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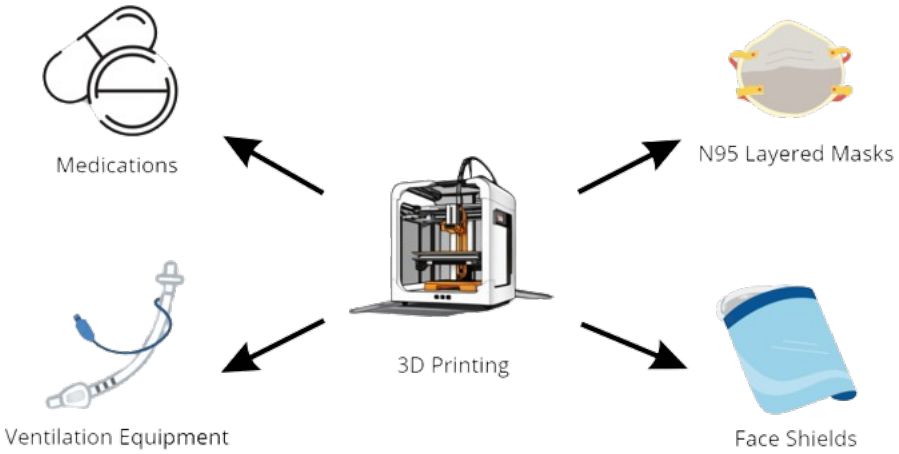

Additive Manufacturing Capabilities for Emergency Manufacturing in Healthcare

How Additive Manufacturing Capabilities Can Be Utilised to Increase Healthcare Resilience in the Event of a Crisis

Master's thesis in Quality and Operations Management

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Cover: Illustration of potential areas of application for additive manufacturing in healthcare. Source: Authors, inspired by Ishack and Lipner (2021).

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Abstract

Disruptions in global supply chains can severely impact the availability of medical equipment. Additive manufacturing (AM) presents a potential solution for the on-demand, decentralised production of critical medical parts. This master's thesis investigates the current capabilities of AM for medical equipment manufacturing and what role AM could have in improving the supply chain resilience of medical equipment during a crisis. A comprehensive literature review of AM capabilities for medical equipment and areas surrounding the implementation of AM in healthcare, along with data collection through 17 semi-structured interviews with personnel from hospital 3D units and AM companies were conducted. The results of this study suggest that AM capabilities can be used to produce certain critical medical equipment to improve healthcare resilience. Furthermore, AM was found to enable a decentralised manufacturing structure that can further be used to improve resilience toward supply disruptions. This presents an opportunity to create a national collaboration to develop, manufacture and deliver critical items at shorter lead times and increase supply chain robustness. On this basis, this study presents a recommendation to map the existing AM capabilities and production sites and establish collaborations between 3D units and AM companies to manage decentralised manufacturing at various scales effectively. Given the novelty of AM in medical equipment and the limited research that has been conducted in this field, further research is needed to better understand AM's capabilities and factors for a successful implementation.

Keywords: additive manufacturing, medical equipment, decentralised production, supply disruptions

Acknowledgements

We are thrilled to reach the end of our academic journey in the Quality and Operations Management master's program. This master's thesis has provided us with the opportunity to synthesise various perspectives, literature, and insightful discussions with knowledgeable individuals, alongside our own experiences, to develop a comprehensive improvement strategy aimed at increasing resilience in healthcare.

We would like to express our sincere gratitude to our supervisors, Martin Kurdve and Patrik Stenlund, for their unwavering support and for engaging in numerous conversations about this inherently uncertain topic. Their guidance has been invaluable in shaping the direction and quality of our work.

Finally, we would like to acknowledge all the participants who contributed to our research by sharing their insights and experiences. Their real-world perspectives have been crucial in grounding our theoretical work in practical reality.

Once again, this has been a very valuable experience. Exploring the area of healthcare and AM has provided us with a wealth of new knowledge and understanding. The lessons learned and experiences gained will undoubtedly benefit our future endeavours.

Martin Hörnell & Ludvig Lindahl, Gothenburg, June 2024

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List of Abbreviations

- AM - Additive manufacturing
- B2B - Business-to-Business
- B2C - Business-to-Consumer
- CAD - Computer-aided design
- DED - Directed energy deposition
- DFAM - Design for Additive Manufacturing
- EU - European Union
- EUAs - Emergency Use Authorisations
- FDM - Fused deposition modelling
- FFF - Fused-filament fabrication
- IM - Injection moulding
- JIT - Just-In-Time
- MDR - Medical Device Regulation
- MJF - Multi Jet Fusion
- NVA - Non-value added activities
- PBF - Powder bed fusion
- PP - Polypropylene
- PPE - Personal protective equipment
- RISE - RISE Research Institute of Sweden
- SCM - Supply Chain Management
- SLA - Stereolithography
- SLS - Selective laser sintering
- TRLs - Technology Readiness Levels
- UV - Ultraviolet
- VA - Value-added activities
- VOCs - Volatile Organic Compounds

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1

Introduction

The healthcare sector is heavily dependent on the global supply chains for medical equipment which poses a great risk in the event of a crisis or supply chain disruption. During the beginning of the COVID-19 pandemic, the whole world experienced a crisis where supply chains were completely disrupted while at the same time, the healthcare sector saw a huge surge in the need for personal protective equipment (PPE) and medical equipment (Gereffi, 2020). The blockage of the Suez Canal in March of 2021 further exposed the vulnerable supply chains when the massive cargo ship Evergreen went aground and caused a week-long blockage, affecting at least 422 ships and causing delays of several weeks. As a result of these vulnerabilities in the supply chain, there is a greater need to identify new ways of improving the resilience of healthcare supply chains (Ramos et al., 2021).

1.1 Background

Before the COVID-19 pandemic, the production of PPE and medical equipment was heavily concentrated in two countries, China and the US. China was producing half of the world's supply of surgical masks and the two countries together were responsible for over 60% of the world's PPEs (Burki, 2020). Most PPEs and medical equipment that are manufactured are made from various types of polymers. The manufacturing processes for these types of equipment can have lead times of several months and are often dependent on outsourcing some parts of the process. However, as the pandemic led many countries' manufacturing capabilities into isolation, it became necessary to find new ways of overcoming the dependencies (Cubas et al., 2023; Saleeby et al., 2020).

Additive manufacturing (AM), also known as 3D printing, has long been known to have superior design freedom, manufacturing flexibility, and to enable decentralised production facilities where needed, helping to circumvent supply chain disruptions (Ishack & Lipner, 2021; Kunovjanek & Wankmüller, 2021). Its capabilities have even showcased cost-effective production capabilities at small scales, producing complex geometries, and individualised products while minimising waste (Holzmann et al., 2020). The technology was novel in many areas of manufacturing before the pandemic with two of the main hindrances to AM implementation being performance expectancy and anxiety tied to a limited understanding of the technology (Holzmann et al., 2020). However, during the pandemic when manufacturers and supply chains were facing disruptions, AM technologies proved to be able to manufacture several types of medical equipment by anyone with the right 3D printer which enabled people and companies to produce critical components and support their local healthcare centres (Ishack & Lipner, 2021; Kunovjanek & Wankmüller, 2021).

According to Manero et al. (2020), AM can be used to increase the healthcare sector's resilience to potential supply chain disruptions by enabling manufacturing capabilities on-site that can produce the specific equipment needed. On the other hand, Saleeby et al. (2020) investigated the concept of hybrid manufacturing, where AM technology is used to improve resilience by facilitating faster re-tooling for conventional manufacturing technologies. Typical production processes for PPEs require special moulds or dies that often take between two and three months to produce from foreign suppliers but with AM, a working mould was created in under 72 hours (Saleeby et al., 2020).

Given the diverse applications of AM in production, a thorough investigation is required to explore AM capabilities, meaning the spectrum of products that can be viably manufactured using AM, and explore how these capabilities could be used to increase resilience in the healthcare sector.

1.2 Aim

The purpose of this master's thesis is to examine how additive manufacturing can be used to aid in the emergency production of medical equipment to increase healthcare resilience in Sweden in the event of a crisis. To answer the purpose of the thesis, the study sets out to answer the following three research questions:

RQ1: How are the current capabilities of AM utilised in a medical and industrial context?

After gaining an understanding of how AM is used today in Sweden from both a medical- and industrial perspective, it is necessary to examine the feasibility of producing medical equipment using AM. Thus, the second research question is:

RQ2: What elements influence the feasibility of emergency manufacturing of medical equipment using AM technology?

When the current capabilities of AM and elements influencing the feasibility of utilising AM for the production of medical equipment in a crisis are known, there is a need to investigate how AM capabilities could be coordinated to enable a fast and effective response during a crisis. Therefore, the last research question this thesis sets out to answer is:

RQ3: How can AM capabilities be coordinated to improve healthcare resilience?

1.3 Delimitations

This study is limited to common polymer-based AM technologies that can be used to produce medical equipment in Sweden. To maintain a clear focus on the capabilities of AM and its role in emergency manufacturing for healthcare, the study does not investigate the material supply chain or other associated logistics. Furthermore, legal challenges surrounding AM, such as intellectual property rights, fall outside the scope of this thesis. Additionally, the material properties of polymers and regulatory requirements for medical equipment will only be explained briefly as they are too extensive to cover in detail in this thesis.

2

Theoretical Framework

This section presents the theoretical framework encompassing literature related to the concepts and theories of this thesis. Firstly, the topic of crisis management is described to give an overview of key considerations in crisis scenarios. Secondly, Swedish healthcare and healthcare improvement initiatives are described to provide information on the current state of Swedish healthcare and how it is progressing. Thirdly, polymers and traditional manufacturing are explained to give context to polymeric processing and to compare different manufacturing methods. Fourth, the area of AM is reviewed, including topics such as AM technologies, potential applications, drawbacks, and AM for medical equipment. Fifth, the concept of technology readiness level is explained by comparing the maturity of conventional manufacturing methods with the upcoming AM technology. Sixth, regulatory requirements are discussed as they are a critical part of manufacturing to healthcare. Lastly, supply chain disruptions are discussed to understand what consequences crises can have on the supply chain.

2.1 Crisis

The emergence of the COVID-19 pandemic sent shockwaves through every corner of the globe, fundamentally, changing the way a global crisis is viewed (Atilgan, 2020). As the virus spread rapidly, nations scrambled to implement containment measures, grappling with the unprecedented challenges it posed to public health, economies, and daily life. organisations faced high levels of uncertainty and unpredictability since prediction and prevention mechanisms were generally not in place to inhibit the consequences of the pandemic, making many businesses end up in a crisis situation (Atilgan, 2020). The pandemic underscored the critical importance of effective crisis management strategies, highlighting the need for comprehensive preparedness, swift decision-making, and coordinated responses across borders (Atilgan, 2020). In broader terms, a crisis can be of many types but often possess similar characteristics. Therefore, it is crucial to adopt a holistic crisis management approach in order to best prepare for future crises.

2.1.1 Crisis Management

The concept of crisis management involves many different types of crises and presents strategies for how to best deal with them (Coombs, 2021). Hence, reviewing the literature surrounding crisis management is of importance for this thesis, to gain a deeper understanding of how it can be implemented and utilised in a more direct crisis involving the medical industry. A general description of the concept of crisis management is given by Coombs (2015) where it is defined as "a set of factors designed to combat crises and to lessen the actual damage inflicted by a crisis". This set involves four factors, namely prevention, preparation, response, and revision. Moreover, Coombs and Laufer (2018) explain that these factors are commonly associated with a three-stage model of crisis management called the pre-crisis-, crisis-, and post-crisis stages. The pre-crisis stage involves the prevention and preparation factors, the crisis stage involves the response factor, and the post-crisis stage involves the revision factor, as well as an additional factor of learning.

The pre-crisis stage is about minimising the potential damage of the crisis. Since this stage firstly includes the factor of prevention it focuses on how organisations should act to avoid a crisis. Coombs (2021) acknowledges the importance of understanding that not all crises can be prevented. Hence, the prevention factor should be about mitigating the risk of crises and making organisations resistant to a crisis. To mitigate the risk of crises, organisations should take action towards eliminating the threats of crises by learning to detect and respond to early warning signs that a crisis is imminent (Coombs, 2021). A crisis risk can be both known and unknown to an organization. Successful crisis mitigation means organisations detect and put countermeasures in place to deal with known crisis risks and decrease the probability of an unknown crisis

risk by enhancing organisational communication and detection of early warning signs. Doing this increases organisational resilience by taking action to mitigate the risks of crises as much as possible (Coombs, 2021). Secondly, the pre-crisis stage is about preparation for a crisis and is about how organizations should best prepare for a crisis when it is not possible to be prevented. A study by Griffith and Ryans Jr (1997) argues that communications functions can play a key role in the preparation of a crisis. It is explained that large multinational organisations could benefit from creating brand equity teams with the purpose of swaying the company's brand image for its customers. Such actions are explained as mitigation strategies to minimise the negative impact a brand image crisis may have on the company (Griffith & Ryans Jr, 1997).

The crisis stage is about the response factor and essentially describes how an organisation deals with the crisis stage they are faced with (Coombs & Laufer, 2018). Coombs (2021) describe that developing a crisis response strategy is crucial. How businesses address and manage such a crisis response strategy differs and depends on what type of crisis it is. However, clear crisis communication is core in every crisis response in order to send messages to the target audience regarding the organization's way of dealing with the crisis (Coombs, 2021). Doing this allows businesses to keep a good reputation and relations with stakeholders. This is commonly done through Instructing Information and Adjusting Information (Coombs, 2021). Instructing Information refers to providing stakeholders with information about the crisis, what it means for them, and how they should protect themselves from it. Stakeholder safety should be addressed by prioritising people first, e.g. by providing information on how to evacuate areas, find shelter, find assistance, or return defective/harmful products (Coombs, 2021). Adjusting Information firstly involves communicating important information to stakeholders about the nature of the crisis and what led to the crisis situation so they understand what happened. Secondly, adjusting information also involves communicating to stakeholders what action the organisation is taking to deal with the crisis situation, also called corrective action (Coombs, 2021). Doing this can relieve the stakeholders of stress and uncertainty by assuring them that the organisation is actively working to manage the crisis by prioritising their stakeholders' well-being first.

The post-crisis encompasses the revision factor and is about what a post-crisis organisation must do to not end up in a similar situation in the future. Hence, undertaking post-crisis actions is crucial. Coombs (2021) explains that such actions should be taken for three reasons, they make the organisation better prepared for the next crisis, make sure relevant stakeholders have a positive view of the organisation's crisis management efforts, and routinely check to make sure the crisis is fully over. Coombs and Laufer (2018) explain that learning is an important factor of post-crisis management and acknowledge that there is little literature that has specifically researched post-crisis action in organisations. Moreover, Coombs and Laufer (2018) highlights a study by Baird et al. (2009) who propose that post-crisis reviews can lead to increased organisational learning. However, it is further explained that the acceptance of post-crisis reviews may not be uniform among all types of organisations, and cultural factors play a significant role in determining the degree of acceptance, hence also impacting how much the organisation is actually capable of learning from the crisis (Baird et al., 2009). Figure 2.1 summarises the stages of crisis management.

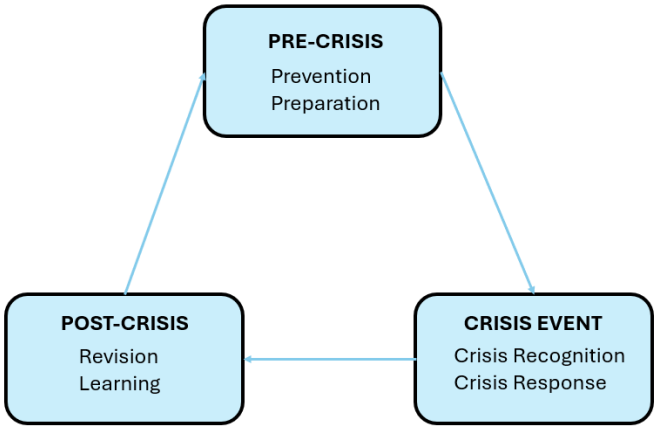

Figure 2.1: *The stages in crisis management.* Source: Authors, inspired by Salma (2019).

2.2 Healthcare in Sweden

In Sweden, the healthcare system operates under a shared responsibility between the state, regions, and municipalities (SKR, 2023). At the national level, the Swedish healthcare system is governed by the collaboration of the government, the parliament (Riksdagen in Swedish), and various authorities. This collaboration focuses on establishing the legal framework to ensure an effective and equal healthcare system for the entire population (SKR, 2023). The parliament and the government are responsible for setting the overall direction and creating the right conditions for the healthcare system. The parliament is mainly responsible for the legislation and legal frameworks whilst the government works on tasks such as strategic planning, budget allocation and assigning tasks to national authorities (SKR, 2023).

National authorities, including the National Board of Health and Welfare (Socialstyrelsen in Swedish), The Public Health Agency of Sweden (Folkhälsomyndigheten in Swedish) and The Health and Social Care Inspectorate (Inspektionen för vård och omsorg in Swedish) are responsible for various parts of the healthcare in Sweden, including tasks such as drafting provisions, knowledge support and performing evaluations (SKR, 2023; Socialstyrelsen, 2023).

The healthcare in Sweden is geographically divided into six regions, each having at least one regional hospital, see Figure 2.2. This regional structure works by having close collaborations between municipalities to ensure a comprehensive healthcare (SKR, 2023). Furthermore, the responsibilities between regions and municipalities are outlined and regulated by Swedish law, specifically, the Health and Medical Services Act (2017:30) commonly referred to as HSL (Socialstyrelsen, 2020c).

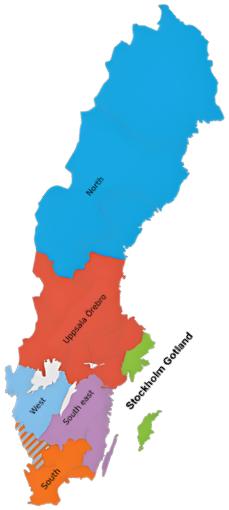

Figure 2.2: Visualisation of the six healthcare regions in Sweden. Source: Authors, inspired by NSPH (2020).

2.2.1 Improvement Strategies in Swedish Healthcare

There are many laws that dictate how the healthcare system should be run (Socialstyrelsen, 2020b). The Patient Safety Law (PSL, 2010:659) is one of the central laws in Swedish healthcare and aims to create a more systematic approach and to promote overall patient safety.

Socialstyrelsen, with the help of other national authorities, has put together a national action plan for patient safety. This plan provides a framework for regions and municipalities to refine their own action plans, aligning with principles, priorities and goals for advancing patient safety efforts (Socialstyrelsen, 2018, 2020a). Socialstyrelsen also works with knowledge management to ensure the different healthcare authorities have access to the same information and can share their experiences to improve the overall healthcare system (Socialstyrelsen, 2018).

However, the Swedish healthcare sector has long been under pressure to increase the efficiency of the care process and reduce costs which resulted in several organisational changes and top-down decisions (Eriksson et al., 2016). Improvement approaches in healthcare are often hindered by an understanding between managers and healthcare workers due to their different logics, namely managerialism and professionalism. This refers to how managers focus on performance metrics, and top-down decision-making as value whereas professionalism emphasises patient care and clinical excellence (Colldén et al., 2017). More recent attempts to improve healthcare have been to implement organisational development concepts, where the most prominent concept is Lean Methodology (Eriksson et al., 2016).

2.2.2 Lean Methodology

Lean is often depicted as a methodology, a technique, or a strategic approach aimed at streamlining operations and enhancing daily workflows. It is often simplified as a conceptual framework as a key driver of success or a catalyst for transformative change management (Gadolin, 2019). While many proponents assert that Lean should be seen as a long-term process linked to ongoing improvements across various domains, others advocate for a more targeted approach, focusing on swift and intensive interventions to address specific acute challenges (Gadolin, 2019). The Lean methodology aims to achieve high quality through continuous improvements of production processes instead of relying on mass inspection. To achieve this, identifying and eliminating different types of waste in the process is crucial (Miller et al., 2005). This is done by distinguishing value-added activities (VA) and non-value added activities (NVA). The sources of waste originating from NVAs are what the Lean methodology opts to eliminate. These types of waste are commonly referred to as Lean muda

and consist of defects, overproduction, waiting, non-utilised potential, transport, inventory, motion, and overprocessing (Sundar et al., 2014). Moreover, Gadolin (2019) emphasises the importance of establishing a Lean culture centred around continuous improvements to achieve a successful implementation of Lean. Training and education is often necessary to anchor the Lean culture in organisations previously unfamiliar with it (Gadolin, 2019).

History

The Lean methodology originates from the Japanese car manufacturing company Toyota in the 1950s (Dekier, 2012). In 2001, The Toyota Way, a book detailing the lean culture, was published (J. Liker & Hoseus, 2008). This publication marked the first time that the principles of lean culture were documented and made accessible to managers outside of Japan. Consequently, many businesses attempted to implement lean thinking as described in The Toyota Way, with varying degrees of success. While they achieved short-term success, they struggled to sustain continuous performance excellence (J. K. Liker & Convis, 2011). Multiple attempts at using lean as a quick fix for business problems failed, revealing that successful, long-term lean initiatives require leadership commitment and a culture of continuous improvement. This realization advanced the understanding of the lean concept (J. K. Liker & Convis, 2011).

Lean Methodology in Healthcare

A recurring theme in Western countries is that healthcare is facing budget issues of different kinds. This combined with an ever older population means increased consumption of healthcare services which drives costs even further and puts a heavy strain on healthcare systems (Trägårdh & Lindberg, 2004). Hence, healthcare centres have adapted strategies to mitigate these issues to ensure meeting patient needs despite the challenges facing the sector. One common way to implement such a strategy is to utilise Lean methodologies in healthcare, also referred to as Lean Healthcare (Machado & Leitner, 2010). Gadolin (2019) explain that in a healthcare setting, education of lean principles and mindset to switch to a culture of continuous improvements starts with managers. After that, the education is proceeded with professional employees, physicians, and other employees. The education is often complemented with Lean simulations or Lean games held by Lean coaches and consultants, to further solidify the mindset of continuous improvements in the culture (Gadolin, 2019).

Kovacevic et al. (2016) explains that a lean tool that is commonly implemented in healthcare is the 5S methodology. 5S is used to organise workspace and is explained to commonly be implemented early in a Lean transformation phase in healthcare combined with the establishment of rules and standards ensuring proper maintaining of achieved progress and results (Kovacevic et al., 2016). The name 5S is an abbreviation for the five Japanese words seri-seiton-seiso-seiketsu-shitsu which means organise-orderliness-cleanliness-standardise-discipline. To keep the 5S abbreviation intact in English, it can also be called sort-straighten-scrub-standardise and sustain (Machado & Leitner, 2010). In greater detail, the first S called sort, is about having a well-sorted workspace, meaning unneeded items or tools in the workspace should be removed to achieve a more efficient work area. The second S called straighten means that the remaining items in the workspace should be well-organised. This includes having pre-specified slots where certain items should be kept and storing frequently used items closer to the work area (Machado & Leitner, 2010). The third S, scrub, is about putting great emphasis on achieving and maintaining a clean workspace, which can increase comfort for the workers and in turn increase the quality and efficiency of work. The fourth and fifth S, called standardise and sustain, respectively, are closely related and essentially tell how achievements made in earlier steps should be kept long-term. Maintaining and creating a habit of the new way of working is of high importance and crucial to achieving this is frequent communication throughout the organisation, instructing and educating new staff, and management taking responsibility and leading by example (Machado & Leitner, 2010). Lastly, Kovacevic et al. (2016) explains that in healthcare, an additional S called safety should be implemented throughout the whole 5S process. Ensuring patient and staff safety should be the number one priority in healthcare and one could argue results achieved from the 5S process without taking safety into account would be seen as useless and violate basic healthcare principles.

Additionally, the Just-In-Time (JIT) principle is often utilised in the straightening phase, referring to the

delivery of supplies just before they run out or the provision of services as needed. The primary reason to utilise JIT is because of its ability to eliminate buffers in between stages (Machado & Leitner, 2010). By using it, you may make sure that in an emergency, medical care is available right away. It is also an effective remedy for the structural shortage of storage space. In terms of supply, this often means larger bulk deliveries once a week, which quickly can fill up storage spaces. If this becomes too large of an issue, daily deliveries might be preferred. However, as less stock is supplied, the likelihood of a supply failure rises. The provision of optimal supplies can be exceedingly challenging, especially of the unpredictable nature of healthcare demand (Machado & Leitner, 2010).

Change Management in Lean Healthcare

Implementing Lean methodologies in healthcare often necessitates the implementation of various changes across processes and structures in an organisation. Therefore, establishing frameworks that guide the management of change initiatives is crucial (Van Rossum et al., 2016). Such activities are categorised under the structured approach known as Change Management. Change Management can be seen as a systematic strategy for navigating organisational transitions encompassing goals, processes, and technologies (Al-Haddad & Kotnour, 2015). This approach can be divided into five key phases: assessing the need for change, creating a plan for change, communicating the change, implementing the change, and evaluating the change results (Al-Haddad & Kotnour, 2015).

While change initiatives often bring positive results in the long run, it is not uncommon that obstacles hindering the change process may appear along the way. One often-seen obstacle is the phenomenon known as resistance to change. According to Schein et al. (1995), resistance to change tends to come from employees in the form of Learning Anxiety or Survival Anxiety. Learning Anxiety stems from the apprehension associated with acquiring new skills and the potential for failure. Survival Anxiety, on the other hand, is a broader concern encompassing the perceived threat to organisational or individual well-being posed by the change. This could involve anxieties about job security or the organisation's future viability (Schein et al., 1995).

Regarding Lean initiatives in healthcare, the change process can often be successful. For example, D'Andreamatteo et al. (2015) found that change initiatives in implementing lean in a healthcare setting had positive impacts on productivity and efficiency. Mazzocato et al. (2010) concluded that improvements in time and service efficiency, cost reductions, and process quality were achieved from the initiative. However, Van Rossum et al. (2016) highlights important metrics that can stifle change initiatives in healthcare. Healthcare is often of hieratical structure which inhibits the bottom-up leadership advocated for by the Lean methodology. The hieratical structure often leads to healthcare practitioners working in silos, inhibiting crucial work flexibility needed in a transformation process. Moreover, working in silos has become prominent in healthcare since healthcare practitioners often have their own way of working that they tend to stick to, thus making them unwilling to open up to work flexibility, inherently making them resistant to organisational change (Van Rossum et al., 2016).

