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Business models and supply chain of personalized medical products made by additive manufacturing

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Abstract: In the last years, Additive manufacturing (AM) has gained increasing interest among practitioners in manufacturing personalized medical products. Researchers have consequently aligned to this increasing interest from practice, trying to support the development of AM for personalized medical products. However, researchers are currently overlooking one of the main aspects that would ensure the successful development of AM in the medical sector: the supply chain configuration. Practitioners are left alone configuring their supply, such as centralized or decentralized production, what to insource and what to outsource, etc. Some guidelines to support them in their decisions are hence needed. However, before doing that, it is necessary to understand the possible business models that can be adopted. In this work, we aim to do so. Specifically, we have conducted a narrative literature review, interviews and a workshop. Nine possible business models, three current ones and six future ones were identified. In addition, to describe the different business models, we have also identified their main challenges. The study represents preliminary work necessary to support the development of AM for personalized medical products in terms of business models and supply chain configurations.

Keywords: Business models, supply chain, 3D printing, additive manufacturing, rapid manufacturing, medical

1. INTRODUCTION

Due to its capability to produce highly complex products easily and quickly, additive manufacturing (AM) has gained broad interest in many sectors. One sector that has benefited the most from AM is the medical sector. Here, the need for medical products that are highly customized and personalized (i.e., based on patient geometry) renders AM very attractive. Consequently, over the last few years, products like implants (Akmal *et al.,* 2020), preoperative models (Mäkitie *et al.,* 2010) and surgical guides (Huotilainen *et al.,* 2019) have been increasingly produced via AM. It is a well-known technology in the medical sector and already has a long history.

This increasing interest from practitioners resulted in a similar increasing interest from researchers. Researchers have mainly focused on investigating AM materials' mechanical and biological properties and improving their bio-mechanical properties by developing new medical product designs, such as topology-optimized implants (Peron *et al.,* 2018; Wang *et al.,* 2016). This represents a crucial aspect of ensuring the safety of the patients, but not the only one. The correct products must be available at low costs to render them accessible to as many patients as possible in private healthcare or not burden the public healthcare systems. Consequently, researchers have to focus also on the supply chains of the medical products, finding the most suitable supply chain configuration (i.e. centralized or decentralized productions, insourcing or outsourcing, etc.) that can guarantee the highest service level at the lowest costs. In addition, different AM processes suit differently centralized or decentralized production (Salmi et al., 2022). For simplicity, this paper looks AM process at a general level.

However, this is something overlooked in the literature. The focus on the supply chain is scarce, and the few available articles are either qualitative or discuss specific case studies without providing general guidelines (Section 2). There is, instead, the need to provide general guidelines that can support practitioners in deciding the best supply chain configuration when adopting AM to guarantee the highest service level at the lowest costs. Before doing that, however, it is crucial to understand the possible business models adoptable by the medical sector and the corresponding challenges. In this work, the aim is to do this. Only by determining the possible business models will it be possible to understand the possible supply chain configurations associated and hence provide support to practitioners in their choice. To achieve the goal, a narrative literature review and interviews with hospital and company personnel were conducted to map the current business models adopted in practice. After that a workshop was organized to verify the findings and suggest alternative business models that might become a reality. These two steps could also identify the main challenges of the different business models. The results reveal that three main current medical business models are present, and six future possibilities have been identified. Moreover, six main challenges have been identified, common to all the nine business models but with different risk probabilities.

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The remaining is structured as follows. Section 2 deals with a brief review of the literature on AM for medical supply chains, highlighting the need for this work by clarifying the research gap. Section 3 then reports the methodology adopted, providing details of the narrative literature review, interviews, and workshop. The results are then reported and discussed in Section 4, showing the identified current and future business models. Moreover, their challenges are also reported. Finally, Section 5 concludes the work.

2. LITERATURE REVIEW

As described before, the interest of researchers in AM for the medical sector has increased over the years. Two main research streams dealing with this topic can be identified: one on the bio-mechanical compatibility of AM medical products and one on their supply chain configuration. While the former research stream will not be discussed since it is out of the scope of this work, the primary literature related to the latter research stream is summarized.

