - both because they know the clinical problem and situation better, and because they interact with the technology from the user point of view. Developer Goodall exemplifies this:

> *"Sometimes they say that 'yes, you have a very nice visualization, but it's totally useless because it's not fast enough'"* - Goodall

From this feedback, the application can be adapted to combine advanced technology with the practical requirements of the clinical problem.

Business developer Johnson describes frequent sessions, preferably every or every other week, to confirm with surgeons that "this feature - what do you think about it? Is it someting you want?". Otherwise, he describes, the risk is that you "develop and develop and you show something and the response is 'well, we don't want this'". Clinician Wollstonecraft mentions how the format of tests depend

on the element of the application that is to be evaluated. While aspects such as tracking technology may be evaluated in terms of accuracy, the application as a whole may be evaluated in terms of usability, and the images displayed may be evaluated in terms of their quality. For this reason, there will typically be several rounds of testing, involving different groups, in order to cover various aspects of the application. The tests may look very different depending on the stage of development. Developer Tubman highlights how testing is an aspect of the research methodology that can be optimized in order to deal with bias. He suggests including a variety of participants and having a careful randomization process to reduce the effect of bias. By comparing various groups, the biases of the groups can be identified and understood.

3.3.1.5 Patient safety

While the applications are to be used on patients, considerations must be taken in order to ensure their safety throughout the development process. Developer Collett describes that early stage testing will be done in a "lab setting", and Wollstonecraft gives the example of using a phantom organ. Animal testing is also mentioned by Collett and Steinem, but described not to be common. Clinician Ginsburg describes that patient safety is considered by attempting not to let holograms impact surgical decisions. He explains that during the first study evaluating the planning tool, planning would happen using traditional methods. In a separate session, holograms were used and a suitable strategy written down. The surgery would then be performed at a later stage, when the holograms were no longer fresh in memory of the surgeon. Steinem describes how any potential negative impact on the patient was avoided during testing of the bronchoscopy navigation tool: the procedure was performed in the traditional manner until the goal was reached. At that point, the doctor put on the HoloLens for a short period of time to perform an evaluation. It is described how regulations require documentation of previous demonstrations and safety to be present in order to move on to procedures in which patients are more exposed to the technology. Thus, patient safety is ensured through a gradual and carefully considered process.

3.3.2 Interdisciplinary Collaboration

Medical technology is inherently interdisciplinary as it combines the medical discipline and fields like electronics and computer science. The following section describes aspects of the interdisciplinary collaboration. First, the ways in which clinicians are involved is presented, aiming to map out their role, the ways in which they contribute to the development process, and how research projects are combined with clinical work. Secondly, ways in which different backgrounds and perspectives affect the dynamics are examined.

3.3.2.1 Involvement of clinicians

Clinicians are the end users of XR tools for healthcare purposes, and are described by clinician Ginsburg as being absolutely "crucial" in the development process. This sentiment is elaborated with the familiarity clinicians have with the proce-

dures in question, and their understanding of how the tool can be used in practice. Developer Goodall emphasizes this:

> *«You really need some feedback because you [as a developer] don't know exactly what is important for them [as users]»* - Goodall

Similarly, Tubman describes how important feedback from clinicians is:

> *"What feedback they could give me, I couldn't come up with that feedback on my own. Like it's just very specific things that only they would know. As a researcher, I would not care that much, but they would."* - Tubman

Thus, clinicians offer insights that are unique to their knowledge and experience in the medical field. Clinicians will typically be responsible for setting up tests cases relevant for the task, as described by Wollstonecraft, Ginsburg, Goodall, and Collett. From the clinicians' perspective, their involvement is a way to ensure that their needs are being met, and that choices and priorities are not only being made from the perspective of a developer. Wollstonecraft explains that what constitutes interesting research in computer science may not correspond to what is the most useful for clinicians. For this reason, clinicians must be involved during the development process.

Moreover, involving clinicians provides a "foot in the door". Business developer Johnson describes hospitals as "closed worlds". He explains that it is difficult to make contact with staff in order to receive feedback unless a clinician is already actively involved in the project. Similarly, clinician Lovelace describes it as difficult for the start-up company to continue developing the product on their own due to a lack of clinical resources. Additionally, involving a clinician opens up their network to the developers. Developer Goodall explains that clinicians are important when it comes to recruitment for testing. Because this exposes more clinicians to XR technology, it may also have the long-term effect of sparking interest in future collaboration and projects.

Time is a scarce resource, and clinicians are described as typically having a part-time position in development projects - or even in addition to their clinical positions. The challenge of scheduling was mentioned by several interviewees, as doctors are known for having busy schedules - clinician Ginsburg humorously described his 50/50 position split between research and clinic rather as a 100/100 split. Business developer Johnson calls it "basically impossible" to get a hold of their own surgeon and describes the effort made to utilize openings in the surgeon's schedule for things like testing:

> *"We make sure that it's all in order beforehand, prepare everything, have things ready for him to come in and 'check, check, check, this is good, this is bad' and then leave for his next engagement"* - Johnson

Developer Collett describes how clinicians will often be forced to prioritize clinical work, as the hospital schedules offer little flexibility. He explains that weekly meetings are held between clinicians and developers, but usually at least some of the clinicians will not be able to attend or they "join in wearing a white coat and have to run back and forth [between the meeting and clinical tasks]". He

expresses a need for more time to have common meetings including all clinicians. Furthermore, only being involved part time and having clinical work take precedence means that time-consuming tasks are difficult to prioritize. As described in section 3.3.5.3, developing AI powered applications requires a large basis of medical data. This has to be both collected, labelled, and quality controlled. Collett explains how doctors are important with regards to labeling clinical data, but that they typically only have 20% of their time dedicated to research. Clinical PhD candidates have a larger portion of their time dedicated to research, making it preferable to have such tasks handled by them if relevant for the PhD project. With limited time dedicated to research, tasks such as building up the foundational data may be spread out over a long period of time, thus slowing down the process.

3.3.2.2 Dynamics of interdisciplinary collaboration

In several of the interviews, the effect of different perspectives were discussed. Developer Tubman describes how clinicians and developers express themselves at different levels of abstraction and using different terminology. While a clinical problem exists with a high level of abstraction, technical solutions must be expressed with very specific requirements. Tubman illustrates this with the following example:

> *«Like if a neuroscience person says that this object is distracting. That is not a very good way to put it to a developer, right? Because OK, it's distracting. And what? So then we would work on 'OK, well, how we can solve it in a technical basis'? So we would be like 'OK, we can decrease the size by 0.5 and put it at a place like this'»* - Tubman

For this reason, several participants describes collaboration between the disciplines as a process of translation and uses the comparison of speaking different languages. Clinician Lovelace describes his own role as an intermediary and how translating problems between clinicians and developers is a key component. He includes the example of how he may want to describe a clinical problem to a colleague from a technical background:

> *"This is a 3D-problem. Here, there is a 3D structure in another 3D structure, and here there is another 3D structure. And you're trying to remove the first structure, but you have to get around this one"* - Lovelace

Different understandings and perspectives may lead to different priorities, and clinician Wollstonecraft emphasizes the importance of clinicians taking an active role throughout the process. He uses an analogy to describe the dynamics:

> *"It's kind of like renovating a house. If you have a lot of workers and several things to do and correct, you have to kind of breathe down their back to make sure they don't do anything you didn't agree upon, or you may end up not getting molding in that room because they thought you wanted something different. Everything depends on a mutual understanding of what you need and how to get there"* - Wollstonecraft

Because it is limited what the clinicians can do themselves, they have to speak up and make sure their needs, requirements and wishes are heard and understood by the developers.

The "how-to" when it comes to developing a mutual understanding can be considered an acquired skill. Lovelace describes that experience is important in order to understand how to express a problem to a specific target, and how to interpret an issue that is expressed by someone else. Wollstonecraft describes that the clinicians and developers within the project he is involved in "talk understandably to each other", as the engineers "have been involved for that long". Thus, they have been exposed to the clinical setting over a longer period of time. Conversely, developer Tubman expresses that collaborating with clinicians that are new to working with people of a technical background is challenging - "we are literally talking in different languages". Hence, it is not just the technical development in itself that requires conscious effort, as summarized by Steinem:

> *"That's what it [the development process] is really about - how to close this gap between engineers and technology, and medicine."* - Steinem

It is also clear that personal relationships have a significant impact on the dynamics. Clinician Wollstonecraft describes it as give-and-take, where it is important to be attentive and helpful.