2.3 Traditional Manufacturing

The manufacturing industry is always seeking ways to improve the efficiency of production whether it's through lowering cost, energy consumption or their overall capability (Pereira et al., 2019). In contrast to additive manufacturing, traditional manufacturing often involves a different set of techniques, such as subtractive processes, formative techniques and joining processes. Subtractive processes, such as machining and drilling, involve the removal of material to achieve the desired final form, whereas formative techniques involve casting and moulding, shaping the material without removing it. lastly, joining processes, including welding and fastening, connect separate pieces of material to create a single component (Conner et al., 2014).

The design of any manufacturing system must consider three critical attributes: production volume, customisation needs, and product complexity. These factors, as illustrated in Figure 2.3, play a crucial role in determining the most appropriate manufacturing approach (Conner et al., 2014). Volume refers to the

production volume of parts within a certain timeframe. customisation focuses on the uniqueness and individualistic variability of a part. Complexity is an aspect that focuses on the number of parts, the geometric complexity and the location of the features (Conner et al., 2014; Pereira et al., 2019).

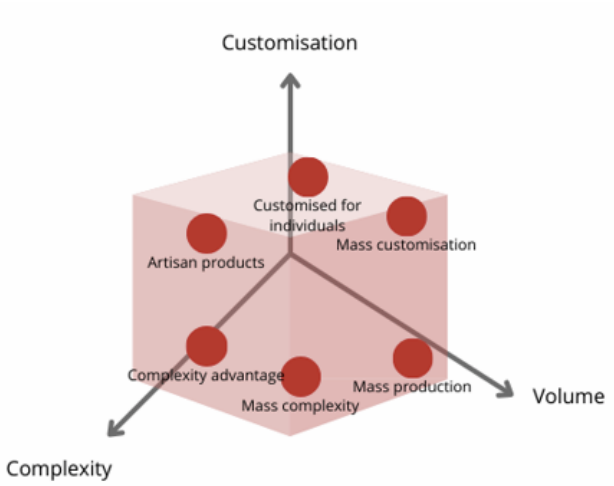

Figure 2.3: Illustration of the key attributes of a manufacturing system. Source: Authors, inspired by Conner et al. (2014).

Traditional manufacturing is mainly focused on mass production which often involves a large initial investment in machinery and toolings that is amortised over the quantity of parts produced. However, due to the significant capital investment that is required for toolings and fixtures as well as long lead times before production can take place, they are not suitable outside of the high-volume region (Conner et al., 2014). Pereira et al. (2019) explains that for high-volume manufacturing, traditional manufacturing is better suited whereas products that are complex or require customisation are better suited for AM. The flexibility of AM allows it to manufacture a wide range of products without the need for special tooling which makes it suitable for products that require customisation or complexity. Additive manufacturing offers a unique advantage in creating moulds for traditional manufacturing methods, particularly for applications requiring mass customisation such as Invisalign® braces (Conner et al., 2014; Pereira et al., 2019).

The selection of a manufacturing process requires a thorough evaluation. Apart from the above-mentioned key attributes of manufacturing, factors such as cost, environmental impact, quality management and timeframe must all be taken into consideration (Pereira et al., 2019).

2.4 Polymers

The Greek terms mono, poly, and mer respectively signify "single," "many," and "parts". Polymer translates to "many parts" and refers to large molecules formed through polymerisation, a process where multiple monomer units link together to create a larger polymer structure (Gowariker et al., 1986).

Polymers can be categorised based on various criteria, including their source, molecular forces, and thermal behaviour. Among these classifications, natural and synthetic polymers stand out due to their origins. Natural polymers are sourced from natural materials, including cotton, silk, and rubber, while synthetic polymers are artificially produced, often sourced from petroleum oil, coal, natural gas, and cellulose (Berry et al., 2023; Gowariker et al., 1986).

Synthetic polymers can further be classified into two main categories in terms of thermal behaviour, namely thermoplastics and thermosets (Berry et al., 2023). Thermoplastics are a type of polymer that is softened when subjected to heat, allowing them to be moulded or shaped and then solidified upon cooling, a process

that can be repeated multiple times (Vlachopoulos & Strutt, 2003). Thermosets on the other hand are hardened into an infusible mass from the effects of heat and pressure, making them unable to be reshaped once hardened (Berry et al., 2023).

Although synthetic polymers can achieve great material properties due to their high stability and resistance to degradation, achieved by incorporating stabilisers and antioxidants, the stability presents an environmental challenge and medical challenge (Höfer & Selig, 2012). Driven by these challenges, there has been significant progress in developing biodegradable polymers. These materials can not only be degraded in the environment but also pose minimal toxicity to human health (Chandra & Rustgi, 1998; Okolie et al., 2023). According to Chandra and Rustgi (1998), biodegradable polymers have been developing the fastest in the medical industry where a crucial aspect of polymers is biocompatibility. Biomaterials, which mostly consist of synthetic polymers, must be biocompatible to interact with biological systems. However, depending on the medical application, there can be a need for both degradable polymers and nondegradable polymers (Höfer & Selig, 2012). In medical applications where the material is used temporarily and does not require long-term mechanical stability, such as certain sutures, degradable biomaterials offer advantages by being able to be removed through degradation. On the other hand, applications such as implants that are supposed to provide mechanical stability over the long term require non-degradable biomaterials (Chandra & Rustgi, 1998; Höfer & Selig, 2012).

2.5 Polymer Processing

Polymer processing covers the entire process of transforming polymers into a new product. According to Tadmor and Gogos (2013), polymer processing covers all the engineering activities involving polymers to increase their utility, including compounding polymers to alter their material property.

2.5.1 History

Polymer processing of synthetic materials has been around since the 1800s when rubber technology emerged and polymer processing has since evolved through the inventions of new synthetic materials. One of the major breakthroughs in synthetic polymers was the invention of Bakelite by Leo Hendrik Baekeland in 1907 which had significantly better properties over previous plastics and quickly replaced materials in electrical applications and home appliances (Britannica, 2023).

Vlachopoulos and Strutt (2003), describes the screw extruder, consisting of one or two Archimedean screws inside a barrel, as "the workhorse of the plastic industry". Archimedean screws were originally used as a pump but in the 1870s when they were introduced to the plastic and rubber industries, they were used for compounding materials. In the 1920's the screw extruders started to become more specialised, focusing on mixing various rubbers and compounds (White & Min, 1989). This trend continued during World War II when the plastic industry saw rapid growth, resulting in further specialised screw extruders with special mixing sections and screw flights to control the melting quality and increase stability (Vlachopoulos & Strutt, 2003; White & Min, 1989).

One of the most important polymer processing techniques is injection moulding (IM). Injection moulding is a technique that uses a mould which allows it to mass-produce objects with a certain shape, and handle a variety of materials such as thermoplastics, thermosetting plastics and rubber (Whelan & Whelan, 1982). The process was first patented in 1872 by John Wesley Hyatt and Isaiah Hyatt who were motivated by an advertisement offering a $10,000 reward for a substitute for ivory billiard balls due to the unsustainability of ivory (Olatunji, 2024).

2.5.2 Polymer Processing Techniques

Most polymer processing techniques rely on the utilisation of a screw extruder. The screw extruder consists of three different zones, namely the solids conveying zone, plasticisation zone and metering zone, see Figure 2.4. The solids conveying zone begins by loading a hopper with thermoplastic pellets, granulates or powder

that feeds the screw extruder. The propelling action of the screw compacts the material into a solid bed of material (Colwell & Nickolls, 1959; Vlachopoulos & Strutt, 2003).

Plasticisation or melting zone is where barrel heaters are used to elevate the temperature and begin to melt the solid bed of material. The melting begins at the barrel surface where the melt film is subject to significant shear stress due to the viscosity of the polymer, which generates enough heat to melt the material as a result of viscous dissipation (Lafleur & Vergnes, 2014; Vlachopoulos & Strutt, 2003).

The final zone of the screw extruder is the metering zone where the flow of molten polymer is stabilised before being ejected (Vlachopoulos & Strutt, 2003). The specific die design varies depending on the intended final product shape and the specific polymer processing technique employed (Lafleur & Vergnes, 2014; Vlachopoulos & Strutt, 2003).

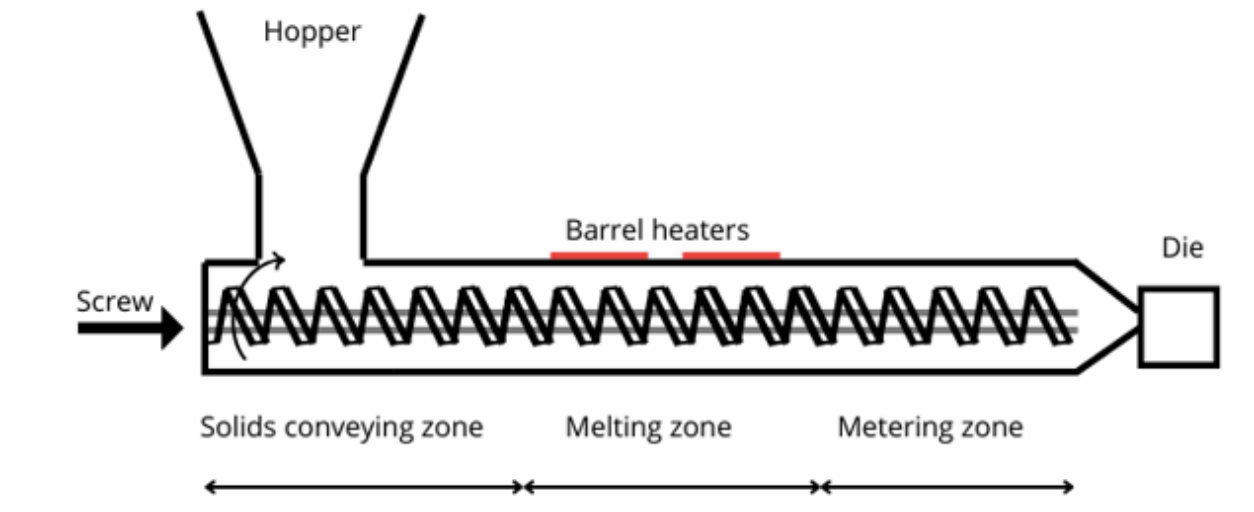

Figure 2.4: Illustration of the single-screw extruder process. Source: Authors.

Injection Moulding

Injection moulding is a process where a molten polymer is injected into moulds, and the process can be divided into two main phases. The first phase is the melting phase, which uses a screw extruder to transform the polymer from a solid into a liquid as it is propelled forward through the above-mentioned screw extruder process (Vlachopoulos & Strutt, 2003). The second phase is the filling phase, where the molten polymer is injected into a mould by ramming the screw forward (Vlachopoulos & Strutt, 2003). The filling phase is often followed by a packing stage to offset shrinkage that occurs as the part is cooled, and once the part has been cooled, it is ejected, and the process is repeated (W. Yang & Zhiwei, 2009).

As seen in Figure 2.5 and Figure 2.6, The molten polymer is injected into the mould through a spruce that connects runners and gates to the cavities of the mould where parts are created. These moulds can contain over a hundred cavities which are filled each cycle, and with cycle times ranging from seconds to minutes, IM becomes capable of mass-producing parts (Vlachopoulos & Strutt, 2003).

However, the IM process is a highly complex process that requires deep material knowledge to understand how the material will behave and to create optimal conditions, both in material selection and in the mould design (W. Yang & Zhiwei, 2009). The melting of the polymer is not only affected by the temperature of the barrel but also through shear friction depending on the viscosity of the material (Vlachopoulos & Strutt, 2003). Furthermore, the runners and gate system must be carefully designed with the right cross-sectional areas, length, and shapes to control the speed and flow rate of the polymer as it affects the finished quality and properties of the produced part (W. Yang & Zhiwei, 2009). Another critical aspect is the cooling system during solidification which consumes roughly 80% of the cycle time (W. Yang & Zhiwei, 2009). Solidification

of the part is performed by cooling channels that are distributed throughout the mould to achieve as uniform cooling of the part as possible. Agazzi et al. (2013) explain that inappropriate cooling can lead to defects, including warpage, sink marks, shrinkage and thermal residual stresses that affect the overall quality of the produced part.

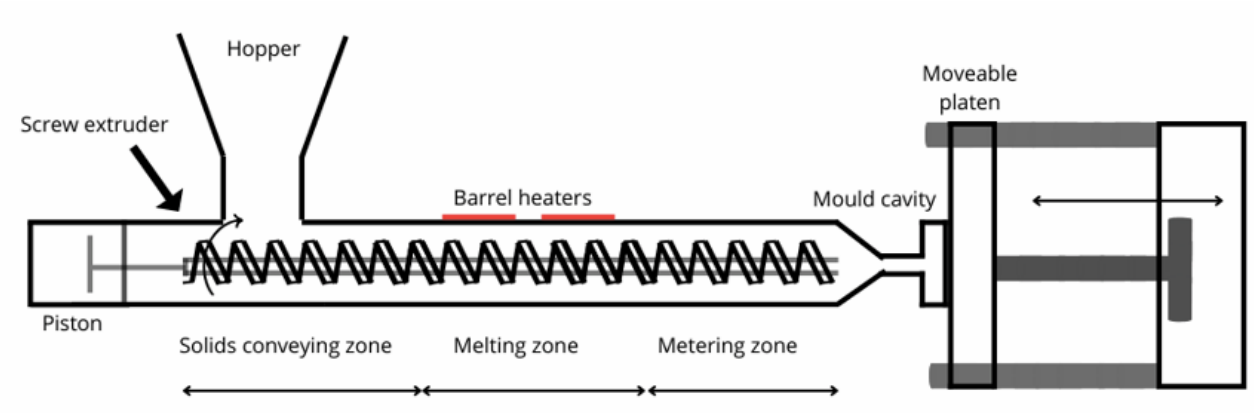

Figure 2.5: A general overview of the injection moulding process. Source: Authors, inspired by Svečko et al. (2013).

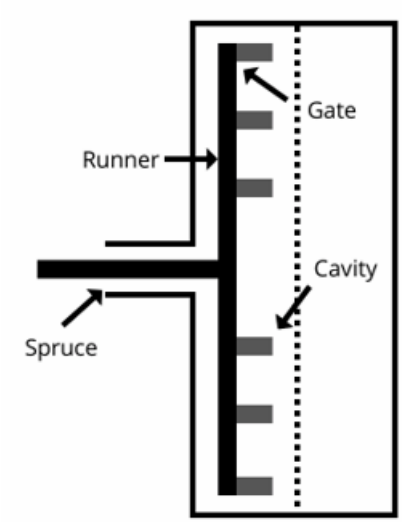

Figure 2.6: Illustration of the mould for injection moulding process. Source: Author, inspired by Vlachopoulos and Strutt (2003).

2.6 Additive Manufacturing

Additive manufacturing, also known as 3D printing, is often described as a manufacturing technique that utilises the blending of materials via fusion, binding or solidifying of materials such as liquid, resin or powders using a layer-by-layer methodology (Abdulhameed et al., 2019), see Figure 2.7. The AM process from idea to finished product usually goes through three steps, design, build, and post-processing (Gibson et al., 2021b). The design step involves approving product specifications, computer-aided design (CAD) modelling of the product, and transferring the finished file to the AM printer. The build step is about setting up the printer and choosing printing specifications, building the product, and removing the product. Lastly, the post-processing step refers to any additional operations on the product post-printing. This can be e.g. removing support structures, heat treatment, coating, etc. (Abdulhameed et al., 2019).

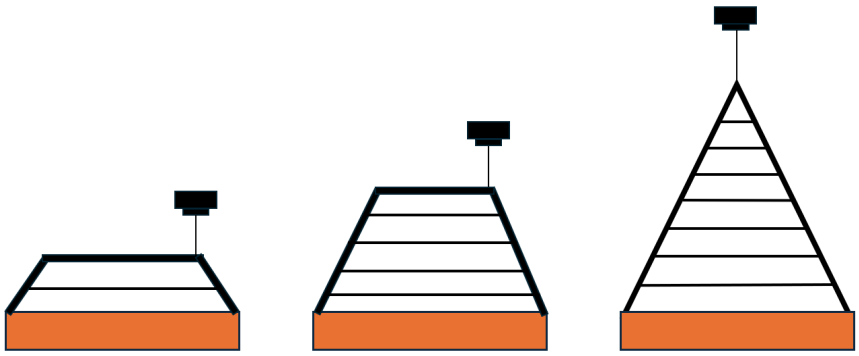

Figure 2.7: Illustration of the layer-by-layer AM methodology. Source: Authors, inspired by Thakur et al. (2023).

The layer-by-layer production is inherent in all types of AM techniques and this unique production style offers several benefits over other manufacturing techniques (Gibson et al., 2021b). Producing models in a layer-by-layer fashion offers great design freedom, meaning a high degree of build complexity can be achieved as well as frequent design changes according to updated needs or desires. Because of this, AM is best used when low production volumes and high product distinctiveness are sought (Abdulhameed et al., 2019). This makes AM highly useful for prototyping in the manufacturing industry. Apart from prototyping, recent developments in AM techniques have allowed for the technology to be ever more applicable for end-use products. This requires the printed parts to be of high material quality for the technology to be applicable in multiple industries (Palanisamy et al., 2022). Additionally, AM also allows for the production of spare parts or outdated legacy parts which can aid in maintaining older machines operational (Rouf et al., 2022). The application of AM is being investigated in a wide variety of other industries such as construction, fashion, robotics, military, and aerospace (Palanisamy et al., 2022). Apart from the above-mentioned industries, AM has also gained significant importance in healthcare. The high degree of customisation options offered by AM has great use potential in the medical industry where customisation is crucial in patient-specific implants, prosthetics, etc (Manmadhachary et al., 2019).

History

S. Singh et al. (2022) explains that AM originates from the unification of the two solid modelling techniques photosculpturing and topography. Photosculpturing and topography evolved separately in the nineteenth and twentieth centuries due to their different purposes and the availability of tools materials and scientific understanding. Photosculpturing is more about trying to make accurate replications of e.g. objects, people, or animals whereas topography is about the creation of maps through accurate depictions of contour data (Horvath, 2014). Ultimately, the two solid modelling techniques were unified in the mid-1930s which laid the groundwork for modern additive manufacturing.

Later in the 1980s a new application and methodology of AM called rapid prototyping was developed to help engineers realise and visualise their ideas through the creation of printed parts, not just models. This was the first time AM was used with the help of computer-aided design (Wong & Hernandez, 2012). The technology created many benefits for the advancement of product development through cost and time reductions and reduced human interaction, which in turn affected the entire product development cycle (Ashley, 1991). At this time rapid prototyping had not yet been adopted by the manufacturing sector. Still, instead more private use of the technology was utilised by scientists, doctors, students, researchers, and artists to ease their work by easily being able to prototype and test new products, procedures, and ideas (Ashley, 1991).

Later on in the 1990s and early 2000s AM technologies became more commonplace in several industries. New types of AM techniques are developed which increases the complexity of what can be produced (González, 2019). It is in this time period that breakthroughs with AM in the medical industry take place. Multiple

medical-related stuff is produced such as the first organ printing, functional 3D kidneys, and various types of prosthetics (González, 2019).

2.6.1 Resin-based Additive Manufacturing

Epoxy resin is a thermosetting polymer with high-performance characteristics used in a range of applications such as coatings, electronic materials, adhesives, and additive manufacturing (Jin et al., 2015). Epoxy resin is used in these types of applications because of its high-performing mechanical properties, electrical insulation properties, and corrosion resistance, where its mechanical strength properties make it suitable in layer-by-layer additive manufacturing (Peerzada et al., 2020).

Stereolitography

The stereolithography (SLA) technique is based on the curation properties of epoxy resin to build 3D objects in a layer-by-layer fashion through a photopolymerisation reaction triggered by ultraviolet (UV) radiation (Huang et al., 2020).

This process is computer-spatially-controlled and depending on the 3D printer configurations, it can take both a bottom-up or top-down, layer-by-layer approach, where bottom-up and top-down refers to whether the UV laser is mounted in the bottom or at the top of the printer (Robles Martinez et al., 2018). SLA is capable of producing parts with extremely high precision and having smooth surface finishes. For medical purposes, SLA is favourable because it is capable of using biocompatible materials. Furthermore, due to the characteristics of the photosensitive epoxy resin used in the SLA printing process, it is possible to achieve high scanning speed, low processing time, and high strength of the print (Oliaei & Nasseri, 2020). Figure 2.8 shows an illustration of the SLA working process.

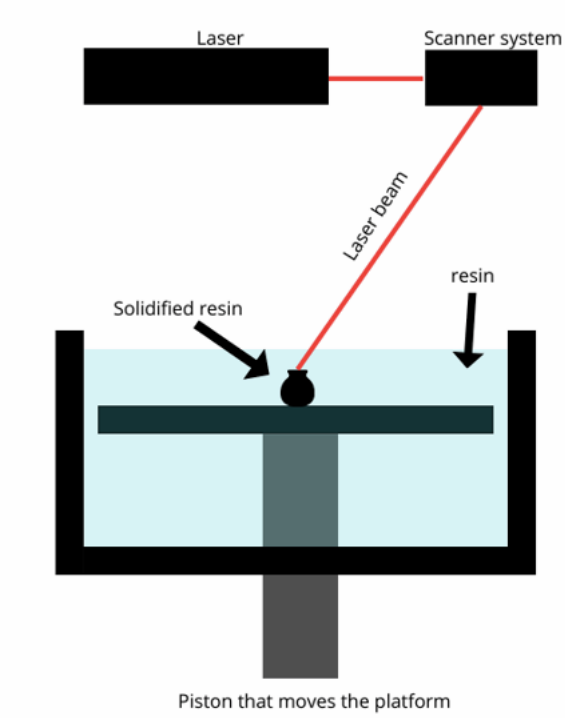

Figure 2.8: Illustration of the SLA process. Source: Authors, inspired by Zhou et al. (2019).

2.6.2 Powder-based Additive Manufacturing

Powder-based additive manufacturing uses powdered material to create objects by binding the material using heat to melt the material or by having a binding agent to the powder. The two prominent AM techniques that use powder are powder bed fusion (PBF) and directed energy deposition (DED). PBF operates by spreading a thin layer of powder on a heated bed and selectively sintering it with a laser. DED is a process that deposits a stream of powder that is melted using a laser beam (Taheri et al., 2017).

Selective Laser Sintering

Selective laser sintering (SLS) is an additive manufacturing technique that employs a layer-by-layer approach to construct three-dimensional objects as shown in Figure 2.9. In this process, a high-powered laser selectively fuses powdered material particles, binding them together to form a solid structure (Han et al., 2022).

The SLS process begins with a recoating roller that deposits a thin layer of powdered material onto the build platform. Subsequently, a high-powered laser selectively sinters the powder particles according to a predefined 3D model of each layer. Upon completion of a single layer, the build platform descends, enabling the roller to deposit another layer. This cycle iterates until the entire part is constructed (Han et al., 2022).

SLS offers a wide range of materials with properties like biocompatibility, high robustness, and chemical resistance (Kafle et al., 2021; Tan et al., 2005), and it also has advantages in creating multiple parts through nesting. Nesting is a technique where multiple parts are strategically positioned within the build volume which allows for superior print speeds compared to other methods (Chergui et al., 2018). Furthermore, SLS is also capable of printing parts without the need for support structures as the surrounding powder bed works as support (Han et al., 2022).

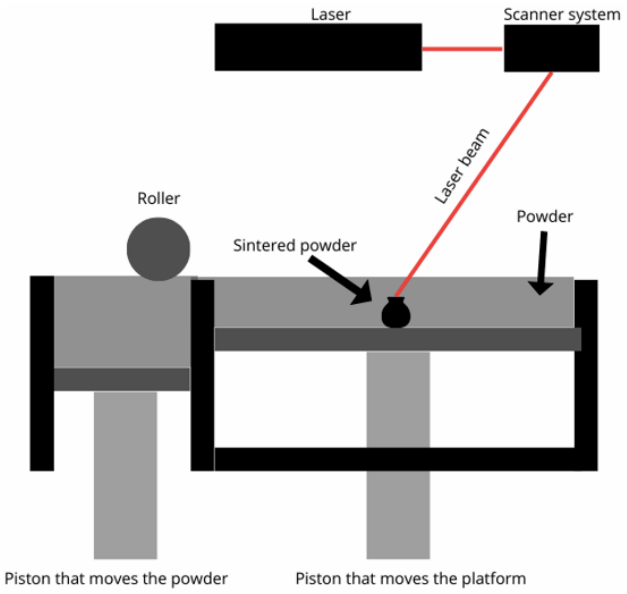

Figure 2.9: Illustration of the SLS process. Source: Authors, inspired by Kumar et al. (2021).

2.6.3 Filament-based Additive Manufacturing

Fused-filament fabrication (FFF), also known as fused deposition modelling (FDM), is an additive manufacturing process that builds objects through extrusion. FDM is a versatile technique that can use a variety of materials such as polymers, composites, ceramics and metal (Dey et al., 2021).

Fused Deposition Modelling

Fused deposition modelling is the most common AM technique for its ease of use. As shown in Figure 2.10, FDM works by having a heated nozzle that melts filaments into a semiliquid and extrudes it to build objects using layer-by-layer deposition (Kristiawan et al., 2021). The resolution and effectiveness of FDM are dependent on the specific material and most low-end FDM printers are often limited to one type of thermoplastic, namely PLA. There are higher-quality FDM printers that are capable of using far more materials such as, polypropylene (PP), polyethylene (PE), wood and nylon (Mwema et al., 2020). However, due to the process of melting filaments using a heated nozzle, FDM becomes limited in terms of printing speed and materials with low melting points (Wickramasinghe et al., 2020). Furthermore, the process of depositing material to build an object layer-by-layer also makes it dependent on support structures when printing parts with an overhang (Jiang et al., 2018; Wickramasinghe et al., 2020).

FDM is an attractive technique due to its affordability, relative ease of use, and wide range of readily available, low-cost filament materials. These factors contribute to the potential for mobilising global resources, such as volunteer networks, to produce parts (Mwema et al., 2020; Wickramasinghe et al., 2020).

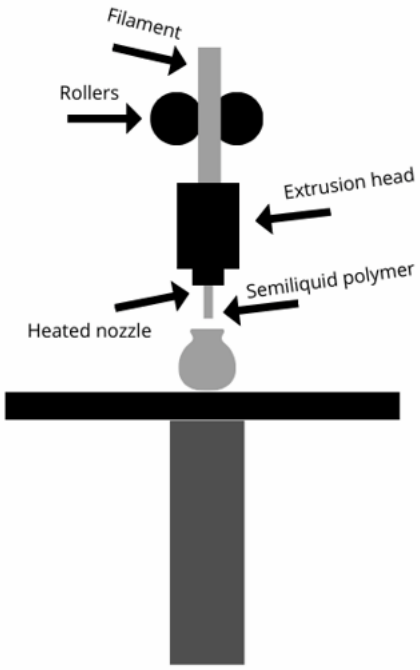

Figure 2.10: Illustration of the FDM process. Source: Authors, inspired by Chohan et al. (2020).