Dealing with medical supply chains, researchers have focused on describing the impact on supply chain configuration of adopting AM and comparing different AM supply chain configurations. Initially, researchers were interested in understanding how producing medical products in AM could have changed the supply chain configuration, trying to identify the benefits. An example of this work is that of *Özceylan et al.* (2017), who compared traditional and AM-related supply chains of orthopedic insoles and showed that AM enables moving the production closer to the final point of use (even inside), with huge benefits in terms of increased responsiveness and lead time reductions. Similar results were found by Emelogu *et al.* (2016), that also compared the two medical supply chains from an economic point of view, adopting a holistic perspective. They reported that AM supply chains were economically convenient only if the price of AM medical products was lower than 3.5 times that of conventional counterparts. This is, however, case-specific (the results were based on a case study) and dependent on the choice of decentralized production, which is a very debated issue. The decision about centralized and decentralized production, in fact, is not straightforward and requires careful investigation due to the relatively high AM machine and production costs. Other authors have investigated this decision, such as Verboeket *et al.,* 2021 and Emelogu *et al.* (2019).

However, these studies are all case-specific, being based on case studies. This renders it hard to generalize the results and find some guidelines for practitioners to support them in the choice of how to configure their medical supply chains. However, before developing a tool that can support managers in their decisions, it is necessary to understand all the possible medical business models, how they differ from each other and the related challenges. In this way, it would then be possible to determine the feasible supply chain configurations and support practitioners in their choice. In this work, we will focus on the former aspect, identifying the possible medical business models.

3. METHODOLOGY

The methodology adopted consists of two main parts, i.e. a narrative literature review and interviews used to map the current business models adopted (Section 3.1) and a workshop to verify the findings on the current supply chain configuration and to propose new business models that might become a reality in the future.

3.1 Literature and interviews – current business models

A literature review and interviews were used to map the current state of existing medical business models. A narrative literature review was conducted to identify case study-based literature with existing medical supply chains to identify the corresponding business models. The database for the search was Google Scholar with search terms: "additive manufacturing" OR "3D printing" AND "medical" AND "supply chain". Top search hits were filtered based on the paper's title, excluding pandemic-related and non-medical-focused ones. The results of the narrative literature review were then utilized as background material for the interview questions. Interviews were carried out by phone one by one, and the interviewees are reported in Table 1. The details were anonymized. The interview questions were:

- Who is the provider of additively manufactured personalized medical products, and what do you know about the supply chain?
- What challenges are related to the current business model and supply chain?
- Do you have the contact details of those performing additive manufacturing of the personalized products?

Based on these interviews and literature (Table 1), three current business models for different additively manufactured personalized medical products were defined (Figures 1-3). These business models were then generalized into different actors and elements existing in the process. All the possible variations were not taken into account.

Table 1 Interviews and literature

Existing Literature	AM service provider case study (Verboeket *et al.,* 2021). AM of implants - supply-chain cost analysis (Emelogu *et al.,* 2016). Supply Chain Networks of Orthopedic Insoles (Özceylan *et al.,* 2017) AM medical models for education (Ransikabum *et al.,* 2019) Orthosis and prosthesis cases (Soares *et al., 2021)* Barriers to the adoption of additive manufacturing in the medical sector supply chain (Choudhary *et al.,* 2021) Supply chain configuration of AM biomedical implants (Emelogu *et al.,* 2019). 3D-printed medical models supply chain: barriers modeling and analysis (Verma *et al.,* 2023)
Hospital	Professor - Head and Neck Chief Physician - Head and Neck
University	Researcher – 3D modeling & 3D printing 3D printing lab manager
Medical company	Business Director

3.2 Workshop – Future business models

After forming examples of current business models, these examples (Figure 1-3) were presented to the verifying group in the form of a workshop. The workshop included six researchers in the area of additive manufacturing, each with at least an M.Sc. level education and an understanding of medical applications. The workshop started with an introduction to the topic. It was followed by verifying the three business models identified from the previous step, where these have been presented and discussed with the attendees. After this step, the workshop attendees were asked to suggest future alternative business models and discuss the challenges associated with existing and future business models.