> *"In order to be heard by others, you have to listen very interested to what the engineers bring to the table."* - Wollstonecraft

Hence, by showing respect for the people on the other side of the table, the relationship is strengthened and one may expect to be met in the same way. However, he also describes lending the authority of more senior members of the research group by running new ideas or suggestions through them, as "it's a way to have a greater impact". Developer Tubman describes a similar tactic when trying to approach someone new for a collaboration:

> *"Usually if it's someone that is really like a very successful professor who would never answer my emails, then I would ask someone to introduce me to them."* - Tubman

This indicates a certain power dynamic, and Wollstonecraft uses the word "politics" in order to describe the interactions.

Various strategies are described in order to support communication and achieve mutual understanding. Wollstonecraft describes using practical examples - purchasing necessary tools to demonstrate what is possible. He describes how "over time I've realized that if you show initiative and do practical things instead of just discussing, it has a bit of a greater impact", playing into the stereotype of engineers being of a practical rather than theoretical nature. Clinician Lovelace describes that it will often be more effective to have clinicians from the R&D center handle the initial meetings with other clinicians and communicate the problem internally, rather than having direct communication with the developers. Developer Tubman described a similar tactic of having someone in the middle who is experienced in medical technology research when conducting meetings between clinicians and developers. Thus, conscious effort is put into this process, and various strategies are available.

3.3.3 Added Value

Examining the added value of XR tools can imply whether lack of widespread implementation is due to a lack of usefulness, or whether other factors are of bigger importance. Overall, development is described as a gradual process rather than depending on a "make or break" idea. This section presents strategies of ensuring added value, the effect of different perspectives on the perceived value, and some challenges in determining added value.

3.3.3.1 Ensuring Added Value

Several strategies are presented as means to ensure and identify added value. Developer Goodall emphasized the importance of a sound clinical problem - "if you have a good idea behind it [the project], it [added value] kind of comes by default". However, he explains that interaction with clinicians leads to adaptations toward a useful end product. Testing will provide feedback on whether an application is of value in a practical setting. Similarly, developer Tubman notes how "of course it's very hard to come up with something that is the best application", but that through an iterative process of feedback and adaptation, it can be refined. Goodall and developer Steinem both explain that the aim is typically to integrate a tool with the current workflow, but improving it. These improvements can come in different forms: new way to visualize data - such as with the surgical planning application as described by clinician Ginsburg, a reduced number of screens to handle - such as in the bronchoscopy navigation tool described by Wollstonecraft, possibility of assessing patient data and imaging in a sterile environment through gesture control - as described by Steinem, or a low risk environment to practice a procedure - such as the education tools described by Goodall. It is the feedback from clinicians through testing and discussion that ensures that the end product adds value, as Wollstonecraft, Goodall, Steinem, and Ginsburg emphasize.

3.3.3.2 Perceptions of Added Value

What is considered to be of added value differs between individuals, and especially between those with significantly different backgrounds. Developer Goodall illustrates this with an example of a visualization application running live on the HoloLens:

> *"For me it was really nice from a technical perspective. For them [the clinicians] it was actually very nice to communicate something to the surgeon.(..) that's the benefit that they see. Like, it's not the fact that it runs live on the HoloLens."*- Goodall

Coming from a technical perspective, the technically sophisticated aspects may appear to be what is useful. However, for the end user, it may in fact be something completely different. Similarly, developer Tubman recounts expecting an application running on HoloLens 2 to be preferred over one on HoloLens 1 - "the new HoloLens is better, so it basically makes it better, right?" - but being surprised to find out that the opposite was true. After interpreting the feedback from users, he found that the gesture control on HoloLens 2 actually made the application more strenuous to use compared to handheld controls, outweighing the positive

effects of performance improvements. Clinician Wollstonecraft reflects that while the bronchoscopy navigation tool looks great it faces similar challenges as traditional methods in navigating in the periphery of the lungs. He emphasizes how doctors performing these procedures get a very high volume of practice and thus "it's possible that the engineers believe these programs are a bit more useful than they actually are". However, he considers it possible that it may be useful as a practice tool for less experienced doctors. Furthermore, Tubman points out that the concept of added value is not a black and white issue.

> *«It's not a question of if this is better or this is better. It's a question of 'this is better in terms of this and this is better in terms of this'»* - Tubman

This is illustrated by the example of HoloLens 2 compared to HoloLens 1. While several performance measures are objectively better on HoloLens 2, added value must be evaluated in the context of how the application will be used.

3.3.3.3 Limitations in establishing added value

At the current stage of research it is difficult to fully establish the added value of XR for healthcare. Clinician Lovelace explains that larger clinical studies are necessary, but this requires certain bottlenecks to be resolved. Because the current process of creating holograms requires time and training, widespread and continuous clinical use is not possible at this point. For this reason, the overall value and comparison to traditional methods cannot be determined. Lovelace emphasizes that current studies have merely illustrated that it is *possible* to use holograms for planning, and have reported subjective experiences of improvement. Clinician Wollstonecraft points out how limited exposure to the tools makes it difficult for clinicians to become fully acquainted with their practical use. Subsequently, it can be difficult to fully understand their potential in clinical practice.

> *"We should actually have some of these navigation systems available on a daily basis and be able to use them more often."* - Wollstonecraft

However, the current level of usability means that an engineer available for help is required. This is not realistic from a cost perspective. Business developer Johnson explains that the final product is not fully developed - "the way we do the procedures today is not how it will look later" - and evaluation of the cost-benefit will be necessary at a later stage. He emphasizes that usability will be an important factor, which is ensured by the envisioned plug-and-play-solution.

Technology acceptance factors come into play when subjective measures are evaluated. The technology acceptance model postulates that the consumers' intention to use is influenced by perceived ease of use and perceived usefulness. However, developer Tubman describes that novelty and enjoyment also plays a significant role when it comes to XR. He explains that excitement around a new technology can lead to it being perceived as more useful than it actually is. This introduces a bias when evaluating the added value. Clinician Ginsburg describes strong positive reactions from clinicians when using the planning tool for the first time - "when a clinician sees it their reaction is always 'wow'". While this does not negate the possibility that this tool adds significant value to surgical planning,

part of the reaction may be due to excitement regarding a novel application. Developer Tubman describes how this excitement wears off over time, resulting in a reduction in perceived value:

> *«If you are very excited about it, you would just say «I like very much», but then there's a learning curve, so you would get used to it and then your excitement goes down and then maybe you will not see any use of it in two years»* - Tubman

For this reason, exposure over time is necessary in order to determine the added value.

3.3.4 Commercialization and Intellectual Property

Commercialization emerged as a topic in several interviews. In this section, it is described in terms of three subtopics. First, the process is described from the perspective of medical technology research - what it entails for the stakeholders, and what makes the process challenging. Secondly, the options mentioned that help facilitate commercialization processes are covered. Finally, some issues of intellectual property related to commercialization are presented.

3.3.4.1 The Commercialization Process

Commercialization is the process of bringing new products or services to market. While some patients may gain access to new methods and treatments through experimental research, this represents a small number.

> *"That's the thing about research, right? You create some solutions, and they look good, but if you don't make a product out it, only the patients from the study had any use of it. (..). But if you create a product, you have - in principle - the entire world, all the patients in the world who have the opportunity to benefit from it"* - Steinem

For this reason, creating a marketable product is the end goal.

It was evident from the interviews that medical technology can be a difficult industry to navigate. Several of the interviewees are or have been involved in commercialization processes. Clinician Ginsburg describes it as a "long process and a lot of work to bring it to market". Furthermore, he describes that if one decides to handle the process on one's own, it is essentially a full time job. As a business developer, commercialization is the main task of Johnson. In the description of his role, he includes patent related matters, working with lawyers to handle things like trademark related issues, market analysis, and maintaining contact with suppliers, among other things. Essentially, there are several aspects of creating a medical technology product that is not directly related to research and development. Thus, it involves a different set of expertise. Johnson mentions that commercialization is especially challenging because medical technology is dominated by a few large corporations, making it difficult to enter as a small start-up company.

Developer Steinem outlines how a medical device on average takes take 5-7 years from idea to market and costs around 100 million Norwegian kroner(NOK)

in development. It is thus evident that the process requires significant efforts dedicated to procure funding. The efforts and challenges related to funding are also described by Johnson, Wollstonecraft, and Steinem. Business developer Johnson explained that both loans and external investments have been necessary in order to achieve proper funding, stating that grants and other "soft financing" were not sufficient. Investments from external parties become a necessary part of the process, but as Johnson puts it: "you get watered down". Ownership is redistributed as another party buys into the company, reducing the share of those already involved. However, he emphasizes that this is necessary because "the industry is the way it is" and that from the outset "you have to be aware that this is a part of the journey".

