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Adoption of Additive Manufacturing in Hospitals – Multiple Case Study

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Abstract

Adoption of Additive Manufacturing in Hospitals

Xiang Li

Additive Manufacturing (AM) is a technology that can revolutionize the healthcare industry in terms of customization. Various studies and ongoing practice have proved the potential of AM in clinical use as enormous. However, to reach a routine level of adoption of AM in patients' care, there are various things to consider. The purpose of the thesis is to reveal the key factors that will affect the hospital adoption of AM in different Swedish regions.

The literature revealed the advantages and disadvantages of different manufacturing systems for hospital AM use and the main benefits and challenges in the different clinical applications of AM. Four exploratory case studies were carried out to identify the key factors in terms of AM hospital adoption, which have a comparative design. The four case studies are four different regions with different levels regarding AM hospital use. Purposive sampling was applied to choose the interested regions, while snowball sampling was used for selecting interview participants. The findings were analyzed via thematic analysis.

Results show that key factors will mostly have both pushing and pulling effects regarding AM hospital use. Key factors were divided into the themes of Implementation, Management and Behavior. Aspects falling under Management are mentioned the most frequently in the interviews, suggesting that these factors play an important role in the adoption of AM. Theme Behavior is not previously found in the literature on AM in clinical use. Close communication among different levels and cross disciplines will positively affect the adoption of AM, as it will improve the AM awareness rate and result in more clinical champions.

Concluded that a centralized AM adoption faces numerous factors which should be properly evaluated before the initiation. Apart from having an economic model to prove the business possibility, a top-down strategy to build an intensive AM information exchange will lead to a better and smooth adoption in healthcare.

Keywords: Additive Manufacturing, healthcare, implementation, key factors, centralization, decentralization

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Popular Science Summary

Additive Manufacturing (AM), commonly known as three-dimensional printing, is a technology that manufactures a three-dimensional object by adding a layer to another. It is a technology that has achieved freedom of design. Hence, in the healthcare system, where patient uniqueness is of great importance, this technology has great potential since it can meet the patients' specific needs. The use of AM in hospitals is still rare and under development. However, more research has proved the benefits of using AM in hospital cases. Therefore, this thesis aims to identify the key factors in adopting AM in hospitals by studying some big regions in Sweden.

Several known issues connected to the adoption of AM were discussed by reviewing different studies on AM uses in different clinical applications. To further complete and update the information found in the literature, four regions in Sweden were studied. Interviews were conducted with the key persons who have certain experience and knowledge of the AM use in the healthcare system. Through analysis of the interview data, it was found that the studied regions are mostly (three out of four) at an early stage of using AM, where the use is scattered. And the use is mostly organized by the clinician, not the hospital. Only one region has built up a 3D center inside the hospital where the design and manufacture of AM products are scheduled and managed through this center. Among the studied cases, maxillofacial and orthopedic departments have adopted AM in an advanced manner, where pre-operative planning and surgical guides are the most common applications.

In addition, two main aspects influencing the adoption of AM were identified. In the literature on AM clinical applications considering key factors of AM use in hospital, social aspects like personal awareness, communication channels, or leadership involvement gain low attention. These aspects were emphasized throughout the case studies. Moreover, an AM center where the hospital or region can provide technical support in a controlled manner is believed to be a push for wider use of AM. Further, the interviews show that support and decisions from the management level related to AM use can further increase the AM awareness among clinicians, resulting in more use of AM.

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Abbreviation

3D	Three dimensional
AM	Additive manufacturing
CAD	Computer aided design
CFIR	Consolidated framework for implementation research
MRI	Magnetic resonance imaging
CT	Computed tomography
DICOM	Medical data imaging and communication
STL	Standard tessellation language
LED	Light-emitting diode
SLA	Stereolithography
DLP	Digital light processing
CDLP	Continuous digital light process
CLIP	Continuous liquid interface production
ASTM	American society for testing and materials
COVID-19	Coronavirus disease
SLS	Selective laser sintering

Table of Contents

List of tables

List of figures

1. Introduction

The following section gives a brief introduction to Additive Manufacturing in healthcare, clinical applications, and implementation aspects, followed by the purpose and research question of this study.

1.1 Background

Additive Manufacturing (AM), also known as three-dimensional (3D) printing, is a mechanical process in which a solid object is manufactured using computer-aided design (CAD) and built on a layer-by-layer basis (ASTM, 2015). Unlike traditional manufacturing methods of material reduction, such as cutting and casting, AM has apparent advantages in saving material. The ability of AM to produce any CAD model can provide great potential for customization. Due to its fast development, AM is widely applied in many industries, such as medical, automotive, aerospace, and electronics. This technology is considered disruptive and can make a difference in the manufacturing process, product life cycle and supply chain (Marak et al., 2019).

There are various applications of AM in the healthcare system. In fact, the launch of the journal '3D Printing in Medicine' is a sign that the use of AM in the field of healthcare is progressing (Hurst, 2016). Every year, AM expands its applications in the healthcare field, saving and improving lives in ways that were previously unimaginable. AM has been used in a variety of medical fields, including cardiothoracic surgery, cardiology, neurosurgery, oral and maxillofacial surgery, orthopedic surgery, plastic surgery, radiation oncology, and transplant surgery (Aimar et al., 2019; Bahnini et al., 2018; Durfee et al., 2019; Fan et al., 2020; Hurst et al., 2016). The main direct application of AM technology in medical and clinical fields are as follows:

- For personalized pre-surgery treatment and pre-surgery planning. With 3D printing technique, the surgeon is able to use a physical/visional 3D model of the specific patient anatomy which will achieve an accurate surgical plan, cross-sectional image, or customized prosthesis (or surgical tool). Preoperative preparation has been proven in several studies to shorten the operation time and complications. Other possible benefits include shorter postoperative hospital stay, lower re-intervention rates, and cheaper healthcare expenses (Perica et al., 2017; Chae et al., 2015; Keller et al., 2021; Louvrier et al., 2017; Malik et al., 2016; Sheha et al., 2019).

- For customized surgical instruments and prothesis. Mass customization of surgical tools and prothesis usually means a reduction of cost (De La Peña et al., 2018).

- For improvements in medical education and patient consent. Patient-specific models in 3D printing can provide information in a more straightforward and accessible way to both trainees and patients. It is a better informative and efficient way of communication and education (Bernhard et al., 2016; Garcia, et al, 2018; Javaid et al., 2018).

- Bioprinting. Bioprinting is a 3D production technique that uses cell-laden biomaterials to create sophisticated 3D functioning live tissues or artificial organs. Bioprinting technologies have shown the potential utility in regenerative medicine, and can make a

series of transplantable tissues, including skin, cartilage and bone, despite the fact that they are still in the early stage of development (He et al., 2018; Mandrycky et al., 2016).

- 3D printed medicine. With 3D printing, it is possible to make drugs in different shapes and sizes using ingredients based on specific patients (Ramola et al., 2019). Spritam (a medicine used to treat epilepsy) was the first successful attempt to print the drug, and it was authorized by the US Food and Drug Administration (FDA) in 2015 (Di Prima et al., 2016). With the emergence of 3D printed tablets, pharmacies can now shift from mass production of dosage forms to personalized production for patients (Choonara et al., 2016). The doctor's prescription will appear in the form of a CAD file, and the patient can print it in the pharmacy. This indicates that there may be such a scenario in the future, in which pharmacies can print medicines according to customers' needs, or a customer can print their own medicines simply by adding the correct ingredients and issuing a print command (Ramola et al., 2019).

As a result, these examples demonstrate that 3D printing is a disruptive technology that can drastically alter the clinical landscape, enhance medical care, and make medical care more inexpensive, accessible, and individualized. In Sweden, the healthcare system is decentralized, which means it is managed and run entirely by the regions, local authority or municipality. Health, medical and dental care is divided into public and private sectors. Every region, local authority or municipality is responsible for managing and prioritizing its own healthcare resources. Hence, the type of healthcare services available may vary (Socialstyrelsen, 2020). In Germany, a national survey about the AM adoption in oral and maxillofacial surgery was conducted in 2021 (Pabst et al., 2022), and the results show that most hospitals (73.6% among a total of 156 respondents) did not have 3D printers. In Finland, a national survey of AM adoption in university hospitals was conducted in 2016-2017 (Pettersson et al., 2020), the study has shown that most users are outsourcing the production, design and orders were usually done online in collaboration with engineers from commercial 3D printing vendors. In France, there is no health center that can produce in-house medical devices according to the new European standards, a national study has provided practice guidelines for in-house 3D printing (Khonsari et al., 2021). Similar research is rarely found regarding AM adoption in the Swedish healthcare system.

1.2 Problem Formulation

According to National Health Service, 70% of people are unique, so the traditional large-scale drug production is ineffective. This individuality challenges the traditional ‘one-fit-for-all’ treatment, as a result, the healthcare system needs to adopt a new system for customized treatment (Trenfield et al., 2019). As 3D technology has become better and more advanced, more and more interests are growing in the possibilities that this technology could bring. With more and more companies bringing AM into medical research, development and production, such as GE Healthcare Life Science, the agility of the supply chain will increase and the efficiency of logistics and sourcing will enhance (Additive, 2019). However, 3D technology is not fully implemented in healthcare and is used in a few scattered areas, as there are limited patients today with treatment related to 3D technology. To better adapt this innovative technology with wider users and higher success rates, a number of factors are needed to take into consideration, as Oettmeier et al. (2017) examined the determining factors into Technology, Firm, Market

structure and Supply chain. Grol et al. (2003) have pointed out the importance of comprehensive approaches at different levels (doctor, team practice, hospital, wider environment) to be able to have effective adoption of the change in the healthcare system.

Additionally, there are different levels on which these factors can affect the adoption. Scholl et al. (2018) have conducted a scoping review on organizational- and system-level characteristics that will affect the adoption of the Shared Decision-making approach. They have identified organizational-level characteristics, including leadership, workflow, priorities, resources, and system-level characteristics, including policies, incentives, education and providers. They believe organizational-level and system-level characteristics should be addressed more focus as they do play a role in the adoption of the Shared Decision-making approach. It can be assumed that a similar situation, such as the complexity of the healthcare system, will also apply to the adoption of AM in the Swedish healthcare system.

Sweden's medical system is among the most developed in the world. Sweden's expenditure on health and medical services accounts for about 11% of its GDP (in 2019), equal to most other European countries. Sweden's per capita health care expenditure is very high, around $ 5,700 (International Trade Administration, 2022). According to the survey by Kianian et al. (2015), compared with other countries such as Germany, France, and Belgium, the overall adoption rate of AM in Sweden is lagging. A systematic literature review on AM adoption in healthcare from 2007 to mid-2018 (Ramola et al., 2019) revealed that, although AM has a vast application in healthcare, its utilization is mainly limited to academic learning and research. For commercial use of AM, such as the adoption of AM in hospitals, people are still hesitant due to high investment (Ramola et al., 2019). A study in German has revealed that low cost-efficiency and lack of funds were the main barriers to AM adoption (Pabst et al., 2022). A study in Finland indicated that high time-consuming outsourcing was a barrier to large-scale adoption of AM (Pettersson et al., 2020). A study in France pointed out that technical challenges elated to printers and CAD software have passed, and the current central issues related to in-house adoption of AM are economical and regulatory (Khonsari et al., 2021). The challenges in the adoption of AM in the Swedish healthcare system could come from the technology itself or relate to the adoption process, including economics from a management point of view. With all being said, the adoption of AM in different hospitals is an exciting field to study further.

1.3 Purpose

This thesis is aiming to create an overview of the latest adoption of AM in different Swedish regions, more specifically, the current clinical practice and the journey of adoption in the Swedish healthcare system. By exploring how hospitals perceive AM and adopted AM from the perspective of inside- and outside-hospital strategists, key factors that affect the adoption of AM in different regions will be detected in connection to the implementation science, in terms of barriers and facilitators Furthermore, the study will also discuss bottlenecks and limitations regarding the adoption and production mode. With all these being done, a base for further research on strategies regarding AM adoption in healthcare will be built.

1.4 Research Questions

Given the problem formulation and purpose of this study, the following research question will be addressed:

1. What is the production mode in different hospitals in different regions?

2. From the managemental perspective, what are the key factors that affect the adoption of additive manufacturing in hospitals in different regions?

1.5 Delimitations

This study will be focused on studying the key factors from the managemental perspective that affects the adoption of AM in different Swedish regions, more specifically, in the healthcare system. Given the time constraints and the scope of the thesis, a limited number of regions will be studied.

1.6 Thesis Structure

The thesis consists of seven chapters that are briefly described below:

Chapter 1 – Introduction: The section gives a brief introduction to Additive Manufacturing in healthcare, clinical applications, and implementation aspects, followed by the purpose and research question of this study.

Chapter 2 – Literature review: First, this section summarizes the main advantages and limitations regarding AM adoption in general, followed by a section introducing the main technology with its characteristics. Then the third section is about the advantages and disadvantages of different manufacturing systems regarding AM hospital use. Forth, some popular clinical applications of AM, with their benefits and challenges are discussed.

Chapter 3 – Theoretical background: This section introduces implementation science and the main framework that will be used in this study, CFIR.

Chapter 4 – Methodology: This section describes the methods that are used in this study, including research design, data collection as well as data analysis. In the end, the data quality, ethical considerations and method limitations are presented.

Chapter 5 – Results: In this section, first, a general description and comparison of each case are given. Then the main themes derived from all cases are presented in both table and text, which will address the research question. A detailed analysis of how these factors affect AM adoption is given in the form of a table, and the topics are divided into barriers and facilitators.

Chapter 6 – Discussion: This section is about the discussion of the finding in relation to the literature review and reasoning the findings' meaning, significance, and relevance to the literature review. The first subsection focuses on the manufacturing system for the first research question.

In contrast, the second subsection discusses the second research question: What are the key factors that affect the adoption of additive manufacturing in different regions?

Chapter 7 – Conclusions: This section is about the conclusion of this work, which is based on the literature review, the results from the case studies, and reasoning from the discussion. The limitation and implications of this study are also present at the end.

2. Literature Review

First, this section summarizes the main advantages and limitations regarding AM adoption in general, followed by a section introducing the main technology with its characteristics. Then the third section is about the advantages and disadvantages of different manufacturing systems regarding AM hospital use. Forth, some popular clinical applications of AM, with their benefits and challenges.

2.1 Additive Manufacturing Technology

Additive Manufacturing (AM) is defined by ISO/ASTM as the 'process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing technologies' (ASTM, 2015). During the modern development of AM, there have been a plethora of appellations: additive fabrication, additive techniques, free-formed fabrication, and rapid manufacturing (ASTM, 2015). AM was formally adopted on January 14, 2009, in West Conshohocken, Pennsylvania (Sach et al., 1993). The name '3D printing' was against for it is inappropriate to label all the technologies with one name since 3D printing was referred to a specific binder jetting process. Today, both AM and 3D printing are used. The former is more common in the technical community, whereas the general public is more often with the latter (Bourell, 2016).