4. RESULTS AND DISCUSSIONS

4.1 Current medical business models

Three different medical business models from the narrative literature review and the interviews were identified. These are referred to as "AM service provider providing surgical guides", "University helping hospital with medical models" and "Medical company providing personalized implants", and they are reported in Figure 1, Figure 2 and Figure 3, respectively. As can see from the Figures, these are all characterized by the same actions (3D modeling, Segmentation, Sterilization, etc.), which are, however, carried out by different actors.

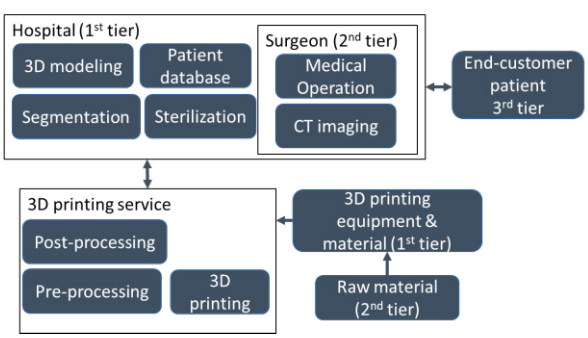

Figure 1. Supply chain structure – AM service provider providing surgical guides (Verboeket et al., 2021).

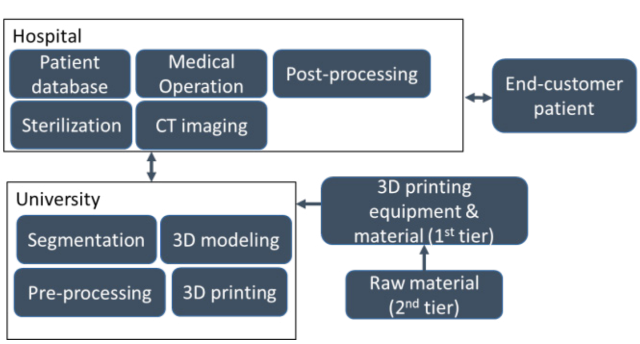

Figure 2. Supply chain structure – University helping hospital with medical models

In the "AM service provider providing surgical guides", the 3D modeling is done in the hospital, while in the other two business models, the 3D modeling is performed either by a university or by a medical company. Sometimes, the hospital is even doing post-processing, such as removing support structures, as in the case of "University helping hospital with medical models".

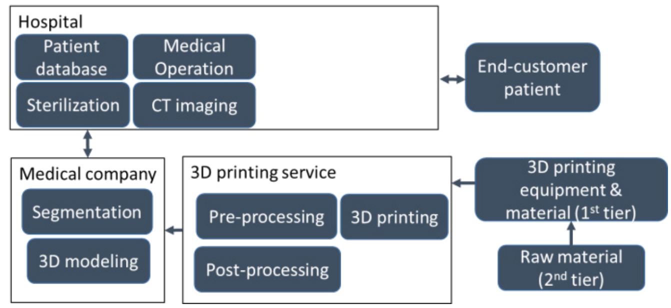

Figure 3. Supply chain structure – medical company providing personalized implants

Normally, the data each actor produces are controlled and stored by the actor himself. In each business models, the 3D printing equipment and raw materials are provided by 1st and/or 2nd tier suppliers. In business models, data flow, feedback and logistics can move in both directions.

4.2 Future medical business models

From the workshop, six possible future business models were defined. Those are referred to as "Public hospital-based", "Private hospital driven – outsourcing", "Private medical company-driven – insourcing", "3D printing manufacturer driven", "Patient driven", and "Digital medical service model". These are depicted in Figures 4-9, respectively.

In the "Public hospital-based" business model (Figure 4), most actions are located inside the hospital. It is assumed that public hospitals are pretty big, working together with other hospitals and the demand is enough to insource most of the actions, especially the production. 3D printing equipment and materials are purchased with the required certificates and approvals. However, the hospital is responsible for the process and quality and has all the patient data itself.