2.6.4 Alternative AM Technologies

Apart from the most common AM technologies of SLA, SLS, and FDM, there are also other AM technologies that are used to a relatively large extent. These alternative AM technologies often share similar features as the above-mentioned technologies and can also be seen as subcategories of AM. Two of the most prominent alternative AM technologies are described in greater detail below.

Polyjet is a resin-based AM technology and is a subcategory of the SLA method. Similar to SLA, Polyjet also uses the curation process of UV light to cure liquid resins (Muthuram et al., 2022). The main difference between SLA and Polyjet is that SLA uses a laser to outline the curation of the resin while Polyjet sprays droplets of resin onto a building plate which is then cured with a UV lamp layer-by-layer (Moldovan et al., 2018). Polyjet allows for the use of a larger variety of materials and can print using multiple materials at a time, meaning Polyjet can print a product consisting of more than one type of material. Polyjet offers superior

printing speed compared to SLA when smaller products are printed. However, for larger products, the Polyjet printing speed significantly decreases making SLA the more viable option (Moldovan et al., 2018).

Multi Jet Fusion (MJF) is a powder-based AM technology and a subcategory of the SLS method. Both SLS and MJF use a powder-fusing process to print parts layer-by-layer (A. P. Singh & Pervaiz, 2021). While SLS uses a laser to scan and fuse each layer, MJF utilises the dispensing of ink as a fusing agent to start the fusion of inked layers together. MJF is faster than SLS which means its manufacturing cost per unit is usually lower than SLS. Hence, MJF is beneficial when a higher amount of parts is needed due to its fast printing speed (Prabhakar et al., 2021). On the other hand, SLS offers higher accuracy of surface finish and a larger selection of compatible materials than MJF (A. P. Singh & Pervaiz, 2021). Additionally, SLS can produce larger parts than MJF.

2.6.5 Design for Additive Manufacturing

Additive manufacturing offers significant advantages for product designers and engineers. It overcomes many limitations inherent in traditional manufacturing processes, enabling the creation of more complex geometries (Gibson et al., 2021a). However, the inherent layer-by-layer nature of AM can restrict design freedom in certain aspects. To address this, Design for Additive Manufacturing (DFAM) was established. DFAM allows designers to move beyond geometrical and process constraints, allowing for the creation of complicated parts and the consolidation of multiple components into a single unit (Thompson et al., 2016).

DFAM can be characterised as a comprehensive set of design methodologies and tools. It optimises a part or product's functional performance and life cycle considerations, such as manufacturability, reliability, and cost, all within the framework of AM capabilities (Leary, 2019). This framework encompasses a collection of principles and best practices that guide designers and engineers towards achieving successful outcomes in 3D-printed parts. DFAM takes into account the chosen AM technology, part geometry, material selection, and any post-processing steps required to enhance the part's strength or aesthetics. Cost-effectiveness is a crucial consideration, as design choices can significantly impact the final price (Leary, 2019). The following sections provide explanations of some prominent design methods that characterise the DFAM process.

Parts Consolidation

Parts consolidation refers to the ability to combine multiple parts into a single one. The feasibility of consolidating originally separate parts into a single more complex component using AM processes is a significant advantage. This is because additive manufacturing processes enable the production of geometric shapes that otherwise require the assembly of multiple parts (Yang et al., 2015). Furthermore, Leary (2019) suggests that parts consolidation not only reduces the overall component count but also has the potential to enhance product functionality. The design method can also yield significant reductions in production costs and speed up manufacturing processes. This strategy offers a multifaceted approach to production, optimising various aspects of the manufacturing process (Gibson et al., 2021a).

Topology optimisation

Topology optimisation is a powerful design methodology for achieving optimal, complex geometries by utilising AM capabilities. This technique aims to create the most efficient material distribution within a part to satisfy critical performance requirements such as weight, stiffness, and strength (Gebisa & Lemu, 2017). In contrast to conventional structural optimisation methods like size or shape optimisation, topology optimisation offers the unique capability to modify both the shape and the topology of a part. Topology optimisation often yields highly complicated optimised shapes, which makes it difficult to apply the method to traditional manufacturing processes. However, utilising the layer-by-layer production nature of AM makes the fabrication of these topology-optimised structures much more feasible (Leary, 2019).

Lattice Structures

Lattice structures is a design methodology which utilises a cellular, open design that mimics the structure of atomic crystals with the aim of achieving low weight and high strength mechanical properties while simultaneously decreasing the amount of material used (Leary, 2019). Lattice structure designs originate from the increased design freedom achieved from utilising the unique capabilities of AM to create parts with multiscale complexities. Similarly to topology optimisation, the free-form layer-by-layer AM capabilities also make the design of lattice structures much more feasible than for traditional manufacturing methods, hence making it a useful design strategy in DFAM (Thompson et al., 2016).

2.6.6 Additive Manufacturing in the Medical Industry

The unique capabilities of AM allow for a wide variety of options for the utilisation of the technology in the medical industry. The ability to generate customised medical devices and anatomical structures with AM facilitates enhanced patient outcomes and overall well-being. (Salmi, 2021). This is because patient-specific care is common in healthcare since every patient is unique. Given the superior design freedom and customisation options AM holds over other production methods, the technology is particularly suitable for the creation of personalized medical solutions of different kinds (Rouf et al., 2022; Salmi, 2021). The use of AM for rapid prototyping is also particularly suitable to adopt in the medical industry since production with AM significantly decreases lead times, which can save valuable time for patients in emergency situations and reduce overall healthcare costs (Li et al., 2020). The following subsections present some common applications of AM in the medical industry described in the literature.

Anatomical Models

Anatomical models refer to non-implantable replications of patient anatomical parts used both pre-and post-operatively. Such models are most commonly used by surgeons or medical students as training material or as direct guides with the aim of improving surgical accuracy (Salmi, 2021). The anatomical models are often used for a wide variety of surgical cases, such as limbs, bone structures, spine, or pelvic parts. The design freedom provided by printing such anatomical models with AM technologies allows for the scaling of different anatomical sections, e.g. highlighting important areas where the surgical intervention is to be made (Manmadhachary et al., 2019). The models can also be highly customised and patient-specific due to the design freedom capabilities of AM. Anatomical models require post-processing sterilisation if they are to be used operatively, but usually, this is not the case, which opens up the possibility for different AM techniques to be used when creating the models (Salmi, 2021).

Implants

Contrary to the anatomical models, implants are used operatively to replace defective or missing tissue in the body (Salmi, 2021). There are strict requirements and long approval processes for implants since they need to be both compatible with the tissue it is replacing, and biocompatible, meaning it should be non-toxic and harmless to the body. Similar to anatomical models, the AM design freedom makes it feasible to design highly patient-specific in this case as well, which arguably is of even greater importance for implants than anatomical training models (Li et al., 2020). However, the choice of AM technique is mostly limited to metal and the material used is mostly titanium since it has high-biocompatibility properties. The use of metal AM techniques requires post-processing steps such as removing supports, polishing, heat treatment, and strict sterilisation before clinical operation (Salmi, 2021).

Medical Equipment

Using AM for the production of medical equipment is a broad term that encompasses many aspects. Firstly, medical equipment in the form of templates and individual parts can be produced with AM for surgical aid. An example of this is patient-specific produced templates for drilling cranial bones with extremely high precision (Salmi, 2021). Secondly, highly customised medical instruments that are useful in certain surgeries can be manufactured from scratch with AM, meaning entirely new products can be manufactured to fit

patient-specific needs (Rouf et al., 2022). Lastly, apart from medical equipment for surgical needs, AM has also been utilised for the production of medical devices and PPE, most recently to aid healthcare during the COVID-19 pandemic (Advincula et al., 2020). There were widespread shortages of critical PPEs and medical devices, leading to many countries prioritising production for their home country in the first hand (Advincula et al., 2020). There were shortages of PPEs such as face shields, HEPA masks, and suits. For medical devices, there were shortages of e.g. respirators and venturi tubes (Ishack & Lipner, 2021). Contrary to the patient-specific use cases of AM for medical equipment in surgical purposes, printing medical devices and PPEs during the COVID-19 pandemic was done mainly as an improvised way of meeting dramatically increased demand with the help of domestic companies when global supply chains were highly disrupted (Advincula et al., 2020). Figure 2.11 shows examples of medical equipment that can be printed with AM technology.

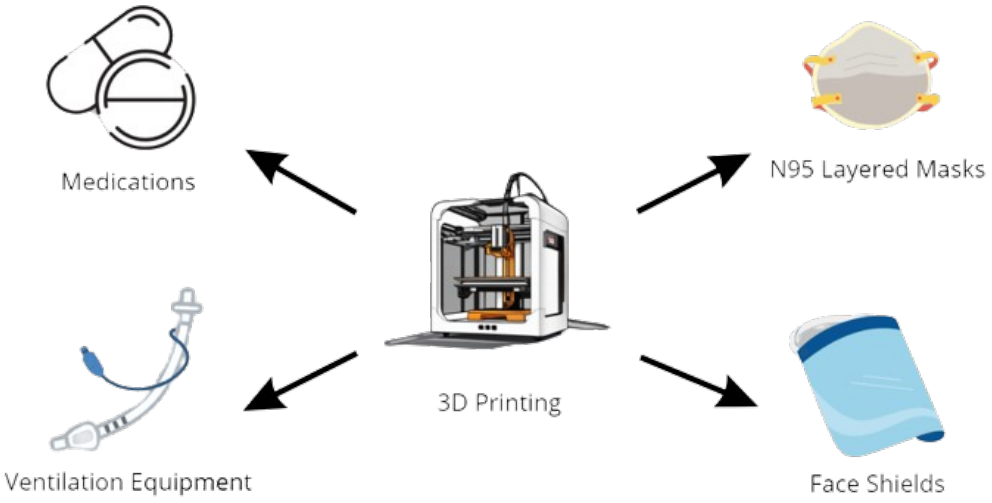

Figure 2.11: Some medical equipment that can be printed with AM. Source: Authors, inspired by Ishack and Lipner (2021).

Medical Aids

Medical aids commonly refer to different types of prostheses produced with AM for use external to the body. Such external medical aids can however come in many forms other than prostheses, such as postoperative supports, motion guides, fixators, or orthopaedics applications (Salmi, 2021). To ensure patient-specific fit by the medical aids, medical imaging, segmentation, and 3D scanning and measurements are often carried out before the printing process starts. Besides the advantages of tailor-made medical aids and prosthetics, patient waiting time is significantly reduced when using AM compared to injection moulding since AM allows for much shorter lead times from initial medical imaging to printed product (Rouf et al., 2022). Medical aids typically require post-processing activities such as support removal, heat treatment, and coating (Salmi, 2021).

Post-processing Requirements in the Medical Industry

Parts produced using AM may require post-processing depending on the printing technology, printing material and requirements of the final part. Post-processing techniques are used to achieve greater surface quality, mechanical properties, excess material washing, and sterilising parts (Dizon et al., 2021).

Sterilisation is a process that destroys or removes all microorganisms, including spores, viruses and viroids, from an object (Tipnis & Burgess, 2018). In the healthcare sector, sterilisation is a necessity for medical devices in healthcare to prevent nosocomial infections, infection(s) that are "acquired during the process of receiving health care that was not present during the time of admission" (Sikora & Zahra, 2020). Depending

on how the medical device will be used, there are different levels of risk. The Spaulding classification system established by Earle Spaulding in 1939, categorises three levels of sterilisation based on the degree of risk involved (Dempsey & Thirucote, 1988). Dempsey and Thirucote (1988) explains that critical items are parts that enter sterile tissues or the bloodstream. Semicritical items come into contact with mucous membranes but do not penetrate body surfaces, and noncritical devices are those that come into contact only with the intact skin of the patient.

The selection of sterilisation processes varies depending on the criticality of the medical device and the materials of the product (Tipnis & Burgess, 2018). There are many different types of sterilisation, including heat-based sterilisation, chemical & plasma-based sterilisation and irradiation-based sterilisation (Pérez Davila et al., 2021). Heat-based sterilisation is the most common form of sterilisation at hospitals that achieves sterilisation through an autoclave, which exposes the part to high heat, moisture and pressure. This is an effective, safe and simple procedure compared to the other sterilisation methods. However, this process cannot be applied to heat-sensitive polymers which can be a limiting factor for some AM technologies in healthcare (Pérez Davila et al., 2021).

2.6.7 Limitations of Additive Manufacturing

Additive manufacturing has gained significant interest across several business sectors in recent years. A large contributor to this is that the technology offers a wide range of advantages e.g. product customisation, design freedom, and its ability to minimise production waste because of its inherent layer-by-layer printing process (Shukla et al., 2018). However, despite the many advantages of AM, it is equally important to review its potential disadvantages in order to obtain a holistic view of the technology (Sonar et al., 2020). In the literature, such disadvantages are commonly referred to as barriers or factors that must be considered before choosing AM over other production methods. Moreover, there are different types of limitations of AM described in the literature which can be categorised as technical and organisational factors. This section presents some common technical and organisational factors in greater detail.

Technical Factors

Object size is the first technical factor that is important to consider when opting for the use of AM methods. Although printers allow for high customisation of build sizes, the total build volume is constrained to the printer interior itself (Shukla et al., 2018). Hence, printers offer significantly lower build volumes than other large-scale manufacturing technologies like laser cutting, horizontal mills, and metal casting (Rylands et al., 2015).

Production volumes should also be taken into account when considering AM methods. That is because AM primarily functions as a low-to-medium volume production process. This limitation is caused by the layer-by-layer nature of the technology, meaning objects need to be printed one at a time which complicates production volume scale-up (Shukla et al., 2018). Additionally, if the printed parts require high quality, thinner layers in the layer-by-layer process need to be placed at a time, further slowing the process and making volume scale-up even more complicated. It should be noted that exceptions do exist, for example, the HP Multi-jet printer can utilise its entire printer volume to print multiple parts. However, the cycle time is still significantly slower than other more mature manufacturing technologies (Weller et al., 2015).

There is also limited material availability for AM which also is a factor that has to be considered. Material availability is constrained to materials that are compatible with the currently established AM techniques, such as resin-, powder-, and filament-based AM (Weller et al., 2015). While the range of plastics and metals compatible with AM is steadily increasing, the available materials remain limited in comparison to more established manufacturing technologies (Shukla et al., 2018). In addition, the rather limited selection of materials suitable for AM makes the use of the technology more vulnerable in the case of raw material shortages or supply chain disruptions (Thomas, 2016).

Considerations regarding speed of printing when opting for AM production must also be taken into account. The slow printing speeds AM offers is one of the reasons the technique, despite being readily available since

the late 80s, still has very niche applications (Shukla et al., 2018). Producing a single product with AM may take hours whereas an IM tool can do it in seconds. Slow printing speeds are also a major factor contributing to difficulties of economies of scale with AM production. (Weller et al., 2015).

Cost of AM is another technical factor that also must be considered and follows somewhat naturally from the previously identified factors. When considering the costs of opting for production with AM, the cost of the printers and the raw materials must be taken into account (Shukla et al., 2018). Printers that offer high quality and resolution of the printed parts are often expensive, which means high capital costs for companies opting to integrate AM into their business. Additionally, companies may have already invested significantly in traditional manufacturing methods, making a switch to AM a difficult and costly proposition to make (Thomas, 2016). Lastly, limited materials suitable for AM and the fact that AM is unfavourable for higher volumes make for poor economies of scale when procuring material for the printers (Weller et al., 2015).

Organisational Factors

The first important organisational factor to consider when implementing AM is management commitment. As AM has gained significant interest in recent years, companies deciding to invest in AM technology over traditional production methods must have full management commitment for the initiative, especially considering the large capital costs of printers and materials (Shukla et al., 2018). Constant support from management is a crucial part of fostering a culture of knowledge creation and sharing among the employees. Without such support, employees may not see the value in AM implementation which can ultimately lead to decreased productivity and firm competitiveness (Sonar et al., 2020).

Constant information sharing is also vital for the success of AM implementation in an organisation. Sonar et al. (2020) suggest that a constant flow of information regarding product design, CAD software, printer technology, and AM processes in a necessity. This is because AM is a knowledge and competence-driven technology where collaboration is key to achieving successful results. Without information flows, important communication will be stifled, leading to decreased collaboration and knowledge utilisation across the organisation (Sonar et al., 2020).

To foster the knowledge and competence crucial for the success of AM initiatives, sufficient education and training is an important factor to consider. Shukla et al. (2018) explain that CAD software can be complex and that there might be a lack of expert designers knowledgeable of DFAM in the organisation. Hence, Sonar et al. (2020) emphasise the importance of regular education and training programs across the organisation initiated by top management, where knowledge is shared among the employees to raise the competence level needed for effective utilisation of the AM technology.

Lastly, financial capability must be ensured when opting to implement AM technology in an organisation. Considering that (Shukla et al., 2018) described that high-quality printers are expensive and material selection limited, Sonar et al. (2020) arguing that reliable financial support is necessary to develop, utilise, and effectively practice AM technologies in an organisation is understandable. Ultimately, financial capabilities are what drive top management to pursue or deny supporting AM implementation in the organisation in the first place (Mohanty, 2018).

2.7 Technology Readiness Level

According to Mankins et al. (1995), Technology Readiness Levels (TRLs) are a systematic metric to assess a technology's maturity and to compare the maturity between different types of technology. The scale was originally developed by NASA in the 1970s but has since become a de facto standard in multiple industries to assess the maturity of a technology (Olechowski et al., 2015).

The TRL scale is divided into nine distinct levels, with each level representing a progressively more advanced stage of development, see Figure 2.12.

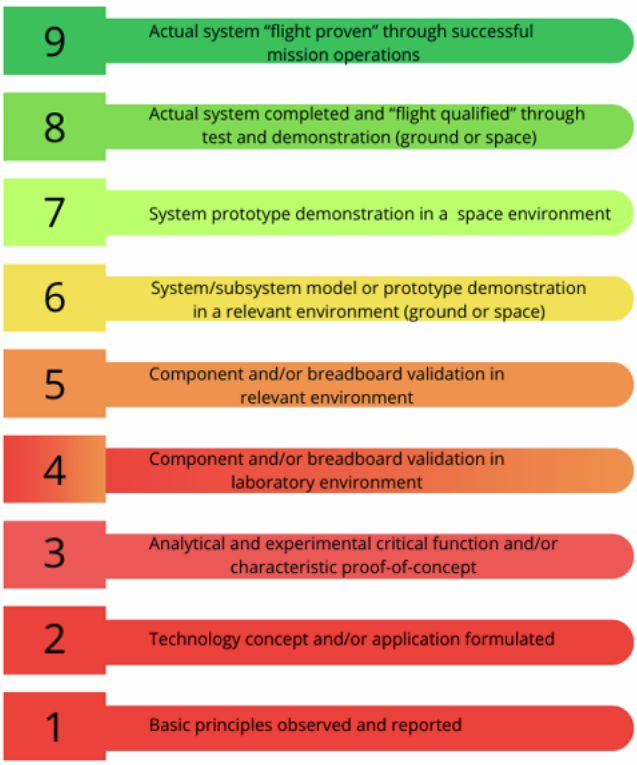

Figure 2.12: Visualisation of the different steps of TRL. Source: Authors, inspired by NASA (2023).

Despite AM's growing potential, the industrial application of AM remains limited, with the primary focus being on prototyping, tooling and creating highly customisable parts (Spalt & Bauernhansl, 2016). The TRL for AM varies depending on the application but it is found to be the highest within medical use (Spalt & Bauernhansl, 2016). However, because AM has a lower process reliability and requires post-processing techniques, the perceived readiness level can be limited (Kretzschmar et al., 2018; Spalt & Bauernhansl, 2016).

Although the widespread adoption of AM remains limited, the technology itself and its applications are continuously growing. Notably, AM offers unique benefits not only to parts that are produced using this method but also in terms of manufacturing capabilities that could enable a fully decentralised supply chain (H. Khajavi et al., 2018; Spalt & Bauernhansl, 2016).

2.8 Regulatory Requirements

For the past two decades, medical devices have frequently been in the spotlight due to safety concerns. The incidence of safety alerts and field safety notices has risen significantly, prompting the development of new regulations for introducing medical devices to the European Union's (EU) single market under Regulation (EU) 2017/745, commonly referred to as the Medical Device Regulation (MDR).

Up until 2017, medical devices that were placed on the EU market had to be compliant with the Medical Device Directive 93/42/EEC for general medical devices and Directive 90/385/EEC for active implantable devices (Vasiljeva et al., 2020). Prior to the implementation of a harmonised regulatory framework within the European Union, individual member states often possessed their own regulations concerning medical devices (Cheng & WHO, 2003). However, as some medical devices that were compliant with previous directives failed, it became necessary to develop uniform testing to promote patient safety and facilitate free movement within the Union (Vasiljeva et al., 2020).

Regulations exist to control and prevent the importation and use of medical devices that are substandard. Medical devices always carry some degree of risk which could compromise the safety of the patient or user of the equipment (Cheng & WHO, 2003). Cheng and WHO (2003) explains that Regulations are often complicated and extensive, requiring thorough and detailed technical documentation. Regulations can also cover material declarations, rules for different levels of sales representatives, packaging with appropriate markings, instructions, conformity assessment procedures, and more (Regulation 745/2017). Conformity assessment procedures involve the testing of the medical device according to appropriate standards to ensure the safety and efficacy of the device. The assessment procedure also ensures that the device works according to the user's instructions and carries the appropriate markings (Cheng & WHO, 2003). Depending on the level of the medical device, which is based on the degree of risk, there may be additional requirements for post-market surveillance and audits at the manufacturing facility (Regulation 745/2017).

Although the MDR was designed to enhance patient safety and streamline sales within the EU, regulatory changes can also impede innovation and potentially compromise patient safety by restricting access to certain life-saving products. The resulting stagnation in technological advancements could negatively impact patient safety by preventing the introduction of potentially safer materials and methods into the EU market, as manufacturers may be compelled to concentrate on existing devices (Vasiljeva et al., 2020).

Furthermore, it should be noted that there is an extensive range of standards that covers different aspects of medical devices, such as quality systems for the manufacturing of medical devices, biocompatibility, sterilisation, risk assessment and more (ISO, 2020).

2.9 Supply Chain Management

Supply chain management (SCM) is an integrative approach to managing the steps of a supply chain, from planning to controlling the flow of materials, all the way from suppliers to end users (Ellram, 1991).

SCM is meant to make the flow of information more effective by removing communication barriers, increasing the visibility of the supply chain to identify bottlenecks, facilitating improved decision making and improving the resilience of the supply chain (Power, 2005). Although supply chain disruptions are unavoidable, how often they occur and their severity can be mitigated through proper SCM (Craighead et al., 2007).

For this thesis, the main aspect of a supply chain that is of interest is dealing with supply chain disruptions, thus that will be the focus of this section.

2.9.1 Supply Chain Disruptions

Craighead et al. (2007) describes supply chain disruptions as "unplanned and unanticipated events that disrupt the normal flow of goods and materials within a supply chain". When investigating supply disruptions, it is necessary to understand the network structure of the supply chain(Kim et al., 2015). Modern supply network structures are far more complex and dynamic, making it more difficult to comprehend how disruptions affect various parts of the supply chain (Harland et al., 2003). A common way to analyse supply networks is using graph theory, where the supply network can be visualised as nodes and arcs, where nodes represent facilities and arcs represent transportation that links the nodes (Kim et al., 2015). This method is used to differentiate between network-level disruptions and component-level disruptions which are often misunderstood when trying to improve resilience in supply chains (Kim et al., 2015).

According to Harland et al. (2003), the complexity of the supply network increases the risk for disruption. To improve stability in a supply network structure, Harland et al. (2003) recommends designing the proper supply network structure depending on the situation and having appropriate relationships with the suppliers. Furthermore, Adenso-Diaz et al. (2012) found that source criticality and the average number of suppliers of raw material to the final customer had the strongest positive effect on network reliability. Many companies are highly dependent on supply chains that revolve around labour costs and skilled personnel that are often found at specific locations (Mourtzis et al., 2013). This dependency creates a vulnerability in the supply chain as the source criticality becomes limited (Adenso-Diaz et al., 2012; Mourtzis et al., 2013).

Decentralised manufacturing is a more recent approach that distributes manufacturing activities across various locations, offering better delivery times, lower transportation costs and improved agility (Mourtzis et al., 2013). Additive manufacturing emerges as a well-suited technology for decentralised manufacturing because its flexibility, versatility and digital development enable the establishment of production networks. Production networks can be seen as decentralised manufacturing facilities that can react faster to change and offer high product mix flexibility without increasing costs disproportionately. Furthermore, production networks also offer far better volume flexibility, a factor that could become very important in turbulent times or disruptions that affect global demand (Spalt & Bauernhansl, 2016).

3

Methodology

This chapter describes the research methodology of this thesis. In greater detail, firstly the empirical context and background of the study are presented. Secondly, the employed research strategy and research design are explained. Third, the data collection methods utilised are described, which include two types of interviews and a literature review. Fourth, the employed data analysis method is explained, which consisted of a thematic analysis using the tools of interview coding and affinity diagram. Lastly, research quality as well as ethical, societal, and ecological considerations are accounted for.

3.1 Empirical Context

This research was conducted in collaboration with RISE Research Institute of Sweden (RISE), which is an independent state-owned research institute. RISE collaborates with several partners in industry, academia, and the public sector, with the goal of developing technologies, products, services and processes to increase the competitiveness of Swedish businesses and promote sustainable development (RISE, 2024). RISE have around 3300 employees all across Sweden who specialise in research, engineering, and innovation. RISE operates over 130 test and demonstration environments with advanced lab equipment. These facilities allow businesses to experiment with new technologies and get real-world data on their products and services. Additionally, RISE actively collaborates with international partners, ensuring that Swedish businesses stay on the cutting edge of technology and contribute to global advancements (RISE, 2024).

The Swedish Civil Contingencies Agency (Myndigheten för samhällsberedskap in Swedish: MSB) is a Swedish government agency aimed at strengthening society by preventing and managing accidents, crises and the consequences of war (MSB, 2024). The agency protects people's lives and health, the functionality of society and fundamental values such as democracy, legal certainty and human rights. MSB operate with high levels of trust and cooperation with stakeholders to become successful in their missions (MSB, 2024).