Haleem et al. (2020) have conducted a literature review study to identify the research status on AM and its application based on the Scopus database. The advantages and limitations of adopting AM are described as follows. The design of an AM product does not need any tools or fixtures. With capable computer skills, the setting time for the design and development is generally shorter. The manufacturer can easily modify the revised version of the product. For customization, AM offers the possibility to achieve at a lower cost. Compared with the traditional manufacturing process, AM has less energy consumption and less material waste in production. The main advantage of this technology is flexibility, which has different flexibility in product design and manufacturing (Haleem et al., 2020). AM also has some major limitations. Compared with this technology, the traditional manufacturing process is usually much faster in mass production. The size of the printing bed has limited the manufactured product size. The production cost of each product may be very high because the basic materials could be expensive and lack economic scale. The AM machines and design usually require skilled human resources. The production process normally cannot be interrupted. Once there is any breakage in the printing process, the parts will be damaged and wasted. The post-processing will increase the cost of the product (Haleem et al., 2020).

2.2 Different AM Technologies

According to ISO/ASTM International standard, there are seven groups of AM processes. A relatively brief introduction of each AM process is given below, as well as in table 1.

Binder jetting is 'an AM process in which a liquid bonding agent is selectively deposited to join power materials' (ASTM, 2015). It was originally known as three-dimensional printing (3DP).

This process can be applied to virtually any high-productivity powder, and successfully processed materials including polymers, metals, and ceramics. However, developing printing and post-processing methods that maximize part performance remains a challenge (Ziaee et al., 2019).

Direct energy deposition is an AM process 'in which focused thermal energy is used to fuse material by melting as they are being deposited. Focused thermal energy means that an energy source (e.g., laser, electron beam, or plasma arc) is focused to melt the materials being deposited' (ASTM, 2015). This process is generally used with metals in powder or wire form and ranks the second most popular technology among various metal printing technologies (Dutta, 2022).

Vat photopolymerization is 'an AM process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization' (ASTM, 2015). Regarding the methods of curing, photopolymerization is classified into three groups: cured with a laser (Stereolithography (SLA)); cured with a projector (Digital Light Processing (DLP)); cured with LEDs and oxygen (Continuous Digital Light Process (CDLP) / Continuous Liquid Interface Production (CLIP)) (Pagac et al., 2021).

Material jetting is 'an AM process in which droplets of build material are selectively deposited. Example material includes photopolymer and wax' (ASTM, 2015). This technology is widely used in different industries due to its advantages in producing parts in a relatively short time. Compared with other polymeric material printing technologies (FDM, SLA), material jetting can print parts with higher dimensional accuracy and lower surface roughness (Gülcan et al., 2021).

Material extrusion is 'an AM process in which material is selectively dispensed through a nozzle or orifice' (ASTM, 2015). It is the second most popular form of AM process on Google. This process allows producing of quick and low-cost printing with a wide variety of materials, from commodities and engineering to high-performance thermoplastics, composites and functional materials. However, due to the minimum nozzle size being 0.2mm, it is not good at producing intricate or miniaturized parts (Hsiang et al., 2020).

Powder bed fusion is 'an AM process in which thermal energy selectively fuses regions of powder bed' (ASTM, 2015). It is well-suited for polymers and metals, to a lesser extent to ceramics and composites. The most attractive area of development and research is laser-based powder bed fusion using metals (Gibson et al., 2021). Compared with other AM processes, laser-based powder bed fusion has a higher colling rate and better surface finish (Sun et al., 2017).

Sheet lamination is 'an AM process in which sheets of material are bonded to form an object' (ASTM, 2015). It is one of the earliest commercialized AM techniques, but it has had only limited success in the marketplace. One of the disadvantages is that each layer will consume an entire sheet, hence the waste of material could be high if the usability of the build volume is low (Gibson et al., 2021).

Table 1 A brief introduction of each AM process

Technology	Main Characteristics
Binder jetting	• Can be applied to high-productivity powder, including polymers, metals, and ceramics • Challenges in developing printing and post-processing methods
Direct energy deposition	• Generally used with metals in powder or wire form • The second popular technology among various metal printing technologies
Vat photopolymerization	• Cured with a laser (Stereolithography (SLA)) • Cured with a projector (Digital Light Processing (DLP)) • Cured with LEDs and oxygen (Continuous Digital Light Process(CDLP) / Continuous Liquid Interface Production (CLIP))
Material jetting	• Producing parts in relatively short time • Can print parts with relatively high dimensional accuracy and low surface roughness
Material extrusion	• Allows to produce quick and low-cost printing with wide variety of materials • Minimum nozzle size is 0.2mm, which is not good at producing intricate or miniaturized parts
Powder bed fusion	• Well-suited for polymers and metals, lesser extent to ceramics and composites • The most popular technology is laser-based powder bed fusion using metals, which has high colling rate and good surface finish
Sheet lamination	• One of the earliest commercialized AM techniques • One of the disadvantages is that each layer will consume an entire sheet, could cost high waste of material

2.3 AM with Manufacturing System

Multiple studies have shown the key benefits of AM for different players in the supply chain, such as cost-saving for material suppliers and manufacturers, and faster responsiveness for logistic providers and customers (Haleem et al., 2020; Kubáč et al., 2017; Zeltmann et al., 2016). With AM technology, it is possible to achieve cost-effective production of small batches (Berman, 2012). Berman (2012) has made a comparison of AM with mass customization and other manufacturing

processes and concluded that for areas like dental crowns, and artificial limbs, which require small quantities of customized goods, AM has a promising future and potential with relatively low costs. AM also increase the responsiveness between design and product (Kubáč et al., 2017). Standard CAD software can be used to design and redesign products with a high level of freedom. Any complex design is printable as long as it has been designed (Kubáč et al., 2017).

Compared with traditional manufacturing method, AM provides the possibility to serve with better quality and higher service level since the product can be more scattered and closer to the customers, especially during the COVID-19 pandemic where the localized supply chain has been proved the effective and efficient (Ber-Ner et al., 2017; Silvestro et al., 2021; Larrañeta et al., 2020). Oettmeier et al. (2017) in the study of determining factors of AM adoption in industrial parts production reveal that customer benefits are an important driving force when AM has proved to provide higher value. Khajavi et al. (2014) have discovered several potential benefits of a decentralized production system using AM technology, one of which is the reduced need for inventory management and logistic information system.

Sometimes, AM is more about changing the role of players in the supply chain and these players can appear in different fashions than before (Tolio et al., 2019). For instance, the hospital can change from customer to manufacturer by facilitating the production line (Tolio et al., 2019). Hospitals can implement AM in their ecosystem in two ways: centralized or decentralized manufacturing models. Table 2 have listed summarized the characteristics of these two different systems.

Production facilities and equipment are housed within hospitals in a centralized system. Calvo-Haro et al. (2021) aim to present the results of the integration of 3D printing technology in a manufacturing university hospital. The study has approved that a multidisciplinary team with valuable experience and clinical knowledge can achieve fast response times and keep most hospital departments registered in the Point-of-Care manufacturing model (Calvo-Haro et al., 2021). This research identifies the possibility of integrating 3D printing technology into hospitals with easier and more frequent interaction between medical and production staff. However, the prerequisites for desired outcomes would rely on the trained personnel inside the hospital to be able to use AM technology and the hospital that must accept responsibility for obtaining regulatory board approval for printed objects (Bastawrous et al., 2022; Calvo-Haro et al., 2021). This distributed production represents a paradigm shift in the health system that is becoming critical during the COVID-19 pandemic (Perez-Mañanes et al., 2021).

Hospitals in a decentralized model rely on an external supplier for their products. Doctors place orders for the needed products, which are then manufactured and shipped to hospitals. Hospitals benefit from not having to invest in a manufacturing facility, and suppliers will handle the approval process with regulation issues (Pettersson et al., 2020). The disadvantages of this method are that hospitals lose control and rely on suppliers and it lengthens the lead time and raises the final cost of the product (Pettersson et al., 2020; Pourabdollahian et al., 2014).

Table 2 A summary of characteristics on two manufacturing system

Manufacturing System	Advantages	Disadvantages
Centralization	• Short lead-time • Fast response • Easier and more frequent interaction among multidisciplinary team • Imaging and postprocessing software is already in place • Potential to serve the entire hospital-based system	• Need for specialized support • Need for dedicated space • Lack of specialized production facility • Lack of access to printers and materials • Regulation qualification
Decentralization	• Less financial risk • Less investment for setup and maintenance • No need for dedicated stuff and space • No responsibility in regulation wise	• Lost control on time • More expensive • Data safety concerns • Complex chain of custody

According to the annual report of Medical Additive Manufacturing 3D Printing (SME, 2018), in-house production seems to be more common for products with low risk-level (the average rate of outsourcing anatomical models is around 20%). As for patient-specific implants and others with high risk-level, outsourcing the production is more popular (the average rate of outsourcing is around 40%). This report also identified that the Regulatory environment, Material, Funding and Capital are the major challenges to increasing medical AM applications. The report also predicts that hospital-based manufacturing would continue to grow with some sort of oversight or standards to be set (SME, 2018). However, 88% participants of in this survey were coming from North America. For the vast majority of maxillofacial cases in France, the surgeons using AM were still heavily relying on external services providers (Khonsari et al., 2021). No French health center is currently producing in-house medical devices due to regulation restrictions (Khonsari et al., 2021). Khonsari et al., (2021) also pointed out that economics is a key factor to have a successful in-house 3D platform. In a national wide survey of AM uses in oral and maxillofacial surgery in Germany (Pabst et al., 2022), most hospitals did not own the printers. The university hospitals seem to be more willing to adopt AM for research purposes and they have the funding for that. For private clinics, lack of resources and poor cost-effectiveness are the main reasons for not having their own printers.

2.4 Medical Application Cases

The introduction of 3D printing techniques has resulted in significant advancements in medical technologies over the last 20 years. AM technologies have found widespread application in medical materials, particularly medical training models, medical instruments, orthodontic and orthopedic implants, and prosthetics (Bahnin et al., 2018; Fan et al., 2020; Ramola et al., 2019; Tuomi et al., 2009).

2.4.1 Medical Training Models

Medical models are aimed at planning or simulating pre-, intra-, and/or postoperative surgical procedures; educating medical students; informing patients and their families (Tuomi et al., 2014). The traditional way for surgical trainees is to practice on models, animals or cadavers. However, the characteristics of animal organs are often different from those of human organs. Cadavers are limited in sources and require a high cost to preserve and transport. This surgical system has many shortcomings in terms of efficiency, cost, flexibility and safety (Lin et al., 2014). In 2010, Rengier et al. (2010) conducted an experiment using a 3D printed model for pre-surgical training, which not only reduce the cost but also the time for the operation. For complex anomalies and complicated procedures, AM models are able to offer a better understanding, especially helping in deformities or anatomical abnormalities (Javaid et al., 2018). Depending on the specific case, requirements regarding the material properties, anatomical accuracy, haptic response, transportability, storability, or behavior in the process are different (Tuomi et al., 2014).

For medical education and training, AM models can offer a detailed illustration of a medical problem without making any inconvenience to the patient (Javaid et al., 2018). Fasel et al. (2015) present an innovative approach for anatomy teaching, integrating a surgically relevant trend with 3D printing, which has proved the efficiency and effectiveness of using CT-based 3D printed models as accurate representations of anatomical reality. Compared with the traditional anatomical atlas, a randomized controlled study (Kong et al., 2016) showed that 3D models can improve anatomy teaching significantly.

Another area in which 3D printing has made a significant difference is surgical planning (Malik et al., 2016). Between October 2015 and December 2016, 3D printing individualized models and guide plates for making preoperative surgical planning and intraoperative treatment were used in 5 patients with bone tumors (Xu et al., 2017). The study shows that 3D printing technology can improve preoperative planning and evaluation in bone tumor surgery, and it can serve as a new standard for individualized treatment in patients with bone tumors (Xu et al., 2017). 3D printing technology can improve preoperative planning and evaluation, achieve accurate resection around delicate structures, shorten operation time, reduce intraoperative blood loss, and reduce the incidence of complications during the surgery (Chae et al., 2015; Keller et al., 2021; Louvrier et al., 2017; Malik et al., 2016; Sheha et al., 2019).

However, there are still certain limitations. The printer's dimension may not be able to easily catch on a detailed structure like vascular mapping which requires high resolution and significant computer engineering proficiencies (Chae et al., 2015). Salmi et al. (2013) have studied the accuracy of medical models made by AM. The focused technologies in their study are selective laser sintering (SLS), three-dimensional printing (3DP) and PolyJet technologies. Since the AM

process includes various steps, each of which could be a source of error. Their results also showed that different manufacturing methods will cause significant errors (Salmi et al., 2013). Clinicians should be aware of which places require precise representation and which areas can tolerate slight roughness on AM medical models (Keller et al., 2021; Salmi et al., 2013). Another consideration is the delivery time. In maxillofacial surgery, if the printed model is left to the industry, planning time plus printing time may easily take several weeks, delaying surgery, which could be harmful in the case of cancer (Louvrier et al., 2017). Such a problem is also mentioned in the study of the main clinical use of AM in Finland (Pettersson et al., 2020). The study finds out that different service providers will have different work timescales, hence, it is one of the barriers to large-scale adoption of AM (Pettersson et al., 2020). Regulation is another complex issue. Inhouse versus outsourcing is different, and one product needs to meet several criteria if it is in-house produced (Pettersson et al., 2020).

2.4.2 Inert Implants

The purpose of this technology is to replace defective or missing tissue with customized fixtures and implants (Javaid et al., 2018). Standard-size implants is lacking individual specificity, and are unable to achieve precise implantation, which may have a certain influence on the postoperative quality of life of patients. CAD and AM technology can fabricate case-specific implants, such as knee joints, spinal implants or dental implants to fit the patient comfortably (Javaid et al., 2018). Since the implant may have long-term contact with body fluids, organs, or tissues due to being wholly or partially implanted into the body, the requirements for the material are often strict and tissue-compatible (Salmi, 2021). It often takes a long time to get approval for the material and the membrane properties may affect cell adhesion (Tuomi et al., 2014). And the requirements for durability, and mechanical and surface properties are depending on the cases.

To amplify the advantages of AM into clinical translation, the AM techniques need to be relatively cheap, easy to use and ideally easy to install and use directly in a hospital (Garot et al., 2021). Garot et al. (2021) have studied the state-of-the-art of the different materials and AM techniques used for bone regeneration. The main AM techniques used in this area are extrusion-based, powder-based and vat photopolymerization. Considering the costs, usability and space requirements, different technologies have their own advantages and are suitable for different clinical uses. Pre-clinical studies have revealed the prospect and advantages of applying AM to bone tissue engineering, but so far, commercial products are still rare. This is due to the lack of medical-grade materials, as well as the costs related to the material, manufacturing process and on-site training of clinicians so as to be able to use AM machines and software (Garot et al., 2021).