Another significant challenge is related to the regulations surrounding medical devices. Business developer Johnson described it as "one of the biggest challenges we have" as a company when moving from a prototype to a commercial product. Namely, he addresses the lack of guidelines for how to adhere to the current standards:

> *"There is no kind of veteran rulebook to follow, telling you to do this and that, rather you have to develop everything yourself and try to live up to the standards and then you're inspected thereafter. (..) It doesn't tell you that you have to do this and that many operations with this and that outcome – you have to do it all yourself and hope it's enough, so it's an enormous challenge."* - Johnson

If there are no clearly defined criteria, one can easily imagine that companies may find themselves struggling to adhere to the standards. Ginsburg and Johnson both mention how the Medical Device Regulation(MDR) was recently brought into effect, replacing the previous Medical Device Directive(MDD). MDR is an EU regulation governing the production and distribution of medical devices. While an EU directive sets out a goal all member nations must achieve, an EU regulation must be applied in its entirety – making a regulation stricter in terms of *how* specific goals are achieved. Clinician Ginsburg describes that the uncertainty around legislation changes has been difficult:

> *"It's been unpredictable. It's been a challenge in itself because you don't know what rules you have to deal with. It's been 'Sorry, next year they [the rules] may look different.'"* - Ginsburg

Business developer Johnson describes that as a consequence of the new regulation, existing medical devices have had to undergo reclassification, making the waiting process for approvals longer. Hence, it is possible that they recount a regulatory process that has been even more challenging than usual. However, the challenges are also described by developer Steinem, characterizing the approval process as "extremely bureaucratic" and "a paper mill". He explains that while researchers do not necessarily handle the regulatory process, it is considered even at early stages as a precautionary step.

> *"Classification of devices is extremely important to consider early on in the process so you know what kind of regulatory challenges will appear along the way"* - Steinem

Further, he describes how "a lot of people are not aware" of how long things like approval take, describing how he will often need to remind new and eager scientists that saying that "you cannot take any shortcuts - you have to go through all the steps."

3.3.4.2 Facilitation of commercialization

Clinician Ginsburg explains that the most common choice is to seek help from a Technology Transfer Office(TTO) for the commercialization process. TTOs help manage the intellectual property assets at a university and the transfer of technology and knowledge to industry. The TTO can evaluate the business value of an idea, provide advice on legal and regulatory matters, and choose to start a company and seek out investors. Business developer Johnson describes involving the TTO at their institution:

> *"They helped the entire incorporation process. They outlined agreements and structures - you know, shareholders agreement. They helped the process related to IP [intellectual property], making sure it belongs to the company and so forth. And they made a small investment"* - Johnson

Clinicians Ginsburg and Lovelace explain how their institution has a three-part model, in which it is standardized that a third each is owned by the hospital, the TTO and the inventors. However, when external investors are brought in, the share of the inventors can be reduced to near nothing – unless they have the means to do their own investment. Hence, one may have to choose between having a larger portion of ownership and autonomy over the company but face a challenging process and most likely needing to step down from the research itself – or one can receive help and guidance, while continuing to work with research and development, but also have to "give away" the idea.

While a TTO may be of help with many aspects of the commercialization process, their assistance is of service to the institution they belong to. Essentially, they are meant to protect the interest of the university, rather than of the inventors. Clinician Lovelace discusses this conflict of interests:

> *"They don't want to make a decision - they're not interested - until they have seen the entire potential. (...) They want to accept it if it's successful, but they don't want to let go of things that are unclear or unfinished. So the help and the advice is not necessarily the best for the founders."* - Lovelace

Additionally, the advice is given related to further development and commercialization – not whether the idea is medically sound. Lovelace brings attention to this gap and the need for "someone to look at it with more academic eyes and with that [medical] expertise". He compares this with options for having research evaluated:

> *"It's much easier with research. It's much easier that you can send it to The Norwegian Research Council. There is an expert group to evaluate it."* - Lovelace

For this reason, the idea of a medical advisory unit, separate from the TTO, was mentioned.

Business developer Johnson describes additional ways in which his educational institution helped facilitate commercialization of a research project. As described in section 3.2.1, Johnson was a student at an entrepeneurship school when he became involved with the project. The program in question is a two-year Master's degree in Entrepreneurship and Business Design, and Johnson explains that students are typically paired up with researchers for development of real R&D innovation projects. This allows the students to not only be connected to relevant research projects, but also to engage in several processes related to commercialization with guidance from a network of experts - in a low risk environment. Because it is the part of their degree, issues like salary and any consequences of the endeavors proving fruitless are less dire than had it been their full time job. Additionally, a venture capital company is associated with the institution and can provide financing of start-up companies resulting from the process.

3.3.4.3 Intellectual property

Commercialization was described to typically involve several parties, which involves matters of intellectual ownership. Intellectual property are intangible creations of the human mind - the result of activities that are not necessarily evident in a physical object. Intellectual property is protected by patents, trademarks, and copyrights, defining who has the right to use, sell, and distribute the creation. Developer Steinem describes how in collaboration between the research institution, the hospital, and an industry partner, intellectual property will have to be defined beforehand:

> *"Obviously, you have to have an agreement as a foundation in order for everyone to know who is responsible for what and who has the rights to the product when the project is finished. (..) Often the industry [partner] has the rights, of course. Otherwise there will be no new product"* - Steinem

As described in section 3.3.4.2, clinician Ginsburg outlines the three-part model at their institution, and how the researchers' third in the ownership has been reduced to "a small fraction" due to external investments. As the intellectual property belongs to the company, reduced ownership in the company also gives the researchers smaller ownership of their own work. As described in section 3.3.2.1, clinicians are considered crucial in order for the development process to result in a useful product, making it a paradox that they are given little ownership and rights to what is the product of their professional expertise. Ginsburg discusses how there is a lack of incentive for clinicians to continue to provide new thoughts, ideas, and further developments:

> *"If you feel like you have to give away a lot at a very early stage, that may be demotivating."* - Ginsburg

He describes how "in an ideal world", the original inventor should have a right to the patent:

> *"I think that is very important - that you get something in return for a really good idea."* - Ginsburg

Often, there will be a consistent progress from input over time once the idea has begun to take shape. In these cases, Ginsburg describes how clinicians can be incentivized economically to continue contributing:

> *"I think a natural option would be to generate some means that went back to the research environment. Having a kind of fund that you build up by offering goodwill for development. (..) If you [the company] succeed, we [the researchers] get some kind of options that build up a fund for developing new ideas."* - Ginsburg

Additionally, he suggests a dynamic ownership model, where shares are distributed depending on how much the entities have contributed:

> *"If they do relatively little, they don't get a lot in return but if they go in heavily and do a lot they should get more in return"* - Ginsburg

Thus, adjustments to how intellectual property and ownership are managed may provide incentive for clinicians to contribute to innovation projects.

3.3.5 Bottlenecks and Barriers

Several challenges related to widespread use of XR for medicine were discussed, and grouped into three categories. User acceptance is determined by the subjective experience of whether a system meets the users expectations and requirements. Technological challenges are challenges directly related to the software and/or hardware of the XR tool. Challenges related to funding describe ways in which scarcity in resources manifest for the stakeholders at various stages of development.

3.3.5.1 Usability, User Preference and User Acceptance

The experience of the end user is determined both by human and technological factors. Usability refers to the ease of use - the effectiveness, efficiency and satisfaction which which a user can achieve a goal. The technology acceptance model is a framework to explain factors that influence users' acceptance of a technology and consists of perceived usefulness and perceived ease of use.

Overall, the importance of practical and user friendly solutions are stressed. Clinician Wollstonecraft mentions ease of use as a current challenge with the bronchoscopy navigation tool, inhibiting more widespread use. Developer Steinem recounts how in previous research projects, the HMDs were too heavy and uncomfortable to wear during procedures. However, the HoloLens is smaller and lighter than some of the earlier HMDs, making the current application feasible. Ginsburg argues that acceptance of the surgical planning tool will be self-driven as long as it is easy enough to use and the 3D modeling is fast enough. However, clinician Lovelace mentions how the current 3D modelling for the application is too time consuming for widespread use by "any surgeon across the hallway". Business developer Johnson explains that the choice of a "plug and play" product was made in order to reduce the reliance on internet bandwidth and other external factors.

This way, they avoid the risk of latency reducing the ease of use. Overall, the applications do not appear to have reached a satisfactory level of user friendliness.

Developers Steinem and Goodall mention how clinicians have so far displayed a preference towards AR rather than VR. In AR, the real environment is augmented with virtual objects, while in VR, the user is presented with a completely virtual environment. This preference pertains especially to cases in which the application is used while interacting with a patient, such as performing a procedure. Goodall explains that "You can do much more and much fancier stuff there [in VR], but usually they want to have an eye on the environment or the patient". While this preference is related to safety, as for example loosing sight of a surgical field may be dangerous, it may also be due to a lack of familiarity with XR technologies. Steinem describes how he imagines a gradual development towards more acceptance in the long term.

