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Research paper

Barriers and facilitators to the implementation of additive manufacturing in cardiology: A qualitative study

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ABSTRACT

Background: Additive manufacturing (AM) is a fast-developing technology with possible applications in cardiology. Existing research has identified two general factors that can influence implementing AM in cardiology: economics and technology.
Objective: In this study we aimed to identify barriers and facilitators to implementing AM in cardiology.
Methods: We conducted a multiple case study of two Swedish cardiac surgery departments representing implementers and non-implementers of AM. We interviewed key stakeholders (n=8) who had been or were involved in implementing AM in cardiology or AM in general at the hospitals: cardiologists, physicians working with AM but not specialized in cardiology such as radiologists, company representatives, and individuals involved in the 3D-printing facilities. A combination of an inductive and deductive approach was used to analyze the interviews.
Results: Several barriers and facilitators influenced implementing AM in cardiology. Most barriers (n=4) were related to innovation factors, whereas most facilitators (n=4) were related to healthcare professionals. No barriers and facilitators were related to patients.
Conclusion: Our findings show that AM in cardiology is in its very early phases in both hospitals and mostly the work of a few individuals. In the two hospitals studied, there were some unique differences in terms of barriers that could explain the low level of implementation. These barriers could be important to address when supporting implementation of AM at hospitals where AM use is still low.

1. Introduction

Whereas subtractive manufacturing technologies remove material, additive manufacturing (AM), also known as 3D printing, creates objects from 3D model data by adding layers of material [1]. In other words, rather than removing matter, AM adds material one layer at a time [1]. Originally, AM was invented for quickly creating prototypes [2]. Today, AM is perceived to be an important technology for the future of humanity [3].

AM in cardiology is mainly used in preoperative planning, teaching, and device development [4–7]. Also, tissue engineering is a promising area in AM, comprising research on blood vessels, complex vascular networks, and the tissue vascularization [8], including techniques to fabricate 3D-bioprinted vascular conduits that can grow in the patient's body [9].

Although AM has the potential to be a useful tool in clinical practice and medical education, barriers to implementation exist. Vukicevic et al. [5] identified several difficulties associated with using 3D-printed implants related to the material's cardiac properties. Haleem et al. [4] and Luo et al. [6] found that 3D-printed applications in cardiology are more expensive than standardized care. Luo et al. [6] also found that 3D printing could be used to improve presurgical planning, but the technology and solutions surrounding 3D printing are still in the experimental stage. Haleem et al. [4] acknowledged that more research is needed about the materials, for example, in terms of a 3D-printed heart. Consequently, existing research has identified a set of factors mostly related to technology and economics that hinder implementing AM in cardiology. These two factors might not provide a complete picture as the factors (i.e., barriers and facilitators) that often influence implementation also encompass factors related to patients, healthcare professionals, and organizations [10]. This paper will address two research questions: What are the barriers and facilitators to implementing AM in cardiology? and What are the similarities and differences between implementers and non-implementers

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Table 1
Characteristics for Hospital A and Hospital B.

Case	No. of employees	No. of beds	Cardiac surgery department	Complex heart diseases	No. of patients per year	Type of hospital	3D printing at hospital	AM in cardiology
Hospital A	Around 8000	1100	Yes	No	Around 700,000	University hospital	External facility	No
Hospital B	Around 12,000	1400	Yes	Yes	Around 1,000,000	University hospital	In-house	Yes

Table 2
Respondent characteristics.

Respondent	Position	Experience with AM	Experience with AM in cardiology
Respondent 1A (Hospital A)	Cardiologist, professor	No	No
Respondent 2A (Hospital A)	Senior consultant in cardiology	No	No
Respondent 3A (Hospital A)	Vascular surgeon	Yes	No
Respondent 4A (Hospital A)	Research engineer AM	Yes	No
Respondent 5A (Hospital A)	Sales manager AM	Yes	No
Respondent 6B (Hospital B)	Pediatric cardiac surgeon	Yes	Yes
Respondent 7B (Hospital B)	Radiologist (e.g., imaging for cardiology)	Yes	Yes
Respondent 8B (Hospital B)	Researcher, entrepreneur AM	Yes	Yes

in terms of barriers and facilitators to implementing AM in cardiology?