In orthopedics, although typical implants are designed to fit the majority of the general population, in circumstances where the anatomy differs or if no other implant is available, a personalized fit is required (for example, severe bone loss for trauma, cancer, and infection), where AM plays a significant role (Wixted et al., 2021; Wong, 2016). Only two patients reported failures after receiving treatment with a 3D-printed custom implant (Dekker et al., 2018). Patients who had custom implants lost less blood, had fewer adverse events and were less likely to be admitted to rehabilitation or acute care facility than those who received off-the-shelf implants (Wixted et al., 2021; Wong et al., 2016). The hospital could reduce implant inventory when using patient-specific custom implants (Wong et al., 2016).

Apart from the potential and advantages, there are certain limitations. The expensive cost of the implants, the design and manufacturing time required to fulfil surgical deadlines, the lack of intraoperative flexibility, and the difficulty of establishing proper implant placement are all problems (Wixted et al., 2021; Wong et al., 2016). Although the manufacturing cost of the custom implant may be higher than off-the-shelf implants, it is best to evaluate the total cost of surgery in terms of preoperative planning, implant design and manufacturing, implementation of the surgical procedure and long-term clinical results (Unwin et al., 2016). The potentially superior long-term performance of custom implants may reduce costly revision surgery due to implant-related failures and lower overall lifecycle costs (Unwin et al., 2016). In addition, a great deal of pre-operative work and demands on professional designers, manufacturing equipment and personnel should be recognized before use. The surgeon's involvement in this process is critical and they must work closely with the 3D printing company to design the implant (Wixted et al., 2021).

Similar problems also occurred in maxillofacial surgery. In a state-of-the-art overview of the usage of customized facial implants (Memon et al., 2020), the author has pointed out that the actual process of designing and manufacturing a face implant is somewhat challenging, as it necessitates numerous measurements and waiting hours prior to the final procedure. Preoperative planning, imaging processing, and implant design and manufacture are not only time-consuming but also costly and difficult. Moreover, the manufacturing of patient-specific implants is under very strict regulations in Europe, especially for hospital-made 3D printing (Louvrier et al., 2017).

2.4.3 Tools, Instruments and Parts for Medical Devices

With AM, tools instruments and parts for medical devices can be patient-specific in order to improve the efficiency of a medical or surgical procedure and reduce overall costs (Tuomi et al., 2014). Such devices and instrumentation could expose to body fluids, organs, and tissues for a limited time, hence, requirements for the sterilization process are necessary. Since the tools are used invasively not implemented, as long as the material is not immediately toxic or allergic to the contact human body, and no particles are shedding off from the tools, it is secure to use additively manufactured tools (Tuomi et al., 2014). Other requirements are depending on the specific cases. One successful and large business in this medical application area is to use VAT photopolymerization for models of vacuum forming clear orthodontic aligners (Gibson et al., 2021). Other external aids include operation-specific equipment such as custom-fit surgical guides and performs, more specifically, a mandible fracture reduction instrument (Kontio et al., 2012).

Through various systematic reviews of 3D printing in surgery (Martelli et al., 2016; Tack et al., 2016), surgical guides and templates are one of the most popular medical applications of AM. These devices were created to aid the surgeon in achieving the ideal alignment or position of surgical instruments during surgery, as well as harvesting and grafting bone flaps (Martelli et al., 2016). The most-reported advantage of using 3D printed surgical guides is these devices improved the precision and location of incisions, especially in the case of osteotomy-assisted bone reconstruction (Martelli et al., 2016; Tack et al., 2016). Another advantage is the time-efficient procedure (Martelli et al., 2016; Tack et al., 2016). With operating time being saved, 3D printed constructions utilized in patients' operative treatment give significant downstream value to health systems, despite being resource-intensive (Ballard et al., 2020). Surrogates of value and financial viability of 3D printing in preoperative planning and reducing intraoperative time are demonstrated in the current study's literature-based financial evaluations (Ballard et al., 2020). However, time

saved is subjective and depends on the perspective employed to evaluate or appreciate it (Martelli et al., 2016). It appeared that the most time-consuming portion of printing was not the printing itself, but rather the imaging and data processing and the breakeven number of 3D printed guides depend (Ballard et al., 2020; Martelli et al., 2016). When new and expensive technologies are introduced into medical practice, the problem of cost is frequently a cause of worry and becomes a key constraint (Martelli et al., 2016; Sorenson et al., 2013).

2.4.4 Medical Aids, Supportive Guides, Splints and Prostheses

In this class, the AM parts are external to the body, or at least noninvasive. AM technologies assist with customization in addition to standard appliances (Salmi, 2021). Examples of applications include long-term and postoperative supports, motion guides, fixators, external prosthesis, prosthesis sockets, personalized splints, drill-guiding microtables, orthopedic and oral applications (Tuomi et al., 2014). Personalized devices will aid in healing from trauma or defect, and ensure the repair is precise. Since the manufactured pieces are mostly wearable and external, the material should be nonallergic to the contact skin. Other requirements regarding surface and mechanical properties are decided by specific cases. One of the advantages of employing AM is time and cost-saving. Compared with the traditional manufacturing process to produce prosthesis sockets, which normally take two to three days for one, AM has successfully reduced to less than four hours (Ng et al., 2002). In the mid-2000s, the production of hearing aids shifted almost entirely to 3D printing. Using difference-in-differences and synthetic control methods (Freund et al., 2020) examine the effects of this shift on trade flows. In the hearing aids industry, 3D printing technology will increase global trade by lowering production costs (Freund et al., 2020).

2.4.5 Biomanufacturing

The purpose of this technology is to fill incorporate a biologically active tissue into the human body, sometimes also referred to as ‘organ manufacturing’. A biocompatible scaffold with unique geometry characteristics is fabricated with AM, and cells are delivered to the scaffold and grow through it. The scaffold not only acts as a skeleton for cell cultivation but also offers support and protection as an optimal medium (Tuomi et al., 2014). The scaffold is generally with a porous structure to capture and attract cell growth, and the shape is personalized to match the damaged tissue with medical imaging or 3D scanning (Javaid et al., 2018). AM techniques like FDM have proved to be a suitable method for printing scaffolds (Costa et al., 2015). Since the final application is embedded into the human body, the procedure and the printed parts must be sterilized. The material for the scaffold must be biologically compatible and active with the human body, some common materials are polymers, ceramics, and composites (Salmi, 2021).

2.4.6 A Summary of Different Applications with Their Challenges

Through the above reviews on the different clinical applications of AM, it is not hard to say that the mainly popular applications are anatomical models for operative rehearsal and treatment planning, surgical tools and patient-specific implants (Aimar et al., 2019; Durfee et al., 2019; Pugliese et al., 2018), there are certain similarities regarding the benefits of this technology as table 3 shown. The freedom of design gives the possibility for individual specificity, which in the healthcare industry, it will offer a higher quality of care, especially for those complicated cases where customization is demanded. For different clinical surgeries, AM could be applied pre-operationally for viewing and planning, operationally with surgical guides and implants. In both

circumstances with the help of AM, it could shorten or reduce complications and result in shorter postoperative hospital stay, lower re-intervention rates and cheaper medical expenses.

With these being said, AM technology is ideal for mass customization, especially for the healthcare industry. However, like any disruptive innovation, AM has challenges that must be addressed in terms of technology and finances, regulations and quality. From the technology point of view, the capital outlay for building a 3D service can be substantial and will require time or new investment in personnel to develop technical expertise. Basic requirements include post-processing software and printing equipment or outsourcing contracts for printing services (Ballard et al., 2018). Generally, the 3D printing process consists of the following steps (Keller et al., 2021):

a. Data collection. Acquisition of a 3D model of a medical picture (CT, MRI) in DICOM format (Digital Imaging and Communications in Medicine)

b. Image manipulation. Anatomy segmentation and DICOM to STL (stereolithography) conversion utilizing an appropriate software tool.

c. Slicing/Printing in 3D. Using an appropriate printing technology, slice the STL model into numerous 2D slices and print the 3D model by stacking the slices on top of each other.

d. Postprocessing. The printed 3D model must be finished by reducing superfluous material, enhancing mechanical strength, removing support structures, and improving the object's look, depending on the printing procedure.

In the design stage, the manufacturing process needs the necessary engineering skills and the ability to use relevant software. However, the medical personnel may not have this ability and need additional help. The option of decentralization as stated before would be less cost- and time-effective, which will limit the use of AM in critical cases. While building a centralized workflow inside the hospital, those personnel and financial expenses regarding hard-and soft-ware set-up and maintenance, technical support and regulation qualification would be initially overwhelming compared to using conventional technologies.

The above literature review gives a detailed understanding of AM used in the medical industry regarding various clinical applications. Although the interest in AM in healthcare is growing, the types of research on the adoption of AM in hospitals from an organizational level is limited. There are few types of research on the application of AM in hospitals from the perspective of social science, especially the implementation of science. As AM adoption in hospitals is still lacking publications regarding management-level point of view, this thesis will help to create a broad overview of those key factors in terms of AM adoption in hospitals, especially in Sweden. In short, current gaps in research are summarized as follows:

- Low involvement of social sciences including management sciences as well as implementation science concerning AM in hospital use

- Lack of organizational considerations like the influence of organizational structure, leadership, personal relationships, and networks on AM implementation

- Lack of qualitative case studies concerning AM implementation at the organizational level

Table 3 Benefits and challenges for main clinical application of AM

Main clinical applications	Main Benefits	Main challenges
Anatomical models	• Reduce cost compared to alive models • Better understanding for complex cases • Improve surgical efficiency and results	• Errors on detailed structure due to printing dimension • Long lead time for decentralized manufacturing • Regulation responsibility for in-house production
Surgical guides	• Improve the precision and location of incisions • Time-efficient procedure • Significant downstream value to health systems	• Imaging and data-processing is time consuming • Cost balance at break-even point is uncertain for centralized manufacturing.
Patient specific implants	• Individual specificity • Precise implantation • Better patient care • Less hospitalization	• High manufacturing cost • Medical expertise is heavily needed for design • Time frame is tight for critical cases • Strict regulation for in-house production • Strict requirement on material

3. Theoretical Framework

This section will introduce implementation science and the main framework that will be used in this study, CFIR.

Implementation science is the research process that systematically integrates scientific findings and evidence-based intervention programs into clinical practice and health policy to improve the quality and effectiveness of health care delivery (Eccles et al., 2006). Therefore, implementing science is not to establish efficacy evaluation of interventions but to identify factors that affect the "implementation" of effective interventions. These factors determine the reasons for adopting or not adopting interventions with evidence-based evidence support in specific health care or public health environment and use this information to formulate and test the effect of implementation strategies in order to improve the speed, quantity and quality of evidence transformation in practice, and narrow the gap between evidence and practice (Eccles et al., 2006). As an interdisciplinary discipline born in response to the complex problems of today's society, the concepts and research results of implementation science have attracted widespread attention worldwide.

In implementation science, different applied theories, frameworks, and models help to understand and explain the factors that influence implementation outcomes (Nilsen, 2020). The selected framework should only focus on the successful implementation of AM in healthcare. As the literature review also reveals some common factors of AM at different levels in medical care, the selected framework should also be a multi-level determinant. Furthermore, for the adoption of AM, the result of the framework should be the successful implementation of an innovation (such as the technology itself) or the successful implementation of an intervention (such as routine changes due to the implementation of new technologies). To understand the key factors in the adoption of AM in hospitals from a managemental perspective, the framework suitable in this study is the Consolidated Framework for Implementation Research (CFIR) as it helps to guide the qualitative research, i.e. to understand the plan for the adoption of AM and factors that must take into consideration (Damschroder et al., 2009). The results of a survey conducted by Birken et al. (2017) from 2015 to 2016 showed over 100 theories, frameworks, and models used in implementation research, with CFIR being the most frequently used. Moreover, Birken et al. (2017) and Kirk et al. (2015) have revealed that CFIR is more appropriate than other frameworks and theories when accessing the community and health system-level factors that affect the implementation. It will be overwhelming to study all factors in the CFIR model, hence the knowledge gathered through literature review will help filter some of the crucial factors for this study's interview guide.

3.1 Consolidated Framework for Implementation Research

CFIR is a rigorous evaluation process whose main purpose is to identify potential and actual factors that have an impact on the progress and effectiveness of implementation (Damschroder et al., 2009). CFIR classifies the implementation of intervention programs into different categories and components that can be used to guide the formative evaluation in the implementation of intervention programs from a multi-level, individual-organizational-system (Damschroder et al., 2009). There are 37 implementation constructs in the 5 domains, which are Intervention characteristics, Outer setting, Inner setting, Individual characteristics, and Implementation process as table 4 showed and detailed descriptions are given below.

Table 4 CFIR domains and constructs

Consolidated Framework for Implementation Research				
Intervention characteristics	**Outer setting**	**Inner setting**	**Individual characteristics**	**Process**
Relative advantage	Patient needs and resources	Structural characteristics	Knowledge and belief about intervention	Planning
Adaptability	External policies and incentives	Networks and communications	Self-efficacy	Engaging
Trialability	Peer pressure	Culture	Individual stage of change	Opinion leader
Complexity	Cosmopolitanism	Implementation climate	Individual identification with the organization	Formally appointed internal implementation leaders
Cost		Tension for change	Other personal attributes	Champions
Intervention source		Compatibility		External change agents
Design equality and packaging		Relative priority		Executing
Evidence strength and quality		Organizational incentive and rewards		Reflecting and evaluating
		Goals and feedback		
		Learning climate		
		Readiness for implementation		
		Leadership engagement		
		Available resource		
		Access to knowledge and information		

3.1.1 Intervention Characteristics

Usually, unadjusted intervention programs are difficult to adapt to the implementation environment, and the implementation process will be resisted by relevant personnel, so an active process is needed to encourage individuals to participate and complete the implementation project

(Damschroder et al., 2009). The intervention scheme usually contains various contents and has various interactive components. Intervention programs can be conceptualized as "core parts" (essential elements of the intervention programs themselves) and "adjustable parts" (adjustable elements, structures and systems related to the implemented intervention programs and organizations) (Damschroder et al., 2009).
There are eight constructs in this domain. The first four are coming from Rogers' diffusion of innovation theory, which are relative advantages, adaptability, trialability and complexity. Another four, the cost, the intervention source, design quality and packaging, and evidence strength and quality are added for evidence supporting the intervention.

3.1.2 Outer Setting

This domain includes the external factors like social, economic, political and other factors that affect the implementation in the environment (Damschroder et al., 2009). However, the boundary between external and internal factors is not completely clear, but dynamic and unstable. The change of external factors will affect the implementation, which is usually regulated by internal factors. Whether a specific factor is "external" or "internal" depends on the implementation situation (Damschroder et al., 2009).
There are four constructs in this domain. First, patients' needs and resources. In order to improve the outcome for patients, organizations must consider patients' needs and resources in the process of implementing intervention programs. Patient-centered organizations are more likely to implement changes efficiently (Damschroder et al., 2009). Second, cosmopolitanism. Supporting and promoting employees' collaboration with the outside world will make the organization more likely to implement changes quickly (Damschroder et al., 2009). Third, peer pressure. Peer refers to any external organization that can make the organization feel affinity or competitiveness. Because other peers or competitors have already implemented or are preparing to implement the program in order to gain competitive advantage, the pressure of implementation may be even greater for organizations that adopt the intervention program later (Damschroder et al., 2009). Fourth, external policies and incentives. External factors also include external policies and incentives that are helpful to popularize intervention programs (Damschroder et al., 2009).