The background of this study originated during the COVID-19 pandemic, a period characterised by significant shortages within the medical equipment supply chain. RISE, in collaboration with MSB, undertook investigations into the production and supply of medical equipment to identify ways of increasing resilience in healthcare. This thesis, alongside other projects by RISE, aims to provide comprehensive research with detailed information to MSB on how to navigate shortages of medical equipment best.

3.2 Research Strategy

The research strategy opted for in this study was a qualitative research strategy with an exploratory approach. Bell et al. (2022) explains that an exploratory approach is recommended when studying topics where there is limited knowledge and high uncertainties. Moreover, a qualitative research strategy is recommended when an exploratory approach is employed. The aim of this research was to investigate how AM capabilities can play a role in increasing healthcare resilience by producing medical equipment in the case of a crisis. Since crises where substantial shortages of medical equipment are seen and AM technology in healthcare is novel and constantly evolving, there was limited knowledge regarding the feasibility and capability of emergency manufacturing using AM in the healthcare sector. Hence, the focus of this study is well-aligned with utilising an exploratory approach and a qualitative research strategy as outlined by Bell et al. (2022).

Furthermore, this study used an iterative inductive research approach to assess the relationship between theory and empirical research data, which is often emphasised in qualitative research strategies (Bell et al., 2022). Generally, inductive research approaches entail employing the process of theory development by

starting with observing specific instances and seeking to establish generalisations about the observations that steer the development of an observation-oriented theoretical framework (Spens & Kovács, 2006). To put it more simply, the inductive approach allows for theory to be the outcome of empirical findings and the theoretical framework can be reinforced and complemented iteratively as new empirical data is collected, allowing for the generation of new hypothesised, theories, and conclusions as the study progresses (Bell et al., 2022; Spens & Kovács, 2006). Figure 3.1 shows the inductive approach of this study.

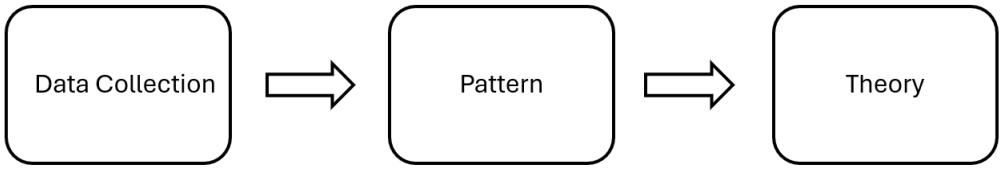

Figure 3.1: Illustration of inductive research. Source: Authors.

3.3 Research Design

This research was aimed towards assessing how AM should be used to increase healthcare resilience through the production of medical equipment in the case of a crisis. To investigate this, current AM capabilities were to be studied, elements that influence the use of such AM capabilities were also of interest, as well as understanding how coordination of AM capabilities can play a role in increasing healthcare resilience. To achieve this, an exploratory case study research design was chosen because of its ability to provide researchers with insights into a new phenomenon or topic (Bell et al., 2022). Since crises involving shortages of medical equipment are rare and AM in healthcare is a new and evolving application as explained in Section 3.2, an exploratory case study research design aligns with the aim of this research.

The research process in this thesis was conducted in three phases. Firstly, the first phase of the thesis was focused on formulating general research questions to get a broader understanding of the topic investigated. To facilitate this, initial pilot interviews were held with people familiar with the use of AM technologies within the healthcare sector and the manufacturing industry to better understand the capabilities and requirements to develop a feasible emergency manufacturing structure. The pilot interviews were unstructured interviews. This type of interview can according to Bell et al. (2022) be a useful tool to gain a deepened understanding of the topic of interest as well as seeing things from the interviewees' perspective, allowing for a more realistic view of the topic. Secondly, phase two of this thesis' research design involved performing an extensive literature review to gain further understanding of the relevant topics. The primary objective of conducting a literature review was to develop an initial theoretical framework which could later be reinforced and restructured according to the findings from the empirical data. By doing this, the literature review also served as a basis for developing an interview guide for the semi-structured interviews. Moreover, the literature review was also conducted to learn from potential mistakes made by previous researchers in the field and to gain knowledge of various theoretical and methodological approaches to the topics of interest in the thesis. Furthermore, in phase two of the thesis research design, qualitative data from interviews of semi-structured characters was also collected. During the semi-structured interviews, new and relevant knowledge emerged that was not previously found in the literature review. Given the iterative inductive approach of this study, it was possible to converge the empirical findings with existing theories to complement each other in generating new hypotheses and theories as outlined by Spens and Kovács (2006). Lastly, the third phase of the research design in this thesis was about analysing the gathered data and writing up conclusions. The gathered empirical data was thoroughly analysed and comparisons between the findings and the literature review were made. To analyse the data, a thematic analysis was used. The use of thematic analysis is favoured in qualitative research due to its flexibility in analysing a variety of qualitative data (Bell et al., 2022).

An overview of the research design used in this thesis is visualised in Figure 3.2. Additionally, a more detailed explanation of the employed data collection methods in the thesis is presented in Section 3.4.

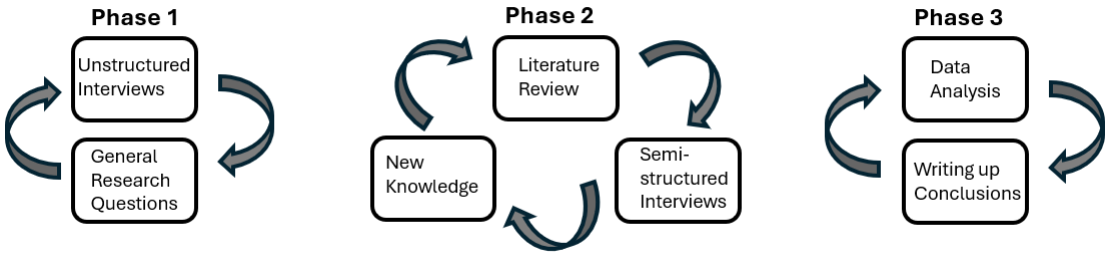

Figure 3.2: Visualisation of the employed research design. Source: Authors.

3.4 Data Collection

Bell et al. (2022) explains that there are two different types of data, primary data and secondary data. Primary data is the type of data that is being collected by the researcher, while secondary data is data that already exists, such as data that has been collected by other researchers. The data collection methods used in this thesis were interviews and a literature review. Each subsection in this section describes the used data collection methods in greater detail.

3.4.1 Primary Data

Primary data constitutes the main way of obtaining empirical findings in research and consists of original information collected by the researchers to answer the purpose and research questions of the study. Primary data allows for new insights to be made and has the potential to contribute substantially to the field of study (Bell et al., 2022). In this thesis, two sets of interviews of different structures and quantities were utilised to collect primary data. These are pilot interviews and main interviews which are described further below.

Pilot Interviews

Unstructured Pilot interviews were conducted early on in this research. Unstructured interviews are usually flexible, promoting an open conversational flow rather than following interview questions. Unstructured interviews are often used for gathering rich and detailed information from the interviewee's point of view (Bell et al., 2022). This was also the goal of the pilot interviews conducted in this thesis. Initially, the topic of AM, emergency manufacturing in healthcare, and everything connected to it was relatively novel to the researchers. Hence, two pilot interviews were conducted with people recommended by the thesis supervisors at RISE because of their profound knowledge and experience in the field. These interviews were conducted in person without a script of interview questions. However, both researchers were present at the interviews, where one led the conversation with the interviewee and the other took notes. Additionally, the interviews were recorded and transcribed to ensure no important information was lost. The pilot interviews provided valuable insights into the field of study and gave the researchers a clear view of topics that needed to be addressed in the main interviews.

Main Interviews

Since the aim of this thesis was to understand how AM can be used in healthcare equipment manufacturing in the case of a crisis, data needed to be collected in order to reinforce the theoretical framework, gain new insights, and draw meaningful conclusions from the research. Given the exploratory research approach

opted for in this thesis, exploring and understanding the perspective, experience, and opinions of people knowledgeable in the area was of great interest. Hence, it was deemed appropriate to collect primary data in the form of interviews to be able to answer the proposed research questions. Some interviews were conducted in person whereas others were conducted remotely digitally via Microsoft Teams. The reason for this mixed interview approach was that a wide variety of interviewee perspectives was sought after, meaning the interviewees were spread out and located at different places in Sweden. Hence, for both cost, time, and environmental reasons the mixed interview approach was chosen. However, the same procedure for recordings and transcriptions was used in both types of interviews.

Interviews are a valuable tool for gathering in-depth information from participants. However, Yin (2018) explains that it is important to be aware of potential biases, where the interviewees might provide answers that they believe the interviewer wants to hear instead of what they actually think. Therefore it is important to prepare before the interviews by having properly phrased questions to reduce the risk of misunderstandings and biases. Furthermore, recordings and transcriptions should be used when possible to help facilitate the analysis of the empirical data according to Bell et al. (2022).

Interview Sampling

To achieve a detailed and holistic view of how AM can be utilised in emergency medical equipment production, interviewing people with great knowledge and relevance in the field was crucial. Bell et al. (2022) describe that a suitable sampling strategy for this approach is called purposive sampling. This is a non-probability type of sampling where the participants are strategically chosen depending on their relevance to the topics covered in this study. To achieve this, participants from two relevant sectors were interviewed. Those were 3D units at hospitals and companies working with AM in their business. Both of these branches share a deep understanding of AM technology and provide two different perspectives on the technique. 3D units at hospitals work closely with different departments at the hospitals, providing them with great insight into how AM is and can be further used in healthcare. The companies that work with AM on the other hand, use AM in their operations for various purposes such as prototyping, aiding in traditional manufacturing techniques, and creating new products. They thus provide a larger perspective on the use cases of AM in industry. Additionally, a snowball sampling strategy was used as a way to reach relevant participants who might possess knowledge that is of interest to this research. A snowball sampling involves contacting a few people who are relevant to the topic of the research and having them refer to other people who they believe could help contribute further to this study (Bell et al., 2022). Figure 3.3 shows a more detailed structure of the employed sampling strategy.

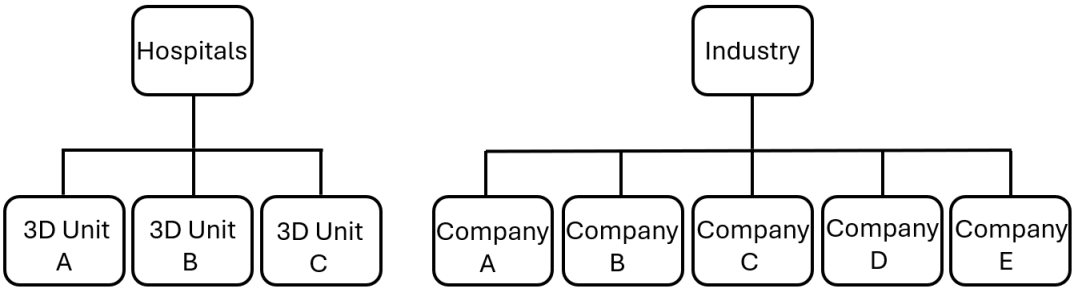

Figure 3.3: Visualisation of the sampling strategy of the study. Source: Authors.

The snowball sampling strategy led to a higher number of participants from both companies and 3D units.

Three 3D units at three different hospitals were interviewed and five AM companies were interviewed. In total, 17 interviews were conducted, nine at 3D units and eight at AM companies. Table 3.1 shows a summary of

the interviewee distribution and the duration of each interview. 3D unit interviewees are denoted H (hospital) and AM company interviewees are denoted C (company).

Table 3.1: *List of interviewees and interview durations.*

Interview Group	Interviewee	Time (minutes)
3D Unit	H1	30
3D Unit	H2	30
3D Unit	H3	35
3D Unit	H4	30
3D Unit	H5	35
3D Unit	H6	30
3D Unit	H7	30
3D Unit	H8	30
3D Unit	H9	50
AM Company	C1	40
AM Company	C2	45
AM Company	C3	55
AM Company	C4	40
AM Company	C5	40
AM Company	C6	40
AM Company	C7	40
AM Company	C8	55

Interview Structure

The structure of the conducted interviews in this thesis was chosen to be semi-structured interviews due to their several benefits in the research topic of interest. A semi-structured interview follows a more flexible approach than a structured interview, meaning the interviewees are not constrained to only answering the specific questions asked, but are instead encouraged to keep an open conversation with the interviewer (Bell et al., 2022). This allows for deeper conversations where many perspectives, opinions, and experiences can be shared. Achieving detailed and nuanced information from interviewees was crucial in order to reach a profound understanding of how AM can be used in emergency medical equipment manufacturing. Hence, the semi-structured interview approach was deemed appropriate for this research. The flexibility of semi-structured interviews also meant the two researchers conducting this thesis could alternate between taking a leading role in every other interview without changing the interview guide to any meaningful extent, thus upholding scientific integrity and preserving research validity (Bell et al., 2022).

Furthermore, to facilitate the natural progression of conversation in semi-structured interviews, it is essential for both the interviewee and the interviewer to have the capacity to pose follow-up questions and provide responses. To allow for additional flexibility of follow-up questions, the interviews were scheduled to take approximately 30-45 minutes but initially booked in 60-minute time slots. This ensured that there was sufficient time for follow-up questions and additional input without making the interviews too lengthy, potentially discouraging people from participating. Moreover, when conducting semi-structured interviews, Bhandari (2021) explain the importance of addressing several considerations during the process of collecting data through interviews to enhance research validity. The semi-structured interviews needed to be constructed to touch upon the specific topic of interest while at the same time allowing for personal and individual answers. The respondent may consider some questions as sensitive making them unable to answer truthfully, which makes it essential to be aware of the limitations of the explanations. Also, making it clear from the start about the

intentions of the interview and research, as well as being careful in the formulations with few independent interactions is important (Bell et al., 2022).

To address these considerations, an interview consent paper was handed out to the interviewees at the start of each interview. Bell et al. (2022) explains that an interview consent paper is a beneficial way of assuring informed consent among the interviewees to participate in the study. The interview consent paper contained detailed information to the interviewee about the purpose of the interview. The paper provided general information about the thesis work and emphasised several aspects of interviewee safeguarding to maintain scientific integrity. It was stated that there are no correct or incorrect answers, that an open discussion with a natural flow is encouraged, and that the interviewee will remain anonymous. It asked for permission to record and transcribe the interview while explicitly stating that only the researchers conducting this thesis will have access to the material and that it will be deleted when the research is finished. For the in-person interviews, the consent paper was shown to the interviewees in physical paper form, whereas for the online interviews via Microsoft Teams, the consent paper was shown through screen sharing. The interview consent paper in its entirety is presented in Appendix A.

Both researchers conducting this thesis were present in every interview and, as explained earlier, switched between taking a leading interviewer role and a secondary role in every other interview. More specifically, the one taking the leading interviewer role was the one asking the main questions, whereas the secondary role focused on taking notes and providing follow-up questions. Having one researcher take notes combined with recording the interview, as well as being able to ask follow-up questions ensured that no information was lost during the interview process and that sufficient data was collected. Simultaneously, this made the leading interviewer able to fully focus on the interview conversation knowing the discussion could be reinforced or expanded on by the secondary interviewer if necessary.

Interview Guide

To further enhance research validity it is recommended to use an interview guide (Bell et al., 2022; Bhandari, 2021). Semi-structured interviews with an interview guide offer the researcher greater control over the discussion while still providing the flexibility to explore new themes and ideas as they emerge (Bell et al., 2022). To understand how AM can be used in emergency medical equipment manufacturing from both 3D units at hospitals' and AM companies' perspectives, two separate interview guides were created. The goal was to keep the general interview guide structure intact for both groups but adjust some questions to better capture the perspectives, experiences, and ideas that may differ between the groups.

In greater detail, the interviewees of the 3D units were asked questions related to several different topics. Besides the introductory personal questions, these topics were focused on the interviewees' relation to AM, AM in the medical industry, COVID-19, and crises. The questions about the participants' relation to AM provided good baseline knowledge about what competencies 3D units at hospitals possess, how they work, and how they view the use case of AM. This knowledge made it possible to then discuss more generally the use of AM in the medical industry. Here, topics discussed were the pros and cons of AM for medical industry purposes, what AM technique is most suited for producing medical equipment, regulatory requirements, etc. The COVID-19-related questions aimed at understanding how operating procedures changed during a crisis event and how the supply of material, production, and costs were affected by the pandemic. The questions about crises were of a more open nature where the interviewees were asked to describe how they would act if there were to be a crisis again and how they could use AM to mitigate the effects of such a crisis.

The interview guide for the AM companies followed a similar structure with the same topics as the interview guide for 3D units, but with a slightly different focus. The questions about the interviewees' relation to AM were kept the same since the contrast between AM knowledge in AM companies and 3D units was seen as valuable insights for a comparative analysis to be made. However, since most of the AM companies also work with traditional manufacturing techniques such as injection moulding, the second topic was more tailored towards comparing AM and traditional manufacturing techniques, and how these can play a role in the medical industry. Lastly, the question topics of COVID-19 and crises were kept similar to the interview guide for 3D units, in order to again be able to make a comparative analysis and draw useful conclusions for the thesis.

The topics in the interview guide and the related questions were asked in top-to-bottom order. However, some interviewees provided more comprehensive answers than others and they sometimes answered multiple questions in one answer. Hence, when answers were comprehensive it was chosen not to ask all the questions in the interview guide to avoid redundancy and keep the natural conversation flowing. This was possible due to the semi-structured nature of the interviews. This combined with the fact that several interviews were held, it was deemed possible to still achieve saturation in answers when choosing this procedure. For the interviewees who provided less comprehensive answers, greater emphasis on follow-up questions was made, which is in line with the recommendations by Bell et al. (2022). The interview guides for 3D units and AM companies are presented in Appendix B and C, respectively.

Interview Processing Strategy

The interview processing strategy of this research was conducted through recordings and transcriptions of each interview. According to Bell et al. (2022), the subjective nature of qualitative research using interviews as a main form of data collection requires extensive records of the retrieved data in order to facilitate a smooth data analysis process. Hence, utilising recordings and transcriptions was a crucial part of the methodology of this study. As previously described, every interviewee was asked for permission for their interview to be recorded and transcribed in the interview consent paper that was distributed before each interview. To account for potential errors in the recording process, both researchers recorded every interview. The interviews that were conducted in person were recorded by the researchers' mobile devices, whereas the online interviews were recorded through the built-in record function in Microsoft Teams.

To ease the transcription process of the interviews, a speech recognition function provided by Microsoft Word was utilised. However, the software yielded some errors and occasional redundant repetition of some words. To manage this, the errors in each interview transcription were corrected manually in order to further facilitate a smooth data analysis process down the line. All transcriptions were manually reviewed to ensure the retention of all valuable data. Listening through the interviews also provided the researchers with the opportunity to potentially gain new perspectives on the information that was initially provided during the interviews, allowing for a more detailed analysis of the data, which is recommended in qualitative research according to Bell et al. (2022).

3.4.2 Secondary Data

Secondary data is data that has already been collected through various types of previous research (Bell et al., 2022). The secondary data of this research was gathered through official government agencies, RISE, and other trusted sources available online. Furthermore, this data was used as a complement to the primary data gathered from the interviews, allowing for secondary analysis that can strengthen the validity of the research (Bell et al., 2022). In particular, the secondary data gathered through these sources constituted the baseline of an extensive literature review complementing the empirical findings of the thesis.

Literature Review

A comprehensive literature review was conducted in this thesis. Bell et al. (2022) explains that there are several reasons as to why conducting a literature review is of great use in a research project. Conducting a literature review in this thesis was appropriate due to the following benefits of the review. The literature review provides the researchers with a holistic understanding of the existing knowledge in the research field or topic of interest, allows for the identification of gaps in the literature, and can give the researcher inspiration for relevant research designs based on similar types of studies (Bell et al., 2022). Moreover, Bell et al. (2022) further explains that there are two main types of literature reviews that are commonly used in research, the *Narrative Review* and the *Systematic Review*. The characteristics and applications of the reviews differ depending on the type of study conducted, where the Narrative Review is associated with qualitative studies and the Systematic Review is more common in quantitative studies (Bell et al., 2022). In greater detail, the Systematic Review follows a structured approach where the goal is to create a foundation of advice for future researchers in the field regarding the available peer-reviewed research on the topic. In contrast, the Narrative

Review is of more open character aimed at creating a more general understanding of the topics of interest in the study (Bell et al., 2022). Additionally, the Narrative Review is also of inductive style and combined with its relevance in qualitative studies like this thesis, opting for a Narrative Review in this thesis was a natural choice.

The literature review process in this thesis was initially started early on in order to expand on the deepened understanding of relevant topics achieved from the pilot interviews. The literature review was also started early to move relatively quickly towards refining the initial general research questions and creating more focused research questions better suited to answer the purpose of the thesis. Multiple keywords such as *Additive Manufacturing*, *Injection Moulding*, *3DP Process*, *Medical Industry*, *Medical Devices*, *Crisis*, *Regulatory Requirements*, *etc* relevant to the topic and purpose of the thesis were utilised in the process of retrieving articles. Using these keywords among others, the literature review in this thesis put great emphasis on retrieving relevant academic journals to a greater extent than books. This was because academic journals are usually more credible sources of information than books because they undergo rigorous peer-review processes and have higher standards of reliability, accuracy and relevance since they are the outcome of extensive academic research (Salomao, 2023). To retrieve the relevant literature, several databases such as *Chalmers Library*, *Google Scholar*, and *Scopus* were used. A large base of literature was initially retrieved to create a stable baseline of information to rely on. After this, the literature was filtered out to remove duplicates and redundancies of sources that were outside the scope of the thesis. The remaining literature that was not filtered out was further evaluated and analysed in greater detail. However, in accordance with the inductive research approach of the thesis, some literature was added or removed iteratively during the data collection and analysis process, to reinforce the theoretical framework to achieve greater coherence with the empirical findings. Figure 3.4 shows an overview of the literature review process employed in the thesis.

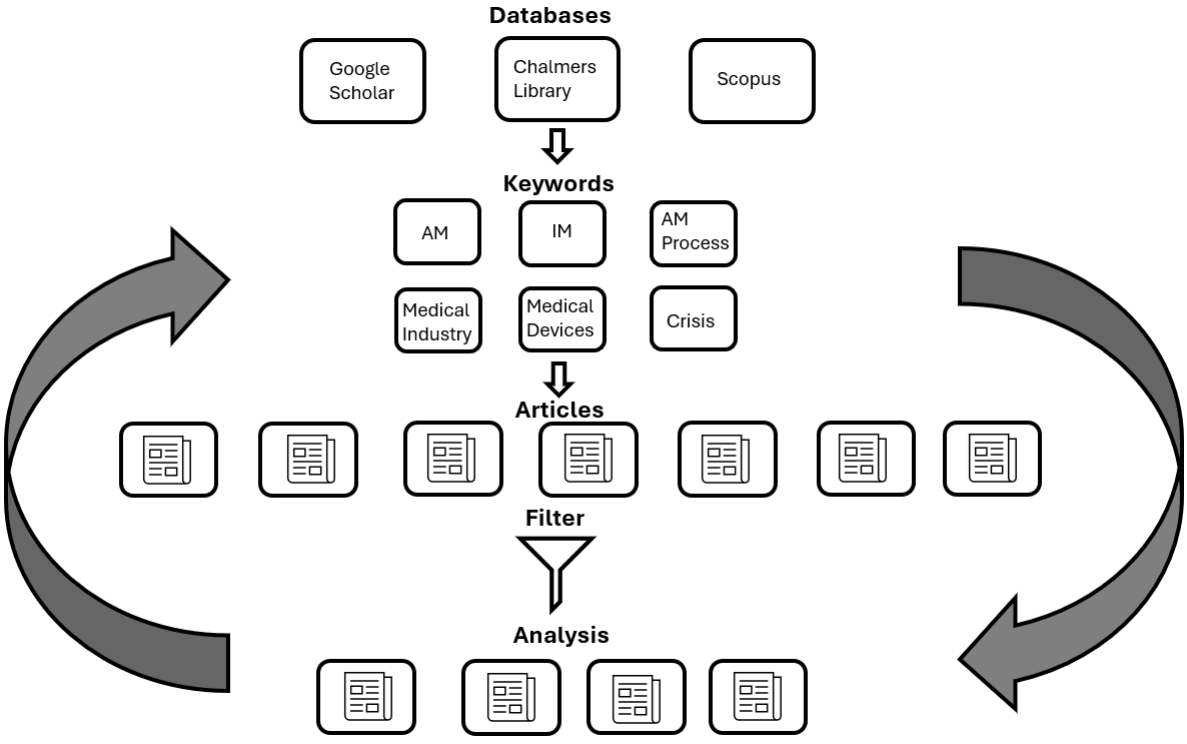

Figure 3.4: Illustration of the literature review process of this thesis. Source: Authors.

3.5 Data Analysis

Analysing data in qualitative research is explained by Bell et al. (2022) to be a complex and often time-consuming process since the data is often unstructured in the form of field notes, transcriptions, or other documents. Hence, there are few well-established and widely used rules regarding the ways of analysing qualitative data. One of the most frequently used ways of analysing qualitative data is through a thematic analysis, which subsequently also was the data analysis method opted for in this thesis. The thematic analysis and the tools interview coding and affinity diagram used in the analysis process are described in greater detail in the following section.

3.5.1 Thematic Analysis

The data analysis method opted for in this thesis was a thematic analysis. A thematic analysis is a common tool used for data analysis in qualitative research and is about the identification of patterns in the data that can be further categorised into themes (Bell et al., 2022). Moreover, Bell et al. (2022) explains that identifying patterns in data using a thematic analysis implies looking for repetition, typologies, categories, analogies, etc, with looking for repetition being the most common approach in qualitative research. Hence, the strategy of primarily looking for repetition in the data set was also utilised in this thesis. Looking for repetition in this context means trying to identify topics or patterns that recur multiple times in the data set (Bell et al., 2022). This strategy formed the baseline of the thematic analysis approach used in this thesis.

In particular, the thesis followed a similar data analysis structure as the thematic analysis proposition made by Gioia et al. (2013). This approach follows a three-step analysis of the data set, categorising it into first-order codes, second-order themes, and global themes. The first-order codes are the outcome of an interview coding process (explained in greater detail below), where valuable interview data segments are highlighted for further analysis. The second-order themes are the result of grouping several first-order codes into overarching sub-themes in the data set. Lastly, the global themes are synergies of the second-order themes, spanning over the entire data set and representing the final abstraction level of the data analysis process (Gioia et al., 2013).