2. Methods

2.1. Research context, case selection, and respondents

This study builds on a qualitative multiple case study [11] conducted in Sweden. Sweden was selected for three reasons. First, Sweden invested around 16 billion USD in R&D in 2017, which is 3.4% of its GDP [12]. Second, Sweden has many medical technology (medtech) companies. In 2016, there were around 640 medtech companies in Sweden employing around 250,000 people [13]. Third, Sweden has a publicly-funded healthcare system that provides high quality healthcare. Sweden excels in several indicators for high quality care, including a life expectancy (82.5 years) greater than other OECD countries (80.7 years) [14]. These three aspects suggest that Sweden has an innovative healthcare system where high-quality care is provided, which implies that the healthcare system is prone to adopt new innovations such as AM in cardiology. Since AM in cardiology is still in an early adoption phase [6], Sweden provides a suitable context to study implementation of AM in cardiology.

In Sweden, two university hospitals were selected – out of seven possible – based on our previous understanding of their cardiac surgery departments and whether they had implemented AM in cardiology. This selection was made because we wanted to study both successful and not yet successful implementation cases of new technology. We selected university hospitals, which seem to be more prone to adopt 3D printing in healthcare than non-university hospitals [15]. We included two hospitals with cardiac surgery departments – one had not implemented AM in cardiology (Hospital A) and one had (Hospital B). Table 1 provides an overview of the two hospitals.

We included key stakeholders who had been or were involved in implementing AM in cardiology or AM in general at the hospitals: cardiologists, physicians working with AM but not specialized in cardiology such as radiologists, company representatives, and individuals involved in the 3D-printing facilities. In total, eight respondents were included (Table 2).

2.2. Data collection and data analysis

Using an interview guide, we conducted semi-structured interviews between March and May 2020. The interviews lasted between 30 and 60 minutes and were conducted either on the telephone or in person. Probing questions were posed when necessary. The interviews were recorded and transcribed verbatim.

A combination of an inductive and deductive approach was used to analyze the interviews. First, two authors (AW, SS) independently coded the interviews and identified themes. Each theme was supported by at least two respondents. The authors discussed the outcomes and resolved disagreements through discussion. During this stage, we adhered to a six-stage procedure that is common in qualitative content analysis [16]. Second, we used the Flottorp et al. [17] checklist (Flottorp framework) to identify determinants of practice. We connected our themes from the first stage with the factors and sub-factors from the Flottorp framework. The Flottorp framework includes 57 sub-factors that could be barriers or facilitators to implementation, which are divided into seven factors: guideline factors; healthcare professional factors; patient factors; professional interaction; incentives and resources; capacity for organizational change; and social, political, and legal factors. Each factor comprises several sub-factors. The Flottorp framework provides a detailed way to identify and categorize the barriers and facilitators to implementation and is used to guide research and practice. In this paper, we used the Flottorp framework to categorize the barriers and facilitators to implementing AM in cardiology. Each barrier and facilitator was included only once in the findings, independent of the number of times they were mentioned by the respondents. That is, we did not count the frequency of the different factors. We noted how many sub-factors were mentioned within each factor to evaluate the importance of each factor. One author (AB) categorized the themes based on the Flottorp framework. Again, all the authors discussed these outcomes and solved disagreements through discussion.

2.3. Ethical approval

No ethical approval was required as the requirements stated in the Swedish law on ethical approval (paragraphs 3 and 4) were not fulfilled [18]. All respondents gave their verbal consent to participate in the study when the invitation to participate in the study was followed up by telephone or face-to-face before the interview. The study conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

3. Results

3.1. Hospitals (implementers and non-implementers)

Hospital A has no internal AM facility although it has access to an AM facility run by researchers who are part of the local university. Hospital B has its own in-house AM facility run by part-time employees. In both hospitals, researchers set up the 3D-printing facilities, investing both time and money. Hence, in both cases, certain

Table 3
Barriers and facilitators to implementing AM in cardiology.