3.1.3 Inner Setting

The internal factors refer to contextual factors such as internal culture, organizational structure and network that affect the implementation of intervention. Factors among the internal factors are interrelated and influence the implementation of intervention programmes (Damschroder et al., 2009). There are twelve constructs in this domain.
First, the structural characteristics of the organization. The more stable the team (members and the team to maintain close contact; Low mobility), the greater the likelihood of successful implementation (Damschroder et al., 2009). Management density (the ratio of managers to total staff) is positively correlated to implementation (Damschroder et al., 2009).
Second, networks and communication. Collaboration and communication between levels within the organization may be strong or weak, formal or informal, tangible or intangible. High-quality formal communication improves the effectiveness of implementation. In addition, relationships between individuals may be more important than individual attributes, and the establishment of these relationships can have a positive impact on the implementation of interventions (Damschroder et al., 2009).

Third, culture of the given organization. Culture is an important part of internal factors. Most change efforts are aimed at the objective aspects of the organization, such as tasks, organizational structure, and behavior. One of the reasons that many changes fail is the failure to change the invisible culture and way of thinking in the organization (Damschroder et al., 2009).
Fourth, the implementation climate. The implementation climate can be assessed through practical means, such as policies, procedures and incentive systems (Damschroder et al., 2009). There are six sub-constructs under this main construct, see table 4.
Fifth, implementation readiness. This includes leadership input, available resources, and the accessibility of knowledge and information. Leadership can come from leaders at any level within the organization, e.g., executive, middle management, clinical frontline managers who have an impact on implementation (Damschroder et al., 2009). There are 3 sub-constructs under this main construct, see table 4.

3.1.4 Individual Characteristics

This domain is related to individuals involved in the intervention process. Individuals have agency, and individual choices will affect other people, thus affecting the implementation results. It is the carrier of individual culture, organization, specialty, individual mentality, behavior standard, interest and subordination (Damschroder et al., 2009). There are 5 constructs in this domain.
First, the knowledge and belief about intervention. Subjective opinions obtained from peers are easier to understand and more convincing. These opinions are helpful to stimulate individual enthusiasm for implementation, while negative opinions usually cause individual resistance to implementation. In addition, the importance attached to change can affect the individual's willingness to change (Damschroder et al., 2009).
Second, self-efficacy. Self-efficacy is determined by the ability to perform specific behaviors in a specific environment. Individuals need to make certain changes in order to achieve their implementation goals. The more confident they are in their ability to change, the higher their self-efficacy. Individuals with high self-efficacy are more likely to accept the intervention plan and will implement the intervention plan with a firm attitude even in the face of obstacles (Damschroder et al., 2009).
Third, the individual stage of change. The specific stage of the individual in the process of using the intervention plan depends on the basic model used in the study (Damschroder et al., 2009).
Fourth, the individual identification with the organization. The sense of identity with the organization will affect the individual's willingness to participate in the implementation. Individuals who get along well with the organization are willing to make extra efforts and take risks for the organization, and these individuals have a good recognition of the organization (Damschroder et al., 2009).
Fifth, other personal attributes, refer to other personal traits that may affect the intervention, including tenure, intelligence, values, and competence that received less attention (Damschroder et al., 2009).

3.1.5 Implementation Process

This domain mainly refers to the methods of promoting the adoption of intervention programs at the individual and organizational levels. Successful implementation usually requires a positive change process, with the aim of realizing individual and organizational intervention programs. Individuals from inside or outside (for example, local advocates, and external change agents) can actively promote the implementation process (Damschroder et al., 2009). The implementation

process can be seen as a series of interrelated sub-processes, which occurs at multiple levels in the organization. The order of these sub-processes is not fixed, which also reflects the complexity of implementation and evaluation (Damschroder et al., 2009). These sub-processes can be planned or spontaneous, conscious or subconscious, linear or nonlinear. But ideally, all processes point to the general direction of effective implementation (Damschroder et al., 2009). There are eight major activities in this domain.

First, planning. A good plan should meet the following five factors: consider the needs and opinions of stakeholders; tailor-made strategies according to the characteristics of the population (for example, grouping by specialty, population, culture and organizational attributes); identify appropriate styles, images and metaphors and use them to provide information and education; determine and use appropriate communication channels; use strict monitoring and evaluation methods to track the progress of implementation goals (Damschroder et al., 2009).

Second, engaging. Early members of the team need to be carefully selected, especially "implementation leaders" and "advocates". If the early users or leaders have similar socio-economic, professional, educational and cultural backgrounds to the expected users, individuals will be more likely to take intervention programs (Damschroder et al., 2009). There are four sub-constructs under this main construct, which are Opinion leaders, Formally appointed internal implementation leaders, Champions and External change agents.

Third, executing. The implementation of the plan is constantly changing, so it is difficult to evaluate it. The quality of implementation can be evaluated with reference to the following points: the accuracy of implementation according to the plan, the intensity (quality and depth) of implementation, the timeliness of task completion and the participation of key individuals (such as implementation leaders) in the implementation process (Damschroder et al., 2009).

Fourth, reflecting and evaluating. It includes traditional forms of feedback, such as reports, charts and qualitative feedback. Investing time to reflect or report before, during and after the implementation of the intervention program is an important way to promote common learning and improve the implementation (Damschroder et al., 2009).

Recalling table 2, the advantages of decentralization AM manufacturing system is about the regulation qualification, corresponding to External policies and incentives from CIFR; financial risk and investment corresponds to Cost from CFIR. The disadvantages, such as loss of control on time and data safety concerns, are Relative disadvantages. The advantages of the centralization of AM manufacturing systems, such as fast response time and the potential to serve the entire hospital system, correspond to the Relative advantage of CFIR. The disadvantages for resources and investment costs belong to Cost. Connecting the discussed benefits and challenges of main clinical applications to CFIR, the main benefits of AM clinical applications mainly refer to Relative advantages and Patients outcomes. As for the challenges, some relate to the regulation aspect, some relate to the Cost, and some relate to the Design quality as the printer could create errors. All aspects related to the AM use seem to belong to the Intervention Characteristics and Outer Setting domains.

A systematic literature review on the organizational adoption of AM (Ukobitz, 2020) has revealed that technology contexts are the most prominent category of adoption drivers. This study did not limit study AM adoption in the medical but in every industry. It has also been discovered that the survey on how external conditions would influence the 3D printing adoption is hardly discussed. A study to determine the key factors influencing the 3D printing adoption in

the Taiwan manufacturing industry also showed that cost is the most critical factor (Yeh et al., 2018). Hence, all the constructs belonging to the domain Intervention characteristics and Outer setting will be used to develop an interview guide to discover how these factors affect the hospital adoption of AM in different Swedish regions.

4. Methodology

This section describes the methods that are used in this study, including research design, data collection as well as data analysis. In the end, the data quality, ethical considerations and method limitations are presented.

The methodology part begins with the research problem, mainly introducing who, what, when, where and how to conduct the research. It will cover the strategy that serves for the whole research process as fundamental philosophy and framework (Opoku et al., 2016). Research design, a plan of actions that links the philosophical assumptions to specific methods, and methods are specific techniques for data collection and analysis.

4.1 Research Strategy

A research strategy is a general orientation to the conduct of business research (Bell et al., 2018). Generally, there is quantitative research and qualitative research. According to Bell et al. (2018), a quantitative research strategy is focusing on quantification in the collection and analysis of data, it involves deductive reasoning as the connection between theory and research, and it takes the social reality as objective, external, and independent of social actors. Meanwhile, a qualitative research strategy is focusing on words rather than quantification in the collection and analysis of the data, it predominantly adopts inductive reasoning as the connection between theory and research, and it takes the social reality as a result of social interaction and are in a constant state of revision (Bell et al., 2018).

The research questions in this study aim to explore the hospital use of AM and figure out the determinant factors behind such use in hospitals. With the aid of literature reviews on other successfully implemented AM in hospital use, the goal here is not limited to validating the existing studies, but also discover additional findings, which are aligned with the inductive approach.
To answer the research questions, this study depends on the participants' interpretation of their experience within the real world, and how they observed or participated in the adoption of AM, therefore the qualitative method is appropriate as it helps to understand the phenomenon with in-depth insights. And the research questions cannot be addressed in a way of quantification.

4.2 Research Design

Research strategy is the general direction of business research. To go further, more details are needed. Research design describes the framework for the collection and analysis of the data. It reflects the decision to give priority to a series of dimensions of the research process (Bell et al., 2018).

Bell et al.(2018) have suggested five different types of research design, namely experimental design, cross-sectional design, longitudinal design, case study design and comparative design. For this study, comparative design is chosen to be the fundamental research design. There will be several interesting regions to study. Since different regions will have AM adoption within different areas, thus makes it interesting and possible to compare different cases, and consider what is

unique and what is common across cases (Bell et al., 2018). The logic of comparison implies that comparing meaningfully contrasting cases will assist in understanding social phenomena better (Bell et al., 2018).

4.3 Sampling

Considering the distinguished characteristics of the case study and the aim of this study is to investigate the hospital adoption of AM in different regions, recalling from Bell et al. (2015) that probability sampling is more time and cost involved in the available resource level and the chance to study a certain representative group is too good to miss, the probability sampling techniques seems less appropriate for the present study, while the non-probability technique is more appropriate. This is due to the researcher wanting to have access to a wide range of individual units relevant to the research questions as possible, so as to have more different perspectives and ranges of activities, and better draw a holistic view (Bell et al., 2018). In this paper, participants for the data collection are identified via purposive sampling, more specifically, snowball sampling. Purposive sampling is a non-probability sampling, the participants are selected in a strategic way in order to keep the samples relevant to the proposed research questions (Bell et al., 2018). This paper is trying to figure out the determinant factors in the adoption of AM in hospital use, thus, large regions in terms of population are targeted, and the characteristics of the sampled regions are described in table 5. Those four regions are strong in life science as they have covered some best hospitals in Sweden (Newsweek, 2022).

Table 5 A summary of characteristics of sampled regions

	Number of hospitals (Vårdguiden, 2022)	Population in 2021 (Statista, 2022)	Location
Västra Götalandsregionen	Eight in total with one university hospital	1,744, 859 (second largest in the country)	Western coast of Sweden
Region Skåne	10 in total with two university hospitals	1,402,425 (third largest in the country)	Southernmost region of Sweden
Region Östergötland	Three in total with one university hospital	469,704 (fourth largest in the country)	Southeastern of Sweden
Region Uppsala	Two in total with one university hospital	395, 026 (fifth largest in the country)	Eastern coast of Sweden

The population here is chosen to be people who work related to AM technology and hospital use. Meanwhile, since the AM adoption in Swedish hospitals is relatively new and niche, snowball sampling will be applied to increase the sample size. Snowball sampling is a sampling technique where the researcher initially samples a small group of people who are relevant to the research questions, and these people introduce others who is qualified to be sampled. The criteria applied for selecting research participants is: working with AM in relation to hospital use. The

participants are listed in table 6. In total there are eight respondents from four regions. There are three respondents in Region Uppsala, one respondent in Västra Götalandsregionen, one in Region Skåne and three in Region Östergötland. Even though their positions are not consistent, their work and knowledge of AM in hospital use are qualified to answer the research questions, as they are able to speak from the managemental point of view.

Table 6 Participant lists

Respondent	Region	Position in the region	Gender
1	Region Uppsala	Business strategist	Male
2	Region Uppsala	Project management	Male
3	Region Uppsala	Surgeon	Male
4	Västra Götalandsregionen	Engineer	Female
5	Region Skåne	Engineer	Male
6	Region Östergötland	Business strategist	Male
7	Region Östergötland	Business investigator	Male
8	Region Östergötland	Operation manager	Female

4.4 Data Collection

Interviews are a popular data-collection technique which is commonly used for qualitative research (Bell et al., 2018). It is able to collect information about feelings, motivations, and beliefs through an interview (Göttfert, 2015). In general, there are three different types of interviews, namely standardize, semi-structured, and unstructured. Table 7 have listed different characteristics of three different types of interviews (Opoku et al., 2016). For qualitative research, the top option would be semi-structured interview and unstructured interview.

An unstructured interview is not standardized or ordered in any form, i.e. it does not have any prepared questions. The interviewee will guide the direction of the conversation and relate any topic or questions that are considered to be relevant (Göttfert, 2015). Semi-structured interview, on the other hand, has an interview guidance which covers some prepared questions and information related to the research topic. The interviewee is free to rearrange the order of the questions and bring in additional questions if it seems related during the interview (Göttfert, 2015). From table 7 it can be concluded that in both types of interviews, the process is flexible, the main difference lies in the difficulties of data analysis. Bell et al.(2018) also stated that for multiple case study research, it is better to follow a script to a certain extent so to ensure cross-case comparability.

Table 7 The characteristics of interview types (Opoku et al., 2016)

Structured interview	Semi-structured interview	Unstructured interview
• Mainly for quantitative data • Use strict interview format • Data usually easy to analyze	• Mainly for qualitative data • Use flexible interview format • Data sometimes hard to analyze	• Mainly for qualitative data • No interview guide • Data usually take efforts to analyze

Before the interviews, an interview guide was developed as given in Appendix A. It was based on the knowledge gathered from literature reviews as well as theoretical background. The interview started with a brief introduction about the thesis itself and the main context of the interview to give the participant an overview. Then the questions began with some introducing questions asking for participants' background and experience with AM. Apart from introducing questions, the interview guides also contained structuring questions with different topics and focus. The questions can be categorized under suitable domains of CFIR. The follow-up questions, which are mostly depending on the interview situations, were not included in the interview guides. Except for respondent 1 who was interviewed face-to-face, the rest interviews were conducted online. And all the interviews were recorded with participants' permission and then transcribed through an online platform.

4.5 Data Analysis

The data obtained through semi-interviews and focus groups are generally rich in text and contained in-depth information that the analytical paths through the richness may be difficult to find (Bell et al., 2018). In contrast to the analysis of quantitative data, where clear-cut rules could be followed, the analysis of qualitative data is a process where the researcher systematically organizes and transform the collected information, which could be file-notes, interview transcripts, or documents and notes of observations, to interpret and understand the studied phenomenon. Most analysis of qualitative data will adopt coding as a key process for data transformation and interpretation (Bell et al., 2018). One of the most common ways for qualitative data analysis is the thematic analysis (Bell et al., 2018) which will also be used in this study.

'Thematic analysis is a method for systematically identifying, organizing, and offering insights into patterns of meaning (themes) across a data set' (Braun et al., 2012). The preference to apply this strategy over others is due to its accessibility and flexibility. Researchers can use thematic analysis in many different ways. Braun et al. (2012) stated that this method can use for an inductive approach where the codes and themes are driven by the data and a deductive approach where ideas and concepts are pre-determined before the data was interpreted. This flexibility helps get sufficient details from the complex data and offers various perspectives. Inductive thematic analysis will better serve the aim of this thesis, which is to identify the determinant factors for the hospital use of AM technology and draw a holistic picture of the AM value chain from the hospital's point of view.