Interview Coding

Interview coding is a common tool for structuring and analysing qualitative data (Ritchie et al., 2013). The process is carried out by performing the activities of labelling, separating, compiling, and interpreting the data set (Bell et al., 2022). This is done with the help of codes, meaning relevant information about concepts, quotes, and other valuable parts of the interviews is coded through colour labelling as a way of highlighting its importance in the analysis. This process was carried out in Microsoft Word and the information was compiled in sections allowing for the identification of themes and patterns in the data. This allowed for a systematic interpretation of the interview data which increased research validity. However, it should be noted that the process of standardising the collection of data through qualitative research is difficult, which necessitates that the researchers have a clear vision of their data analysis at all times (Bell et al., 2022). Hence, it is important to acknowledge that this step of the data analysis is time-consuming, and assuring that it is completed carefully is vital. Therefore, both researchers proofread each other's codings to guarantee their accuracy and relevance to the study, increasing research validity in the process.

Affinity Diagram

The last part of the data analysis process involved visualising the highlighted codes from the interview coding in order to structure the data around common themes and patterns. To facilitate this process, an Affinity Diagram was used. An Affinity Diagram is a hierarchical way of structuring and representing data commonly performed in four steps, *note making*, *note grouping*, *labelling*, *grouping of labels chart making*, and *explanation* (Lucero, 2015).

The Affinity Diagram methodology was carried out digitally in a co-operated program called Canva and the process was performed as follows. In the first step, *note making*, notes with names representing the identified codes in the interview coding process were created. Next, in *note grouping* all individual notes containing codes from the interviews were shuffled together and iteratively rearranged until note clusters were formed. In the third step *labelling*, a label symbolising the theme of each cluster was created. In the fourth step, *chart making*, each note cluster's relation to other clusters and themes was arranged with the help of symbols and signs showing the connection and interdependencies between them.

Lastly, in *explanation*, the produced note chart was explained and commented on by each of the researchers, assuring equal perception and unity in the produced data structure. The resulting Affinity Diagram is presented in Appendix D.

3.6 Research Quality

When planning a research project, it is important to include quality criteria to ensure the scientific integrity of the study and maintain a high research quality (Bell et al., 2022). In business and management research, Bell et al. (2022) explains that such quality criteria commonly are evaluated through ensuring research *validity*, *reliability*, and *replicability*.

Validity is a criterion that concerns the validity of the researcher's conclusions and is often measured in terms of credibility, transferability and dependability. These criteria cover the integrity of the conclusions, and how the findings can be applied to other contexts and in other situations (Bell et al., 2022). Furthermore, reliability is concerned with the reliability of the results, ensuring the results of a study remain consistent under the same circumstances. Additionally, replicability is concerned with the ability to reproduce a study's findings under similar conditions, ideally yielding consistent conclusions (Bell et al., 2022).

However, it should be noted that Bell et al. (2022) further explains that the above-mentioned quality criteria are mainly geared towards quantitative research since the criteria in many ways are concerned with the adequacy of measurements, which characterises quantitative research. Hence, multiple scholars have highlighted the difficulties of accurately assessing the quality of the in-nature subjective qualitative research (Bell et al., 2022; Tracy, 2010; Yadav, 2022). To resolve these issues, Lincoln and Guba (1986) proposed alternative quality criteria for qualitative research using the trustworthiness framework, constituting the evaluation criteria of *credibility*, *transferability*, *dependability*, and *confirmability* (Bell et al., 2022; Yadav, 2022). Since this thesis employed a qualitative research strategy, its research quality was described and evaluated using the trustworthiness framework.

Credibility aims to examine how believable the results obtained from a research project are (Bell et al., 2022). A common way of assuring credibility is through triangulation. Triangulation means contrasting multiple data sources against each other to develop a comprehensive understanding of the result (Patton, 1999). In qualitative research, this can be done through comparing findings from interviews with observations and existing literature (Bell et al., 2022). In this thesis, it was not possible to perform observations which limited the data collection methods to interviews and a literature review. To minimise the effects this may have on research credibility, both the technical and business literature of AM, as well as interviewing two distinct interview groups was done to ensure a comprehensive understanding of the findings.

Transferability refers to how applicable the findings of a study are in other contexts (Bell et al., 2022). To increase the ability to transfer and generalise the findings of this thesis to other contexts, firstly the employed research methodology was thoroughly explained. Each step of the research process has been described in detail to maximise the ability of other studies to generalise its results. Secondly, several aspects of the study have been described and narrated in detail. This includes descriptions of the medical industry, the AM industry, a clarification of the empirical context of RISE and the request by MSB to investigate how AM can be used to aid emergency manufacturing in healthcare. This was done to highlight the context of the study, which increases transferability according to Yadav (2022). It should be noted that the empirical context of this research being in collaboration with a state-owned company on behalf of a government agency complicates the transferability of the study. However, findings from this study of how AM can be used for

emergency medical equipment manufacturing in healthcare from a broader perspective may be generalisable to countries in similar situations or other areas in healthcare.

Dependability refers to making sure that the conducted research is trustworthy. This is often done by employing an audit trail approach, meaning complete records of field notes are preserved and easily accessible (Bell et al., 2022; Yadav, 2022). Hence, to achieve adequate dependability in this research, several measures were taken to allow for auditing of the research process. The problem formulation of the thesis was stated and stored early, the selection and categorisation of interview participants were documented, notes of ideas and questions were documented in a field log, and the data analysis process was kept intact, as well as the recordings and transcriptions of interviews were saved until the research was completed.

Confirmability refers to taking actions towards minimising potential biases in the research to uphold scientific objectivity (Bell et al., 2022). However, Bell et al. (2022) describes that it is important to acknowledge that achieving complete objectivity is difficult in qualitative research due to its subjective nature, and instead highlights that achieving sufficient confirmability is done by assuring that the researchers have acted in good faith throughout the research process. Actions towards minimising biases were taken in the data analysis process of this research. The data analysis process followed the structured thematic analysis approach proposed by Gioia et al. (2013), where the data was analysed and categorised into three orders of themes. Moreover, each researcher proofread the other's interview codes and each note in the data visualisation process was carefully explained to ensure equal perceptions. Additionally, the thesis was peer-reviewed by colleagues with a neutral stance on the conducted study, meaning they did not have a stake in the research. This allows for objective feedback on the findings to limit the researchers' bias, which strengthens research confirmability (Yadav, 2022).

3.7 Ethical Considerations

In a research project, it is important to critically evaluate ethical considerations. Assessing ethical aspects is crucial to ensure adequate accuracy and trustworthiness of the collected data (Bell et al., 2022). Moreover, addressing ethical issues of the research also upholds the integrity of the scientific method and safeguards the interviewee's rights (Bhandari, 2021). Failing to adhere to ethical research practices can lead to misleading or faulty results, which can decrease the quality of the research. Bell et al. (2022) highlight four ethical aspects geared towards the research methodology of a study that should be taken into consideration in business research, namely *harm to participants*, *lack of informed consent*, *invasion of privacy*, and *deception*. Hence, these aspects were considered when performing this thesis's methodology, and are described in greater detail below.

Harm to participants is described by Bell et al. (2022) to include many aspects of potential harm to participants, such as physical harm, stress, or harm to the participant's personal development. To minimise the risk of putting the participants under unnecessary stress, a thorough explanation of the purpose and relevance was given to the interviewees when they were first contacted by e-mail. The participants were initially contacted via e-mail early on in the study to provide them with the opportunity to pick an interview date and time immediately or later depending on their preference. The participants were also given the option to choose whether they wanted to perform the interview in person or online. Moreover, it was of high priority to ensure the full anonymity of the interviewees to mitigate the risk of leaking their identities which could potentially harm their personal development. Company or hospital names have been anonymised and no roles or titles of the interviewees have been mentioned. It should be noted that mentioning interviewee roles or titles would have enriched the nuance of the presented findings, but preserving anonymity was chosen in order to reduce the risk of ethical harm to the participants. *Lack of informed consent* refers to not providing the participants with detailed information for them to make an educated decision of whether to proceed to participate or not (Bell et al., 2022). To mitigate this, the interview consent paper presented in Section 3.4.1 was handed out to the interviewees before the interview. In the consent paper, issues regarding informed consent were addressed by asking for permission to record and transcribe the interview, informing that their identity would be fully anonymous and that their interview data would only be handled by the researchers and deleted after the study was finished. Additionally, after the interviewees had given their consent to the

above-mentioned terms, they were also given the opportunity to choose whether they wanted to change or discard some of their statements or opinions in the interview up to a specific date.

Invasion of privacy is similar to lack of informed consent as it is about potentially private or sensitive topics to the participant that may arise in e.g. interviews and can become increasingly problematic if informed consent is not given (Bell et al., 2022). To ensure the risk of invasion of privacy of the interviewees was minimised, the documents containing the collected data and lists of interviewees in this thesis were kept private and only accessed by the researchers during the study and were deleted afterwards. Moreover, the interviewees' ability to withdraw from the study at any time before a specific date as per the interview consent paper further decreased the risk of invasion of privacy since the participants could demand that shared information they deem private be excluded from the study.

Deception refers to misleading the participants to believe the purpose of the study to be different from what it truly is (Bell et al., 2022). To mitigate the risk of potential deception, the purpose of the thesis was clearly stated to the interviewees multiple times. Firstly when making first contact with the participants through e-mail, secondly through the distributed interview consent paper, and thirdly as an introduction at the start of each interview.

In addition to the above-mentioned ethical considerations regarding the methodology of this thesis, it is also important to mention more general ethical dilemmas that can arise as a consequence of conducting this research in the field of AM and healthcare. Since this study investigates the potential use of AM as an emergency manufacturing structure for medical equipment in the event of a crisis, ethical dilemmas related to deviations from standard procedures as a consequence of the crisis may arise. Medical equipment is heavily regulated and often requires a CE mark to ensure quality and safety compliance in the European Union (Maresova et al., 2015).

However, in the event of a crisis, it could be necessary to rapidly produce medical equipment to save lives, allowing for temporary shortcuts in the testing procedures to grant Emergency Use Authorizations (EUAs) even if the medical equipment does not uphold all the regulatory requirements. Therefore, ethical concerns arise, whether deviating from regulatory compliance is the right thing to do since rapid production without regulatory compliance may save lives in the short-term, but could potentially have negative long-term health consequences that outweigh the benefits.

3.8 Societal Considerations

Since this study investigates the effects of emergency manufacturing using AM in the healthcare sector, it is necessary to consider the societal aspects and how this research affects society. The findings of this study may provide guidance and knowledge regarding what investments need to be made to strengthen the healthcare sector's resilience to potential disruptions. According to Morgan and James (2022) the return of such investments can lead to more benefits other than directly health-related. It is argued that more resilient healthcare systems enable substantial economic and societal benefits by avoiding the need for costly containment measures in potential health crises and making society better prepared overall. In addition, this can also lead to faster treatment for patients where AM could produce certain medical equipment and patient-specific parts directly, reducing the lead time from months to a matter of hours as conventional alternatives and transport times slow the process significantly (Attaran et al., 2017).

It is also important to consider the health and safety of the work environment where AM is taking place. AM with polymers often uses materials that could emit volatile organic compounds (VOCs) and other toxic vapours during the heating process which creates a health hazard. It is often required to have proper ventilation systems in place to ensure a safe work environment and protect the workers from emissions (Stefaniak et al., 2019). Furthermore, it is necessary to have proper maintenance management of the additive manufacturing equipment and operational training to ensure the staff knows the safety procedures and the competence to operate the machines. Ensuring that the manufactured part is according to specifications is critical for patient safety and regulatory aspects which is why having the right knowledge and competence in place is a crucial aspect to take into account when investigating a decentralised manufacturing structure.

The role of competence and knowledge is further needed in the event of a crisis where this becomes a critical part of enabling manufacturing capabilities.

Regarding societal considerations of the methodology used in this thesis, the interviewees who participated in the study were treated with great respect. They were given the freedom to choose the time, date and whether their interview was to be conducted in person or online. The participants were deeply thanked for their contribution to the study and were offered to have the thesis sent to them once the research was finished.

3.9 Ecological Considerations

It is also necessary to take into account the ecological aspects regarding emergency manufacturing of medical equipment using AM and how it affects the environment.

Regarding general ecological considerations, the use of AM in a decentralised structure as a complement to a conventional manufacturing structure could enable waste reduction by creating parts on demand, reducing the risk of overproduction significantly. AM technology has also developed significantly over time, opening up the possibility to optimise the geometry of the produced parts in ways that would not be possible in traditional manufacturing and incorporating new biodegradable materials (Javaid et al., 2021). However, aspects such as volume, time, machine utilisation, materials, and operating procedures are all critical when determining the environmental impact of the two structures. Faludi et al. (2015) mentions that although AM might be producing less waste per part produced, the energy use per part increases with volume and the material needed for AM could contain higher levels of toxicity in its ingredients compared to equivalent conventional manufacturing.

To compare these two manufacturing methods and their ecological impact, it is necessary to make a comparison where these aspects are taken into consideration and adjusted depending on the scenario (Faludi et al., 2015). However, it should be noted that this study primarily focuses on crisis scenarios, in which the ecological impact may be deemed less significant due to the prioritisation of patient health and safety.

4

Empirical Findings

This section presents the empirical findings obtained from the conducted interviews in this study. Firstly, a structural illustration of how the findings are connected is described and visualised. Secondly, findings regarding how AM is currently used in healthcare and in industry are presented. Thirdly, several key elements found to affect the facilitation of AM capabilities are described. Lastly, findings regarding resilience are presented and how they contribute to the coordination of AM capabilities are explained.

4.1 Thematic Analysis

This section presents the final structure of the thematic analysis. The data has been analysed and categorised into first-order codes, second-order themes, and global themes.

In total, 19 first-order codes were identified and clustered into six second-order themes, ultimately forming three global themes of the analysis. Figure 4.1 visualises the outcome of the data analysis and the connections between codes and themes. Each theme and its corresponding codes are described in greater detail in the following sections.

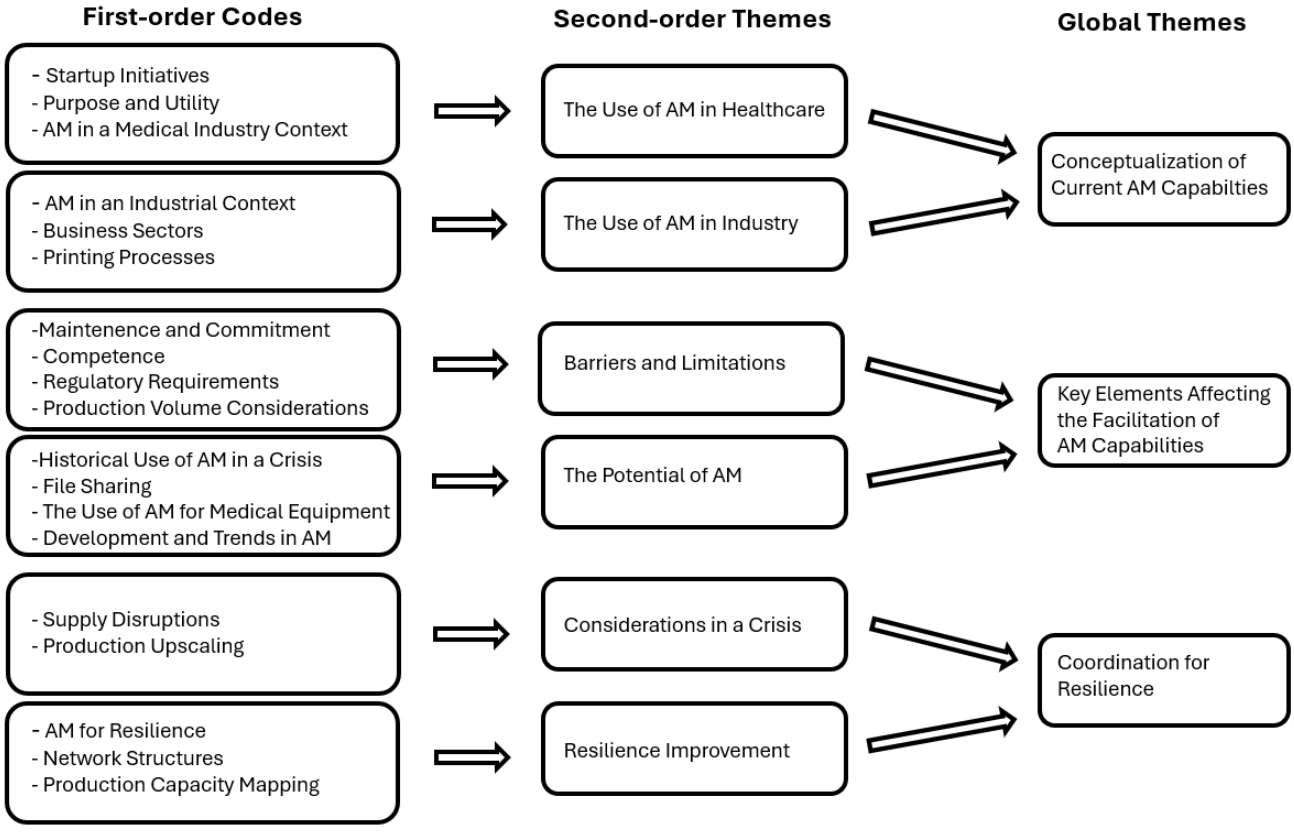

Figure 4.1: Illustration of the thematic structure of the data analysis. Source: Authors.

4.2 Conceptualisation of Current AM Capabilities

The first global theme derived from the interview data analysis is an overview of the current state of the use of AM. This is a crucial part of understanding how AM is utilised and worked with today. The empirical data obtained regarding current use cases and how AM is used in different sectors provides a baseline to further understand the capabilities of AM from a broader perspective. As visualised in Figure 4.1, this global theme is the outcome of the results presented in the second-order themes of *The Use of AM in Healthcare* and *The Use of AM in Industry*.

4.2.1 The Use of AM in Healthcare

The use of AM in healthcare is the first identified second-order theme relating to the key activities and initiatives within the healthcare sector that drive the innovation and utility of AM in healthcare. Understanding how AM is used in healthcare today opens up the possibility to assess strengths and weaknesses in the current use of AM in this sector which can then be further analysed from the perspective of producing medical equipment in a crisis. As seen in Figure 4.1, the use of AM in healthcare is a second-order theme combining the first-order codes of *Startup Initiatives*, *Purpose and Utility*, and *AM in a Medical Context*.

Startup Initiatives

Startup initiatives refers to the ideas built upon to get AM units at hospitals up and running and such initiatives explain why there is a need for AM in healthcare in the first place. The interviewees from the different hospitals answered this question rather similarly, which paints a clear picture of what initiatives drive the startup of 3D units in healthcare. The data from the interviews points to the existence of a lot of engineering competence among the workers at the hospitals. Furthermore, utilising this competence plays a key part in startup initiatives from a business perspective, as evident by this quote:

> *"We wanted to utilise the knowledge and competence of AM at the hospital instead of paying large amounts to hire external companies for the job." - H3*

The interviewee continued to describe that several units at the hospital had people who possessed engineering skills and an important driver of the 3D unit was the initiative to try and collect all in-house knowledge and make use of it. According to an interviewee, it was explained that printing and engineering competencies in general at the hospital have been important startup drivers. It was described that other departments at the hospital already utilised AM to some extent. The following quote exemplifies this:

> *"The initiative began with a mix of laboratory departments that worked a lot with 3D, and 3D has been part of other departments of the hospital already as well [...] A perfect mix of competence and use cases. -H5*

According to another interviewee, the need to support other surgical departments was often mentioned as a key initiative by providing printed anatomical models. The interviewee stated:

> *"We saw a need for an AM unit as there was a demand from surgeons to print anatomical models to get a better understanding of the planned surgery." - H2*

Purpose and Utility

Needing to understand the main purpose of the 3D units at hospitals follows naturally after the presented startup initiatives. During the interviews, the participants were asked to define what they believe is the main purpose of their 3D unit. This yielded larger diversity in the answers than for the startup initiatives, but the larger theme of aiding other departments, previously presented among the startup initiatives, is also relevant when discussing the purpose and utility of 3D units. One interviewee described how they would define their 3D unit's purpose as follows:

> *"I think our main purpose and task is to support other departments at our hospital with improved healthcare" - H1*

Other interviewees conveyed the same message of supporting healthcare but in some cases explained it more explicitly. For example, one interviewee mentioned that they are supporting other departments by providing printed anatomical models for operation planning purposes. Similarly, another interviewee mentioned that they print anatomical models as training material for surgeons. It is evident that supporting healthcare can be done in many ways but seems to be mostly focused on surgical purposes in the case of 3D units. One interviewee explained that their AM capabilities provide new methods that are not widely used yet:

> *"Our purpose is to aid in surgery but also to increase the technology level at the hospital [...] Surgeons tend to use outdated methods for surgery planning and our unit aims to use our printing capabilities to change that." - H4*

Moreover, the interview data also reveal that AM can have another purpose besides pre-operatively supporting surgeons in operation planning. One interviewee explained that their 3D unit is working to achieve additional services, including the production of medical equipment as well. To achieve this, the 3D unit's purpose also includes a plan for full-scale production by utilising a machine park, consisting of multiple printers, as evidenced by the following quote:

> *"We are in the early phases of developing a 3D unit with the purpose of providing the hospital with a machine park and design centre [...] The plan is to have our facility fully ISO 13485 certified, this will allow us to produce medical devices for personal use at the hospital." -H5*

AM in a Medical Context

After gaining an understanding of startup initiatives and purposes of the 3D units, another important aspect to consider is what distinguishes the use of AM in healthcare at 3D units from other sectors. To answer this, questions were asked to the interviewees regarding how they use AM in their 3D units. From this, this section about AM in a medical context presents information on how AM is used at 3D units, its main advantages, and what specific AM techniques are used in this context.

Regarding how AM is used in the 3D units is tightly connected to what the main purposes of the 3D units are. The data shows that a patient-specific focus is central to how AM is used in 3D units. This originates from the fact that surgical work by nature is highly patient-specific oriented. Prioritising quality over quantity is also a crucial part of how the 3D units work since there is a great need for precision in surgery and hence the printed anatomical models need to provide the surgeons with pre-operative training material of that same

precision. The patient-specific focus and the prioritising quality over quantity is exemplified by the following quotes:

"We print anatomical parts to aid surgeons [...] Our work is very patient-specific and not so much about prototyping as in industry." -H2

"We have a patient-specific focus, not to mass produce [..] You could say we work more with quality than quantity." -H1

Furthermore, the interview data also highlight what can be seen as a major advantage of conducting 3D unit business at hospitals. This advantage is about collaboration between the 3D unit workers and surgeons. Having close collaboration with surgeons both in terms of work and distance is advantageous for the 3D unit business to successfully fulfil its purpose of aiding the surgeons since they can easily conduct meetings and plan their work together. These aspects make working closely with surgeons beneficial compared to outsourcing the service, as evident by the following quote:

"We see great benefits in working in close proximity to the surgeons, we sit together and plan which is advantageous compared to sending the details to an external company [...] If the surgeons need to change anything they can just come by us, it would not be that easy if you worked with an external company." -H8

Additionally, one interviewee also explained that they work as closely as possible with the surgeons by installing their workspace in the same corridor as the surgeons. Another interviewee highlighted the large information exchanges that can be made when working near surgeons as advantageous since they can discuss and work with trial and error to develop the most user-friendly anatomical training model possible. Lastly, one interviewee commented that their close collaboration with surgeons has helped them get the attention of doctors in other departments as well. This shows the impact this tight collaboration can have in positively branding the image of the 3D unit, paving the way to further expand the business at other parts of the hospital.

The last part of understanding how AM is used in a medical industry context at the 3D units is about what types of AM techniques are being used and why they are used. Table 4.1 summarises what AM techniques are used in the different 3D units. The interview data shows that FDM is the most frequently used technique in the 3D units. This is because the technique is cheap and the printing process is relatively fast, as depicted by this quote:

"We mainly use FDM for anatomical models because it is a relatively fast and cheap technology." - H4

FDM was also explained to be relatively easy to learn compared to other AM techniques. Hence, the 3D units mainly use FDM for printing basic anatomical models for the surgeons to get a quick overview in the surgery planning phase. These are non-clinical prototypes for the surgeons to practice on, as evident by the following quote:

"We use FDM for non-clinical purposes as test models for the surgeons to practice on." - H3

In the interviews, it was also explained that the 3D unit workers know that FDM yields a lesser degree of precision than other methods, but that it is sufficient for rough training models for surgeons. Moreover, the interview data also show that some 3D units also use SLA, since it yields higher precision than FDM and is thus better suited for printing more complex anatomical parts where high precision is necessary. SLS also yields high precision but comes with some complications. Some interviewees explained that since SLS is a powder technique, special rooms with sufficient ventilation are needed for printing with this technique. The data indicates that such facility requirements are not met by the 3D units. However, one 3D unit worker explained that their facility does not meet the requirement for SLS but they still use it via outsourcing, as seen from this quote:

"We cannot use SLS in-house at the moment due to insufficient facility spacing and ventilation requirements [...] As of now we order SLS from a subcontractor." - H2

Table 4.1: *Number of 3D units using each AM technology.*

AM technology	# 3D units using the method
FDM	3/3
SLA	2/3
SLS	1/3

4.2.2 The Use of AM in Industry

The use of AM in industry is the second identified second-order theme that relates to understanding how AM is used from an industrial perspective. Having an industrial perspective on the technologies being used, what sectors AM is used in and understanding their work processes becomes necessary to further investigate the enabling factors of AM and how AM can play a role in increasing supply chain resilience in a crisis. This second-order theme encompasses the first-order codes of *AM in an Industrial Context*, *Business Sectors*, and *Printing Processes*.

AM in an Industrial Context

AM in an industrial context refers to the additive manufacturing technologies being used in an industrial context. Table 4.2 shows the frequency of specific AM technologies used by the interviewed companies. When asked about which AM technologies were used by the companies, the respondents mainly answered SLA, SLS and FDM, with some companies also mentioning the use of sub-technologies, including PolyJet and MJF.

One of the interviewees emphasised that it is important to remember that not one technology is necessarily better than the other, it merely depends on the requirements of the product and what environments it is supposed to be used in.

"There are no bad production methods, they (the AM technology) are simply good at different things" and "[...] it depends on the required properties of the component, its use case, [...] and cost of course." - C8

Operating AM machines with different technologies can be a complex task that requires strategic planning for controlling the production process and having an efficient workflow. One respondent explained that: *"we are working with FDM, SLA, SLS and other AM techniques but that they are strategically spread out at different sites to operate more effectively." - C5*

Another respondent from a different company under the same corporate group further elaborated that having different sites is partly because each technique uses different materials that are not readily available at all sites.