Factor	Sub-factor	Theme	Barrier/ Facilitator	Hospital A/B
Innovation factors	Quality of evidence	Clinical evidence needed for implementation	B	A & B
	Feasibility	Material that is very similar to the vessel wall is lacking	B	A & B
	Compatibility	There is no 3D-printing technique to actually visualize the wall	B	A
		Difficult to see major applications for us (added value)	B	A
Healthcare professional factors	Awareness and familiarity about the treatment	No exposure to 3D printing at hospital	B	A
		Meet in conferences and receive knowledge about 3D printing	F	A & B
	Skills needed to adhere	Clinicians are trained to see 2D images and then transfer it to 3D. No clear benefit of printing and looking at it.	B	A
	Expected outcomes if adhered to treatment	It is not possible to see the valves in the CT	B	A & B
	Intention and motivation to adhere	You can examine the routing and plan for surgery	F	A & B
		Fulfilling the needs of clinicians is imperative	F	B
	Alignment with existing habits and routines	Use 3D printing to better explain surgery to patients	F	A & B
Professional interaction	Peer communication and influence	Good thing to have national cooperation in order to learn from each other	F	A & B
Incentives and resources	Availability of resources	There was no central money in the beginning we worked evenings and invested own money	B	A & B
	Financial incentives	3D printing can provide an affordable solution	F	A & B
	Financial disincentives	Investing in new tech is always a cost	B	A & B
	Non-financial disincentives	Complex organizational structure, no time for innovation	B	A
	Non-financial incentives	Central facility & 3D infrastructure	F	A & B
Capacity for organi-zational change	Mandate, authority, and accountability	Management decision to invest in 3D printing	F	A

individuals who did not belong to management drove the initiatives and funded initial establishment with research money. In both hospitals, the upper management had low involvement in the AM implementation process. Hospital B has more experience with AM, and the individual running the AM facility had started to reach out and spread AM knowledge more systematically. Comparatively, the AM facility near Hospital A is rather unknown among cardiologists. To spread knowledge about AM, facilities connected to both hospitals offer free 3D prints to clinicians. Both facilities agree that an economic model for AM in the hospitals is needed to further integrate AM in the two hospitals. Hospital B has an advantage compared to Hospital A since the software for AM is developed in-house and the individual responsible for the AM facility is also employed by the hospital. Hospital B treats complex heart diseases (i.e., congenital heart diseases), but Hospital A does not.

3.2. Barriers and facilitators

We identified ten barriers and eight facilitators to implementing AM in cardiology (Table 3). Most barriers (n=4) were related to innovation factors, whereas most facilitators (n=4) were related to healthcare professionals.

3.2.1. Innovation factors

Four barriers and zero facilitators were identified concerning the innovation—i.e., AM in cardiology. Respondents from both hospitals perceived that clinical evidence was needed for implementation and therefore the lack of it would be a barrier. Interestingly, they did not explicitly reflect on whether there was clinical evidence for AM in cardiology. Respondents from both hospitals considered that one important barrier to implementation was the lack of suitable material such as material similar to a vessel wall. Respondents from Hospital A perceived that there are some deficits concerning the printing technique and in general they had difficulties identifying major applications for the technology.

3.2.2. Healthcare professionals

Three barriers and four facilitators were identified relating to healthcare professionals. Respondents from Hospital A were not exposed to the technology, which posed a barrier to implementation. In addition, respondents from Hospital A were concerned about the skills needed to work with the technology since their education and experience was with 2D-printing. Respondents from both hospitals perceived that the technology can be used in preoperative planning and as a way to better explain surgery to patients. Respondents from Hospital B perceived that an important facilitator to implementation is that the technology and solution are based on physician's needs.

3.2.3. Patient factors

Respondents did not mention any barriers or facilitators relating to patients.

3.2.4. Professional interaction

Respondents mentioned one facilitator relating to professional interaction. Respondents from both hospitals perceived peer communication and cooperation facilitators to implementation.

3.2.5. Incentives and resources

Three barriers and two facilitators were identified relating to incentives and resources. Respondents from both hospitals perceived that investing in new innovations always entails a cost; however, they believed that 3D printing could provide an affordable solution. Respondents from both hospitals perceived that a centrally-located in-house 3D-printing facility is an important facilitator to implementation. Respondents from Hospital A believed that a complex organizational structure that does not provide any time to work with innovation is a barrier to the implementation of new innovations.