Braun et al. (2012) have outlined six phases of inductive thematic analysis, see table 8. The thesis will try to follow the same steps to analyze the data. The details regarding each step are explained as follow:

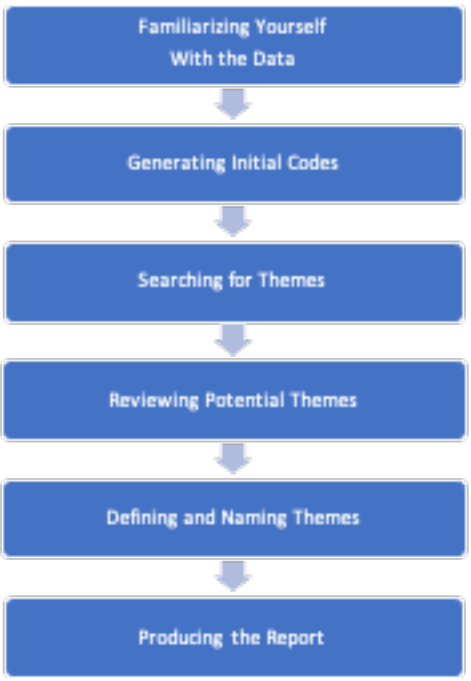

Figure 1 Six phases in inductive thematic analysis

The first stage of analysis is to get intimately familiar with the data content and take notes of things that may be relevant to the research questions. No rush to be systematic or inclusive since it may exclude important information if the preference is made. Repeated times of reading and listening will assure the accuracy of information so as to make a reliable foundation for the following stages (Braun et al., 2012). After multiple times of listening, the transcribed notes were also corrected and tagged interviewer and interviewee.

Then with a comprehensive understanding of the data, it is time to create codes. The coding was data-driven. And the generation was done by hand. The data were analyzed in detail and possible aspects related to the research questions were also coded (Braun et al., 2012). For codes that have certain similarities or can fall under similar concepts, they can be incorporated into a theme. Different themes should have a certain logical connection, which in this study was the frequency of being mentioned. Further reviews on the themes and codes were carried out as it is necessary to assure there is no important information left out and there is sufficient information covered by all themes to be able to answer the research questions (Braun et al., 2012).

With the defined themes, it is important to be able to clarify the uniqueness and distinctions among different themes. A good theme should follow three rules according to Braun et al. (2012), ideally, each theme should have a clear focus, scope, and purpose, together with themes that are related but not overlapped so as to draw a coherent overall story of the data, and be able to directly address the research questions (Braun et al., 2012). A good story not only needs to have good themes, but also requires good writing. The order of the themes and logic behind is important for a convincing and clear yet complex story which also fits the scholar's paper requirements (Braun et al., 2012).

4.6 Data Quality

The criteria for evaluating the quality of qualitative research in Bell et al. (2018) book are different from those used by quantitative researchers. In the book, Bell et al. (2018) have discussed the use of trustworthiness and authenticities as the two primary criteria for accessing the qualitative study. And trustworthiness, to be more specific, have categorized into four criteria, namely credibility, renderability, dependability and confirmability (Bell et al., 2018).

4.6.1 Credibility

Credibility is an evaluation of the truth value of the study and reported data. It describes the internal validity of the research (Bell et al., 2018). There are several ways to establish credibility. One is called respondent validation, where the findings of the research will be examined by research participants. The other one is peer debriefing (Anney, 2014), where the researcher gets peer reviews on his/her work continuously. This study has been under review by peers and subject readers with scheduled seminars. The research is conducted with the consideration of feedback received from peer reviews.

4.6.2 Transferability

Transferability parallels external validity and refers to the extent that the qualitative research can be transferred to another context, or the same context at another time (Bell et al., 2018). For qualitative research, it is not easy to obtain high transferability due to the contextual uniqueness and research orientation. It is one of the limitations of the study due to purposive snowball sampling and the small sample size. However, the case studies with clear settings will provide valuable information for future studies to replicate.

4.6.3 Dependability

Dependability parallels reliability. To increase the trustworthiness of the qualitative work, and auditing approach is suggested by Bell et al. (2018). The whole process of conducting the qualitative work, from questions formulation to data analysis, should be recorded in an accessible manner, so as to be audited by peers (Bell et al., 2018), as the content of this study will be reviewed by peer and supervisors via written and oral presentation.

4.6.4 Confirmability

Confirmability parallels objectivity. In qualitative research, complete objectivity is impossible, but the conduction of the research and conclusions should not be obviously influenced by personal values or theoretical tendencies (Bell et al., 2018). In this thesis, the researcher is trying to be completely honest when displaying data and findings, and continuously peer reviews will also assist in assuring confirmability.

4.6.5 Ethical Considerations

Bell et al. (2018) in their book have discussed four main areas regarding the ethical principles in business research, namely harm to participants, lack of informed consent, invasion of privacy, and deception. To avoid harm to participants, the research design and interview questions are designed not in any way to harm the participants mentally or physically. To avoid a lack of informed consent, before the interviews, the research participants are invited with enough information regarding the

interview aims, research purpose, and how their answers will be used. Participants are free to choose whether to participate in the study. As for the invasion of privacy, their personal information such as their organization, and occupation. will be revealed in the thesis only if received their permission. Their name will be coded to protect their privacy. Any recording or documentation actions will be carried out only with their approval.

4.7 Limitations

The method of this study has several limitations. First, reaching out to potentially qualified candidates is not easy as AM is still rare and new in the healthcare system. Not many people have practical experience with AM in healthcare. The studied cases include the second largest region to the fifth largest region in terms of population. The first largest region was also invited. Still, unfortunately, there was no one able to participate. The total response rate regarding all the invitations to the studied regions was around 50%. One possible explanation was those invited people generally have several affiliations. Hence not everyone has the availability to participate in a master thesis. Apart from this, since the sampled regions represent large regions, the data and results might not be applicable to smaller regions.

Although eight interview participants could give a decent insight into the research questions, additional interviews may be able to provide deeper understanding into the study. Another thing is the data saturation. There are two cases, and each case only has one interview. Although the participants are qualified to provide enough information about key areas, there is still the possibility that others might provide additional information, thus adding more details to the comparison results. Moreover, the case-to-case comparison might not be accurate as the interviews come from different backgrounds regarding AM adoption in healthcare. Some come from the hospital, while others come from the regional management. Their different working experience and focus would lead to a certain level of preference by nature when answering questions to identify the key factors affecting AM adoption in hospital use.

Another limitation that could reduce the accuracy of the data is the language, as English is the used in all steps, while it was neither the researcher’s first language nor the participant's. Hence, some information may be lost or misinterpreted, which will affect the credibility of the study. Also, most respondents were men, which might result in a one-sided response. Including both genders in the sample could lead to a more nuanced picture of AM use in hospitals. Another constraint is the analysis as the thematic method is used. With one researcher working only, this kind of coding and clarification might lose some degree of objectivity. Although there are peer reviews regarding the codes and themes, it is still the researcher who makes the final decision. Without another eye, there might be some subjectivity.

5. Results

In this section, first, a general description and comparison of each case are given. Then the main themes derived from all cases are presented in both table and text, which will address the research question. A detailed analysis of how these factors affect AM adoption is given in the form of a table, and the topics are divided into barriers and facilitators.

5.1 An Overview of the Studied Regions

The following sections will generally describe the AM adoption in different regions through analyzing the interview data.

5.1.1 Västra Götalandsregionen with a Focus on Sahlgrenska University Hospital

The beginning of using AM is built on some doctors' interests, and it is doctors themselves decisions to put AM into clinical cases. The doctors are responsible for finding a way to design, segment and produce, which requires a lot of extra work. Right now, the university has a radiological engineer focused on 3D printing projects, the design and segmentation are in-house handled, but the production is outsourced to a certified company. At present, they are using AM for creating surgical guides, and they are trying to implement an in-house workflow for surgical planning with AM. But right now, they are at the early stage of creating a centralized mode. They are collecting evidence for the use of AM and investigating the time and effort to build an in-house production line, as well as to what level (how many cases) this technology will pay off. The respondent stated that the advantage of using AM in preoperative planning had been approved in practice. The reduction in surgical time, the better results for the patient, and the more prepared the surgeons. With AM, some complicated cases that require experienced and skilled surgeons now can be handled with junior surgeons with the same outcome. They have also conducted an in-house study to test the printed guides and the outcome of surgeries with AM, and so far, the results are promising.

One of the difficult things is that AM requires close collaboration between surgeons and the engineering department. Details regarding the scan and segmentation are essential to assuring the outcome of the surgery, which depends on medical knowledge. The doctors and engineers need to communicate closely to have good results. The ongoing project assured the technical side could have close communication with the medical side, which is essential to have good results from using AM for surgical planning. The radiology department is working as a driving force since the clinicians do not have the possibility to push AM more forward. At the same time, the technicians are pretty good at working with different clinics and able to have a holistic view. Another issue is the funding to help the AM further used in orthopedic department and for a more centralized mode. Since clinicians are the main driving force in the broader adoption of AM, a centralized mode will help spread the technological advantages and stimulate the interest of more clinicians.

5.1.2 Region Östergötland

In region Östergötland, the AM in-hospital use is still pretty decentralized, but there is an innovation project (East Sweden Medtech) to find the needs among clinicians and how to best solve them together with universities and with various industries. The main clinical use of AM is

surgical guides and planning in the orthopedic department and maxillofacial department. And such use is also developed on clinicians' personal level. There are not many decisions from the management level. The management of the region now is working on building a centralized work mode since the healthcare organization has been really decentralized for the last 15 years. And they have realized the benefits of using AM in clinical practice. As healthcare providers, the most important mission is to offer a better quality of care to their patients. Promoting AM will help them achieve this. However, the problem now is how the central organization (from the hospital level or regional level) could help clinicians to use this technology.

As they have investigated, the boatload of work is lying on the pre-processing and post-processing, where technical knowledge is heavy, and medical clinicians usually do not have the ability. There are clinicians in the maxillofacial department who have involved in AM ten years ago, but such use did not spread out into other departments. Being an early adopter of such innovation requires the adopter to learn new things, and clinicians usually do not have the time or possibilities to have an in-depth understanding of how AM could help them without proper help. Based on the experiences of the orthopedic department, where the segmentation – design- manufacturing are all outsourced to a certified company, it is too time-consuming and costly. The product quality is good and valuable, while the issue is that time could take up to six months to get the results, and it costs a lot of money. For some malignant cases where time is the priority, it is not possible to handle the AM by another company within the time frame. Then the advantages of AM in life-changing cases cannot be disclosed, and the quality of care given to the patient is hindered. In the end, they have to make decisions on what cases should send to the service company and what should not. Such requirements for support and other problems from the clinician level have caught on management level's attention. Decisions regarding how to coordinate different departments and how to better support those clinicians shall be made at the management level.

Then, the situation from a management level would regard more like a business case since investing in technical support could involve extra training or new employment, and machine cost and material cost is also not cheap, especially for metal 3D printing. The regulatory aspect also requires professional help. The level of centralization, for example, how centralized the hub is, does it only provide technical support or is the production is also in-house, or even where should the 3D hub be placed. These are problems that the management level is also evaluating since all investments shall not be wasted.

5.1.3 Region Skåne with a Focus on Skåne University Hospital

In Skåne University Hospital, there is already a centralized 3D hub. They have printed implants and surgical guides for maxillofacial surgery, orthopedic surgery and cardiovascular surgery, as well as anatomical models. The 3D hub facility is 100% integrated into the hospital organization. The in-house production is achieved within it, meaning from scan-segmentation-design-manufacturing is all happened in-house. This centralization was initiated by the technicians who had interests. The initiators worked on evenings and weekends for printing models, prepared showcases for clinicians and applied for funding. With this centralization, other research groups do not have the need to buy their own machines which save resources. Centralized control would reasonably schedule the working efficiency of printers put into use, avoiding waiting queues in those long-term working printers while others are standing in-still.

One of the keys to having a centralized control is the information system, as the hospital has integrated a refereeing system at the early stage. All the information flowing around different departments is free and easy to access. This also assures the efficiency of the communication as a successful printing requires collaboration between different specialties not only just technicians, especially for those complex cases where different clinicians are needed with their expertise. Such referring system would also help to have more widespread adoption of AM inside hospitals. Clinicians are the driving force in the adoption of AM. Even the technicians have the engineering knowledge, and how to apply them to medical cases requires medical proficiency. 3D hub, in a way, is a showroom where clinicians are able to see what other models could look like so as to have more inspiration and discover the potential applications. This is another good thing about having a 3D hub. The need of the technical side to understand the engineering limitation is quite heavy, but between the medical and engineering knowledge, there should be a point where they meet. It is not enough to only have engineers that understand the technique. The engineers also have the need to understand the clinical questions. A close working environment and communication are important to improve and evaluate the work.

Although the hospital has a closed AM process chain, its name is still limited inside the hospital. It is a knowledge limitation in the sense that the benefits of how AM could help clinicians are still underdeveloped. The medical industry is a serious area where it is understandable for clinicians being conservative. Promoting such innovation requires all levels, above, between hospitals and also the clinicians within their own specialty. In some small specialties, In some small specialties, spreading the word and growing interested is easy since communication happens in a tight community. Having a clinical champion will speed up AM use in those areas. Another aspect is the operation and management of such a 3D hub require funding. Collecting evidence and data to prove that the 3D hub is economically saving is not hard. Part of the indirect gains lies in saving surgical time, hospitalization and the number of complications and reinfections. For healthcare providers, the improvement in care offered to the patient is not easy to qualify. For some prints like wafers for maxillofacial surgery, the cost of in-house production could be cheaper instead of buying them from another company. But the more significant gain is time-saving. In-house production allows a quicker response between the different processes as the information flow is happening inside a smaller circle. Yet, the regulation for in-house production is something prior. A quality management system, as well as the interpretation of regulations for in-house, are problems. How to and who to take responsibility for legal aspects are not accessible.

5.1.4 Region Uppsala with a Focus on Uppsala University Hospital

At Uppsala University Hospital, the maxillofacial department is one of the departments that have been using AM for a long time. Other departments such as orthopedic and neurosurgery have adopted this technology, but due to the decentralization control, there is not much communication regarding the technology use. From the management level, the decisions regarding how to implement AM and the regulatory requirements rely on the initiator, in most cases, the clinicians who have personal interests in using AM. In this sense, the clinicians have a great responsibility and devote a lot of energy and work. Such responsibility becomes a hinder to the development of more early adopters since most clinicians do not have the time to work on regulations or technology, especially technical support is a key. For heart surgeons or transplant surgeons, those untouched areas where AM has vast potential, how to expose the benefits and help those early adopters to use AM better and achieve desired results, an organized control would be of great help.

Centralized control within the hospital is one of the developing directions. The benefits of having a centralized hub will help spread out this technology to other departments as it is centrally supported. Better quality of care in terms of the relative advantage of AM will be more easily achieved since there will be support from the management level in terms of technical and production support. The business potential is needed to be proved by solid evidence from the clinicians' side about the benefits of this technology in the form of better care or quantification of saved resources. The investment for building in-house production is not cheap. The cost of printers and organizing technical support is also expensive. One good way to start is to coordinate between different initiatives. Since there are AM facilities at the university, cross-collaboration between hospitals and the university printing labs can be a strategy. By doing so, the clinical application and research fields will influence each other and jointly promote the development.