> *"There is an abundance of different materials but we can't have them in the same place. For example, you might have certain materials in [location X]. There is not enough [material] for all sites to carry, so if we need to print in a specific material, we order from sites in these regions." - C7*

Furthermore, the same respondent explained that professional equipment has higher requirements for the facility in terms of space, ventilation and control of the process.

> *"[...], So it depends a lot on the printing technique, a lot of the professional machines require more in terms of larger facilities, ventilation and control of the process and so on." -C7*

Table 4.2: *Number of companies using each AM technology.*

AM technology	# Companies using the method
SLA	5/5
SLS	4/5
FDM	4/5
Polyjet	3/5
MJF	2/5

Business Sectors

Business sectors targeted by companies that use AM offer insight into the current scope of the technology. Sectors can have very different requirements depending on the use case and type of product. Despite this variability, the interviews provided a broad range of applications for AM as every company was present in several different sectors. One of the respondents said that:

> *"We work toward all sectors, it can be anything from a private individual with a unique idea to revolutionise the world that wants a small prototype, or some of the largest companies in Sweden." – C7*

This statement was further corroborated by a respondent at a different company who also mentioned that they work: *"[...] toward a mix of industries, anything from consumer products, electronics to aerospace".*

The findings showcase the increasing variability of AM technology which was further explained by a different respondent:

> *"We work towards anyone who needs a physical visualisation of a design or anything. Initially, 3D printing was mostly for prototyping, and it's still a lot of prototyping because people want to see and feel their design but it is moving more towards end products." – C4*

The interviews highlighted a distinction between companies that offer AM as a service and those solely utilising AM for internal production. The interviews showed that companies offering AM as a service include private individuals in their customer base whereas the other companies only target businesses. A respondent from one of the companies said that: *[...] it's not a specific sector that we target, we are everywhere. We have a lot of small customers rather than focusing on a few large companies, and we also work with both private individuals and companies."*

One interviewee clarified that their products are exclusively sold to companies as end-users. Another respondent said that: *"We only sell to companies, not private individuals. Although our main focus is manufacturing companies, we have also sold to other industries like hospitals and everything else you can think of."*

Printing Processes

The printing process for AM service providers relates to understanding how these companies work with their customers to print unique and specialised parts. Understanding this process achieves two objectives, mainly the workflow of working with additive manufacturing but also the knowledge to interact and collaborate effectively with AM service providers.

Data collected through interviews revealed a consistent core process for most AM service providers. However, some variations exist depending on the customer type. A majority of the companies offering AM printing services explained that customers often have a CAD file of the desired part ready to be printed. However, for some situations, such as when a private individual requires a new prototype, some of the AM service providers offer the development of a CAD model before printing them. While not all companies offer to create a new CAD model, most companies did offer consultations to discuss potential modifications that are needed for printability or optimising the design.

Following the review and potential changes to the CAD file, the AM company as phrased by one interviewee: *"calculates the dimensions, material usage and printing costs before sending a final quotation to the customer."*

4.3 Key Elements Affecting the Facilitation of AM Capabilities

The second global theme derived in the data analysis process highlights key elements determining the effective utilisation of AM capabilities. These elements include both the pros and cons of the AM technology that are important to consider before assessing the role AM could play in emergency healthcare manufacturing in a crisis. As seen in Figure 4.1, this global theme is composed of the second-order themes of *Barriers and Limitations* and *The Potential of AM.*

4.3.1 Barriers and Limitations

Barriers and limitations refer to various types of hindrances blocking the effective use of AM. These barriers and limitations are present in some capacity both in 3D units at hospitals and in companies working with AM

in the industry. This second-order theme examines the first-order codes of *Maintenance and Commitment*, *Competences*, *Regulatory Requirements*, and *Production Volume Considerations*.

Maintenance and Commitment

Maintenance and commitment include issues both at 3D units and in the industry regarding the consequences of poor maintenance of 3D printers and insufficient commitment to the printing process. Firstly, the findings show that such issues can be present at companies working with AM, where a lack of dedicated people operating the printers can make buying expensive printers a suboptimal investment due to prolonged machine downtime. One interviewee phrased this in the following way:

> *"You need to have someone dedicated who use the printers. Some companies buy expensive printers but does not have a dedicated person to use them, so the printers end up collecting dust instead." - C7*

Secondly, the data also suggest that similar scenarios of machine downtime due to commitment issues may also be present in 3D units. Overambition in printer and material investment while overlooking dedication issues may lead to problems down the line, as evident by the following quote:

> *"One of the mistakes many make is that they invest in many printers and materials before they know what they want to use them for, so they end up with three machines working and five being idle but still requiring maintenance. It's a large investment cost. " - H5*

Lastly, the final dedication-related issue that was identified from the interviews is an issue exclusively facing the 3D units at hospitals. Although the strong collaboration between 3D units and surgeons was previously highlighted as an advantage in the section describing AM in a medical industry context, there seem to be disadvantages in this collaboration as well. Two interviewees explained that the surgeons are often busy and stubborn in their way of working, which can impact their dedication to novel initiatives like collaboration with 3D units, as evidenced by these quotes:

> *"Surgeons are very busy so you need to have constant contact with them or else they will not use our printing capabilities." - H2*

> *"You have to make sure the surgeon is "hooked" and interested to try and learn this new way of working. It takes time and effort which is something the surgeons do not always have." - H7*

Competences

Competences in this setting refer to important knowledge and skills useful when working with AM both in industry and in healthcare. The interview data shows that possessing key competencies related to AM comes in varying degrees, meaning some competencies are easier to master whereas others are more difficult to learn, making them barriers that need to be overcome for the effective use of AM technologies.

The most frequent competencies deemed important to possess according to the interviewees are construction thinking and CAD drawing knowledge. Construction thinking was described by interviewees from the industry to be a rather simple competence to master, given that you have previous experience in the industry. It was explained that printers in essence are very similar to operate to other manufacturing machines, which is why industry experience can take you a long way in AM as well. The following quote shows how an interviewee from the industry explained this:

"Knowing CAD is crucial, the printers are fairly easy to operate but you need general construction thinking." - C4

As previously mentioned and evidenced by the quote above, the next important competence derived from the findings is that possessing CAD knowledge also is key when working with AM. Several interviewees highlighted that it is crucial to know CAD when working with AM, explaining it to be the "backbone" of the AM process. Moreover, some interviewees also emphasised material knowledge as important in combination with CAD skills, where one 3D unit worker explained it as important to know how materials behave to make rigid anatomical structures for surgeons to practice on.

Lastly, the data also suggests that apart from general construction thinking, competence in DFAM is also highly relevant. The interviewees explained that DFAM is more complicated to learn and more technical competence demanding, as it is about optimising the use of AM through various factors. This optimisation is done in terms of material usage, time, and waste, but also in terms of cost and knowing when AM might not be the best option. One interviewee described it as follows:

"DFAM requires an open-minded production thinking to minimise waste but also knowing when to use AM or other production methods." - C8

Regulatory Requirements

Regulatory requirements refer to the need for compliance with regulations, which can hinder the effective utilisation of AM both in industry and healthcare. According to the interviewees, complying with various ISO standards remains complicated but necessary to get a CE mark, which is required for most medical equipment.

It was found that most AM companies that only manufacture prototypes or designs for other companies did not work actively with regulatory requirements since the certification processes were often conducted by their customers. However, a few companies that produce medical equipment directly for consumers require them to have regulatory competence in-house, as evident by this quote:

"We do CE marking in-house. [...] We have to comply with several ISO standards e.g. product development, quality, biocompatibility, and risk handling."- C3

Recalling what one 3D unit worker mentioned in Section 4.2.1 regarding their purpose and utility that they require ISO 13485 (quality assurance for medical equipment) certification to be able to scale up and produce medical equipment, the following quote from another 3D unit explains the limitations of not meeting such requirements:

"When it comes to medical equipment, regulations are a big obstacle. [...] Due to regulations, we cannot produce medical equipment on a larger scale, only small quantities of replacement components."- H4

Additionally, it was explained that there are production volume regulations put in place at the hospital where this 3D unit operates, meaning even if they were able to, they are not allowed to mass-produce on an industrial scale. This further complicates the 3D unit's ability to mass-produce medical equipment in the case of a crisis.

Production Volume Considerations

Production volume considerations refer to the dilemma of trying to achieve cost-effective production in the context of production volume. The findings show that AM seems to be disadvantageous when large production volumes are needed. This was reported both by AM companies and 3D units, suggesting it to be a well-known limitation of AM. This seems to be most prominent in industry since companies tend to favour traditional manufacturing methods over AM in the case of high volumes. An interviewee from the industry explained it like this:

"Injection moulding is dominant at higher volumes since the cost per article is significantly lower than for AM."- C5

Regarding the current purpose of 3D units, their patient-specific way of working emphasising quality over quantity when aiding surgeons, does not seem to be as affected by volume considerations as companies in industry are. This is exemplified by one 3D unit worker who indeed acknowledged the advantage of injection moulding over AM at high volumes, but simultaneously pointed out that it does not affect their business:

"Certainly high volumes favour injection moulding but in our case, the anatomical models are all unique which is why AM is perfectly suited for it."- H4

4.3.2 The Potential of AM

Understanding the potential role of AM in an emergency manufacturing structure for medical equipment necessitates great insights into the capabilities and requirements in a medical setting. This section presents the potential of AM by examining the first-order codes of *historical Use of AM in Crisis*, *File Sharing*, *The Use of AM for Medical Equipment*, and *Development and Trends in AM*.

Historical use of AM in a Crisis

The historical use of AM refers to how AM has been used in healthcare during previous crises to provide insights as to how mature the technology is in this setting. From the interviews, most manufacturing companies explained that they were operational with AM and produced visor holders and respirator components for the healthcare sector when these items were facing shortages.

One of the respondents explained that:

"We had an employee that designed the visor holders which can be a challenge depending on the technique being used but we shared the files so anyone could use it. [...] There were plenty of companies that used this [file] and also worked to create moulds for IM just to make sure they [the parts] got out in sufficient quantities and fast." - C4

The 3D units that were operational during the pandemic only used AM for anatomical models that were used to provide a visual representation of a patient's surgical target for pre-operative discussions. It should be noted that most 3D units were either not operational during the pandemic or to a very limited degree.

File Sharing

File sharing is a unique aspect that distinguishes AM technology from traditional manufacturing methods. With AM, a printer equipped with the necessary materials and an operator can produce a wide range of parts, requiring only a CAD file for the specific part. This ties back to the work process but with a greater focus on the potential of file-sharing.

In today's interconnected world, these CAD files can be shared over the internet in seconds, enabling global collaboration opportunities and on-demand production where the parts are needed. From the interviews, it was explained that a crisis comes with a great deal of uncertainty where you never know what type of product or component is needed, and therefore AM could enable a diverse production capability at the specific location where these parts are needed. One interviewee said that:

"Nothing says that the next crisis will be another pandemic, a COVID. It could be a large fire, an oil leak, or anything which requires different treatment options and thus different types of equipment. We never know what we will need for the next time, that's the problem. [...]. Assuming the AM technology is approved for clinical use, the technology can manufacture many types of products and transition quickly." - H9

Companies were also asked about potential challenges when receiving a CAD file. All interviewees agreed that as long as the CAD file and part were suited for the specific AM technology, it would work without any major adjustments.

One interviewee explained:

"You just need to send the file and make sure the AM machine is loaded with the right material, it doesn't matter if it's located in Australia, Buenos Aires or Sweden." - C4

The Use of AM for Medical Equipment

The use of AM for medical equipment is concerned with the technological feasibility of producing various types of medical equipment using AM.

According to the interviews, most agreed that SLS and SLA are the most suitable AM techniques to produce medical equipment due to their selection of biocompatible materials, physical properties of the printed product/part and smooth surface finish. One interviewee said that:

"SLS and SLA are best suited for end products as they have biocompatible materials. I would say SLS is probably the most favourable technique for a final product that needs to be

mass-produced [for repeatability]. [...]. SLA is suitable where you want high surface quality and details, there are also biocompatible materials for these machines. [...]. FDM is traditionally more for prototyping and although they are great and cheap, their repeatability is not very good. So it depends on what requirements you have." -C4

Another interviewee further explained that it depends on the type of setting the part should be used in and what the requirements are:

"It (the AM technology) depends a lot on the application, sometimes there might be requirements on the product being autoclavable and non-porous or if they are going to be used in clean room environments, and for this, resin-based is great as it is waterproof if I can express it like that and has an extremely smooth surface finish thanks to its high resolution." – C8

The different 3D unit's experience with AM brought the same perspective. They explained that for parts requiring biocompatibility, larger quantities of identical parts and sterilisation, SLS and SLA were the only options. Apart from biocompatibility, sterilisation was one of the key concerns for parts that require sterilisation before use. According to the interviews, these parts require autoclavable materials, meaning that they can withstand high temperatures and pressure which is not possible with FDM as it is a thermoplastic.

However, FDM's limitations do not negate its usefulness in the production of some medical equipment. Interviewees explained that FDM is a great technique for applications that are non-invasive or lower-risk components where biocompatibility and high sterilisation standards aren't crucial. One interviewee explained that:

"I think FDM is quite underrated today, it is a common misconception that the technology has a very poor resolution and thus poor accuracy, but that depends more on the type of machine you use. Many of our customers say that it's difficult to find a better production method with better tolerances than a high-end professional FDM printer, so high resolution and high accuracy do not have to mean the same thing." - C8

It became clear from both the 3D units and AM providers that all AM techniques could technically be used for manufacturing medical equipment but that it depends entirely on the specific type of equipment and the requirements of that part. Therefore, the choice of technology comes down to the product's use case, material limitations, desired mechanical properties and any post-processing needs. An interviewee explained that:

"The use of different AM technologies varies greatly depending on the use case, medical equipment is being produced in all kinds of AM technologies. [...], It all comes down to the requirements from the customer and the product, what mechanical stresses it must be able to handle, what temperature interval it can be used in, if it needs to be resistant to chemicals and so on." – C7

Development and Trends in AM

Development and trends in AM relate to understanding what the current trends are for AM in manufacturing but also the technological advancements to provide context as to where the technology is headed.

To understand the growth trend of AM, interviewees were asked if they had seen an increase in AM use today compared to previous years. Every participant agreed that the use of AM is constantly growing each year and that they are identifying new areas of applications in both the medical industry and in an industrial context. One of the main reasons for the increased growth and awareness has been the availability of AM machines that have become more affordable, easier to use and becoming more technologically advanced. Creating physical prototypes is arguably one of the most common applications for AM according to the interviews where AM can offer fast prototypes with great surface quality. One interviewee explained that:

"In small volumes, AM offer incredible flexibility compared to injection moulding because you do not need to develop and create new moulds. AM is also capable of producing several different parts at the same time." - C8

Another interviewee explained that:

"The use of AM increases all the time. [...], you should never say never, but I doubt it will ever become as large [part of manufacturing] as injection moulding. We are seeing more products though that are currently injection moulded but could be made with AM instead." - C7

The 3D units explained that they are finding more areas where AM could play a beneficial role in the healthcare sector. Today, it is mainly used to make anatomical models that can be used to plan surgeries and print drilling guides to increase the accuracy and safety of operations procedures. However, they explained that they are discovering more applicable areas in multiple departments such as orthopaedic, maxillofacial, neurosurgery, vascular surgery, plastic surgery and radiotherapy.

One interviewee explained that:

"We are seeing a noticeable increase [in the use of AM]. We are trying to increase our business case by showcasing our potential. One of the exciting things about customer inquiries is that they often reveal new applications for 3D printing. As people reach out to us with their specific needs, we're able to identify more and more ways that we can help." - H1

Two of the respondents explained that AM is rapidly advancing with machines becoming faster, more precise and capable of printing larger parts. However, the selection of materials available was said to be the fastest-growing segment. One of them explained that:

"The technology is rapidly advancing but mostly in the selection of materials. There are not only more and more materials available, but the requirements and datasheets are becoming increasingly detailed. [...] A challenge that comes with this is the fact that we need to prove to the customer that the new material works for their design." - C8

4.4 Coordination for Resilience

The third and final global theme derived from the data analysis process showcases the importance of coordination to achieve resilience. This global theme covers the second-order themes of *Considerations in a Crisis* and *Resilience Improvements*, highlighting what needs to be considered and what needs to be implemented to reach effective coordination of AM capabilities.

4.4.1 Considerations in a Crisis

After assessing the potential of AM and the barriers and limitations hindering the effective use of the technology, it is necessary to gain an understanding of important considerations in a crisis scenario. This second-order theme therefore aims to present two dimensions identified from the data regarding what the interviewees view as important metrics to consider in a crisis, those being the first-order codes *Supply Disruptions* and *Production Upscaling*.

Supply Disruptions

Supply disruptions refer to how 3D units and AM companies deal with logistical challenges in the case of a crisis. To collect data on this, the interviewees were asked to describe how they acted and what logistical outcomes they saw based on experiences from the COVID-19 pandemic. Based on this, the interview data suggests that AM companies fared fairly well during the COVID-19 pandemic in terms of logistical supply disruptions, whereas hospitals were more impacted. A majority of the AM companies reported that they saw no major supply chain disruption leading to material shortages during the COVID-19 pandemic. The data shows that there are two key reasons for this. Firstly, the AM companies mostly procure their material locally or from Europe at the furthest, suggesting they hence avoided the supply challenges of procuring from China during the pandemic, as evidenced by this quote:

> *"We saw no major disruptions of material supply during Covid. We have local suppliers and we do not buy from China."– C7*

Secondly, AM companies in some cases seem to have pre-made agreements with their material suppliers, meaning they are guaranteed to receive material deliveries even in the case of a crisis. The following quote exemplifies this:

> *"We have an agreement with our suppliers guaranteeing us to receive a certain amount of material each month. [...] If it were to material shortages we have priority on material supply."– C5*

Regarding the 3D units at hospitals, the interviewees mentioned that their 3D businesses are relatively novel initiatives and therefore they were not operational during the COVID-19 pandemic. However, some of the interviewees worked in hospital settings during the pandemic, meaning they could provide insight into potential supply disruptions affecting healthcare during this period. The interviewees explained that they saw shortages in the supply of medical equipment which led to items having to be sent between facilities to meet demand or even to be bunkered to not run out completely. One interviewee pointed out that this was a multinational problem by explaining that countries with domestic medical equipment manufacturing capabilities prioritised production for their home country, which negatively impacted Sweden as per this quote:

"The countries that had domestic manufacturing prioritised their medical devices to their home country. But even then, component shortages resulted in shortages even in those countries. [...] Since Sweden lacks these manufacturing capabilities, we had a complete shortage."– H9

Production Upscaling

Production upscaling refers to how 3D units would scale up their operations in the case of a crisis and what that would entail. Questions were asked to the interviewees in the 3D units regarding how they would manage to scale up and steer their production toward producing medical equipment instead of anatomical models in the case of a crisis. From the retrieved data on this subject, production upscaling seems to entail financial-, administrative-, and regulative challenges for the 3D units.

The administrative challenges were described as involving reassuring management that a scale-up is necessary and profitable, in order to get the management onboard on the initiative. Moreover, the data suggests financial challenges are a direct consequence of getting the management on board or not since this would determine the approval of additional funding. Increased financing was described as required for the 3D units to invest in more printers, materials, and personnel for scale-up initiatives to work. Lastly, a majority of the interviewees of the 3D units explained that regulations would be a challenge if they were to scale up their production in a crisis. This ties back to Section 4.3.1 about barriers and limitations of AM utilisation, further demonstrating the impact regulatory requirements have in the medical industry. The following quote from an interviewee further highlights this dilemma:

"A big challenge when opting to expand our 3D initiative would be tackling the regulatory work. We need to follow the rules set up by the Socialstyrelsen regarding what products we are allowed to produce."– H3

4.4.2 Resilience Improvements

This section explores the diverse ways that AM technology can be leveraged to achieve resilience improvement in healthcare supply chains. To gain a comprehensive understanding of how AM technology could operate within a crisis setting, the interviews utilised more general and open-ended questions. This approach encouraged interviewees to share their experienced insights and perspectives on the role and impact of AM technology during critical situations. This section examines the first-order codes: *AM for Resilience*, *Network Structures*, and *Production Capacity Mapping*.

AM for Resilience

AM for resilience relates to understanding how AM could be used in the healthcare sector to improve supply chain resilience in a crisis. To gain insights as to how AM could be used in a crisis, open-ended questions were asked to both 3D units at hospitals and companies that work with AM.

From the interviews, the majority saw AM as a potential manufacturing method that was well suited for a crisis setting thanks to the technology's flexibility and rapid transition times. One interviewee explained that:

"A lot of components could be produced with AM, and most likely will be made with AM in the future. Furthermore, short lead times by being able to produce at the hospitals would be advantageous given that a crisis could disrupt logistics." - H4

One interviewee also mentioned that having AM technology readily available is not only a possible complement for manufacturing in a crisis, but a necessity. AM could not only be used to produce medical equipment but also spare parts or components that are needed for the hospital to remain operational. The interviewee gave an example of how AM has been used in the military to provide spare parts and explained that "Having AM as a possibility to print spare parts or components that are needed could save enormous time to get things back running".

Three companies with AM today also mentioned that they are not utilising their entire production capacity and are able to scale up volumes significantly. One of the companies said:

"During a crisis, we could amp up our volumes significantly. Today, our machines are not running 24/7, if we streamline our process and make it more effective, we could run 24/7 at full capacity." - C5

However, some interviewees were still hesitant if AM would be sufficient to increase resilience in a crisis because of the limitations regarding mass production. The interviewees instead saw it as a potential compliment to existing manufacturing capacity that could provide further benefits by being decentralised. One of the interviewees explained:

"I see AM more as a short-term bridging solution. AM can be used initially to see how the demand changes, but once you need high volumes, it's better to create a tool for injection moulding and mass produce. Creating a tool these days does not take too long either depending on the complexity of the product." - C6

It is also important to note that centralised mass production might not always be a viable option in a crisis setting due to the risk of logistical disruptions. This was said to be one of the key aspects of AM, that it enables a decentralised production capability. One interviewee said:

"In a crisis where logistics are disrupted, it doesn't matter if you have a centralised production site that can supply the entire country in volume if the products cannot get to where they are needed." - H9

Network Structures

Network structures refer to different types of network structures that could be utilised with AM technology. The flexibility of AM opens up new possibilities for coordinated decentralised manufacturing, a concept that was believed to be highly effective in a crisis setting according to the interviewees.

Most of the interviewees were unanimous that different AM sites could coordinate as a network since there are printers scattered throughout the country. However, they did express that not everyone is qualified to produce certain products. One interviewee from a 3D unit explained that to manage a network structure with AM and ensure the safety and efficacy of the printed product, you must divide the work depending on capabilities, experience and regulatory requirements.

"To handle networks with AM, you must identify the low-hanging fruits. For example, if a site in [location X] only has a limited production capability, it should focus on simple components that are of a lower [regulatory] class and let experienced printers handle the more complex products." - H5

This was further corroborated by several manufacturing companies who said that their experience and expertise should be used to consult and manufacture complex products whereas AM sites with less capabilities should manufacture simple parts and components. One of the companies said:

"It's important that the person operating the machine knows how to calibrate it, see if there are some defects in the surface quality and how to fix them. You also need to ensure there is competence to handle potential post-processing techniques." - C5

Another aspect that was brought forward by an interviewee in the healthcare sector was the fact that it would be difficult for a 3D unit to have all the different types of materials needed to make a variety of different parts. The interviewee explained that:

"We live by JIT, Just-in-time which means we purchase what we need in the short term. But the problem is storage, we do not have storage [...], since we don't know what would be needed, we would need to store all types of different material. It would have been beneficial but we do not have enough space." - H9

An interviewee from a company also explained that AM supply chains are different from traditional manufacturing techniques because they are not at the same scale. The interviewee said:

"The supply of materials is also a potential problem, companies are probably not ready for full-scale mass production using AM. So you need to take materials into account as well." - C3

To distribute the files digitally and coordinate the production between different sites, many interviewees explained that there would need to be some type of national network or web portal where all AM centres and companies that could provide manufacturing capacity could discuss and plan together. One of the interviewees from a 3D unit at a hospital said:

"It takes a long time to start a collaboration, to get routines into place, regulatory challenges and quality management systems in place. However, if you can coordinate, not everyone needs to do all these things at the same time which would free up resources and time. [...]. We need to utilise the different [manufacturing] site's strengths to eliminate any weakness in the network." - H5

Some of the companies presented proposed ideas to have a web portal to streamline production by coordinating production efforts at different sites. One interviewee said:

"It would be good to have a web portal where hospitals could list what items or components they need and then people can answer and deliver 3D models. Being able to sort the list of items based on complexity or regulatory requirements, having [CAD] files ready to be downloaded and knowing where to send them." - C6

Production Capacity Mapping

Production capacity mapping aims to provide insights into the existing AM production capacity in Sweden. Having an understanding of the production capacity that exists, knowing where they are located and establishing a network with communication is crucial for preparedness.

All of the respondents said that they are not involved in an existing collaboration with the authorities in terms of their production capacity. However, some had been in some smaller collaborations previously but for other purposes not related to AM. One interviewee said:

"We do not have a collaboration with the state in terms of our capabilities at our 3D unit. They know that we exist and that we want to scale, but that's it." - H6

Many respondents, even from companies, expressed similarly, that some authorities may be aware of their existence but do not know about their current capabilities or production capacity. As one interviewee explained:

"We have collaborated with some authorities by providing them services, but in terms of our production, they are most likely unaware of our capacity. - C4

5

Discussion

This section analyses and interprets the empirical findings of the study. The findings are discussed and related to the theoretical framework. Each global theme derived from the data analysis is discussed in greater detail in separate subsections. Additionally, a recommendation based on the derived global themes and theoretical framework on how AM capabilities should be used to increase healthcare resilience in a crisis is provided.

5.1 Conceptualisation of Current AM Capabilities

Part of the aim of this thesis was to investigate and gain an understanding of the current AM capabilities in Swedish healthcare and industry. This section highlights the findings regarding how AM is used in healthcare and industry, discusses potential reasons why AM is used the way it is, and compares the empirical findings to the theoretical framework.

