**Appendix D: Challenges**

***Dependency on supplier***

To reach efficiency, the medical sector has adopted strategies such as just-in-time delivery and global and single-sourcing that have resulted in a strong dependency on few suppliers when adopting CM technologies: as stated by Meyer *et al.* (2022a, p. 6), in fact, *“supplier dependence was considered the most prominent risk”* in these situations. This became a major problem during the COVID-19 pandemic, with supply chain disruptions leading to a shortage of many critical items. AM overcame this issue, ensuring the continuity of healthcare provisions since it enabled more alternative supply sources compared to CM (Tareq *et al.*, 2021). The use of AM, however, shifted the supplier dependency from a dependency on *“largescale contract manufacturers”* to new emerging dependencies ranging *“from design all the way to post-processing”*, with a main focus on production (Jimo *et al.*, 2022, p. 3). In fact, “*process setup and calibration demand close cooperation between producer and user. These inherent dependencies limit supply options*” (Knofius *et al.*, 2019, p. 270). Moreover, few suppliers able to meet the demand in terms of quality and biocompatibility: “*AM raw material supply chains are often dependent on a limited range of suppliers that might be located globally. […], and in turn they are vulnerable to disruption*” (Kunovjanek and Wankmüller, 2020, p. 92).

In conclusion, we can derive the following proposition:

***Proposition C1:*** Only few suppliers are able to procure suitable AM raw materials and/or parts, causing a lack of alternative suppliers.

***High production costs***

As stated by Emelogu *et al.* (2016, p.1), the decision to adopt AM is *“not straightforward and requires careful investigation due to the relatively high production costs”*. The same authors further emphasize that *“a key cost parameter is the ratio between unit production costs of AM and CM”*, with the costs of AM products that *“can be also 5 times the one of injection moulding process”* (Atzeni and Salmi, 2012, p. 1150). The high production costs of AM are due to *“a competitive disadvantage in the form of diminished cost reduction capabilities due to more limited economies of scale compared to CM”*, which hence favors the convenience of CM for medium to high quantities (Meyer *et al.*, 2022a, p.3).

In conclusion, we can derive the following proposition:

***Proposition C2:*** Producing medical devices in AM has production costs which are much higher than those of CM techniques.

***High investment costs***

As stated by Choudhary *et al.* (2021, p.642), *“the cost of superior quality of machine being used in the medical field is high”*, with AM machines able to produce biomedical implants having a mean price of $500,000 and annual maintenance costs of around $50,000/year (Muir and Haddud, 2018, p.376). Consequently, *“initial investment is steep for industrial models”* requiring *“significant financial outlay”* (Muir and Haddud, 2018, p.376). Therefore, *“considering the high costs of AM systems, it may not justify the initial investment when the overall demand levels very low”,* hence limiting AM adoption (Emelogu *et al.*, 2016, p.10).

In conclusion, we can derive the following proposition:

***Proposition C3:*** The investment costs necessary to purchase AM machines are very high.

***High material costs***

Another high cost reported by Choudhary *et al.* (2021) is that of raw materials, especially those of high quality. This represents a further challenge to AM adoption in the medical sector. Muir and Haddud (2018, p.376), for example, stated that the high “*ongoing cost of feedstock”* limits AM adoption.

In conclusion, we can derive the following proposition:

***Proposition C4:*** The costs of AM raw materials are very high.

***IP Issues***

*“As more complex and diversified technologies use AM in their production chains, intellectual property (IP) protection of shared data is becoming increasingly crucial”* (Villegas *et al.*, 2023, p.783). Indeed, the digital nature of AM exposes it to higher risks of IP loss and data breaches than CM: this is critical for the medical sector since parts’ design *“may follow a precisely engineered topology that is not intended to be disclosed”* and contain *“information about the physical description of a patient’s body and diagnostics”* which must be kept secret (Villegas *et al.*, 2023, p.784). Moreover, with AM *“instead of buying the designs of medical implants, one may copy them by applying reverse engineering or scanning the part and producing several copies”* (Choudhary *et al.* ,2021, p.643). This happened during the COVID-19 pandemic where the use of reverse logistics and AM to produce respirator valves and Personal Protective Equipment (PPE) created *“legal trouble for someone with no ill intentions but only to help the community during the COVID-19 pandemic”* (Singh *et al.*, 2021, p.417). This is the case of Isinnova, who was threatened with a lawsuit by the manufacturer of the original part (Medical Device Network, 2020).

In conclusion, we can derive the following proposition:

***Proposition C5:*** The use of AM for producing medical devices is accompanied by issues related to IP infringements and data breaches.

***Social Sustainability***

Contrarily to most CM technologies, “*AM is an automated process that requires fewer number of workers”* (Choudhary et al., 2021, p.642), with one operator capable of operating multiple AM machines. Consequently, AM is perceived as a ‘job killer’, causing employees to resist its adoption (Vlachos *et al.*, 2023). Indeed, Choudhary et al. (2021, p.642) states that *“workers have a fear of losing their jobs and resist to work with new technology*” and that “*organizations may face resistance in workers to adopt new technology due to the anticipation of losing their jobs because AM is an automated process*”.

In conclusion, we can derive the following proposition:

***Proposition C6***: AM requires less workforce than conventional manufacturing techniques and hence employees are reluctant to its adoption.