3.2.6. Capacity for organizational change

Respondents mentioned one facilitator relating to capacity for organizational change. Respondents from Hospital A perceived that a facilitator to implementation is management's decision to invest in the innovation.

3.2.7. Social, political, and legal factors

Respondents did not mention any barriers or facilitators relating to social, political, or legal factors.

4. Discussion

We studied the implementation of AM in cardiology in two Swedish cardiac surgery departments and set out to address two research questions: What are the barriers and facilitators to implementing AM in cardiology? and What are the similarities and differences between implementers and non-implementers in terms of barriers and facilitators to implementing AM in cardiology? Below, we will discuss our findings in light of existing research and answer the research questions.

Recent reviews on the adoption of AM in cardiology identify several technological issues as important barriers to adoption, such as lack of suitable material [4,5], deficits in existing technology [6], and lack of clinical evidence for the technology [6]. The findings in these reviews concerning the innovation characteristics are in line with our findings. In addition to AM in cardiology, technology-related issues have received much interest in previous research concerning implementation of AM in healthcare [19] and in other industries [20]. Several barriers related to the technology and material have been identified such as limited availability of bioink [2,21], poor material properties of bioink required to enable functions such as vascularization [22,23], lack of design tools and guidelines for AM [24,25], poor visualization of images, [25] and low technological maturity [20]. Our findings indicate that lack of suitable material and lack of design tools could be barriers to implementation, which both could be examples of low technological maturity.

Existing research on adoption of AM in cardiology also states that AM implementation entails increased cost [4,6]. For example, AM applications in routine cardiac care are more expensive than CT or MRI, which are sufficient imaging tools in most cases [6]. Our findings do not emphasize the cost of AM in cardiology as a barrier but show that investing in new technology is perceived to entail an extra cost. However, our findings suggest that AM in cardiology could save costs. Existing research also suggests that AM could be cost-effective for complicated cases such as congenital heart diseases by improving, for example, presurgical planning [26]. In a recent review of organizational adoption of AM, high investment costs were found to be the most frequent barriers to adoption of AM [20].

Recent systematic reviews on the adoption of digital technology in cardiology identified several factors related to innovation, healthcare professionals, professional interactions, patients, incentives, resources, and capacity for organizational change [10,27]. No factors related to “social, political and legal factors” were explicitly identified [10,27]. Surprisingly, no patient-related aspects were mentioned by our respondents. This could, however, depend on the fact that AM in cardiology is a completely different type of innovation than digital health technology, which is used, for example, to remotely monitor blood pressure where difficult-to-use technology could be a sizeable barrier [10]. In contrast, AM in cardiology could enable better preoperative planning and provide a better way for a patient to visualize their surgical treatment. In these cases, however, the patient would not be involved in the use of AM.

Of the five factors identified in our study, most barriers (n=4) were related to innovation (e.g., lack of evidence, added value, and compatibility), and most facilitators (n=4) were related to healthcare professionals (e.g., motivation to adhere and alignment with existing routines). Existing reviews in digital health technology provide contradictory findings. For example, one review found that a lack of evidence was among the most frequent barriers [10], whereas another one focusing on digital technology in hypertension management did not identify clinical evidence influencing implementation [27]. Interestingly, existing research in cardiology has not identified the lack of added value and compatibility as barriers to implementation [10]. In contrast, compatibility with existing workflow is an important facilitator [27]. In terms of facilitators, our findings are in line with existing research in cardiology, where the motivation of physicians and alignment with existing routines are two possible facilitators to implementation [10].

Research on healthcare digitalization is a relevant field for AM because AM requires using information technology such as computer-assisted design. Gagnon et al. [28], in a review of factors influencing adoption of digital applications, identified 101 studies exploring barriers and facilitators to implementation. The most frequent facilitator to implementation was the usefulness of the innovation; however, our findings show that lack of usefulness is a barrier to implementation. This difference could depend on the fact that AM is still perceived as a very new and unexplored technology so practitioners are not sure of its added value [6]. In contrast, digital application, such as the electronic patient records system, is an established and well explored technology and therefore more actors perceive it as having clear added value, a perception that would facilitate implementation. Furthermore, consistent with our findings, Cagnon et al. [28] report that many barriers are related to the healthcare professionals, such as motivation to use digital applications.