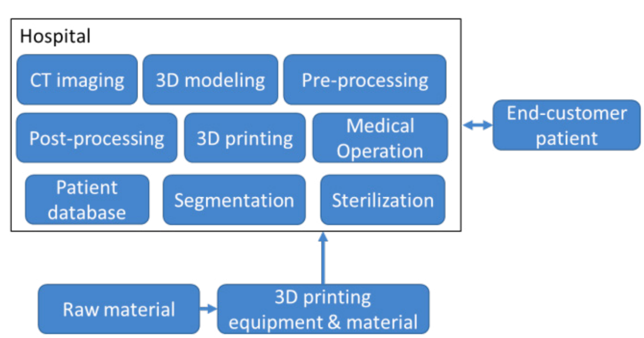

Figure 4. Public hospital-based supply chain structure

In addition, also private hospitals could be the leading players (Figure 5). In that case, it differs from public hospitals in that the need might be less, so it makes sense to outsource the 3D printing. That is the case of the "Private hospital driven – outsourcing" business model. Here, the private hospital would control the patient database, but 3D printing-related data (parameters, orientation etc.) would be controlled mainly by the service provider.

Similar outsourcing is possible for the public hospital also. Other actions that could be naturally outsourced are medical imaging and there are companies already offering only that. Typically, cases require expensive devices and infra, such as magnetic resonance imaging. Basic x-ray-based computed tomography exists locally in public and private hospitals.

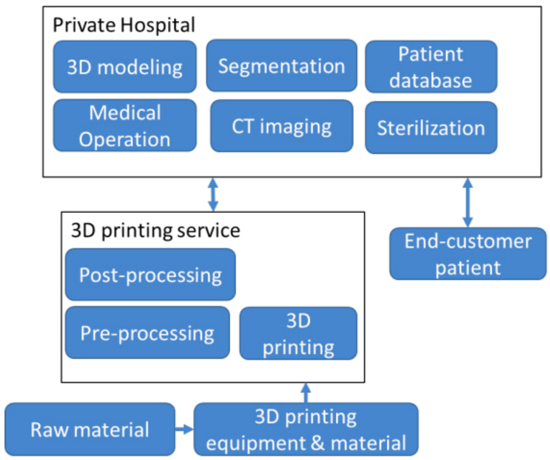

Figure 5. Private hospital driven outsourcing supply chain structure

Hospitals focusing only on the essential treatment of patients and not considering manufacturing or 3D printing could offer the possibility for a medical company to provide service for additively manufactured medical products (Figure 6). This is the case of "Private medical company-driven – insourcing". Here, it is required that patient data are also given to the medical company. The company does segmentation and 3D modeling, but feedback during the process is collected from the hospital. The company might insource the 3D printing, but it is also possible to outsource it.

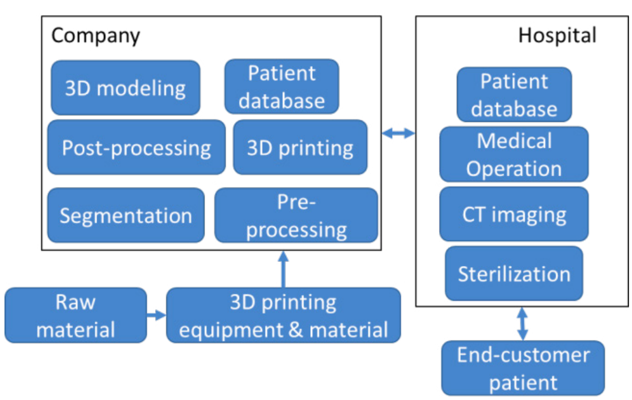

Figure 6. Private medical company-driven – insourcing supply chain structure

Another possible business model is what we refer to as "3D printing manufacturer driven". Here, 3D printing manufacturers take the role of the medical company shown in Figure 6 and control 3D printing data and much from the patient-specific data such as 3D models of anatomy (Figure 7).