5.1.5 A Summary of Cases

Table 9 shows some commonalities and differences among studied cases. In all regions, the most popular use of AM has happened within maxillofacial and orthopedic departments, where clinical champions are located. Their work with AM has proved valuable and revealed the great potential that AM could bring into the healthcare industry. The managemental level also gained awareness of AM technology and its benefits as different levels of support and responses were given according to the interviews. However, the development level of AM technology is quite different, as Region Skåne is an advanced adopter with in-house manufactured implants while Region Östergötland with limited use of implants.

The manufacturing system in each region is also different. In Uppsala University Hospital, the production is partly in-house, partly outsourced to a certified company and partly taken over by a facility inside the university. Such a hybrid production model also can be found in Sahlgrenska University Hospital. One of the main reasons is the regulation. For medical devices with high-risk levels, in-house production would not fulfil the clinical criteria. For in-house production, the decision would be made based on business possibilities as such investment would be costly and need to be properly evaluated and revised. Also, it is a decision that needs to be made top-down since the funding would be an issue.

Although in Skåne University Hospital, the centralization has been set up for three years, the economic model for long-term funding is still a focus of the work in the 3D hub. A similar situation also happen in Sahlgrenska University Hospital, as they are working towards a centralized in-house AM facility. In Region Uppsala, the joint forces would be a start for centralized control of AM since the adoption of AM is quite scattered among different specialties. A similar situation also exists in Region Östergötland, as the involvement from the management level seems to be the most among the four regions, as the region is also evaluating the business model of building centralization.

Table 8 Summary of commonalities and differences among cases

Commonalities	Differences
Technology • Maxillofacial and orthopedic department are the main adopters • Valuable work with AM in practice • Awareness of the AM relative advantage from management level	Technology • Level of use with patient specific implants • Clinical cases of use • Level of technology development
Economic • Economic model is needed	Economic • Demand on funding
Organizational • Bottom-up approach • Demand in more clinical champions	Organizational • Manufacturing system – centralized / decentralized • Involvement from management level • Regulation qualification

5.2 Main Themes Derived from Case Studies

After following the steps described in methodology section about data analysis, table 9 below shows the themes and sub-themes detected through the interviews. Each theme consists of subthemes since similar patterns could be identified. The most popular theme is *Management,* as it has the most sub-themes. A description of each theme and sub-theme with supporting quotes is after figure 1.

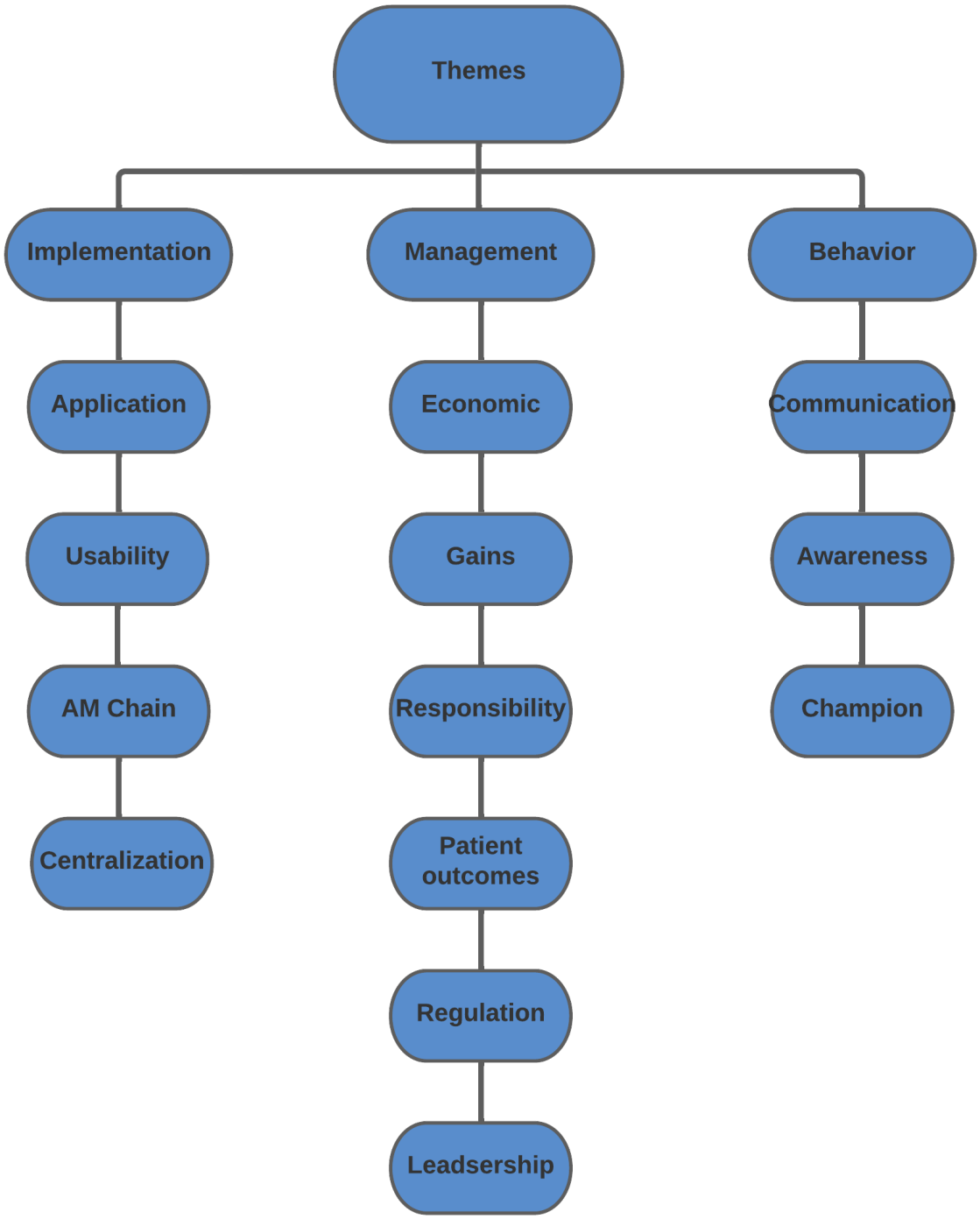

Figure 2 Themes identified from interviews

Implementation

The theme Implementation contains four sub-themes: Application, Usability, AM chain and Centralization. This theme focuses on the current situation of AM implementation in different hospitals.

The sub-theme *Application* is concerned with the practical applications of AM technology. The interviews found that the most mentioned use-cases in four regions include preoperative planning and surgical guides. See the below statements. The most talked-about clinical areas are orthopedic and maxillofacial departments. At Uppsala University Hospital and Skåne University Hospital, patient-specific implants are also common to see. Interviewers from other regions praise these two regions as the most advanced user of AM in Sweden. AM is used in neurosurgery (Uppsala University Hospital) and cardiovascular (Skåne University Hospital). Quotes from each region are attached below:

> "Surgical guides in hand surgery, patients specific anatomical models in some pediatric orthopedics" (Respondent 4 in Västra Götalandsregionen).
> "Surgical guides and viewing, not implants, in orthopedics and maxillofacial" (Respondent 7 in Region Östergötland).
> "I would say surgical guide is a common thing that we use in cancer surgery. And also combinations of patient specific implants, surgical guides and advanced micro vascular surgery for reconstructive patients" (Respondent 3 in Region Uppsala).
> "Right now we have a study ongoing with actually 3D print the implant itself, we do first for maxillofacial surgery" (Respondent 5 in Region Skåne).

The sub-theme *Usability* is about the preparation level of using AM. Individual clinicians have adopted the technology inside the hospitals for many years. See the below statements. At Sahlgrenska University Hospital and Uppsala University Hospital, some doctors started using AM as helping tools at least ten years. However, the technology is not widespread, as its use is still limited to certain clinicians and cases. The idea of a wider spreading out adaption can be interpreted from all interviews. Quotes from each region are attached below:

> "Maybe there was a few others that were also interested, but yeah it wasn't so widespread, it's been growing fast" (Respondent 4 in Västra Götalandsregionen).
> "I think here in the region it's a still quite rare. They would like to use more, but it said they are not, from very structured reasons" (Respondent 7 in Region Östergötland).
> "So I think it's still like a niche thing, it's not so common" (Respondent 3 in Region Uppsala).
> "I think for instance in neurosurgery. Um, they really know about us and use us um, and a lot of other specialties where we're not used to that at all, um, so there are much untapped potential… For the cranioplasty patients they... we have about hundred percent adoption rate basically" (Respondent 5 in Region Skåne).

One reason for the limited use of AM is that this technology will greatly help in life-changing situations. For chronic cases, this technology would not be needed, as respondent 4 from Västra Götalandsregionen said, "I mean these routine cases that they're just gonna do it the way they always do it" (respondent 4). For Region Skåne, "there is no point of making virtual surgical planning for removing an appendix or something like that, but really when the high stake

congenital heart disease where you know it is really life-changing surgeries, if you fail, or you will make it. Those are the ones you should have it (AM)" (respondent 5).

The sub-theme *AM Chain* is about who is responsible for each step in different hospitals and departments. In each hospital, there is a certain level of production that is localized in the hospital. Still, the in-house produced products are limited due to Medical Devices Regulation requirements, as table 10 shows.

At Sahlgrenska University Hospital, they can do segmentation and design of the surgical guides while the production is still outsourced. The hospital has a few printers in house, but only for anatomical models and prototypes, they are not certified to print parts used on patients in surgery. At Linköping University Hospital, the orthopedic department has been used to hire a company that is able to do segmentation, design and production. The maxillofacial department has a machine in-house to handle the production which is regulatory allowed. At Uppsala University Hospital, the maxillofacial department has advanced and standard radiology software for 3D visualization. They also have printers for anatomical models. The design is in-house for medical devices such as surgical guides and implants that need regulatory certification, but the manufacture is outsourced to a certified company. At Skåne University Hospital, the process from the scan, to segmentation, to design and manufacture all happened in-house at their 3D hub. It is the only university in this study that has the ability to produce regulatory certified medical devices, such as patient-specific implants for maxillofacial surgery.

Table 9 Regions with their manufacturing system

Västra Götalandsregionen (Sahlgrenska University Hospital)	Surgical guides for orthopedic surgery CT Scan – Segmentation - Design: in-house Manufacture: outsource
Region Östergötland (Linköping University Hospital)	Surgical guides for orthopedic: Scan: in-house, Segmentation-Design- Manufacture: outsource
Region Uppsala (Uppsala University Hospital)	Patient specific implants in Maxillofacial: CT Scan – Segmentation - Design: in-house Manufacture: outsource
Region Skåne (Skåne University Hospital)	Scan-Segmentation-Design- Manufacture: in-house

The sub-theme *Centralization* is about the use of AM is centralized at what extent from the orgnizational level or even regional level. The current state of the use of AM is still more centralized on clinicians' personal level, meaning the decision and responsibility regarding adopting AM are more reliant on the clinicians who have interests in this technology. In Region Uppsala, respondent 1 said, "some doctors have used AM for quite many years because they have a personal interest in it, but it is not a decision taken on within the hospital on an institutional level,

how we will work with AM is not centralized". Even the decision to build a central hub in Skåne University Hospital came from the bottom-up. It is purely personal interest to take the responsibility of initiation and application for funding. The respondent 5 stated, "it is not that the hospital management have said 'OK, we need to have a 3d printing center', it's not something that they have deliberately focused on". It is worth noting that all interviewers expressed that they would like to build a centralization mode at least at the hospital level, taking Mayo Clinic in U.S. and Radboud University Medical Center in Holland as examples, which have a centralized 3D point-of-care and run in a great success.

Management

The theme Management contains the most sub-themes, which are Economics, Gains, Responsibility, Patient Outcomes, Regulation, and Leadership. The focus of this theme is on aspects surrounding the implementation that the individual or the organization must take into consideration.

The sub-theme *Economics* includes different financial aspects, such as funding, investment cost, operating costs, and cost-efficacy. Almost every participant mentions these aspects. From the hospital and regional level, the business possibilities are more focused. As the current status of AM is still decentralized and being more centralized is already put on every region's agenda, the economic model seems necessary to have a wider AM adoption. After all, the investment should not be wasted. For a more centralized model, the needed resources in terms of technical support, production support or even regulatory support require an evaluation regarding the benefits of AM. At the same time, the gain is more indirect in numbers.

As respondent 6 in Region Östergötland from the regional level has said, "from a central organization point of view, our job is to coordinate the use, and see how can we support it…if it is useful to put something under central support, then we can do it, or if it is good to put the organization somewhere that can produce for the rest of healthcare, then you can do that, but in the end, if it is invested in it, and that it isn't used, and then it's a waste of investment". Funding is another popular topic that has been brought up with Region Skåne and Västra Götalandsregionen. In both regions, it seems there is no long term funding. In order to apply for more funding, raw data regarding the cost and savings needs to be collected. Similar ideas also occurred in Region Uppsala, as the respondents (2 and 3) both on the clinical and technical sides have statements as "in order to adopt this technology, you would really have to have a lot of evidence showing that this tech carries a lot better, or they can save a lot of money, I think if you can show that to shorter surgeries that you save a lot of money, then I think it will be adopted very quickly because it is obviously beneficial".

The sub-theme *Gains* includes the benefits of using 3D printing technology, like how individuals and organizations perceive the advantages. Both technicians and clinicians in different regions have pointed out that, with surgical guides, the surgeons can be more prepared. Junior doctors with the same outcome can handle complicated cases which used to require skilled and experienced doctors now. As respondent 3 from Region Uppsala said, "So you have tools that help you with the result and even though I'm experienced, there could be someone with less experience may be less skills come in and do the job". Some also brought up customization as

3D printing allows a high degree of individualization. As for respondent 6 from region Östergötland, “the individuality in using these technologies can be of a great benefit, I think all healthcare is going to be the more individualized thing, so this is one of the technologies to do that”. Another vital gain is the reduced hospital resources, which is indicated by the shortened surgical time and decreased re-infection time. All interviewees have discussed this gain and believed it would save the hospital’s costs. This gain also interacts with the sub-theme *Economics* from the management level. This gain is one economic factor that is worth investigating.

The sub-theme *Responsibility* is also frequently brought up with almost every participant. Since the adoption of AM is much a personal thing instead of a top-down decision, the person taking the initiative has to take responsibility. For clinicians who adopt AM surgical guides, it is their responsibility to ensure the design of the prints as the medical requirements cannot be fulfilled by a technician, according to some participants:

> “Personal staff has their own legitimation, their own certificate of authenticity, you know, so that's the responsibility they have” (Respondent at management level in Region Östergötland).
> “Who could be more suitable to judge the benefit than I or colleagues” (Respondent 3 in Region Uppsala).