> *"It can be a gradual transition with more and more extended reality and less reality, but I don't think it will be a 100% [VR]."* - Steinem

He reflects that it is generally more difficult to get acceptance of new methods or technologies that lead to big changes in the current workflow. He also discusses the effect of disruptive technologies, as they challenge existing norms and practices and typically require a long time to gain acceptance. However, they make certain activities significantly easier or more convenient. In Steinem's words, "it is so unique and solves so many problems" and "people see that 'shit, this is good'", making widespread use a question of producing the scientific data to support it. Johnson reflects around the challenge of acceptance when introducing new methods, describing that the current workflow often involves open surgery, while the application is aimed at laparoscopic surgery. Thus, the more "old school" surgeons may be more hesitant to use the product. On the other hand, laparoscopic surgery is in itself a disruptive technology, having replaced open surgery in certain procedures. This serves as an example of how new and different technologies can gain acceptance if the benefit is made clear.

The perceived usefulness of XR applications can be influenced both by technology scepticism and enthusiasm. Developer Steinem discusses the hype cycles, and makes a note that XR has probably "been several places on that curve". The hype cycle is a graphical representation of the lifetime of a technology [19], and can be seen in figure 3.3.2. The peak of inflated expectations represents unrealistic expectations, and coincides with high excitement. As the technology fails to live up to the hype, the hype reaches the through of disillusionment, typically accompanied by scepticism and negativity. While the model was created with societal hype in mind, it can be transferred to an individual basis - what the hype cycle within one person may look like over a period of time. While individuals may follow different hype cycles, this corresponds well with the trend of people showing initial excitement which wears down with the learning curve of an application, described by developer Tubman in section 3.3.3. He outlines a polarization between either being very excited or not excited, with no middle ground:

> *"If I talk to experts then they wouldn't like anything. And then if I talk to people, they would like everything. So it's actually kind of a problem from a research perspective."* - Tubman

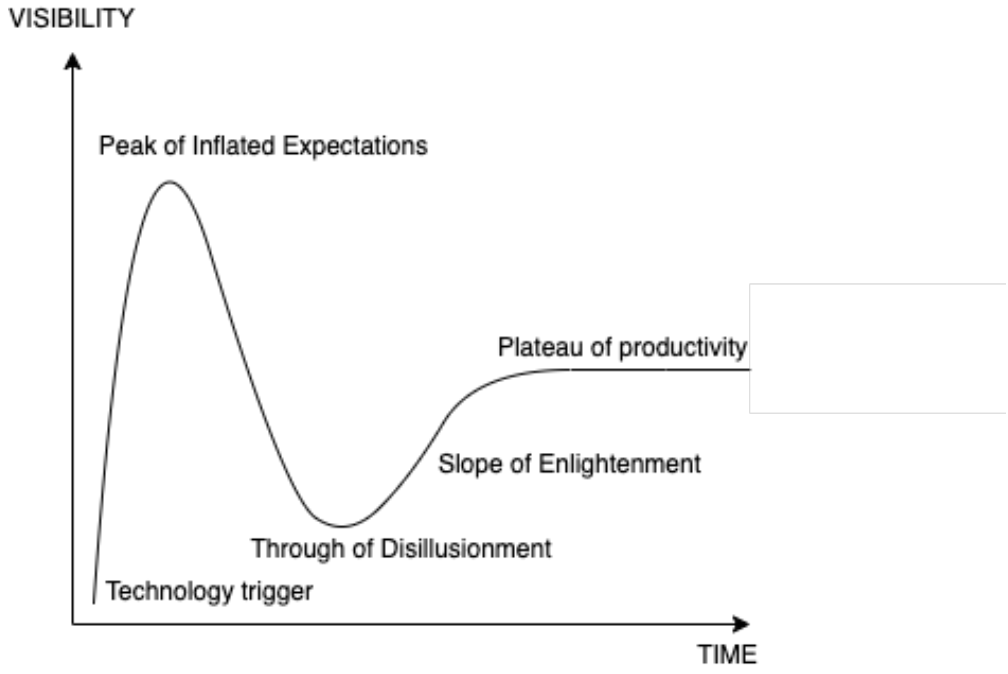

Figure 3.3.2: Visualization of the hype cycle phases

Both scepticism and exaggerated excitement are realistic is terms of what any new technology is likely to encounter when introduced into widespread use. However, excessive polarization does not provide a realistic test scenario.

3.3.5.2 Technological challenges

The technology may be a limitation in itself when it comes to development, as described by clinician Franklin:

> *"Sometimes it's hard to follow the the clinical needs because in VR, for example, there are so many limitations right now, we cannot create whatever."* - Franklin

Some of the challenges may be overcome by improvements in the XR hardware that is being used. Developers Goodall and Steinem both explain how real time performance is a challenge - augmenting images and immediately displaying them to the user. Steinem describes that only milliseconds of delay may be noticeable to the user. The challenge of real time performance was present when running the bronchoscopy navigation on HoloLens 1. Clinician Wollstonecraft describes that the delay "made it impossible to perform an examination in a natural way", and Steinem recounts: "we were about to say 'no, this solution is not good enough'". However, HoloLens 2 was announced with technical specifications indicating higher resolution and lower delays, allowing development to continue. The problem was solved simply by awaiting improvements in technological performance that could not be influenced by the researchers. However, in this case the researchers were extremely lucky with the timing. Had the project taken place long before the HoloLens 2 was announced, it may have been cancelled and possibly never resumed.

Some challenges may not be expected to get solved within the foreseeable future. Clinician Ginsburg describes how medical images are known to be flawed, as the technology with which the images are taken has it own limitations. This indirectly limits the performance of any application based on medical images.

Other challenges are directly influenced by the researchers, but constitute difficult and/or time consuming challenges in software development. Clinician Lovelace discusses the challenge of 3D-modelling, explaining that it has been researched for a long time, yet continues to pose a bottleneck:

> *"That's where it has continued to get jammed up - how to make the 3D-models. And if we're still getting stuck there in 2023 - how to make a 3D-representation of what we see in black and white - we can't move quickly with development."* - Lovelace

He explains how the aim is to have a semi-automatic segmentation of 3D-models, which requires AI technology. AI learns by training on relevant data, in order to make decisions intelligently. The amount of data points necessary for a machine learning model increases with the number of dimensions of the input - a rule of thumb being to have tenfold the number of data points as the number of dimensions in the data. Dimensions of an image are given by the number of pixels in the image, and multiple images are needed for creation of one 3D model. For reference, this thesis was written on a computer with a 13.3 inch screen with 2560x1600 pixels, totalling over 4 million pixels. While the resolution of medical images are significantly lower, this helps illustrate the computational complexity of creating such 3D models, and why applying AI to the problem is a non-trivial challenge. Even in healthy humans there are large anatomical variations, and in people with organ defects or other abnormalities the variations are even larger. Business developer Johnson describes how a big challenge is how to address organ deformation using AI, which is inevitable during surgery as conditions within the abdomen change compared to during pre-procedural images. Clinician Wollstonecraft explains that a request from the clinicians is to include the guiding pathway in the video feed, rather than having a virtual bronchoscopy image with the pathway. However, this also requires AI in order to recognize structures in the video image. He comments that "artificial intelligence takes a long time". It requires recording and labeling of a large number of procedures to learn from, in order to develop a reliable tool. Thus, access to data for AI methods are a significant bottleneck in development.

3.3.5.3 Data, Collaboration, and Competing interests

The idea of collaboration and sharing emerges as an option to help relieve the bottleneck presented by access to data for AI solutions. However, this is not straightforward. In fact, because data appears to be such a significant bottleneck, it may be the most valuable component and thus something to be wary about sharing. Ginsburg describes data as "the core of what we do". Developer Collett explains as long as one has data available "it's quite easy to make [machine learning models]". Hence, the AI itself is not what is of great value, but the unique data is. For this reason, researchers need to be selective with whom they choose to collaborate with. As clinician Ginsburg puts it:

> *"Shit in equals shit out. You need to have good data going in, so you can't establish a collaboration with anyone. You have to know that they are good, that they segment well"* - Ginsburg

While "anyone" can learn to make an AI model, not anyone can access high quality medical data - nor create high quality medical data.

The exclusivity of data and the competitive nature of medical technology makes sharing of data and other kinds of collaboration challenging. In the world of science, publishing is a driving force, but an emphasis is placed on presenting something that is new and unique. For this reason one may want to keep data to oneself in order to protect the uniqueness and novelty of the research. However, reproducibility is a major principle of the scientific method, which is in favor of sharing data. Developer Collett describes how as a researcher he wants to share data. However, with regards to developing a sense of ownership of the technology and making sure the researchers are properly credited, data is withheld until after publishing. Furthermore, he reflects on the value of data, saying "you can actually just publish the data set and get a bunch of citations on that".