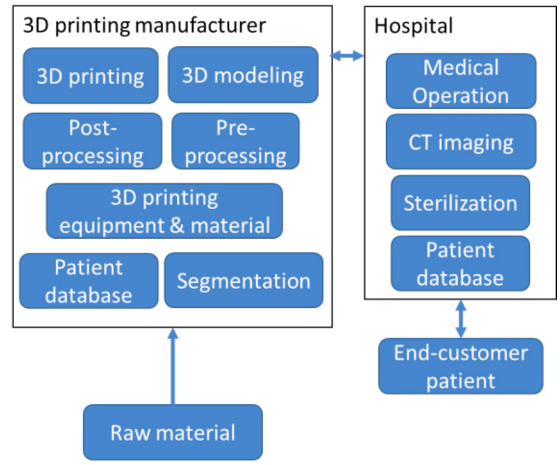

Figure 7. 3D printing manufacturer driven supply chain structure

Then, it is not impossible that the patients themselves would try to utilize 3D printing to improve their healthcare, and this is the case with "Patient driven" business model (Figure 8). Examples already exist, such as prosthetic upper limb devices from e-NABLE project (https://enablingthefuture.org/). In this supply chain structure, patients might get medical images from the hospital and do the segmentation with free open-source software. For 3D printing, some have printers at home or even internet-based 3D printing services could be utilized. In this case, the quality and approvals might be tricky questions. Most probably, applications or products would be the copy of the anatomy, so-called medical or preoperative models. Implants and other demanding applications would require much from the 3D modeling and 3D printing perspective. Also, it is not clear that the hospital would accept the model provided by the patient. However, it is possible if the patient is the paying customer, at least in some countries. In a patient driven case, the patient would also control the data.

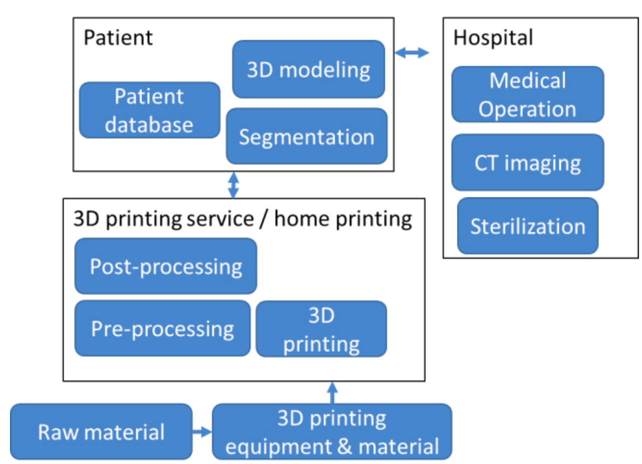

Figure 8. Patient driven supply chain structure

Finally, in many business areas, more and more businesses are based on data, connecting the right actors and digital service models. With a similar approach to additively manufactured medical personal products, it could be estimated that the customer would be in contact with the digital service through, e.g., an app. That is the case of "Digital medical service model" business model. The service could be government or private-based. Operations and medical imaging would still be done in the hospital. However, the user experience would be based on digital medical services. This service would then connect required 3D modeling and 3D printing services. The digital medical service would control the data.