Going beyond digital health, factors related to innovation, healthcare professionals, and patients are reported to be frequent barriers and facilitators to implementation in healthcare [29]. Our findings also support the idea that there could be common barriers and facilitators to implementation in healthcare. In addition, our findings suggest that implementing AM in cardiology can be distinguished from other healthcare fields as AM implementation does not seem to be influenced by patients. This difference is reasonable if the main focus is on using AM in cardiology in presurgical planning with a non-invasive use of AM; however, if AM is used in cardiac implants as well as other invasive devices, the patient factors could become more prevalent.

Our findings show that implementers and non-implementers identify similar barriers and facilitators, but they differ in terms of certain additional unique barriers. Respondents from Hospital A identified five unique barriers, whereas respondents from Hospital B did not mention any unique barriers. These unique barriers could help explain the differences in outcomes between Hospital A and Hospital B. Respondents from Hospital A struggled to see how AM could be compatible with their existing practice, and they had low awareness of AM. Respondents from Hospital A also perceived that they lacked skills to incorporate AM into their routines since they are trained to see 2D images. Finally, respondents from Hospital A stated that they were not provided enough time or support to learn how to use healthcare innovations. In contrast, these types of barriers were not raised by respondents from Hospital B, which indicates that these factors could be important when aiming to support implementation of AM at hospitals where use is still low.

In addition to unique barriers, the different outcomes in terms of AM implementation across the two hospitals could depend on the treatments provided and how these align with the benefits of 3D printing. Hospital B treats children with congenital heart diseases that require complicated surgeries. These children could benefit from presurgical planning or better explanations of cardiac pathology to patients with the help of 3D-printed models [26]. Because Hospital A does not work with congenital heart diseases, it might have less use for 3D-printed models. Although Hospital B runs its own AM facility, this might not be the optimal solution for wide scale implementation of AM. Hospital B basically employs one person to run the facility, so all physicians must work with this employee to access AM. An alternative model and presumably a more effective one would be to establish an AM unit located at the radiology department that employs several imaging specialists who collaborate with physicians from various clinical areas to promote and support AM implementation [30].

5. Conclusions and limitations

Several barriers and facilitators could influence implementation of AM in cardiology. The most important types of barriers relate to

innovation factors and the most important types of facilitators relate to healthcare professionals. In the two hospitals studied, there were some unique differences in terms of barriers that could explain the low level of implementation in the other hospital. These barriers could be important to address when aiming to support implementation of AM at hospitals where use is still low.

Some limitations apply to our study. First, we studied two cases from one country. This small number of cases from one country cannot be claimed to be representative of all cardiology surgery departments in Sweden. Nonetheless, the included hospitals represent two university hospitals, so the findings provide a good overview of barriers and facilitators in one country in terms of university hospital care. To explore and validate our qualitative findings, more quantitative studies focusing on Sweden are needed. Furthermore, we studied university hospitals with the assumption that they would be more interested in adopting AM in cardiology. That is, the findings need to be explored in the context of non-university hospitals to confirm the applicability of the findings in non-university hospitals settings.

Second, we studied one country (Sweden) that has an innovative healthcare system with high-quality healthcare. Therefore, our findings could apply to similar countries in terms of healthcare system innovation and quality of care. However, our findings and findings from other contexts imply that there could be certain general barriers and facilitators to implementation despite the context. To explore this further and compare our findings from the Swedish context, qualitative and quantitative studies from similar and different contexts are needed.

Third, we studied a limited number of stakeholders within each case as we wanted to capture the key stakeholders. This relatively small number of respondents may not provide representative samples from the two hospitals in terms of cardiac surgery departments. However, we reached saturation in our analysis and included both those who oppose and support AM implementation, which indicates that we captured the possible barriers and facilitators to implementing AM in cardiology. Our findings show that AM in cardiology is in its very early phases in both hospitals and mostly the work of a few individuals. Clearly, further integration of AM is needed where upper management is involved and a clear economical model for AM is developed. Due to COVID-19 restrictions, it was not possible to include any patients in the stakeholders studied. Studying the views and expectations of patients concerning AM in cardiology would be another fruitful area of research.

Declaration of Competing Interests

Authors report no disclosures relevant to the manuscript.

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