***Standardization and Certification***

As reported by Prashar, Vasudev and Bhuddhi (2022, p.2230), AM presents “*a gap which required to be closed with regard to AM standardization and qualification*”. For Goda *et al.* (2022, p.614), the challenge of the standardization and certification of AM medical devices even represented *“the major challenge facing the adoption of 3D printing”*. In general, as described by Willemsen *et al.* (2019, p.163), “*regulations tend to be restrictive, and can even impede innovative and improved patient care. […] Consequently surgeons often opt not for the best (i.e, personalised) treatment, but for the more convenient, conventional approach*”. Therefore, “*there is a vital need to advance methods for defect detection and qualification procedures in printing processes”* (Trivedi *et al.*, 2018, p.325).

In conclusion, we can derive the following proposition:

***Proposition C7***: There is a lack of standards and certification processes that complicates the use of AM for medical devices.

***Material Limitation***

According to Choudhary *et al.* (2021, p.652), the *“non-availability of a variety of materials”* is listed among the top three barriers to AM adoption in the medical sector. Indeed, they stated that *“the development of biodegradable and biocompatible material is a challenge for using AM medical SC”*. Similarly, Haghnegahdar *et al.* (2022) stated that available materials limit the capabilities to further enhance the component functionality and efficiency, with Salmi *et al.* (2020, p.13) calling for “*further technological advancements to improve the competitiveness of 3D printing*” dealing with raw material shortages.

In conclusion, we can derive the following proposition:

***Proposition C8***: There is a limited variety of materials producible via AM.

***Specialized Workforce (Design Phase)***

The “*lack of education and training to designers*” was another limitation listed among the top three barriers for AM adoption in the medical sector: “*before wide spread AM adoption on large scale certain obstacles need to be overcome like […] shortage of well-trained skilled labor*” since a “*lack of knowledge in designers […] cause a challenge*” to adopting AM in the medical sector (Choudhary *et al.*, 2021, p.654). Indeed, despite the fact that “*in any organization there is a need for training to get the total benefit of new technology*”, currently “*suppliers of machine and software do not provide proper training*” (Choudhary *et al.*, 2021, p.654). Consequently, “*today we are facing skill gap as it is hard to find skilled labor which applies 3D printing to real world manufacturing. […]. Existing design and management courses offered related to manufacturing and production are not capable to deliver proper skill set required for the efficient AM technology deployment*” (Prashar, Vasudev and Bhuddhi, 2022, p.2232).

In conclusion, we can derive the following proposition:

***Proposition C9***: AM requires specialized workforce during the design phase to exploit design benefits such as those achievable through topology optimization procedures.

***Specialized Workforce (Production Phase)***

Also the production phase is experiencing a “*shortage of well-trained skilled labor*” (Prashar, Vasudev and Bhuddhi, 2022, p.2233). The production phase, indeed, requires “*skilled workers* *to operate machines to get builds with desired properties and specifications*” (Choudhary *et al.*, 2021). More in detail, the required skills deal with “*the selection of part orientation, layer thickness, support generation, using maximum build volume, etc.*”(Choudhary *et al.*, 2021, p.642).

In conclusion, we can derive the following proposition:

***Proposition C10***: AM requires specialized workforce to operate AM machines with proper knowledge on key decisions such as production parameters to be adopted, post process operations, …

***Production Limitation***

“*Due to the layer-wise building approach and the current technologies available, AM is typically slower than mass-production techniques* (i.e. CM) *such as injection molding*” (Mueller *et al.,* 2020, p.4). This is confirmed by other researchers, e.g. Tani *et al.* (2022, p.726) who listed the “*printing process slow speed*” among the three main challenges to using AM in the medical sector. Furthermore, citing an Isinnova engineer, Tani *et al.* (2022, p.723) reported also that CM, and in particular injection molding, “*is still the preferred production technology when you have the time to produce the molds and to ship the final products to the hospital needing them*”.

In conclusion, we can derive the following proposition:

***Proposition C11***: Production speed is limited and lower than conventional manufacturing techniques.

***Need for post-process operations***

As stated by Sefene, Hailu and Asmare (2022, p.1), “*the main limitation of AM continues to be the surface finish that is produced […] as well as tolerances able to be achieved*”, which induces AM production to be followed by post-process operations. The necessity of post-process operations is explained fully in the work of Longhitano *et al.* (2021, p.23), who showed that the lack of post-process operations greatly reduces the quality and efficiency of AM face masks (“*masks without post-processing steps presented an overall filtering efficiency*” reduced by almost 40%).

In conclusion, we can derive the following proposition:

***Proposition C12***: AM parts need to undergo to post-process operations (heat treatments, polishing, …) after production.

***Quality***

In the medical sector, *“quality is of utmost importance”* (Chowdhury *et al.*, 2020, p.287), especially for biomedical implants. These are required to remain in the human body until a patient’s death and implants of insufficient quality would lead to a higher risk of implant failure, with tremendous consequences for patients’ wellbeing (Omiyale *et al.*, 2023). As things stand today, AM suffers from low quality (Singh, Venkatesh and Deoghare, 2021) and *“quality concerns about AM goods are one of the major obstacles for AM adoption”* (Kunovjanek and Wankmüller, 2020, p.91). Indeed, AM products *“can be prone to various defects such as porosity, cracking, balling, warping, and many others”* (Chowdhury *et al.*, 2020, p.287).

In conclusion, despite the causes, we can derive the following proposition:

***Proposition C13:*** AM medical parts are characterized by low quality.

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