5.1.1 The Use of AM in Healthcare

From the obtained interview data it is clear that in Swedish healthcare, there are 3D units specialised in AM capabilities tasked with primarily aiding surgeons in the pre-operative stage. In particular, the 3D units aid the surgeons by printing anatomical models as training material or guides for surgeons to practice on. This is consistent with the literature by Salmi (2021), where it is explained that printing anatomical models is one of the use cases of AM in the medical industry in general. Printing anatomical models is only one of many use cases of AM in the medical industry described in the literature, which might make it seem that these 3D units have a rather narrow use case. There can be several explanations for this. Firstly, 3D units are rather novel initiatives, meaning they have not been operational for a very long period. Hence, printing anatomical models can be seen as a logical first step in the business since these are the easiest to produce. Anatomical models, unlike implants, do not require sterilisation or biocompatibility as explained by Salmi (2021) and can be printed with cheaper AM techniques such as FDM to cut costs, which is explained as an advantage of FDM by Wickramasinghe et al. (2020). Secondly, the interviewees of the 3D units explained that close collaboration with surgeons is crucial for the success of their initiatives. However, the following quote from one interviewee shows that this collaboration may not always work as intended:

> *"You have to make sure the surgeon is "hooked" and interested to try and learn this new way of working. It takes time and effort which is something the surgeons do not always have." - H7*

This quote is interesting since it shows the sort of stubbornness of surgeons or healthcare practitioners in general. Van Rossum et al. (2016) explained that healthcare practitioners tend to work in silos and have their own way of working, which can be an explanation for why it is difficult for the 3D units to convince the surgeons that change initiatives with AM is worth their time. Hence, this may in turn provide a second explanation for why the 3D units mainly print anatomical models. The surgeons may prefer their own way of working with e.g. implants and medical aids and thus not see the need or be convinced enough that they would benefit from using AM capabilities for these purposes.

In addition, the following quote regarding the COVID-19 pandemic also provides evidence of the lack of ambition to change the ways of working in healthcare in general:

"At the hospital, we are in many ways back to the old ways of working. The learnings of the pandemic are forgotten. [...] There is too much focus on the financial situation in healthcare." - H9

This means the hospitals essentially have not managed the post-crisis state after the COVID-19 pandemic in the correct way. Coombs and Laufer (2018) describes in the Crisis Management Theory that post-crisis actions are crucial to facilitate organisational learning to not end up in a similar crisis scenario again. Moreover, it is also explained that the degree of learning in the post-crisis state is influenced by cultural factors in the organisation. Here, it is evident that the healthcare practitioner culture of working in silos may have impacted the degree of learning and change in the ways of working after the COVID-19 pandemic.

It should be noted that the possible connections between the limited use cases of 3D units and the ways of working in healthcare is a speculative interpretation of the findings. Additional research is needed to distinctively determine the causes of the narrow 3D unit use cases.

5.1.2 The Use of AM in Industry

Regarding the use of AM in industry, the interview data show that AM is used mainly for prototyping but that printing of end-products is a use case that is becoming increasingly popular. The following quote is a good exemplification of this:

"[...] Initially, 3D printing was mostly for prototyping, and it is still a lot of prototyping because people want to see and feel their design but it is moving more towards end-products." - C4

The use of AM for prototyping is consistent with the literature presented by Abdulhameed et al. (2019) where it is explained that AM enables frequent design changes, meaning it is ideal for testing and validating design choices in prototyping. Furthermore, the advancements of AM that are making it more common to be used for end-user products were also aligned with literature by Palanisamy et al. (2022), who explains that production improvements and new high-performance materials are capable of meeting different requirements for engineering applications.

Additionally, the interviewees from industry were from different sectors, where some explained that they use AM for their own use production, whereas others print for customer orders. The companies who print for customer orders further described that they print to a wide variety of industries and sectors. This shows the increasing variety of AM applications, which is consistent with the literature presented by Palanisamy et al. (2022), explaining that AM applications have been investigated in many different industries during recent years.

To conclude, the interview data, consistent with the literature, show that the main use of AM in healthcare is through 3D units mainly aiding surgeons by printing anatomical models in a pre-operative state. In industry, AM has a more varied use case where many different sectors use the technology mainly for prototyping but also increasingly more for end-products.

5.2 Key Elements Facilitating the Use of AM Capabilities

This section describes the elements derived from the interview data and how they affect the use of AM capabilities. The elements are compared to the existing literature, their consistency with the literature is further discussed, and some limitations and suggestions from the data are further commented on.

5.2.1 Barriers and Limitations

Regarding the potential barriers and hindrances that can limit the effective use of AM capabilities, the interview data showed that four key elements contribute to this. These elements are *Maintenence and Commitment*, *Competences*, *Regulatory Requirements*, and *Production Volume Considerations*.

Maintenance and commitment were described by the interviewees from the industry to mostly be about the lack of dedicated people operating the printers which can lead to buying expensive printers becoming a suboptimal investment. At hospitals, the interviewees from the 3D units highlighted that their main issue regarding commitment was that surgeons sometimes lack the time or interest in their AM capabilities. These commitment issues can be connected to the importance of management commitment explained in the literature by Sonar et al. (2020). Sonar et al. (2020) explains that management support is crucial for employees to understand the value of AM capabilities, which ultimately can be an explanation for the lack of dedicated people operating the printers in the industry. In healthcare, it was previously explained that working in old habits may be a reason why surgeons are not fully invested in the 3D unit initiatives. Here, a lack of management support may also be a reason why surgeons lack conviction in 3D unit initiatives. Strong management support of the 3D unit initiatives may make the surgeons see more value in them. Management needs to support and effectively communicate the important role 3D Units can play in surgery in order for the surgeons to understand its potential.

Regarding important competencies for the effective use of AM, the interviewees mentioned that knowing CAD and DFAM is necessary. These findings are aligned with the literature presented by (Shukla et al., 2018), where it is explained that CAD software is complex which stresses the need for expert designers who possess the needed competence. Moreover, interviewees highlighted that DFAM also require expert design competence and allows for design optimisation of the build leading to savings in cost, material usage, and manufacturing speed, in accordance with the DFAM theory presented by Leary (2019).

Regulatory requirements were also mentioned by the interviewees to be a factor limiting the effective use of AM capabilities. Regulations seem to mostly concern companies producing products business-to-consumer (B2C) and 3D units. That is because regulations must be complied with when producing in-house, whereas companies who produce products business-to-business (B2B) have their customers handle the regulatory work. Furthermore, regulations seem to be of greater importance regarding medical devices. This aligns with the literature by Cheng and WHO (2003) explaining that regulations of medical devices exist to make sure they are not substandard, assuring patient safety is not compromised. This is understandable since substandard medical devices would pose risks of faulty biocompatibility, sterilisation, etc. Additionally, dealing with regulations can be another reason why 3D units have limited use cases. This can be both regarding regulations of medical devices but also regarding production volumes, as evidenced by this quote:

> *"A big challenge when opting to expand our 3D initiative would be tackling the regulatory work. We need to follow rules set up by Socialstyrelsen regarding what products we are allowed to produce."– H3*

This quote shows that regulations cover more areas than medical devices, making it difficult for novel 3D unit initiatives to expand and increase the use cases of their production.

Lastly, there was great consensus among the interviewees that AM is not favourable when considering printing in large volumes. The inability to achieve economies of scale and slower printing speeds were the main reasons why the interviewees highlighted this. This is consistent with the literature, where Shukla et al. (2018) describes that AM is primarily useful for low-to-medium volume production since the technology can only print one object at a time with a rather slow manufacturing process compared to traditional methods like IM. This is likely a more prominent issue in the industry for companies that produce for many customers than it is for the current AM use cases in 3D units, evidenced by this quote:

"Certainly high volumes favour injection moulding but in our case, the anatomical models are all unique which is why AM is perfectly suited for it."- H4

Although AM favours the current use case of printing anatomical models in healthcare, 3D units are likely to face the same issues regarding economies of scale should they scale-up their business or start printing medical devices in the case of a crisis.

5.2.2 The Potential of AM

The findings from the interviews suggest that there are four important elements that contribute to the great potential for AM to be used for emergency production in healthcare. These are *Historical Use of AM in a Crises*, *File Sharing*, *The Use of AM for Medical Equipment*, and *Development and Trends in AM.*

The interview data show that AM has been used to print some medical devices during the COVID-19 pandemic. Some of the AM companies explained that their companies produced certain medical devices such as visors and respirator components. On the other hand, none of the 3D units were fully operational during this period and for some who were, their use cases of AM at that time did not include medical equipment.

Companies that support healthcare during the COVID-19 pandemic are also described in the literature by Advincula et al. (2020), where it is explained that large medical device shortages led countries to prioritise domestic production with the help of external companies, which seem to also have been the case in Sweden according to the interview data. This shows that collaborative emergency production between healthcare and industry has worked before.

The interview data also showed that AM holds great potential in its ability to enable fast information transfers through file sharing. That is because AM possess unique manufacturing capabilities compared to traditional methods since the printing of products can take place anywhere where there is a printer available. This was further emphasised by an interviewee who said:

"You just need to send the file and make sure the AM machine is loaded with the right material, it doesn´t matter if it´s located in Australia, Buenos Aires, or Sweden." - C4

This shows the value of designing products in CAD as file sharing enables decentralised production capabilities. Production sites that lack certain competencies, such as CAD expertise, can still contribute to high-quality manufacturing by using someone else's files. Furthermore, decentralised production capabilities increase the overall robustness of production. For example, if one production site faces production difficulties, the file can be sent and manufactured elsewhere.

Regarding the ability to produce medical equipment with AM, the interview data suggests that it is feasible depending on the regulatory requirements. Additionally, the findings also show that a wide variety of AM techniques can be used to produce medical equipment. Most of the interviewees agreed that either SLS or SLA are most suitable for producing medical equipment due to the technique's ability to print with biocompatible materials and to achieve a high-quality surface finish of the prints. The ability of SLS and SLA to print biocompatible parts with smooth surface finishes is supported by the literature in the field (Kafle et al., 2021; Oliaei & Nasseri, 2020; Tan et al., 2005). Apart from this, some interviewees also highlighted that the most appropriate AM technique to use for medical devices depends entirely on the application. The following quote shows how one interviewee phrased this:

"The use of different AM technologies varies greatly depending on the use case, medical equipment is being produced in all kinds of AM technologies. [...], It all comes down to the

requirements from the customer and the product, what mechanical stresses it must be able to handle, what temperature interval it can be used in, if it needs to be resistant to chemicals and so on." – C7

Acknowledging that medical equipment is a broad product category is important since a crisis may entail a shortage of several types of medical devices. As most of the interviewees explained, FDM could also be a viable alternative for products that have a lower regulatory class and do not pose requirements for biocompatibility and sterilisation. Such devices could be e.g. visor holders or smaller connective components in devices operating external to the body. Ultimately this shows that AM holds great potential to produce medical equipment regardless of which method is employed. Since crises can be of very different characteristics, there is a high probability that a wide variety of medical equipment will be demanded and that several types of AM techniques will be useful in different situations.

Lastly, the interviewees described that they in many ways see upgoing trends in AM and that the technology is becoming increasingly applicable in many areas. The interviewees from the industry pointed out that AM still is outperformed by IM when high production volumes are needed, but that the technology has become more flexible and cheaper during recent years, hence decreasing the performance gap between AM and IM. This is somewhat consistent with the technology readiness literature of AM presented by Spalt and Bauernhansl (2016), describing that AM is currently limited in industry and mostly used for prototyping and customising parts. However, the interview data suggest that AM is not as limited industrially as described in the literature, and instead used increasingly for end-products. This is likely due to that the current state of AM has evolved substantially during recent years, hence making the study by Spalt and Bauernhansl (2016) somewhat inaccurate today compared to the gathered interview data. In healthcare, interviewees from the 3D units explained that they see increased focus on AM, and thus are trying to expand their business case as much as possible. Spalt and Bauernhansl (2016) explains that the technology readiness level of AM is higher in healthcare applications than in industry. Hence, it is likely only a matter of time before AM is advanced enough, cheap enough, and popular enough for 3D units to gain full support from healthcare management to expand their use cases beyond anatomical models.

It should be noted that the interview data regarding the current state of AM collected in the thesis is limited to the interviewees' perceptions of how AM is evolving and its technology readiness level. Spalt and Bauernhansl (2016) explain that AM is evolving rapidly, meaning the interviewees' descriptions in this study might be outdated and inaccurate in the near future. Hence, additional research is needed to continuously monitor the direction of development of the AM technology to obtain the most accurate and updated view.

In conclusion, four barriers limiting the effective use of AM and four themes that contribute to the potential of AM to be used for emergency manufacturing in healthcare were found. There might certainly be more areas of importance both hindering and enabling the use of AM, which could lead to a more accurate view of the technology. However, the factors derived from the interview data are supported by the literature and contribute to painting a general picture regarding what should be considered when assessing the feasibility of emergency manufacturing of medical equipment using AM technology. Limiting factors of commitment, competence, regulatory requirements, and production volumes should be considered. On the contrary, knowledge gained from the use of AM during COVID-19, file sharing abilities of AM technology, AM's ability to produce medical equipment, and the fast development of AM technology should be utilised.

5.3 Coordination for Resilience

This section presents key findings from AM companies and 3D units crucial towards achieving resilience. Further, the possibility of coordinating AM capabilities is discussed and related to the existing literature.

5.3.1 Considerations in a Crisis

Regarding the supply disruptions that the interviewed companies faced during the pandemic, there were some mixed answers. Most of the 3D units were not operational and the ones that were operational had very limited production, thus very little exposure to the supply chain. Among the companies that manufactured using AM methods during the pandemic, the findings were particularly noteworthy. All companies remained operational with AM, and none reported significant disruptions in material supply. It was found that all companies had material suppliers either locally or in Europe, which seem to have remained unaffected throughout the pandemic. Limiting the exposure to suppliers that are geographically far away and arranging purchasing agreements seem to have helped companies manage supply disruptions amidst the pandemic. However, there exists a possibility that material distributors in Europe have sub-suppliers in other geographical areas that could be affected if their supply chains face disruptions. Given that the focus of this study was to investigate the capabilities of AM in a crisis, investigating the entire supply chain is out of scope for this thesis.

Production upscaling at 3D units was a question dedicated to the 3D units at healthcare centres to understand their potential in scaling and supporting their organisation in a potential crisis. Having a 3D unit at healthcare centres or hospitals was said to be extremely beneficial for the sector to introduce and get acquainted with the new technology, but also in terms of resilience during a crisis.

Most of the engineers at 3D units saw great potential in increasing the capacity of manufacturing at healthcare centres with regulations being the main obstacle. It became clear that this increased capacity was aimed at producing lower regulatory-class products that are easier to handle and develop without extensive regulatory requirements. The managers on the other hand presented hinders in the form of requiring larger storage space for printers and machines, and financial constraints which limited their ability to expand their capacity. While administrative, financial, and regulatory challenges were found to be common hindrances to upscale 3D units for mass production, the challenges of managing storage space while working with JIT principles could also become problematic in supply disruptions. As several interviewees highlighted, hospital storage space is extremely scarce. Even if they found room for the printers, they would not have room to provide sufficient material inventory to sustain production. Holding inventory could be seen as a crucial step in increasing resilience in a case where the supply of material becomes disrupted. However, it contradicts a core principle of JIT which is to minimise inventory.

The results indicate that production upscaling at 3D units is possible to some extent to provide resilience. However, given how the 3D units are still at an early stage of development, regulatory challenges, financial constraints and storage limitations, it is difficult to know how the 3D units' capabilities will change within the upcoming years. The limited sample size and an unequal amount of managers compared to engineers make it necessary to investigate more 3D units to increase the study's generalisability.

5.3.2 Resilience Improvement

To understand how AM could be used to improve resilience, the first step is to understand how the technology could be used in a healthcare setting. The data from the interviews showed that a lot of medical equipment could be made using AM at decentralised manufacturing locations, with the main limitation being the physical requirements of the part and being able to withstand sterilisation. These findings are aligned with existing theory by (Manero et al., 2020) who brought up similar concerns regarding the physical properties of some AM techniques and sterility. However, given some of the respondent's answers regarding newer advancements and rapid growth in material selection for medical applications, there is a possibility that the technology and selection of materials have improved during the last couple of years. Literature by both Spalt and Bauernhansl (2016) and Salmi (2021) have both shown that the advancements in AM are happening at a very fast pace, thus a more thorough and updated study regarding the capabilities of the technology and how people are working with newer regulations is necessary to determine how AM can be used to increase resilience in emergency manufacturing of medical equipment.

While this thesis mainly focuses on increasing resilience by producing medical equipment using AM, an interesting finding from the interviews was the ability to use AM to create spare parts. This is also explained in the literature by Rouf et al. (2022), arguing that AM can play a role in the supply of spare parts or older

legacy parts. In the healthcare sector, using AM to create spare parts or other items that are necessary for the healthcare to remain operational could be critical considering spare parts for older machines or special machines could have long lead times.

As the interviewee explained:

> *" A lot of components could be produced with AM, and most likely will be made with AM in the future. Furthermore, short lead times by being able to produce at the hospitals would be advantageous given that a crisis could disrupt logistics." - C7*

Using AM to create spare parts or other items that are needed for the healthcare to remain operational is crucial considering some spare parts could take several weeks before they are delivered, and even longer if there are supply disruptions. In these cases, being able to have competencies to produce spare parts to maintain and keep machines running could be a critical step in increasing resilience in a hospital, both during a crisis and also during non-crisis settings.

When it comes to the production capacity of manufacturers using AM, it became clear that there are possibilities to significantly increase the production capacity as manufacturers are not at capacity. However, as seen in the results, some companies were optimistic about being able to supply the required amount of medical equipment whereas others were sceptical. These questions were broad to investigate the overall possibilities of AM instead of a specific type of item, which seems to have affected the respondent's answers. For example, some medical equipment, especially single-use products could be required in hundreds of thousands whereas other items might only be required in the hundreds.

Although the production capabilities of AM may be sufficient for some items, logistics becomes a liability during supply disruptions. As one interviewee said:

> *"In a crisis where logistics are disrupted, it doesn't matter if you have a centralised production site that can supply the entire country in volume if the products cannot get to where they are needed." - H9*

This further strengthens the argument for having decentralised manufacturing sites to increase resilience, especially in hospitals. However, as mentioned by several interviewees, a lack of commitment and dedicated people to operate the AM machines leads to increased machine downtime, which makes it a suboptimal investment. H. Khajavi et al. (2018) also found that not only are professional AM machines extremely costly, but machine downtime measured hourly can be very expensive. The significant investments required to establish AM production make it necessary to identify AM applications that could be used during a non-crisis setting to justify the investment. While interviewees at the 3D units acknowledged the limited utilisation of AM machines today, they are constantly finding more applications in this emerging field.

Concerning production networks, the data from the interviews suggests that production networks could be a viable structure to coordinate and manage a decentralised production structure. Even though all interviewees unanimously agreed about production networks as a viable structure, it became clear that challenges such as regulatory requirements, differences in production capabilities and competencies at different sites could become obstacles if not managed correctly. As explained by Coombs (2021), the first two steps before a crisis are to prevent a crisis through steps of mitigation and to prepare for a crisis by having a crisis management plan. Having a crisis management plan could help manage the coordination of decentralised manufacturing sites and make them more effective by utilising each site's strengths. This was further emphasised by an interviewee who said:

"To handle networks with AM, you must identify the low-hanging fruits. For example, if a site in [location X] only has a limited production capability, it should focus on simple components that are of a lower [regulatory] class and let experienced printers handle the more complex products." - H5

To develop a detailed crisis management plan that can be used to effectively manage and coordinate a decentralised network of production sites, it is essential to know where different production sites are located, their production capacity, what competencies each site has and so on. Manero et al. (2020) explained how during the pandemic, various institutes, corporations and US authorities gathered AM capabilities by rallying them. Although rallying additional capabilities is a possibility given the fast responsiveness of AM companies, having the AM capabilities mapped out before a crisis where each decentralised manufacturing site knows its role would increase preparedness and allow for faster response in emergency situations.

Several interviewees emphasised the need for a centralised web portal to handle the distribution of CAD files to streamline decentralised production sites. This web portal would enable AM companies to know what items are needed, manage distribution effectively by having files ready to download and be able to sort items depending on the manufacturer's capabilities. For such a system to work, it is necessary to keep track of medical equipment or components that could face shortages, have pre-validated 3D designs readily available and manage other legal challenges. As mentioned by Manero et al. (2020), one of the limitations of such file distribution is the legal challenges concerning copyright and patent infringements of certain parts. Having a public website with information regarding medical equipment that is facing shortages could also be seen as a national vulnerability, in which case a private platform for certain companies could be utilised instead.

To conclude, the findings from the interview data remain aligned with the literature and highlight several areas where AM could be utilised to improve the resilience of the healthcare sector. These areas are securing material supply, utilising AM for spare parts to maintain operations, and utilising decentralised production networks to overcome logistical disruptions. However, a key underlying theme that is a prerequisite for these applications is preparedness, which includes mapping critical medical equipment, and existing production capabilities, and having a thorough crisis management plan. This preparedness is absolutely necessary for AM applications to enable a fast and effective response to a crisis.

5.4 Recommendations

This master's thesis aimed to examine what role additive manufacturing should play in emergency manufacturing to improve healthcare resilience in the event of a crisis. Based on the existing literature and findings from this study, the following framework has been developed as a recommendation to increase resilience in the healthcare sector amidst a crisis.

I. *Investigate the Current Manufacturing Capabilities*

While AM was found to be capable of manufacturing medical equipment in a crisis, developing a decentralised manufacturing structure using AM requires an understanding of the existing production capacity and where the production capacity is located. Therefore, the authority should attempt to map the existing AM production capacity and evaluate the capabilities of each site. One way to achieve this would be to survey AM companies and 3D units to gather information. Without knowing what production capacity exists nor where these production sites are located, establishing collaborations, planning for a crisis and effectively coordinating production becomes difficult.

To further reduce the risk of supply disruptions, it is necessary to evaluate the risk of shortage for different medical equipment and the materials that they are made of. By mapping medical equipment that is at risk of shortage, it would be possible to prepare for such scenarios and mitigate the effects of shortages. As discussed from the findings, for products that are needed in very large quantities, AM could be used to make toolings

and moulds instead. Furthermore, to establish a robust emergency manufacturing structure using AM, it is necessary to secure material for production as these can also be affected by similar supply disruptions.

The first step in this recommendation is to comprehensively map the AM capabilities, medical equipment, and material supply chain. This creates the foundation for decentralised AM capabilities in crisis.

II. *Establish Contact with AM Companies and 3D Units*

In a crisis, a fast response is critical. A comprehensive mapping of AM capabilities, medical equipment, and material supply provides a lot of insight and information that can be used to prepare for a crisis. However, it is important to act on the information for it to be useful.

As the findings suggest, producing medical equipment using AM can be difficult in terms of regulatory requirements but also in terms of repeatability. By establishing contact with AM companies and 3D units, and developing a crisis management plan, companies can share competencies to lower manufacturing hurdles and have pre-determined roles for how to act in different crisis scenarios, allowing for a faster response to a crisis.

Furthermore, 3D units should establish contact and collaborate with other 3D units to share their competencies and experience. Most of the 3D units are still early in their development phase and going through similar challenges. By sharing competencies and experience, they can develop and achieve more with the limited resources they have available. Competence sharing as a general concept already exists between different regions and hospitals as part of healthcare in Sweden, thus sharing competencies between 3D units should not be too difficult.

Additionally, a comprehensive crisis management plan enables a network of decentralised production sites to more effectively coordinate and respond faster in a crisis. Additionally, a closer collaboration between 3D units allows them to develop their capabilities faster and makes their AM applications more viable outside of a crisis.

III. *Centralised Platform for Coordination*

The third recommendation is to create a centralised web portal with pre-validated CAD files that can quickly be deployed into production at decentralised production sites, ensuring safe-to-use products with fast delivery where the medical equipment is needed.

As the findings suggest, regulatory requirements can be tricky and some products may require testing to ensure conformity to standards. These procedures are often complicated and can be a slow process, thus it would be highly beneficial to have pre-validated files in place before a crisis happens. Working on creating pre-validated files that meet regulatory requirements would most likely require expertise from both 3D units, AM companies and a manufacturer that produces medical equipment. Therefore, it would be highly beneficial to create a collaborative plan on how to manage the development and certification of medical equipment produced using AM.

Furthermore, a centralised web portal where it is possible to sort and access pre-validated CAD files would also allow a decentralised network structure to coordinate more seamlessly and thereby provide a rapid manufacturing response during a crisis.

These recommendations, based on the findings of this study, provide a framework that was found to be the most effective way of increasing resilience in healthcare during a crisis by leveraging AM capabilities.

6

Conclusions

Improving resilience in the healthcare sector during a crisis is a vague area with a lot of limitations but also possibilities.

This research examines the potential of Additive Manufacturing for rapid medical equipment production in crisis scenarios. A crucial aspect is understanding AM's capabilities for producing medical equipment that meets regulatory standards, the production capacity, scalability, and coordination needs of decentralised AM sites. However, crises inherently present a high degree of uncertainty. Trying to predict the specific items that will become critical and may face shortages is impossible, and only focusing preparedness on categories of medical equipment that have historically faced shortages could leave healthcare completely unprepared for a novel crisis with new needs.

Recognising the limitations of pre-crisis planning, this study pivoted towards investigating resilience in a broader sense. We prioritise the inherent flexibility of AM to develop a framework. This framework leverages a decentralised production network, aiming to enhance the resilience of medical equipment production during unforeseen situations.

Furthermore, the three global themes found through the thematic analysis were found to be interrelated and together form an answer to the purpose of this thesis, namely how AM should be used to increase healthcare resilience in a crisis, see Figure 6.1.

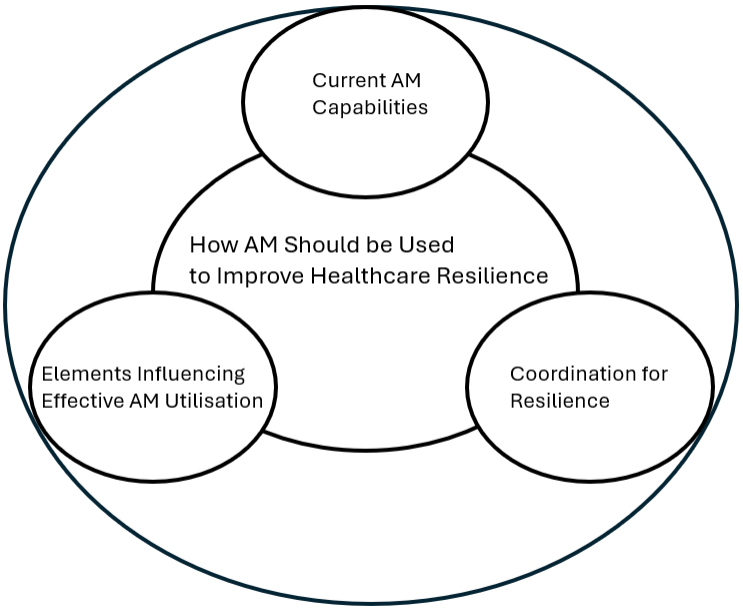

Figure 6.1: Venn diagram showing how the global themes identified in the data analysis are related. Source: Authors.