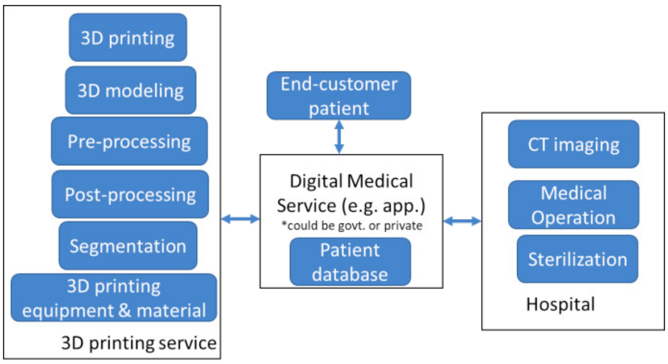

Figure 9. Digital medical service supply chain structure

4.3 Challenges of current and future medical business models

Even though the future would offer more possibilities for AM in the medical sector, all the experts raised concerns about the existing and future business models during interviews and workshop. Several challenges were recognized based on the interviews and discussions from the workshop, and they are reported in Table 2. Some of these are technical and communication-related, such as CT imaging, quality, responsibility, and data management. Others are related to ethical or economic aspects. Suppose CT imaging protocol and parameters are not set for creating a 3D model of the anatomy. In that case, it might be that the layer thickness is too high and produce insufficient 3D model quality in the segmentation phase. That is related to the fact that the radiation dose for the patient is typically minimized. Consequently, ensuring high quality is a big issue. This is responsibility of the manufacturer, which can be a company or even the hospital itself. It is however still to be defined how the manufacturer is responsible, and in what actions. Standards would help here, and those are emerging in AM field. In addition, future business models might bring only supply chain-related challenges but also intellectual property rights-related ones, as seen in 3D printing response to the COVID-19 pandemic (Ballardini *et al.,* 2022). If patients start producing themselves, then, ethics topics rise heavily. In data management might be that all the data is not stored since it can take a lot of storage space. If compressed, medical imaging would impact the quality since some layers might be removed. Moreover, databases often do not support 3D models, etc., and the data is scattered. From a quality perspective, it would help if all the data were collected in the same place. Also, it is necessary to remember that additive manufacturing is only one manufacturing method. Personalized medical implants can be made utilizing a similar process and supply chain but machining as the manufacturing process. The cost is often the driving force, and new manufacturing methods require proof of benefits.

Although all the business models are affected by these challenges, their risk probability differs varying the business model (Table 3). Fewer challenges are related to the hospital-related business model or the business model where the whole supply chain is controlled with a digital service model. Building new digital service data management can be costly in the beginning. Different challenges increase when a third party is driving the actions, requiring, for example, considering data management and responsibilities. For patient-driven business models, all the risks are pretty high, and, at the moment, most challenges are poorly defined. Responsibility, data management and quality are heavily related to supply chain coordination, which might be higher level challenge.

Table 2. Challenges

CT Imaging	Radiation dose, Imaging protocol, parameters and layer thickness consider for segmenting a good 3D model or only traditional 2D images
Quality	Quality check after creating 3D model, standards, certificates, feedback loop, 3D printing with multiple materials – contamination risk, traceability, markings in models for tracking and can it used in operating theatre / sterilized. Segmentation parameters and what anatomy we are looking for – medical/radiology expertise is often required.
Costs	Traditional parts cost vs. personalized, proof of benefits, expensive dedicated medical 3D printer – a utilization rate. Traditional machining of personalized products is some cases, more cost-efficient than 3D printing – still similar process and supply chain
Ethics	Patients /individuals making themselves, trust and quality
Responsibility	Who is the manufacturer, responsibilities in different phases, approvals
Data management	Full data is often not stored: 3D models, parameters etc. Medical imaging data reduced when stored, link between each phase in the process, markings in the products/models

Table 3. Estimated risk probability (1 low, 2 medium, 3 high)

	CT Imaging	Quality	Costs	Ethics	Responsibility	Data
Existing models						
AM service provider providing surgical guides	1	2	2	1	2	2
University helping hospital with medical models	2	3	1	2	3	3
Medical company providing personalized implants	1	2	2	2	2	3
Future models						
Public hospital-based	1	1	3	1	1	1
Private hospital driven – outsourcing	1	2	2	1	2	2
Private medical company driven – insourcing	2	2	2	2	3	2
3D printing manufacturer driven	2	2	2	2	3	2
Patient driven	3	3	2	3	3	3
Digital medical service model	1	1	3	2	1	1

5. CONCLUSIONS

The developments of AM have rendered this manufacturing technology very interesting for personalized medical products. However, as things stay today, it is not obvious how to configure the supply chain for additively manufactured personalized medical products. Literature on the topic is in fact scarce, and the few available articles do not provide general guidelines or support for practitioners. This work represents the first step towards a better understanding of how AM supply chains for medical products should be configured. In fact, this work has first mapped through a narrative literature review and interviews with current business models for personalized medical products. Then, through a workshop with experts in the field, six potential new business models that could become a reality shortly are identified. Furthermore, from this work, it is possible to identify the main challenges associated with the current and future business models. We have determined that these are all characterized by six main challenges but with different risk probabilities. Quality, responsibility and cost are significant challenges over different business models.

In this way, all the possible ways to develop AM personalized medical products and their associated challenges are now thoroughly understood. It is possible to understand which are the possible supply chain configurations that can support these business models. All the information required to develop some guidelines that practitioners can use to understand the best supply chain configuration to adopt exists and represents future work.

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