On the other hand, one can also imagine more of an idealistic motivation - wanting to do what it takes to make improved care available to as many patients as possible. Clinician Ginsburg reflects around the interplay between this and the competitive nature of research:

> *"It's a bit of a delicate balance every now and then. (..) You want to collaborate and do what benefits everyone and helps the field move forwards, but at the same time attend to your own interests as a scientist, research group, and institution - for example in maintaining funding."* - Ginsburg

He does, however, mention several research collaborations with research environments at other institutions, and comments that there "is a lot of goodwill for collaboration".

From a business perspective, the value of a company is influenced by the ability to produce a product that cannot be replicated by competitors. This speaks in favor of not sharing any data in order to maintain a competitive edge. Developer Collett describes how the researchers may withhold data even after publishing for this reason. Business developer Johnson explains that secrecy is important for patenting reasons:

> *"As soon as you disclose anything you can't patent it, so if we were to explain exactly how we do it when it comes to our process and the surgery and everything, we're smoked on the patenting part of it."* - Johnson

He recounts how at an early stage, a research environment investigating XR for liver surgery at another institution was approached regarding collaboration. However, because they were already involved with another company this was not possible. He explains that the facilities of that same institution may be relevant for future studies, but that the commitment to a competitor must be considered. However, he believes that "collaboration will be essential moving forward" and that as a small company in medical technology "you have to be willing to compromise". Clinician Ginsburg imagines that in the future, licensing of the software

may be a way to navigate the conflict between research and business interests. In this scenario, research licenses are generated to other hospitals in exchange for data that can be used for validation or training. This way, a balance between collaboration and competition is upheld.

3.3.5.4 Challenges related to funding

Funding of research and development projects is a challenge that was repeatedly brought up. Clinician Ginsburg notes that "a large portion of the job is actually to get the funding, to be able to work". Developer Collett comments that "all scientists spend too much time on it [applying for funding], wasting a lot of time on it". He explains that the medical field is extremely competitive - even applications that get a good evaluation may not receive financing. Developer Steinem explains that part of the problem is the fact that a large portion of medical research money available is distributed within the health trusts(Norwegian: helseforetak). Consequently, that money is unavailable for many researchers to apply for. Additionally, Collett explains, funding is often tied to the healthcare sector, making only hospitals or doctors qualified to apply for it - "which is a big challenge for those of us who work within research for the healthcare sector". He reflects that while it is important that medical research is grounded in a clinical setting, with relevant staff confirming that it is useful, it should be possible for other parties to apply for funding directly. Additionally, he discusses the possibility of basic funding to reduce the time spent writing applications.

> *"When you are a good and strong research environment maybe there should be more basic funding - when you know the resources are being used in a good way. (...) I understand that there should be some some competition, but it's a bit too much - at least when you've shown that you are an environment that delivers good results."* - Collett

Clinician Lovelace calls for the hospital to invest more in implementing innovative solutions. He explains that while the surgical planning tool is available and possible to test on a wider basis, it is difficult to do so at the current stage. It requires "common" doctors to learn how to create, quality control, and analyze 3D models - something that is a completely new practice for most. This requires time for the doctors to learn these processes, someone providing the training, and time to construct the models on a regular basis. While one possibility would be to have specialized staff for 3D-modeling, it is also difficult to argue for the funding to support that.

> *"Someone has to research it and say 'here are the results. I need someone to do this'. But until we're there we have to do it ourselves and it's time consuming."* - Lovelace

Paradoxically, the results would be produced faster if the hospital invested time and money. Lovelace explains how the research group was "lucky" and received enough funding at an early stage to be able to research XR technologies, making the hospital possibly take for granted that they will continue to have funding and be self driven economically. He explains that at one point the researchers will have to move forward with other research projects, and unless someone else is trained

in the methods no one at the hospital will be able to provide holograms in the future. Lovelace describes how "it is a problem that will arise", but unless it is brought to attention "the hospital will never understand it".

3.3.5.5 Structural challenges

The separation between academia, industry and hospitals is a challenge. Separation of these entities also involve separation of the knowledge, experience and resources associated. Additionally, there are different policies governing the three, and various interests at play. Developing a medical technology device requires the three entities to come together, but with the current organization this is challenging.

While options for facilitation of commercialization are mentioned in section 3.3.4.2, there are still challenges. Additionally, the random element to how clinicians discover research projects, as described in section 3.3.1.2, indicates that clinicians are not systematically updated on ongoing research. Developer Steinem comments how "it's far between clinic and industry", and business developer Johnson describes hospitals as a "closed world" to industry. Johnson describes how after becoming involved in the project as a business manager, the only way to continue was to create a company. There was no option of continuing the project as an academic research project at a university while still maintaining funding for business development. Furthermore, it was not possible for the surgeons to stay involved with the company as a part-time research project combined with their hospital positions. For this reason, they are involved *in addition* to their full-time job.

Developer Steinem recounts how "20-30 years ago it was a bit crazy how the pharmaceutical and med-tech industries were financing these trips for doctors and so on". Now, he explains, this has swung "almost too far the other way", with very limited contact. However, he does mentions NorTrials as an effort to combat this. NorTrials is a national partnerships to increase the number of clinical trials in Norway – or as Steinem puts it "open the doors to the hospital for industry". It appears that the current structures do not succeed in facilitating collaboration, although some attempts are made.

CHAPTER

FOUR

DISCUSSION

In this study, the leading research questions were *How do clinicians av developers collaborate throughout the process in order to ensure added value of XR technology for healthcare?* and *What are the current barriers and limitations that inhibit widespread adoption of XR technology for healthcare, and how do they manifest?*. Nine interviews were conducted with healthcare professionals, computer scientists, and one business developer. A variety of topics emerged from these interviews, as pieces in the puzzle that answer those research questions. By providing a deeper understanding of the context and current state of research and development of XR for healthcare, this can inform future research projects and decisions. In this chapter, the implications of the findings for research and practice are discussed.

4.1 Development Processes

Understanding the development process helps understand the methodologies and mechanisms related to project selection, and interpretation of problems and solutions. This section discusses the described development processes in relation to known methodologies, ways in which new projects are initiated and its effect on project selection, and understanding of problems and potential solutions with an emphasis on requirement specification.

4.1.1 Descriptions of Development Processes

The descriptions of development methodology aligned with iterative and user centered design(UCD) practices. UCD seeks to ground the design of an innovation in the needs of the end user, and thus involve them in the design process [20]. While UCD was not explicitly mentioned, the rationale for involving clinicians throughout the process coincides with the goal of UCD. Involving clinicians was described as key in understanding the problem and potential solutions, as the doctors provide unique input that developers are not aware of. Interviews, discussions, and conversations were described as methods of involving clinicians. A 2007 article on interdisciplinary collaboration in eHealth describes how past eHealth technologies have been prone to insufficient involvement of end-users during the development process [21]. This compromises the usefulness and clinical appropriateness of the

resulting systems. Thus, the findings of this project may suggest that technology development for healthcare has since then adopted a more user centered approach.

4.1.2 Initiation of Projects

Various ways of initiating new projects were described. Several of the participants described how ongoing collaboration and interactions between developers and clinicians uncovers new problems and inspires ideas. Projects were also initiated by developers or by clinicians outside of ongoing collaboration. Several of the developers expressed the importance of grounding projects in a clinical problem and expressed a preference for doctors initiating problems. However, section 3.3.1.2 revealed a discrepancy in how developers and clinicians perceived the initiation of a specific project. Wollstonecraft perceived it as having been motivated by the technology, while Steinem expressed that the clinical problem was the driving factor. Both of these points of view express subjective experiences and there is not necessarily an absolute truth. As Steinem described an ongoing investigation into navigation systems, there is clearly an underlying clinical problem. However, if the current solution does not appear to add significant value at the current stage, the choice of applying XR may be perceived as a technology looking for a problem rather than the other way around. In line with the interpretive approach described in section 2.4.1, the different points of view can be considered as two of several possible interpretations.

Doctors' lack of familiarity with XR may inhibit initiation of potential projects. Developers described how the doctors typically need exposure to XR technology in order to understand its possibilities and potential. Additionally, doctors typically heard about XR projects through word of mouth and exposure such as presentations. This suggests that doctors are not regularly or systematically updated on innovation in medical technology. Increased knowledge may spark interest and positively influence attitudes, leading to more clinical problems being suggested by doctors.