While the segmentation and design, which requires engineering knowledge, are beyond traditional medical education, this point also interacted with *Communication* as the technical side needs to understand what the clinician wants. It is a collaboration between different specialties with different responsibilities which require effective communication. From the management level, their responsibility is to coordinate every side more effectively and cost-effectively. One of the reasons that the decision regarding adopting AM is more common to be bottom-up is that the clinicians have the responsibility and saying when it comes to patients' benefits, as expressed by this respondent:

> “Different level of management which has a legal responsibility meaning it is decentralized by law” (Respondent 6 in Region Östergötland).

However, the in-house production will lead to regulatory responsibility for more centralized management. For Skåne University Hospital, one of the hinders to the AM adoption is to fulfil regulatory requirements. As respondent 5 in Region Skåne said, “One of the hinders is involved a lot of regulatory, and also that means that someone needs to take a responsibility. And for some people, it's always easy to not take responsibility. So that is one problem I think that people are scared of taking as responsibility, or scared of actually doing all the work that needed to do this quality management system”. Similarly, in Region Östergötland, the respondent 8 from the management level is also considering this problem as they believed “legislation and regulation is something you really have to take into account from the very beginning,.. if you outsource it, you don't have to take responsibility”.

The sub-theme *Patient outcomes* are the ultimate goal for all healthcare providers. From the educational point of view, the use of AM preoperatively for better visualization and more informed pedagogue is pointed out. And with surgical guides, it allows better care to the patients, as respondent 4 from the technical side said, “you can have safer surgeries if they can practice or

prepare better or custom tools like guides to make it more secure and their success rate is higher for the service". Respondent 3 from region Uppsala also has the statement that "the better results for the patient is the driving force in AM adoption".

The sub-theme *Regulation* is the legislation aspect of implementing AM, as most of the respondents considered as an obstacle, especially for in-house production. "For anatomical models, it is not classified as medical devices, while for surgical guides and implants which have high level of risks, that will affect the demand on manufacture", as respondent 2, a technician from Region Uppsala has said. Another issue with the newly issued MDR is that, "there is a lot of room for interpretation… basically, you have the text, you do not know how to interoperate the text, the forces will not say this is how it will be applied in the sense that... it's only when you're meeting in the court, that is basically the final saying about what does this new law mean" (respondent 5 in Region Skåne). However, if the production is outsourced to a certified company, then there are fewer concerns from the legislative side, as "it's good for the patient in the end… You can protect patients from implementing techniques that aren't safe" (respondent 4 in Västra Götalandsregionen).

The sub-theme *Leadership* is about the relation of managers to their employees and to which extent they are involved in the implementation process. According to the interviews, the bottom-up approach is quite common. Initially, when this technology is still distanced in the healthcare sector, the benefits cannot be justified from the management level as they usually are not the people with expertise. From the management level, now with the use of AM on the individual level growing faster and faster, the advantages this technology could bring into the healthcare have leveled up the industry into a new dimension. To facilitate the use of AM in more clinical practices in a more efficient way, the leaders from the management level such as regional strategist comes into play, as "I work in an initiative to increase the innovation speed in the region, as such we have been looking into 3D printing or AM, so our task is to find the needs among clinicians and figure out how to best to solve them together with universities and with various industries"(Respondent 6 in Region Östergötland).

Behavior

This theme contains three sub-themes, Communication and Awareness, and Champions. This theme focuses on how individuals or departments work together and how knowledge of AM is spread out and obtained.

The sub-theme *Communication* includes collaboration between the different sides of AM, from medical to technical, from internal to external, and from user to non-users. In an AM project, close communication between the technical side and to the medical side is a key to having a good outcome, as well as technicians in Region Skåne emphasized that "proximity is important" (respondent 5 in Region Skåne), same in Västra Götalandsregionen. At Skåne University Hospital, one example would be when designing a new application with AM, the engineer should have to work closely with the practice "to see what happens and, to really understand how can we really continuously improve things" (respondent 5 in Region Skåne). At Sahlgrenska University Hospital, they

have a project ongoing with all 3D printed hand surgical guides, where the technicians are sitting in the same room with the clinicians. This easy-happened communication is key to having a successful AM project. As the orthopedic clinicians in Region Östergötland, for the outsourced 3D printed parts, the time for design and manufacturing could easily be up to six months with the high cost of money. Hence, clinicians are looking for cheaper and quicker alternatives. This is one of the reasons that Region Östergötland now is working on centralization to have a close community for the clinicians to have technical support. In contrast, at region Uppsala where the production is outsourced to a certified company for some cases, the company has service 24/7, the respondent 3 described such thing as "fantastically quick, I mean.. that's amazing".

The sub-theme *Awareness* includes aspects of how AM knowledge is collected, spread, promoted and supported. As the initiative of using AM is purely personal interest, the early adopters need to be exposed to AM knowledge through conferences, articles, and colleagues. As the adoption of AM is still at a stage in these hospitals and regions, voices from both the individual and the management levels believe that clinicians who are aware of the benefits of using AM will be the driving force for widespread adoption. Respondents from Region Skåne and Västra Götalandsregionen have clearly stated that clinicians not aware of the benefits of using AM would be a limitation for the adoption. To quote responses from region Skåne:

> "The main limitation of adaptation I would say is, that the clinicians don't know or don't see the benefits yet, so it is a knowledge problem in the sense that 'oh this can really help my clinical hard cases', so if you don't know that you still continue as usual".

In Region Östergötland, one of the ways inside hospitals to promote the AM technology is to have a showroom where all the cases and samples are exposed to clinicians to have more inspiration on the use of AM.

The sub-theme *Champion* refers to those who are key individuals that support the adoption of innovation. In a typical situation, their interests are the main driving forces for them to devote time and money to new technologies. The cases involved have champions from the clinical side and technical sides. As clinical champions were present:

> "Getting the first impressions and seeing what others can do and getting ideas and stuff, that's the first and best training, you can get, because once you get the interest in doing, you will figure out the rest" (respondent 7 in Region Östergötland).
> "It's been a few persons on clinics, they maybe hear about this from a conference, or what they read about it, and then they grow an interest, and I think it's also requiring a lot of time for it, but they don't usually have plantations, so you have to be really interested in and put in evenings or weekends to actually use it" (respondent 4 in Västra Götalandsregionen).
> "You need to find early adopters, you're sort of clinical champions. In that sense the application areas to start with is likely going to be largely affected or where you can find a clinicians that are interested and motivated to try new things" (respondent 5 in Region Skåne).

And technical champions were more focused on building a support system to better help clinicians with the use of AM, as Skåne University Hospital has a centralized 3D hub which is initiated by a technician, and Sahlgrenska University Hospital where the radiology department works "as a driving part to take researchers together to push the use of AM forward" (respondent 4 in Västra Götalandsregionen).

5.3 Barriers and Facilitators of Adopting AM

This section describes in detail how these factors found through the case studies affect the adoption of AM. These themes put forward some factors that must be considered in the implementation process. A detailed description of how these factors found through the case studies affect AM adoption is shown in this section. The themes presented factors to consider as part of the implementation process.

Table 11 depicts how these factors are perceived as either barriers or facilitators for AM adoption. Some of the barriers and facilitators may fall under many sub-themes. To keep the table simple, each barrier and facilitator is only stated once in each sub-theme, which the authors believe best suits. Furthermore, different barriers and facilitators apply in different circumstances; hence, not all will be identified for a different random situation.

Table 10 Barriers and facilitators of AM adoption

Themes	Barriers	Facilitators
Management	Economics	
	• Investment in soft-and hard-ware, material, facility, specialized stuff are costly • Lack of resources, i.e. funding, capacity • Lack of economic models	• Research funding/budget • Short surgical time • Less cost in fast responses
	Gains	
		• Better prepared surgeons • Customized product • Fast responses • Reduced hospital resources
	Responsibility	
	• Management decision on internal production responsibility • Clinician takes main responsibility regarding design and segmentation	• Easier with bottom-up initiation
	Patient outcomes	
	• Safety concerns	• Better consent • Customized treatment, better care and certainty

(continued on next page)

Table 10 (continued)

Theme	Barriers	Facilitators
Management	Regulations	
	• Increase workload for in-house manufacturing • Limited in-house application • Limited centralization	• Protection for the patient goods • Certified company have competence
	Leadership	
	• Low involvement in finical and technical support • Prioritize business possibilities	• Freedom of design • Top-down approach
Behavior	Communication	
	• Not enough cross-disciplinary interconnection • Lack of information of competencies outside the own group • No collective platform for knowledge transfer	• Demonstrating technology practically in showroom • Seminars/ Courses/Conferences /Publishing • Word-of-mouth • Proximity to technology • Supplier company promotion
	Awareness	
	• Low interest in new technologies • Few knowledges about AM's possibilities, low understanding of technology • Conservative towards changes • Skepticism • Lack of broader view	• Tentacle around the outside • Self-interest • Clinicians reach out to technicians
	Champions	
	• Clinical champions are scattered • Start from zero • Invest own effort, money and time	• Personal relations and interest • Technology enthusiastic • Pushing the field/ interest • Need clinically driven

6. Discussion

This section discusses the finding concerning the literature review and the findings' meaning, significance, and relevance to the literature review. The first subsection focuses on the first research question regarding the current manufacturing system in different regions. In contrast, the second subsection discusses the research question: What are the key factors that affect the adoption of additive manufacturing in different regions?

6.1 Decentralization versus Centralization

Comparing the cases, one of the key factors concerning a wider adoption of AM that has been brought up is centralization. Three out of four regions still have decentralized manufacturing systems regarding AM adoption in hospitals. Their attitude and opinions toward being centralized have different aspects and attentions.

As Region Östergötland is quite scattered and limited use of AM, one of the reasons is the low-efficient outsourcing with high cost. Some clinicians with an interest in AM are still slow in adopting AM. This is due to the lack of resources regarding necessary technical support. These two main problems are aligned with the literature discovery on the disadvantages of decentralization (Pettersson et al., 2020; Pourabdollahian et al., 2014). Advantages of being decentralized, apart from what is found in the literature review the investment-wise and regulation-wise (Pettersson et al., 2020; Pourabdollahian et al., 2014), being decentralized also assures that the AM technology is used in the right hand to play a full role regarding the medical benefits. Clinicians will have freedom of design, though more involvement by people with decision power would simplify the implementation process. Hence, centralization in this region is considered a possible solution, as the management level investigates the needs and demands of the clinicians. A centralized manufacturing system will avoid procurement, saving time, money and staff (Calvo-Haro et al., 2021). Other advantages include that development and technology are driven forward as medical and technological knowledge are gathered. However, the main challenge of being centralized, as the literature review has mentioned (Calvo-Haro et al., 2021), is the heavy investment regarding money, energy and resources, which would be a waste if the centralization is not well used. From the supervision perspective, the problem is also related to who will take responsibility. If products are ordered from an external company, the company usually takes responsibility for the guarantee of qualification. The responsibility for internal production is a challenge as this needs the management level of decision.

In Region Uppsala, the disadvantages of outsourcing are not solid as the procurement company has 24/7 service, and the time and cost of ordering AM prints from another company are not issues. The management level focuses on the advantages that a centralized mode could bring, which is providing a platform where knowledge is gathered to push forward the development and technology. Since in Region Uppsala, the university holds great competence and facilities regarding AM, a more feasible solution is not to build a center but may seek a close collaboration first, as the best way to implement a 3D center is to start small and expand. Centralization in this region may not be limited to a 3D center, but more refer to close coordination between clinical and technical champions with their competence and joint forces from the management level. This centralization is more likely to be a scattered Point-of-care where expertise from the hospitals,

company, and research sides join together with their specialty and with a minimum cost. The cost to start a center would involve fixed costs for hardware, software, licensing, and building, while variable costs consist of specialized labor, facilities and machine maintenance, and customizable items (Bastawrous et al., 2022). A close collaboration between different parties will possibly avoid initial costs and resources but result in good patient outcomes and innovative treatment.

In Västra Götalandsregionen, the radiology department is now working as a center of this innovation adoption in Sahlgrenska University Hospital, although the production is still outsourced to a certified company. Their aim with the use of AM is to build their Point-of-care. The current semi-Point-of-care has proved the potential return on investment, such as improved patients outcomes with more customized treatment and plan (Martelli et al., 2016; Tack et al., 2016), cost savings and avoidance of hospital resources as saving from reduced operating time (Bastawrous et al., 2022). There are numerous successful cases of how AM have elevated personalized care for the patient, but quantifying and measuring the return of investment is still challenging (Bastawrous et al., 2022; Calvo-Haro et al., 2021; Murtezani et al., 2022). Another critical factor is regulation. Risk-based framework for in-house production is a management level of consideration.

Region Skåne is a typical case of centralization, and the use of AM is the most advanced compared to other regions. The time and cost for in-house delivery and production compared with outsourcing are saved, as discussed in the literature review (Bastawrous et al., 2022; Calvo-Haro et al., 2021). This center also plays a vital role during the COVID-19 pandemic, as Perez-Mañanes et al. (2021) have discussed in their studies. To continue running this 3D center, funding is one issue, as the fixed cost of software and hardware are generally long-term proposals (Bastawrous et al., 2022). An economic model is required to quantify and measure the return on investment. Since this center is initiated from the technical side working at the hospital, technical support is not a barrier in this case. To run the 3D center in the longer term, the quality management system and regulatory consideration are significant challenges, as Bastawrous et al. (2022) and Daoud et al. (2021) discussed in their studies. The quality management system requires the entire team to adopt so to ensure the security and effectiveness of the 3D print model. The regulation is an obstacle considering further adoption of AM as it requires someone to take responsibility.

To summarize the discussion regarding the manufacturing system, the main take-aways from these cases are:

- An economic model is needed to quantify and measure the return of investment in centralization

- To achieve centralization from decentralization, close coordination among different organizations, such as manufacturing companies with regulation qualifications, university AM lab with technician specialties, and hospital with clinical expertise, could build an more time- and cost-effective AM ecosystem as a start

6.2 Main Themes Compared with Literature in Relation to CFIR

Economics, including time, costs, and investment decisions regarding in-house or outsourced which investigated through the literature review related to AM in clinical areas (Garot, C. et al.,

2021; Pettersson et al., 2020; Wixted et al., 2021; Wong et al., 2016; Unwin et al., 2016) are mentioned through the case studies as well as the sub-theme Economics under Management. In addition, the case studies also address the importance of seed funding and economic models as key factors for the adoption of AM. Economics is also tightly related to the decision regarding centralization vs decentralization as section 6.1 have detailed and discussed. In relation to boosting the AM adoption, indirect economic gains are the factors, wherein the absence of a proper economic model, such economic gain cannot be measured. This factor is also related to the *Relative advantage* and *Cost* of CFIR.

Gains together with Patient Outcomes are mainly driving forces as shown in the literature for AM in clinical use (Chae et al., 2015; Keller et al., 2021; Louvrier et al., 2017; Malik et al., 2016; Sheha et al., 2019) as well as in case studies. As patients received customized treatment with the help of AM, the treatment outcome compared to traditional ways is mostly improved both in literature (Murtezani et al., 2022) and in case studies. Gains related to saved hospital resources are also one of the most attractive factors for the AM adoption. These two together are referred to as *Relative advantage* in CIFR and are closely connected to the content of *Knowledge and belief about intervention*.