6.1 Answering Research Questions

Firstly, this thesis sought to find an answer to the research question regarding: *How are the current capabilities of AM utilised in a medical and industrial context?* In healthcare, the interview data shows that AM capabilities are utilised through specialised 3D units tasked with aiding surgeons by printing anatomical models for surgeons to use as training material pre-operatively. This is consistent with the literature where it is explained that anatomical models are a major area where AM is used in healthcare. In industry, the interview data, consistent with the literature, show that companies use AM in many sectors, mainly for prototyping but also increasingly more for end-products.

The second research question of this thesis was: *What elements influence the feasibility of emergency manufacturing of medical equipment using AM technology?* The interview data together with existing literature in the field suggest four elements limiting the effective use of AM and four elements that contribute to the potential for AM to be used for emergency manufacturing in healthcare. Elements limiting the effective use of AM were found to be maintenance and commitment issues, competence, regulatory requirements, and production volumes. Elements contributing to the potential of AM were found to be knowledge gained from the use of AM during the COVID-19 pandemic, file sharing abilities of AM technology, AM's ability to produce medical equipment, and the fast development of AM technology.

The third research question this thesis set out to answer was: *How can AM capabilities be coordinated to improve healthcare resilience?* The data from the interviews along with the literature suggests that the flexibility of AM and its potential to coordinate a decentralised production network could enable an emergency manufacturing solution to improve resilience.

Following the recommendations, AM capabilities enable the deployment of a network of decentralised manufacturing capabilities that can relieve supply shortages and improve resilience in healthcare. However, for this decentralised network structure to operate effectively, coordination and information become critical, which is why a proper crisis management plan is crucial. By having a proper crisis management plan in place and having pre-defined roles for manufacturing actors as defined above, AM capabilities can be used to effectively respond to a shortage during a crisis. Furthermore, by having access to pre-validated CAD files, these decentralised production sites can ensure safe and rapid

6.2 Theoretical Implications

Regarding the current use of AM, the findings of this study is aligned with the literature presented by Salmi (2021). The use of AM for printing anatomical models as training material for surgeons is consistent with the existing literature. However, the findings of this study suggest that conducting AM business in specialised 3D units are relatively novel initiative, since these 3D units have not been operational for a very long time. Previous research predominantly addresses use cases of AM in healthcare and not how the business is conducted in terms of specialised units or similar. Hence, this research adds to the literature that specialised 3D units are a way of conducting AM work in healthcare. It should although be noted that AM is constantly evolving and 3D units are novel initiatives, meaning use cases of AM in healthcare as well as the most optimal way of conducting AM business at hospitals are subject to change in the future. Thus, this research contributes to the literature by providing insights into how 3D units work and how they can be used to aid in emergency medical equipment manufacturing. This research also highlights the need for continuous monitoring and future research of the AM technology and 3D unit business in hospitals to investigate their most optimal use cases.

For key elements affecting the use of AM capabilities, elements limiting the effective use of AM are aligned with previous research by Shukla et al. (2018). The literature presents a wide variety of elements but only some of these presented elements could be derived from the findings of this study. There can be many reasons for this, such as a limited interview sample, but the context of this study also plays a crucial part. Existing literature presents general elements inhibiting and enabling the use of AM capabilities for the general case of using AM in product development. Since the focus of this study is AM in healthcare and producing

medical equipment, it is possible that the found elements is an accurate representation of what inhibits and enables AM use in this specific context, hence explaining why there is a limited amount of elements found. Nevertheless, the findings of this study regarding elements influencing AM use add a layer of knowledge to the literature on some elements that are important to consider when applying AM to produce medical equipment in healthcare.

Regarding the coordination of AM capabilities to increase healthcare resilience, the existing literature is mostly aimed at assessing the feasibility of producing medical equipment with AM, such as the studies by Ishack and Lipner (2021) and Manero et al. (2020). However, Advincula et al. (2020) proposed the idea of constructing a decentralised network of AM capabilities during the COVID-19 pandemic. This research adds to the literature by further enhancing how such a network should be constructed. Through the recommendations from this study that AM capabilities should be mapped pre-crisis, establishing contact with key AM companies and 3D units to secure competence exchange and material deliveries should be made, and a centralised platform bridging AM actors together for effective coordination should be established, the existing literature is reinforced and groundwork for future research in the field is done.

6.3 Managerial Implications

This section discusses the managerial implications of the findings from this study from the perspective of healthcare managers and AM industry managers. Managers in healthcare and hospitals should consider investing in developing in-house AM capabilities like the 3D units studied in this thesis. Securing talent and engineering competence that may exist among healthcare workers is a perfect way to start up a 3D unit that can bring many benefits to the organisation. This can be used to help surgeons in surgery planning by providing anatomical training models. For this to work, it is important that healthcare organisations put emphasis on training both for the people working with AM and for surgeons. Training is needed to ensure key competencies such as CAD and DFAM are possessed among AM workers in order to optimise printing processes. Education is needed for surgeons to understand and appreciate the benefits AM could bring to their work. Consistent and frequent collaboration between AM workers and surgeons is crucial for successful outcomes. Furthermore, healthcare organisations should view the ability to produce medical equipment at the hospital as a long-term investment, as it is crucial to secure the production of a wide variety of components in unforeseen crisis situations.

However, it is important to consider that the findings of this study also suggest that sufficient scale-ups of 3D units needed to produce medical equipment in terms of the amount of AM machines needed, competencies, regulations, etc is a difficult process. Hence, managers in healthcare should consider the recommendations provided in this report regarding collaboration between hospitals and companies working with AM. This collaboration should be done through a centralised platform for coordination as recommended in Section 5.4. Collaboration with experienced AM companies will secure competencies and capabilities that can aid the currently novel 3D unit initiatives until they are scaled up and can handle medical equipment production on their own. These companies can provide an extra layer of resilience for healthcare in a crisis situation, since they have great knowledge and expertise in AM capabilities and are proven to be able to produce medical equipment with AM at a rapid pace, as evidenced by their production during the COVID-19 pandemic. These companies possessing key competencies and skills needed for AM production also means 3D units in healthcare can seek their help and guidance to develop their AM business further and contribute to improved healthcare.

Managers in organisations working with AM should leverage their company's ability to produce medical equipment by marketing its expertise in this area. There is great potential for investments in setting up collaborations with government agencies or hospitals to provide medical equipment in a crisis scenario. For this to work, AM companies should secure their deliveries of material as much as possible in order to be able to produce even when there are supply disruptions. Doing this will put these companies in the position of top providers of AM-manufactured tools in a crisis. organisations working with AM should also investigate their ability to handle regulatory requirements in-house if they are not already doing it. Having the ability to produce medical equipment compliant with ISO13485 standards will further secure these companies as top

alternatives for governments and hospitals to collaborate with during a crisis. AM capabilities in crises can also be scaled up to include more than just medical equipment since having the capability to produce a wide variety of products with many different materials can become very useful depending on the type of crisis. The demands and shortages may be very different depending on the type of crisis being e.g. war, pandemic, or natural disaster.

6.4 Limitations & Future Research

This study successfully addressed its initial research questions, but it is important to acknowledge limitations that influence the generalisability of the findings.

The field of AM is rapidly evolving with new technologies, materials and applications constantly emerging. This makes it difficult to maintain up-to-date information because a lot of previous literature could become outdated quickly. The same applies to a wider use of AM in healthcare which remains a novel area, especially in crisis settings where existing literature and studies remain limited.

The findings from the interviews suggest that there are potential areas where AM could be beneficial in terms of producing medical equipment during a crisis. However, the types of medical equipment were only discussed in general to provide an overview of the technological feasibility, which means that some types of equipment may not be possible or feasible to produce using AM. The lack of specificity regarding the exact type of medical equipment did cause some discrepancies in the answers provided by the interviewees, which suggests that they may have had different ideas of medical equipment in mind when they answered the questions. To avoid this, it would be necessary to conduct a comprehensive study on different types of medical equipment with varying regulatory requirements and investigate the feasibility of AM for each of these medical equipment, which would not be possible given the time constraint of this study.

Furthermore, it was found that most 3D units at hospitals were novel and are still in the early stages of development. Considering how quickly the capabilities of AM at 3D units evolve and how they continue to identify new areas of application shows that it would be necessary to conduct a follow-up study to evaluate their progress and potential once they are fully developed.

Due to Sweden's limited medical equipment manufacturing sector and the relatively new adoption of AM in this field, the study primarily involved AM companies with general expertise, rather than those specialising in medical equipment manufacturing. The study did seek participation from medical equipment manufacturers but these attempts were unsuccessful. Having their perspective would have been valuable to achieve a well-rounded perspective that encompasses the perspectives of hospitals, AM companies and manufacturers of medical equipment.

In conclusion, this study provides an overview of the general capabilities of AM technology to increase resilience in healthcare during a crisis. However, it is necessary to conduct further studies into the various fields that were found and discussed in this thesis. Although this study provides some insights into the resilience improvement efforts in Sweden, they may be difficult to replicate due to limited generalisability.

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A

Interview Consent Paper

Degree project at Chalmers University of Technology in collaboration with RISE.

Emergency Manufacturing Capabilities in Healthcare

How Additive Manufacturing Can Increase Healthcare Resilience in the Event of a Crisis*

*Preliminary title of the work.

Authors / Researchers: Ludvig Lindahl & Martin Hörnell

Expected interview time: 30-45 minutes.

About the work
The work is done in collaboration with RISE, which in turn works with MSB regarding additive manufacturing in **healthcare** to investigate how additive manufacturing can be used to support Sweden's **healthcare infrastructure** in the event of a crisis. We will investigate different additive manufacturing methods and its ability to manufacture various medical devices that may be lacking in a crisis, as well as what there may be for pros and cons of having a decentralized emergency production system that can support today's centralized structure in different scenarios.

The work is expected to be published by early June 2024 via Chalmers University of Technology.

About the interview
The aim is to maintain a natural conversation during the interview and there are no right or wrong answers, your opinion is what matters. You always have the option to decline one or more questions if you are unwilling or unable to answer.

Anonymity
To protect you as an interviewee, your name will be anonymized. Should you have a role that makes you identifiable in any way, further anonymization will be done by either generalizing the workplace or the role further.

Recording
The interview will be recorded unless otherwise requested, also a transcription will be made so that we can go back in the interview and perform an analysis

in the future. Only the authors of this project will have access and review the material recorded.

Amendments
If you would like certain parts of the interview not to be included or you would like to change parts afterwards, please contact us before April 15.

Martin Hörnell, martiho@student.chalmers.se
Ludvig Lindahl, ludvli@student.chalmers.se

How your data will be processed and stored
Your data will be stored during the course of the work and no later than 30 days after completion of the work. Any recording and transcription will only be handled and shown to the researchers of this project and will be deleted no later than 30 days after completion of the work.

Date:

Name:

Title/role

:

E-mail: Telephone

number:

Signature:

B

Interview Guide 3D Units

AM in Healthcare

General

1. Tell us a bit about yourself and your role in healthcare.
2. On what initiative were the 3D units formed and how do they work today?
3. What are the purpose/main tasks of the 3D unit?
4. How did you hear about/got involved in the 3D unit?
5. How did you start working with additive manufacturing and what manufacturing methods do you use today? Is there any difference in methods from when you started?
6. Do you know if your approach to AM differs from manufacturing companies and if so, how and why?
7. How do you approach CAD modelling if you are going to print an existing product versus a completely new one?
8. Do you purchase materials for your AM machines yourselves or do you have a purchasing department that handles this?

Person Specific Questions:

1. Can you explain your job duties and how you work with different manufacturing methods?
2. What additive manufacturing methods do you have experience with?
3. How did you get into AM work?
    a) How was your experience learning to work with AM?
4. How much do you work with AM today?
    a) Do you see an increase in the use of AM today compared to previous years?
5. What skills do you think your staff/workforce need to have in order for your manufacturing to function optimally?

AM in Medtech

1. Which AM method do you think is best suited for different types of medical technology products?
2. How do the 3D units work for you in practice?
    a) What is your view of having your 3D unit located at the hospital compared to buying products from external suppliers?
3. How do you see the possibilities of scaling up and starting up AM manufacturing like yours in several places?
    a) What challenges/opportunities do you see with this?
4. When do you think it is better to choose conventional methods such as injection moulding or compression moulding?
5. What factors influence the choice between AM and conventional methods such as injection moulding in the manufacture of medical technology products?
    a) What do you see as the advantages/disadvantages, obstacles, and opportunities?

COVID Related Questions

1. If we go back a few years, what did it look like for you in terms of material supply, production, costs/prices and lead times before COVID?
    a) During COVID?
    b) After COVID?

In a Crisis

1. If there were a crisis in Sweden and the state needed help to produce certain types of medical device products, how do you think such a production should be done in the best way possible?
2. Do you have any cooperation with the state today regarding production capacity?
3. How do you think a crisis preparation should be set up?

   a) How do you think it would have worked if there had been a crisis preparedness protocol where you had been given information in advance on how to act and help in the event of a crisis?

4. How do you think AM could be used in a crisis for emergency production?
   a) Under what specific circumstances can AM be a more effective or appropriate alternative than conventional methods?

5. What is your view on using AM, for example, to accelerate conventional methods to get mass production started faster?

C

Interview Guide AM Companies

AM Companies

General

1. Tell us a bit about the company, how you manufacture and what manufacturing methods you use.

    a) What industries do you work with?

2. Can you explain your job duties and how you work with different manufacturing methods?

    a) How do you approach CAD modelling if you are going to print an existing product versus a completely new one?

Injection Moulding

1. Can you explain your process when you are going to manufacture something new using injection moulding?

2. What type of product do you choose to injection mould versus other manufacturing methods?

3. What parameters are important for this process?

4. How do you manufacture tools for injection moulding?
    a) What are your approximate lead times for developing a new tool and starting to produce products?

Regulatory Requirements

1. How much experience do you have with regulatory requirements? For example, CE marking and ISO standards.

    a) How do you work with regulatory requirements, such as CE marking and ISO standards?

    b) Is there a difference between regulatory requirements for different methods such as injection moulding and AM?

AM Focus

1. What additive manufacturing methods do you have experience with?

2. How did you get into AM work?
    a) How was your experience learning to work with AM?

3. How much do you work with AM today? Do you see an increase in the use of AM today compared to previous years?

4. What skills do you think your staff/workforce need to have in order for your manufacturing to function optimally?

Retailers of 3D Printers

1. What has the historical development of 3D printers looked like?
2. What is the current development progress for 3D printers? (Such as precision, compatibility with new materials etc)
3. How do you work towards different regulations so that the machines meet the requirements?
4. How is the general development going forward, is there a clear pattern in which AM technology is advantageous?
5. When are the different technologies suitable? (Which areas)
6. How do you think high-volume production will look in the future with additive manufacturing?

AM in Medtech

1. Which AM method do you think is best suited for different types of medical technology products?
2. When do you think it is better to choose conventional methods such as injection moulding or compression moulding?
3. What factors influence the choice between AM and conventional methods such as injection moulding in the manufacture of medical technology products?
4. What do you see as the advantages/disadvantages, obstacles, and opportunities?

COVID-related Questions

1. If we go back a few years, what did it look like for you in terms of material supply, production, costs/prices and lead times before COVID?

    a) During COVID?

    b) After COVID?

In a Crisis

1. If there were a crisis in Sweden and the state needed help to produce certain types of medical technology products, how do you think such production should be done in the best way possible?

2. Do you have any cooperation with the state today regarding production possibilities/capacity?

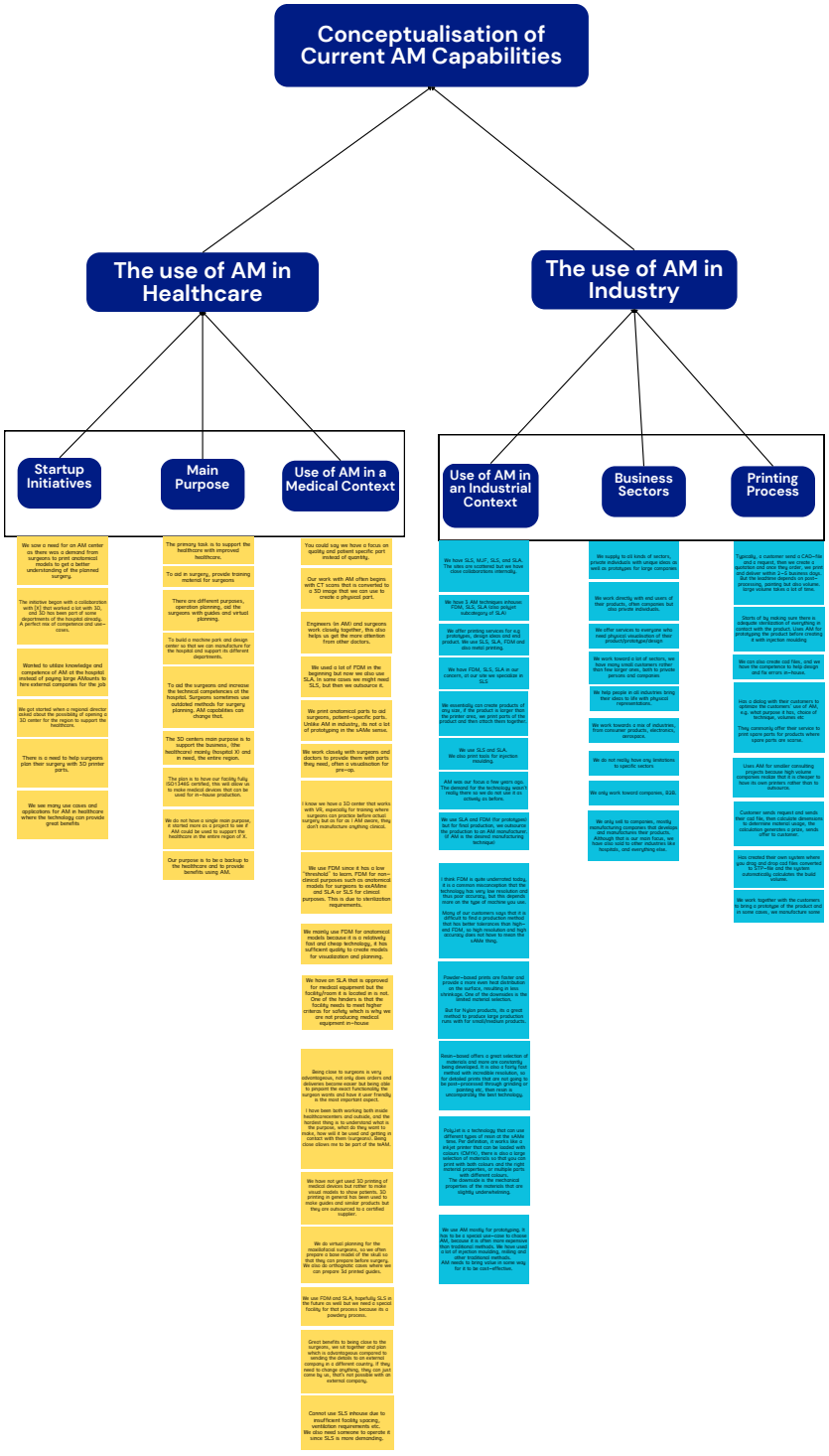
3. How do you think a crisis preparation should be set up to get production started efficiently?
    a) How do you think it would have worked if there had been a crisis preparedness protocol where you had been given information in advance on how to act and help in the event of a crisis?

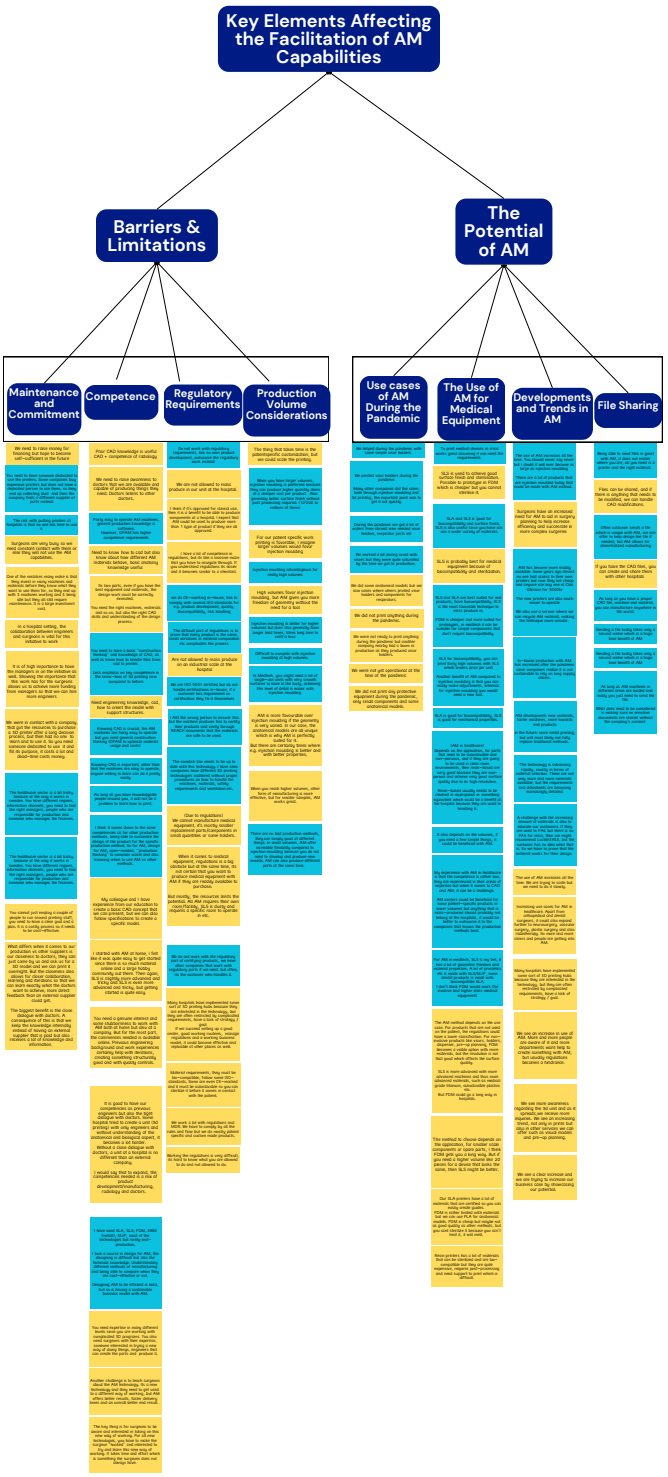
4. How do you think AM could be used in a crisis for emergency production?
    Under what specific circumstances can AM be a more effective or appropriate alternative than conventional methods?

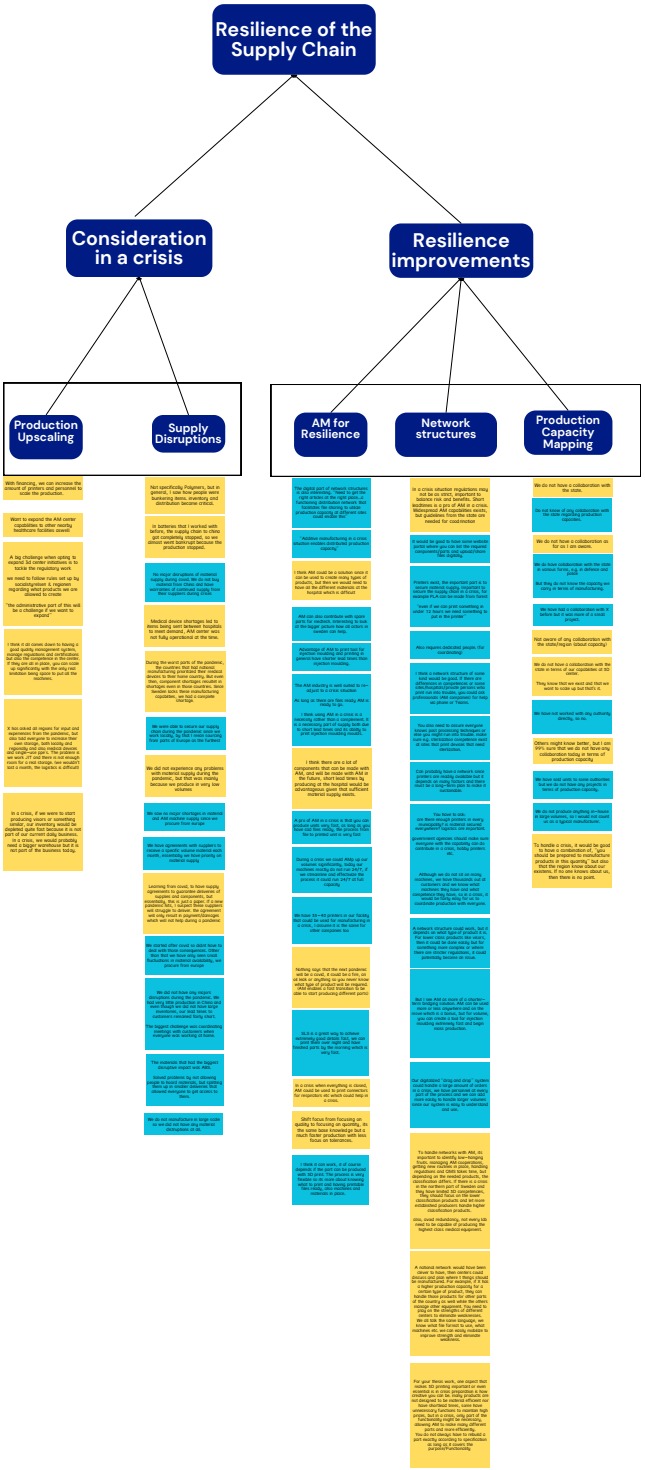
5. What is your view on using AM, for example, to accelerate conventional methods to get mass production started faster?

D

Affinity Diagram




Key Elements Affecting the Facilitation of AM Capabilities
Barriers & Limitations
The Potential of AM
Maintenance and Commitment
Competence
Regulatory Requirements
Production Volume Considerations
Use cases of AM During the Pandemic
The Use of AM for Medical Equipment
Developments and Trends in AM
File Sharing


Resilience of the Supply Chain
Consideration in a crisis
Resilience improvements
Production Upscaling
Supply Disruptions
AM for Resilience
Network structures
Production Capacity Mapping

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