4.1.3 Understanding Problems and Potential Solutions

In defining a solution, formalization of requirements and a lack of cross-domain-knowledge may present a challenge. As described in section 3.3.2, clinical problems and requirement are abstract, while the solution must be expressed in technical terms. These technical requirements should be defined in a way that is unambiguous, complete, modifiable, consistent and verifiable [22]. However, clinicians may express problems such as "we need better visualizations of heart defects" and requirements such as "virtual objects should not be distracting to the doctor". Understanding how such high level problems and requirements can be expressed in a way that upholds the four properties described - lack of ambiguity, completeness, consistency and verifiability - requires thorough understanding of the problem and potential solutions. However, section 3.3.2 describes several challenges in terms of different terminology and lack of cross-domain knowledge in interdisciplinary collaboration. In section 3.3.2.2, Tubman used the example of an object described as distracting by clinicians, which was translated by developers into a need to reduce the size of said object.

Violation of the clinical requirements is exposed through testing and evaluation, as described in section 3.3.1.4, which is in line with an iterative development approach. However, the challenges related to differences in perspective and background, paired with the specific practicalities of clinical settings, may negatively impact the process of formalizing the requirements. As requirement specification is considered to have profound effects on the success of software system testing [22], this may reduce the efficiency of the development process. Participants emphasize conversations, discussions, and frequent meetings between clinicians and developers as a method to understand the problem and potential solutions. However, no specific methodology is described for requirement engineering and formalization.

4.2 Interdisciplinary Collaboration

The interdisciplinary collaboration emerged as an integral part of the development process, but some limitations to the collaboration process were established. It is evident that interpersonal factors such as communication skills are of high importance during the process, in addition to technical aspects. This section discusses the challenge of continuity for clinical staff, the importance of communication and mutual understanding, and strategies to translate between the clinical and technical fields.

4.2.1 Involvement of Clinicians

Continuity was described as a challenge for doctors, as combined positions involving both clinical work and research makes scheduling difficult. With the clinicians described as crucial to the development process in section 3.3.2.1, this can influence the progress. Developer Collett described that frequent meetings are held in order to reduce the impact of this - if a doctor is unable to attend one week, they will not be "out of the loop" for extended periods of time. However, this reduces the effect rather than address the root of the problem. Additionally, it does not solve challenges related to time-consuming tasks such as labeling, which was also described in section 3.3.2.1. The interviews did not go in depth with regards to how the hospitals organize time for doctors to engage in research activities, or possible solutions to this problem. However, the challenge was identified already in 2001, when a survey of Norwegian doctors reported lack of time due to other obligations as the main challenge for engaging in research [23]. The survey was repeated in 2005, and lack of time was still reported as the main challenge [24]. Thus, in order for clinical doctors to be able to contribute to research, hospitals may need to better facilitate this activity.

4.2.2 Dynamics of Interdisciplinary Collaboration

Communication in the interdisciplinary setting was established as a challenging yet important element of the process. Various strategies were described in order to make oneself heard and understood, such as running ideas through more senior members of a research group, conscious selection of points of contact, and using practical demonstrations to communicate a problem or solution. This reveals that personal factors such as social and interpersonal skills and relations play a

significant part. Even the best ideas, skills and knowledge within a field are of little importance if the parties involved are unable to make necessary connections or communicate in a meaningful way.

However, the translation process between healthcare professionals and technical staff was described as an acquired skill. Several participants described how it developed over time through experience and exposure. While a learning process may be inevitable for interdisciplinary projects, there may be ways in which it can be sped up. Tubman and Lovelace described utilizing middle-men with knowledge of both the medical and technical field to facilitate communication. Only Lovelace described having such a position formalized. It is possible that middle-men actually facilitates the learning process of involved parties, and not just the translation process. By having an unknown concept translated in understandable terms, one may develop a deeper understanding of that concept - and do so faster. Tubman additionally suggests the idea of a more formalized module for exposure to each other's fields through seminars, reading, etc. This ensures a standardized baseline knowledge for people going into a project.

4.3 Added Value

Several factors for identification of added value were described. This section discusses the ways in which added value is ensured throughout the development process, issues of quantifying the value of a given tool, and likewise, issues of determining when and how XR tools may be utilized in the most efficient manner.

4.3.1 Methods of Ensuring Added Value

Added value of XR technology for healthcare is ensured through interactions with clinicians. By involving clinicians and utilizing an iterative process, the end result is adapted in order to align with the needs of the clinicians and provide practical value. This can be interpreted that the clinicians define the value - as they have the unique knowledge of the practicalities of the clinical problem, and developers help realize it - as they have the technical skills to provide the end product. Renaissance artist Michelangelo famously said "Every block of stone has a statue inside it and it is the task of the sculptor to discover it". Using this as an analogy, the added value is the statue within the block of stone, the medical professionals are the artists that recognize it, and the developers are the tool that shape the statue from the problem space that is the block of stone. This is a way to describe and understand the roles of the parties involved, when it comes to achieving added value of an XR tool for healthcare. Thus, ways in which interdisciplinary collaboration and understanding can be facilitated may be useful to investigate further.

4.3.2 Identification of Added Value

While methods to ensure added value are defined, it is more difficult to determine and quantify the value that is added. There are currently bottlenecks inhibiting larger scale studies, which in turn makes it difficult to provide objective evaluations based on outcome and subsequent cost-benefit calculations. One challenge is the current ease of use, which was described as not having reached a satisfactory level

- as mentioned in section 3.3.5.1. Additionally, a significant bottleneck is the need for a large foundation of medical data for AI segmentation, as described in section 3.3.5.2. Thus, an explanation for why XR technology has not been able to reach widespread use in healthcare is not necessarily that the applications do not provide value, but that bottlenecks such as availability of data are slowing down the development process and making it difficult to quantify the added value.

Because the clinical value of XR tools are difficult to establish, it is also difficult to determine when and how they are the most useful. While it is impossible to draw conclusions based on this study alone, some interpretation of the results is possible. The visualization tool for liver surgery described by Johnson was developed for procedures that were described as "very complex" and required extensive experience. Despite having the necessary experience, visualizing the 3D-anatomy of the liver offered a significant challenge. The surgical planning tool as described by Ginsburg was developed for complex heart defects, including extremely rare cases that are in practice impossible to gain full familiarity with. Wollstonecraft described that the cost-benefit of the bronchoscopy navigation may not be *as* good as the developers believe, due to the high volume of bronchoscopies that are performed and the fact that it takes time and energy to create 3D-models and set up for the procedure using HoloLens. Based solely on this, it may appear that XR technologies add the most value in cases or procedures that are either rare or especially difficult - or both. For procedures that are frequently practiced they may add less value. On the other hand, Wollstonecraft mentions the potential educational value of the application. This exemplifies how added value is not a property a tool either has or does not have, but rather a question of how and when it is applied.

4.4 Commercialization and Intellectual Property

Several aspects of the commercialization process were described. This section discusses the challenges of navigating the regulatory and legal questions related to a commercialization process, as well as challenges surrounding intellectual property and ownership.

4.4.1 The Process of Commercialization

Bringing a medical technology device to market is established as a long and challenging process, and may be perceived as intimidating. This may explain why not a lot of XR for healthcare is currently available - the process of commercialization may never have been started, or it has proven too arduous and resource demanding to continue. This can especially be imagined in cases where TTOs or other facilitators have not been available or did not want to contribute. Additionally, while TTOs may facilitate the process of commercialization and were described as providing important help especially in legal and regulatory questions, some flaws were identified. Because TTOs are aimed at maintaining the financial interests of the institution they are connected to and lack medical knowledge, it is possible that medically feasible projects with potential to add significant value have been ignored - either because the clinical value is not understood or the business potential of the idea is not considered good enough.

4.4.2 Intellectual Property

Challenges surrounding ownership and intellectual property were established. There are several levels at which one can consider the ownership and intellectual property related to a medical XR tool. Ginsburg points out that medical images are actually defined as the property of the patient, which they have to consent to being used. 3D models and visualizations are created by applying algorithms to the images. This software has been created by a group of developers, and is thus an intangible product of their creativity as well as their expertise and experience in software development. However, clinicians also make a significant contribution throughout the process. While developers are the experts on the technology, clinicians are experts on the clinical problem and related practicalities. They are tasked with setting up test scenarios that are sensible for evaluating the problem, and based on their knowledge and experience they are able to provide feedback and input that developers could not come up with. Thus, the application is also an intangible product of their expertise and experience as clinicians.

From the interviews it appears that the standard policy is to assign intellectual property rights to industry. Trademarks and patents protect the intellectual property and thus provide competitive edge and financial benefit for the company. In this manner, financial benefit from the product and likewise the intellectual creation is determined by ownership of the company. Business developer Johnson and clinician Ginsburg both describe how external investments reduce ownership. Thus, intellectual property becomes a question of money.