Responsibility is a factor that was not directly found in the literature related to AM clinical use, but it is an important aspect when adopting AM. As different level of decision power gives a different level of responsibility, to the wider and more centralized adoption of AM, the question of who to take the responsibility for accidents is like an inevitable wall. For healthcare providers with a great calling, the embedded responsibility will drive them on pursuing better care within the unfamiliar areas. However, not everyone is willing to take responsibility. Clinicians who are skeptical and conservative may drawback when facing unknown areas, especially in treating patients health. This is related to construct *Self-efficacy* from CFIR and was not found in the literature.

Regulations aspects found in the literature related to AM clinical use (Aimar et al., 2019; Durfee et al., 2019; Louvrier et al., 2017; Pettersson et al., 2020) were also mentioned in practice. The role of regulation is more directly affecting the manufacturing system of the AM adoption, as is discovered from the literature as well as in case studies. As mentioned in the discussion on Decentralization versus Centralization, a centralized AM adoption mode will help AM technology be further adopted. A strict regulation will hinder the adoption in terms of increasing the workload as clinicians or hospitals need to be responsible for quality control. What is not mentioned in the literature but mentioned in the case studies is a strict regulation will ultimately be for patients' good as it regulates the use of AM by avoiding using experimental AM products on patients. And certified business companies will have more competence in the high medical level of AM production, which will be easier to develop an outsourcing production chain. This factor is related to the construct *External policies and incentives* from CFIR.

The main theme Behavior is identified through case studies, although not mentioned in the literature review related to AM in clinical use, as the reviewed literature studying AM use in clinical applications was not from social science. Concluded in table 3, the most discussed challenges in AM clinical applications are regulation aspects and cost aspects, some related to the technical quality and evidence strength. The theme involves personal traits, like Awareness

(corresponding to *Knowledge and belief about intervention* from CFIR), being a champion, as well as the organizational settings, i.e. Communication (corresponding to *Networks and communications* from CFIR. The case studies found that communication between levels within the organizations regarding AM technology will highly affect the adoption of AM. Centralized control of AM will offer a platform where proximity among multi-disciplines could happen, taking region Skåne being an example of an advanced adopter in AM. Close collaboration and communication will increase the personal awareness of AM, both from the clinician and management levels. All case studies show a positive attitude toward AM technology. It is confident to say that as more people from different levels are aware of the benefits of AM, the broader adoption of AM would become. The adoption of AM in most studied regions is still scattered into different departments, and the adoption is still limited to certain types of cases. According to the case studies, the Champion is believed to play an essential role in the broader adoption of AM. Those champions are not limited to clinicians but also technicians and leaders. Still, clinicians will be the most suitable champions as they have the most ability to justify the use of AM.

Challenges regarding technical aspects, such as printer dimension is not able to capture detailed structure, complex software, and complicated ordering system that has been discovered in literature as technology barriers (Chae et al., 2015; Salmi et al., 2013; Pettersson et al., 2020; Memon et al., 2020) are not discovered through case studies. A possible explanation is the studied cases are more focused on factors affecting AM adoption from the management level, where the above-mentioned technology barriers are too specific to consider from a management level point of view.

Overall, personal and organizational motivations are not shown in most articles on AM adoption. This could be due to the research gap with low participation of social sciences in AM implementation. Furthermore, papers in the literature review presume a broad interest in AM technology and address more specific medical or technical issues. However, in the case studies, the social sciences of Management and Behavior appear to be the most significant or most prevalent concerns. There is abundant evidence showing that AM can help provide a better quality of care. Most adopters are happy with the technology and support the outcomes after becoming familiar with it and its applications. A lot of potential in AM remains at the research levels, such as in live organs or medicine, but more outstanding societal efforts are needed to bridge the adaptive divide. The table in Appendix B summarizes all aspects that can fall into barriers or facilitators connected to the main themes Management and Behavior, found in literature and case studies.

The main take-away from this section is:

- Behavior gains low attention in AM clinical application literature, although they turn out to be a major role in AM adoption in hospital from managemental point of view

- Economics, Regulation affect the adoption in terms of manufacturing system, whether to be centralized or decentralized

- Responsibility is a major factor while it is uncommon to see in the literature

7. Conclusions

This section is about the conclusion of this work, which is based on the literature review, the case studies' results, and the discussion's reasoning. The limitation and implications of this study are also present at the end.

AM technology is evolving rapidly and in a rapidly changing environment. Although AM has the potential to be a valuable tool for clinical practice and medical education, it still faces challenges, which is why there are still many untouched potential areas. Therefore, this paper aims to outline the challenges of AM adoption in hospitals via different case studies by identifying key factors to consider when attempting to push the use of AM from a managemental point of view.

A literature review was conducted to outline aspects associated with key factors that influence the AM implementation that has been considered in the literature to date. In addition, comparative multiple case studies within different regions were conducted to further understand the key factors' influence on AM adoption at the hospital level. These key factors identified were derived from the thematic analysis of case studies.

In the adoption of AM in hospitals, it is identified that there are two different manufacturing systems, a decentralized system where the hospital outsources the production of AM to the manufacturer and a centralized system where the hospital in-house produces AM prints. Different case studies reveal that to build a textbook centralized hub, a proper business model is necessary to evaluate the cost and gain in terms of economy. Although the centralization can be achieved in a bottom-up strategy, a more practical strategy is through a top-down manner, as it would considerably push the adoption. With more leadership involvement in organizing technical support and quality management, the adoption of AM will be easier and quicker. In reality, a centralized organization can be achieved by starting with cross-collaboration among different disciplines to avoid waste of investment.

The findings of the comparative studies have divided the key factors into theme Management and Behavior. Aspects falling under the theme Management has the most sub-theme, indicating that these factors play an important role in terms of AM adoption. For instance, the necessity for having an economic model to prove the business feasibility of AM adoption is proved as urgent, as positive assessment is widely received through case studies, and how to invest in the adoption of AM more seems to be a business case. Leadership involvement becomes critical and tricky since the role of Responsibility is implicit yet critical.

The theme Behavior is also important, but it is not popular in the AM literature on medical applications and manufacturing systems. Through case studies, clinical champions are the main driving force in the adoption of AM from the managemental perspective. In order to have more of those clinical champions, it is important to build efficient communication channels to spread the AM benefits and provide necessary assistance in terms of technology, regulation and manufacturing aspects at an organized control level. It is not hard to find that there are a lot of initiatives with successful use of AM in the different clinical departments in different hospitals. However, communication across departments, hospitals and regions is less common. The bottom-up decision-making mode is suitable to start innovation as it gives freedom and space for initiators.

However, for broader and quicker adoption of AM, some decisions need to be made from the top-down in order to increase the awareness rate and adoption efficiency of AM.

In conclusion, although a centralized manufacturing system seems to push for the adoption of AM in a broader context, it is a decision with small fault-tolerance from the organization level considering the investment and efforts. To better coping with the need for the expansion of AM use, a cross-discipline collaboration could be a start. A proper economic model for quantifying the gains and measuring the cost is needed for a long-term investment. Another important factor is the Responsibility that needs to be pre-assigned and considered. To have more clinical champions in adopting AM, efficient communication across departments and between levels is needed as a top-down strategy to increase AM awareness.

7.1 Limitations

Although the theme Management and Behavior have been caught up in the case studies, it is hard to say whether it can be applied as key factors to healthcare in all Swedish regions. One of the reasons is that the sampled regions are large regions in Sweden in terms of population. For those small regions with small populations, the situation regarding hospital AM adoption might be different. In addition, with the limited number of interviews, there might be other information outside that this study has not discovered. Although the interviewed participants have a saying about AM adoption in hospitals from the management level, due to different backgrounds, the different knowledge and experience regarding AM adoption in the hospital that they contributed to this thesis could lead to different focuses and results. For Region Skåne, although the interviewee has sufficient experience in managing a 3D hub, it is not confident to conclude that his contribution will cover the opinions from the regional level. A similar situation occurred in Västra Götalandsregionen, as there was no one from the regional level who participated in the interview.

Another limitation is coming from the interview guide. The CFIR model was really helpful for the development of relevant interview questions. The choices of domains was based on findings from literature review which were limited regarding the factors that affect the hospital use of AM from the managemental point of view. Therefore, domains such as Individual Characteristics and Inner Setting, which turned out to be important through thematic analysis were overlooked initially. If these constructs were developed within the semi-interview guide, the validity of the results would increase.

Since the work of the paper is qualitative, it is not possible to draw any conclusions about the significance of the different key factors. Although the topic of management attracted extensive attention in the interviews conducted, it was not possible to determine whether it was the most frequently reported AM-related topic. This study does not use quantitative measurement to determine the priority among factors.

The results given focus on AM innovation in the Swedish hospitals and are therefore limited to use in this context. Specifically, in countries outside Sweden, healthcare systems, including investment and legal issues, may differ from outcomes. AM technology is a disruptive technology, so the results may not be applicable to other technologies innovation.

7.2 Implications

As AM is a technology with enormous potential but limited adoption in practice, especially in the healthcare system in Sweden, one interesting finding through the interview is that the regional level of communication regarding AM in hospital use is very rare, except in some areas such as maxillofacial surgery. Although different initiatives are trying to push the use of AM further, the low efficient information exchange does slow down the process. A straightforward push for wider adoption of AM would be to develop an economic model that can quantify and measure those aspects that AM could improve in healthcare applications.

As for the manufacturing system, other than centralization at the regional level like Region Skåne, a hybrid model could be a cost-efficient alternative. In the hybrid model, the printing facilities owned by external parties other than hospitals are placed inside the hospitals. In France, the manufacturers' 3D printing hardware and services are now sub-contracted by healthcare providers to help fulfil their on-site production needs (Sam, 2021). A similar hybrid model could also achieve in Swedish regions. Considering Region Uppsala as an example, there are surgeons already have a manufacturer for patient-specific implants for maxillofacial surgery with excellent service, and the local university owns several printing labs. Instead of building centralization in this region, cross-collaboration could be of better benefits and less investment. Integrate the resource information of various regions across the country, unite with each other, and build an ecosystem of 3D printing at the national level, where the regional representatives sit together and exchange information to see how regions can help each other.

Although the AM adoption in the Swedish healthcare system is mainly scattered, each region has its advantages, and a lot of small-medium-sized innovative companies are doing well in AM manufacturing. A good start could be collaborating between the regions and those manufacturing companies, as different regions will have other connections among AM manufacturing. Moreover, there is no well-established regulation framework for personalized AM implant production. The government needs a strict and transparent regulatory framework to serve patients better.

Considering the social sustainability, the thesis focuses on a well-developed country – Sweden and how to promote medical progress further there. And it turned out the healthcare services were not equally distributed. As not every country and hospital have the same opportunity to obtain scientific research and establish medical infrastructure, this paper may not provide support for adopting AM from scratch. It may increase global healthcare inequality as it should contribute to a more sustainable healthcare environment.

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Appendix A: Interview Guide

1. Would you like to introduce yourself briefly?? (Name, age, occupation, organization)
Could you describe your work shortly?

2. Are you aware of 3D printing/Additive manufacturing?
a. What is your take on additive manufacturing in healthcare?

3. Is your region working with AM in healthcare?
a. What is your role in these projects/initiatives?
b. Can you exemplify some of these projects or strategies?
c. What clinical areas have started to adopt AM?

Intervention Characteristics

4. Why is AM being adopted in healthcare (if they mention a specific clinical area, you can focus on that)?(intervention source)
a. Who decided to adopt AM in healthcare?
b. How was the decision made to adopt AM? Pilot Project?(testability)

5. What do you think about the effects of using AM?(evidence strength and quality)
a. What changes are needed to adopt AM in healthcare? (adaptability)
b. How complicated is it to adopt AM in healthcare? Any hinders for adoption that you can identify? (complexity)

6. Does the adoption of AM entail costs?
How have costs of adoption impacted the decision to adopt AM? (cost)

7. What advantages does AM have in healthcare compared to traditional manufacturing? And to whom? (Relative advantage)
8. What disadvantages does AM have in healthcare compared to traditional manufacturing? And to whom?

Outer Setting

9. How are patients treated with AM? (Patient needs and resources)
a. How do patients benefit from AM in healthcare compared to the traditional technology?
b. Are patients interested about AM ?

10. What kind of technical problems does AM adoption bring? How are these problems solved?
a. Are the doctors and medical professionals trained to work with AM?
b. Can the hospitals mange to design and produce AM related devices on their own (in-house),
c. If not, how does your organization get access to 3D-printed parts? How does the supply chain look like?

11. What do you think about other regions use of AM?

Is there any meetings or communications regarding experience sharing, or opinions exchange?

12. What kind of local or state policies and regulations influence adoption of AM? How do they influence adoption? What is needed in terms of policies and regulations to facilitate adoption? (external policies)

13. Can you think of any other persons in your region or in other regions that could elucidate the aspects that we have talked about? Who?

Appendix B: Summary of barriers and facilitators from literature and case studies

Themes	Barriers	Facilitators
Management	Economics	
	• Investment in soft-and hard-ware, material, facility, specialized stuff are costly (LR;CS) • Lack of resources, i.e. funding, capacity (LR;CS) • Lack of economic models (CS)	• Research funding/budget (CS) • Short surgical time (LR;CS) • Less cost in fast responses (LR;CS)
	Gains (LR;CS)	
		• Better prepared surgeons • Customized product • Fast responses • Reduced hospital resources
	Responsibility	
	• Management decision on internal production responsibility (LR;CS) • Clinician takes main responsibility regarding design and segmentation (CS)	• Easier with bottom-up initiation (CS)
	Patient outcomes	
	• Safety concerns (CS)	• Better consent (LR;CS) • Customized treatment, better care and certainty (LR;CS)
	Regulations	
	• Increase workload for in-house manufacturing (CS) • Limited in-house application (LR;CS) • Limited centralization (LR;CS)	• Protection for the patient goods (CS) • Certified company have competence (CS)
	Leadership (CS)	
	• Low involvement in finical and technical support • Prioritize business possibilities	• Freedom of design • Top-down approach

<table>
<tr><td rowspan="6">Behavior</td><td colspan="2">Communication (LR;CS)</td></tr>
<tr><td>Not enough cross-disciplinary interconnection
Lack of information of competencies outside the own group
No collective platform for knowledge transfer</td><td>Demonstrating technology practically in showroom
Seminars/ Courses/Conferences /Publishing
Word-of-mouth
Proximity to technology
Supplier company promotion</td></tr>
<tr><td colspan="2">Awareness (LR;CS)</td></tr>
<tr><td>Low interest in new technologies
Few knowledges about AM’s possibilities, low understanding of technology
Conservative towards changes
Skepticism
Lack of broader view</td><td>Tentacle around the outside
Self-interest
Clinicians reach out to technicians</td></tr>
<tr><td colspan="2">Champions (LR;CS)</td></tr>
<tr><td>Clinical champions are scattered
Start from zero
Invest own effort, money and time</td><td>Personal relations and interest
Technology enthusiastic
Pushing the field/ interest
Need Clinically driven</td></tr>
</table>