It is important to note that there is a symbiotic relationship between the parties. Clinicians and developers may have the idea and the specific expertise but not the funding and knowledge of commercialization, while investors may have the funding and knowledge of commercialization but not the idea and required expertise. The three - clinicians, developers, and investors - are in need of each other in order to end up with a product. However, in the dynamic that is described in particular by Ginsburg in section 3.3.4.3, it appears that clinicians - and possibly also developers - do not feel valued for their intellectual creations. There appears to be an expectation for them to contribute from an idealistic point of view, with little in return other than improved treatments and "honor and glory" for having contributed. Ginsburg explained that they may feel demotivated by having to hand over their intellectual property, and one can see the dichotomy of being required for their unique expertise yet not being valued for it - while generating value for someone else. A similar perspective can be considered for the developers, although it was not explicitly addressed during the interviews. This raises interesting questions surrounding how intellectual property is defined and managed. It is clear that in the context of a medical technology device, there are several activities of intellectual creation throughout the development process that should possibly be reflected in ownership - or otherwise - in order to properly incentivize clinicians to continue contributing.

4.5 Bottlenecks and Barriers

Several challenges related to XR development were highlighted during the interviews. The effect of usability issues and data availability on identification of

added value is described in section 4.3. This section mainly focuses on systemic challenges that serve as bottlenecks and barriers, in order to provide a deeper understanding of the wider context in which research, development, and commercialization happens. It is important to acknowledge the challenges and barriers posed by systemic factors such as organization, funding and research allocation, and regulatory frameworks. If the context of XR for healthcare is to be fully understood, these factors cannot be left out, as they impact development projects in a variety of ways. However, by understanding them, one is better equipped to either navigate the barriers or attempt to challenge and change them. The topics for discussion are regulations, funding, and the separation between academia, hospitals and industry.

4.5.1 Regulatory Challenges

Regulations for medical technology devices are described as a challenge. While all medical devices will obviously have to adhere to regulations and standards, the process of obtaining approval is described as long and costly, and navigation of the regulations as challenging. This may be a contributing factor to why XR technology is not widespread within healthcare - the process of obtaining approvals and eventually bringing a product to market is elongated. This coincides with the previous work presented in section 1.1, describing a trend of TRL around 6 and 7. Hence, XR tools may be delayed in a phase just before introduction to market due to prolonged regulatory processes. However, there were several other challenges identified - such as the bottleneck surrounding AI segmentation - that were not related to regulations. Thus, while regulatory processes are long and challenging, they are not necessarily the final frontier for XR in healthcare. However, the challenge and time consumption of navigating regulations may reduce the resources available for resolving other challenges. For this reason it may be useful to understand how the regulatory process can be made easier and less resource demanding to navigate.

4.5.2 Challenges Related to Funding

Funding is one of the challenges medical technology research faces, affecting several stages of development. The need for funding means that researchers spend a considerable amount of time writing applications. This time is not optimally spent with regard to productivity in actual research and development - especially when taking into account that a large portion of the applications will be turned down. Several of the participants describe that the competition for research funding is extremely high. The Norwegian Research Council, a public administrative body for financing of research and innovation, is used as an example of a funding institution at which even highly rated applications may not be given funding. The high competition described by participants may imply that there is too little public research funding available in order to support the amount of ongoing research activity. As a matter of fact, The Norwegian Research Council recommends a public investment of 1.25 % of GDP, yet in 2022 the budgeted investment was only 0.86% and in 2021 the investment was 0.98% [25]. Thus, the funding available is significantly lower than what is recommended.

Developers Steinem and Collett both mention challenges with the ways research funding is distributed. One of the challenges is distribution within the health trusts, making it inaccessible to research institutions outside. Steinem suggests that some of this funding is made available through competition, thus increasing the amount of money available for research environments outside of the health trust - though not increasing the total amount of funding. According to the official statistics of The Norwegian Research Council, 193 million NOK were granted to the health trusts in 2019 [26] - out of around 1.2 billion NOK granted to research and development projects within health and medicine in 2019. However, according to a report from the Nordic Institute for Studies of innovation, research and education (NIFU), funding from the Research Council only made up 7% of financing that same year, while basic funding made up 61% [27]. Such basic funding is inaccessible to research environments outside of the health trusts, and similar funding would have to be procured from elsewhere. Collett suggests more basic funding for established research centres, which reduces the time spent applying for funding. However, this may only be an improvement for some research environments and also not increasing the amount of funding available.

Even in a research environment associated with one of the health trusts, there may be challenges related to funding of projects. Lovelace experienced a lack of willingness to finance further implementation and training of doctors outside the research group to be able to create and use 3D models. This corresponds to the findings of a 2020 study investigating the drivers and barriers of implementing new solutions in the Norwegian healthcare sector [28]. The study highlights how industry partners perceived that there would typically be more means available in the innovation phase than the implementation phase, and the willingness to collaborate fizzles out. The research center Lovelace is involved with is located at the hospital and innovation is encouraged, but the hospitals fails to follow up on the implementation. He describes that the hospital appears to take for granted the services they are currently able to provide, not foreseeing that unless investments are made this will not be able to continue. Failure to sufficiently fund innovation projects at *all* stages may lead to considerable effort and resources being spent on research projects that come to a standstill before reaching their full potential and benefit. Hence, stopping before the projects yield economic benefits on a societal level. This way, research funding becomes spending rather than investments from which returns may be realized. A 2016 analysis estimated a 15-18% annual rate of return on investments in biomedical and health related research in the UK [29]. This implies that the healthcare sector and society as a whole may be missing out on innovations and returns of investments in medical research.

However, there are several challenges to investments in innovative solutions from a managerial perspective. One municipial manager in the previously mentioned study highlighted the possible risk associated as a barrier, as any mistakes can in the worst case harm patients' health [28]. As it is currently difficult to assess the added value of XR applications, it is also difficult to argue that it outweighs the potential risks of implementing a new tool. One hospital director described how high workload can make it difficult to prioritize innovative solutions, even when they may make work easier: "A lot of it is about how busy it is - it's like you're devoured by operation [of the hospital], and you don't prioritize the transition period" [28]. Additionally, the study found that public regulations - especially

laws on public spending - may be an inhibiting factor. Because of the interpretations and enforcement of the laws, "there is no creativity and nothing is allowed". Hence, a perceived unwillingness may be related to challenges for hospital management. However, in order for the health trusts to reap benefits of innovation, investments in time and money required for implementation is necessary.

4.5.3 Structural Challenges

The separation between research, hospitals, and industry contribute to difficulties in navigating the field of medical technology. Bringing an innovative device to market requires efforts and collaboration by all three. As they are separate entities, they have different interests, norms, conventions, and policies. Attempts of reducing the distance between the entities were described, such as TTOs to help bring knowledge and technology from universities to industry, and initiatives such as NorTrials to help bring industry and hospitals closer together. However, several of the interviewees described that despite these initiatives, the challenges are still prevalent. This may discourage researchers and clinicians from getting involved with innovative projects. An increased effort to bring these entities together may be necessary in order to prevent negative consequences for both patients and the quality of research and innovation.

Similar challenges are described in a 2016 study by NIFU [30]. The study mapped out and analysed the policies and practices of the knowledge triangle in Norway - where the "knowledge triangle" refers to education, research and innovation - at a national and institutional level. It found that the responsibility for these entities was divided between several government ministries, which poses a challenge for coordination of policies. Additionally, it found that while strategies of several higher educational institutions emphasized the link between education, research and innovation, the interlinkages are challenging to develop in practice. A possible explanation was the lack of incentive for innovation-related activites, due to institutional reporting systems being based on indicators related to education and research rather than cooperation with private and public sectors. It is reasonable to assume that the challenges highlighted in the study are relevant for the entities described here - research, hospitals, and industry.

In the NIFU report, several recommendations were made to strengthen the interactions between education, research, and innovation [30]. These recommendations require significant efforts both on a national and institutional level. The recommendations include incentivising co-operation between academia and the private and public sector through revised reporting systems, in addition to a revised career system that includes innovation as a promotion criteria. As Collett described, what constitutes good research does not necessarily correspond with what creates the most useful solutions, making research interests sometimes trump the innovation aspect. By incentivising innovation, researchers may be able to prioritize differently. Another recommendation is long term funding aimed at "developing and institutionalizing cooperation structures" between private and public sectors and higher educational institutions. This corresponds well with improvement suggestions that were made during the interviews, as several of the participants did not find the current structures satisfactory. Furthermore, it is recommended that the development and institutionalization is facilitated by a strong

policy environment. Lastly, it is suggested that new types of positions and use of dual affiliations can enhance knowledge exchange and facilitate practice. This brings to mind the role of Lovelace, as an industry consultant as well as a method developer for clinical research.

4.6 Limitations

While the aim of this thesis is to describe the state of XR for healthcare, it is far from a comprehensive study of the field. There are several limitations, related to sample size, sampling bias, and the data collection method.

4.6.1 Sample Size

The study involved a small number of participants. Only nine interviews were conducted. Among the participants there were four developers, four healthcare professionals, and one business developer. Hence, the group sample sizes were even smaller. The low number of participants was a necessity due to limitations of time and resources. A larger sample size would be possible using other data collection methods such as questionnaires. However, interviews were considered the most suitable data collection method due to the exploratory nature of the project as well as the research questions themselves.

The aim was to interview several participants from each perspective, but recruitment of other participants from the business perspective was unsuccessful. A low number of participants makes the interpretation subject to the personal experience and bias of participants. This may negatively impact the generalizability of the study. While the results help understand the context and highlight factors and challenges that exist, more viewpoints on their impact and implications are necessary in order to make definitive statements.

4.6.2 Sampling Bias

The participants were recruited from a limited number of institutions in Norway, and one from a Swedish based company. Several of the participants were recruited through other participants, and for this reason several of them were involved in the same projects. This may influence the generalizability of the study, as other research environments may have other experiences. This limitation was due to limited network within the field of XR for healthcare as well as limited time for recruitment of participants. In several cases, reaching out to potential interview subjects without an introduction was unsuccessful. It was more successful to go by the network of other participants. However, involving participants from several research environments is a way to reduce this bias.

4.6.3 Data Collection Method

The use of semi-structured interviews as a data collection method is a limitation in itself. As it focuses on personal experiences and opinions, there may be a lack of generalizability to the data collected. Certain challenges may be perceived as larger or smaller for some participants, depending on their subjective experiences.

Additionally, because the interviews did not follow a strict set of questions, certain topics were covered more in-depth in certain interviews than in others. For this reason, some perspectives may have been missed. A standardized approach such as a structured interview would cover all topics equally with all participants.

4.7 Recommendations for Policy, Research, and Practice

Based on the discussion, some suggestions for future work are made. Due to the limitations described in section 4.6, validation of the findings in this study may be considered. To do so, studies may involve a larger sample size, participants from a variety of institutions, companies, and projects, and a standardized research collection method. Other suggestions are as follows:

- Investigating which elements of the regulatory process pose the biggest challenges, and possible measures to make it easier to navigate.
- Investigating ways in which the healthcare sector can better support implementation of innovation projects. Additionally, investigating how work conditions at hospitals facilitate or inhibit engagement in research activity, in order to identify best practices for involving clinical doctors in research projects.
- Investigating the effect of formalized facilitation of interdisciplinary collaboration, in order to understand how mutual understanding may be achieved in a more efficient manner. Additionally, investigating the cost-benefit of introducing such measures. Methods of facilitation mentioned during the interviews were training modules for parties partaking in interdisciplinary projects, and utilizing "middle men" to alleviate communication.
- Measures to improve the interactions between education, research, and innovation, as recommended in the 2016 NIFU report. This includes incentivising collaboration between academia and private and public sectors, developing collaboration structures between private and public sectors and higher education institutions, and use of dual affiliation positions to enhance knowledge exchange.
- Evaluation of public research funding of medical research. This includes the distribution of projects within the health trusts and the possibility of making some of the funding available for outside research environments, as well as the potential for basic funding of research environments.

CHAPTER

FIVE

CONCLUSIONS

In this study, a qualitative analysis of XR technology for healthcare was conducted. The aim was to generate insight and develop a deeper understanding of the context of XR development in terms of its related processes, challenges and barriers. The research questions were *How do clinicians and developers collaborate throughout the process in order to ensure added value of XR technology for healthcare?* and *What are the current barriers and limitations that inhibit widespread adoption of XR technology for healthcare, and how do they manifest?*. Data was collected through a series of semi-structured interviews with clinicians, developers, and a business developer involved with XR for healthcare. The data was analyzed and categorized into five main topics: development processes, interdisciplinary collaboration, added value, commercialization and intellectual property, and bottlenecks and barriers.

Clinicians and developers describe a close collaboration throughout the process in order to ensure added value of XR technology. An emphasis is put on having a strong foundation in a relevant clinical problem, and involving clinicians at all stages due to their understanding of the medical aspects and practical use. Testing and evaluation with clinicians are described as a necessity in order to ensure added value. The dynamics of collaborating across disciplines is described as challenging at times, and interpersonal skills such as communication is highlighted in order for the development process to succeed. Additionally, the challenge of maintaining continuity for clinicians was identified.

Several factors are described as inhibitors. Several applications currently do not offer a satisfactory level of usability and require manual set-up as well as time consuming segmentation tasks. Another challenge was the lack of automatic segmentation of 3D models, making the modelling process too time consuming and difficult to be practically feasible in an everyday clinical setting. The reason for this was overall related to data availability for AI modelling. AI modelling requires large quantities of labelled, high quality, and varied data, which is time consuming to collect. Additionally, the process of developing a medical device and bringing it to market is described as long, challenging, and costly. This can be related to factors such as a time consuming regulatory process, challenges in obtaining funding for research and implementation, separation between research, industry and hospitals, and lack of incentivation of clinicians.

These results have several implications. There is potential to investigate how

interdisciplinary collaboration can be better facilitated. Additionally, clinicians may be better incentivized to continue engaging in start-ups and innovation projects. As the regulatory process is described as especially challenging, it may be elongating the process of bringing medical XR to market. Thus, tools or measures that make the process of navigating the regulations may facilitate the process. Challenges related to funding imply that there is room for improvement to how funding is distributed, and possibilities to optimize the time spent by researchers. Additionally, the health trusts appear to have potential for improvement when it comes to implementation of innovative projects. Finally, the interlinkages between industry, academia and hospitals appear not to support development of medical technology devices in a satisfactory way.

The findings highlight several aspects of XR for healthcare. Future work can use these findings as a basis for further investigation, and for information on the subjective experience of parties involved in the development process. Suggestions are made in order to facilitate innovation by strengthening the collaboration between research, industry, and hospital. The results indicate that while XR may have several benefits for healthcare, there are currently barriers that make it difficult to fully understand the impact this technology may have in healthcare.

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APPENDICES

Interview guidelines

Interview section	Questions, notes
Introduction of myself and project	For my master thesis in computer science I am working on a project about augmented and virtual reality in healthcare. The aim of the project is to investigate the development process of AR/VR tools. I intend to learn how people involved collaborate, particularly how added value is ensured, and factors inhibiting use. You have been asked to participate because I am interested in your perspective on and experiences with the development
Interview information	The interview will last around an hour. It will be recorded and later transcribed for most accurate collection of
Information on personal data treatment	The transcriptions will be stored in anonymous format for 6 months, and the interview recording will be deleted immediately after transcription. The transcription will be accessible only to me, my supervisor and co-supervisor and access will require log-in. Information has been provided in written form prior to the interview.
Consent	(Have consent form signed, inform that consent may be revoked at any time and all data will be deleted)
Introduction to the topic	**Can you tell me about the work you have been doing in AR/VR for healthcare?**
Notes	- Position/role - Duration - Type of projects/tools - Areas of application - Type of technology - Type of hardware - Stage of development
Map out development process	**Can you describe the development process of these tools?**
Notes	- Phases/stages - Why is XR used for the specific application - Which people involved at which stages - Initiation of projects - translation form problem —> idea —> prototype - Decision making throughout the process - when, how, why are they changed
Map out role of medical staff	**Can you describe how medical staff are involved throughout the development process?**
Notes	- Type of role, what do developers need of medical staff - Dialog developer - medical staff - Recruitment - Developers role in relation to medical staff
Identify added value	**Can you describe how you ensure that the VR/AR tools provide an added value to the users?**
Notes	- How is it defined for the specific tool (the type of information displayed, change in workflow, etc.) - Testing , comparison to traditional methods - Workflow considerations (seamless integration vs alteration) - Human factors - Challenges from the developer side
Identify challenges in development process	**Can you think of any improvements that can or should be made to the current development process?**
Notes	- Examples - Are there conscious efforts to optimize collaboration
Summary	As mentioned, I am investigating how added value is ensured throughout the development process. From what I have understood…[summary of main points picked up during interview]… Have I understood correctly?
	From what we have discussed, what do you consider the main points I should consider for my project?
Ending	Is there anything we have not discussed you would like to add?
	May I contact you if I have any follow-up questions?
	(Ask about people of interest)