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Abstract: Recent innovations in additive manufacturing (AM) have proven its efficacy for not only the manufacturing industry but also the healthcare industry. Researchers from Cal Poly, San Luis Obispo, and California State University Long Beach are developing a model that will determine the optimal locations for additive manufacturing hubs that can effectively serve both the manufacturing and healthcare industries. This paper will focus on providing an overview of the healthcare industry's unique needs for an AM hub and summarise the specific inputs for the model. The methods used to gather information include extensive literature research on current practices of AM models in healthcare and an inclusive survey of healthcare practitioners. This includes findings on AM's use for surgical planning and training models, the workflow to generate them, sourcing methods, and the AM techniques and materials used. This paper seeks to utilise the information gathered through literature research and surveys to provide guidance for the initial development of an AM hub location model that locates optimal service locations.

Keywords: 3D printing; additive manufacturing; healthcare; hub; location model; medical models; orthotic insoles; preoperative planning; surgical planning; training.

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1 Introduction

Additive manufacturing (AM) is fast becoming a rising tool in the healthcare industry to aid in improved and cost-effective patient care. AM is already well-known for perpetuating technological advances in the manufacturing industry through increased customisation and rapid prototyping (Attaran, 2017). However, healthcare providers have more barriers than manufacturers to access this technology. According to a group of researchers from Malaysia and Australia, their studies indicated that materials and printer

specifications were limitations to AM in healthcare. These products require specific material types that typically have a low lifespan and printers that are capable of fine details for customised, patient-specific 3D printed models (Shahrubudin et al., 2020). In 2019, approximately 2% of all hospitals in US had a centralised 3D printing facility. This research was conducted to determine the need for providing strategically located AM hubs that will enable local healthcare providers to easily access this technology and the parameters required for determining optimal locations. To develop an optimisation model to determine AM hub locations, the following research questions needed to be answered:

- 1 What are the primary AM processes, materials, and applications in the healthcare industry?
- 2 Who would benefit from using AM? Which specialties would have a higher frequency of use if the technology were readily available?
- 3 What technologies or processes could AM improve if used in healthcare? What are the potential unintended consequences of using AM in healthcare?

The two methods used to answer these questions were literature research and a stakeholder survey that was sent to most healthcare providers in San Luis Obispo County in California.

2 Findings from literature research

AM applications in healthcare fall into two categories for this research: novel and feasible. Novel applications of AM are not currently being considered as input parameters for the AM hub location model but are noted for future consideration. Feasible applications and the parameters important for the AM hub location model are discussed in more detail.

2.1 Novel applications

AM applications currently in development requiring Food and Drug Administration (FDA) oversight fall under the novel applications category. For example, 3D printed controlled-release tablets to help with patient compliance for chronic diseases (Varghese et al., 2022), personalised multi-layered polypills (Robles-Martines et al., 2019), and extrusion-based 3D printed controlled release shells for oral drugs (Mohammed et al., 2021) are a few pharmaceutical applications of AM. Another application of AM in healthcare exists within surgical implants, such as a metallic spinal cage (Meena et al., 2021) and inner-ear cochlear implants (Ghomi et al., 2021). Furthermore, a few other unique cases belong to orthotic leg braces with movement assist (Boolos et al., 2022), printing COVID-19 related materials such as ventilator parts and face shields (Arora et al., 2021) and human remains for forensic science purposes (Jani et al., 2021). Lastly, the survey responses included more complex AM models used for preoperative planning and surgical instrumentation devices to simple applications of hooks for masks. These are all examples of useful AM in healthcare novel applications that are not being considered in the development of an initial AM hub location model but display the

growing relevancy and beneficial aspects of AM in healthcare and would be considered in the future.

2.2 Feasible applications

There are a few areas of healthcare where AM has been studied and proven or suggested to be useful: surgical planning and training models as well as custom orthopaedic foot insoles, or custom orthotic insoles. In practice, surgical planning and training models may be considered as a single term: medical models. While several advancements in AM innovation are derived from implants and prosthetics, most current research initiatives focus on the efficacy of medical models, as their lack of requirements for FDA approval for use in practice make it easy to output prototypes. In fact, a recent 2022 study found that "3D printing-enabled preprocedural planning and training are transformative in medical care today" (All3DP). Furthermore, custom orthotic insoles also do not require FDA approval. Thus, medical models, specifically for surgical planning and training, and custom orthotic insoles are selected as areas of initial interest for feeding the AM hub location model.

2.3 AM in surgical planning

First, a good use for AM in healthcare involves surgical planning. In general, preoperative planning enables surgeons to adequately define operation procedures, determine the expected outcome, analyse imaging, and conduct a potential risk assessment for the surgery (Graves, 2013). In the past, surgeons planned their procedures with CT scans, MRIs, or other 2D imaging. With the recent innovations in additive manufacturing, some healthcare organisations have been utilising physical 3D printed models of a specified body part to prepare for surgical operations. These 3D models can leverage AM's high-customisability to personalise a patient-specific figure based on prior imaging.

For example, a research paper titled "3D printed prototype of a complex neuroblastoma for preoperative planning" within Volume 7 of the *Annals of 3D Printed Medicine* explores the use of AM for preoperative planning for neuroblastoma surgeries. With neuroblastoma being the "most common abdominal solid tumour in childhood," the existing surgical planning standards involve analyses of 2D imaging, such as CT scans or MRIs. However, more complex cases nullify the efficacy of these standard preoperative procedures, as 2D imaging alone will not fully illustrate the complexity of these unique occurrences. Thus, these researchers leveraged the existing 2D scans, transferred them into virtual 3D representations, and 3D printed them into a physical model, which is shown below in Figure 1 (Tejo-Otero et al., 2021).

Having accessibility to these physical 3D models enables surgeons to define their preoperative outcomes and reduce potential risks during the surgery more easily. Additionally, utilising varied materials and colours more accurately simulate the anatomical structures in both tactile and visual aspects, which allow for more refined, organised surgical planning and practice.

Similarly, 3D printing has also found use within thoracic surgery, specifically in cases involving the removal of chest wall tumours. A group of Spanish surgeons and engineers collaborated on four different cases that leveraged 3D printed models to plan for this surgery. In all cases, the 3D printed model provided additional clarity on tumour

locations and specific areas to reconstruct. One case specified the presence of a mass that was imperceptible in the 2D imaging but was easily recognisable on the printed model. This finding on the planning model matched the surgical outcome (Sanjuanelo et al., 2021). These cases show the benefit of a more visual and tactile method for preoperative planning and AM's capabilities to provide additional clarity on potential unforeseen health defects.

Figure 1 Surgical planning model for complex neuroblastoma surgery (see online version for colours)

Comparatively, an article in the *Egyptian Heart Journal* lists the multitude of benefits AM provides to cardiology. Within the context of surgical and preoperative planning, they illustrate the use of 3D printed hearts to make complicated surgeries safer and faster for cardiac surgeons, facilitate action plans for surgeons by studying replicas of the patient's cardiovascular tissue, and understand the anatomical positions of the vessels. Also, these 3D printed models provide the benefit of enabling doctors to explain the procedure more clearly and tangibly to the patient (Saxena et al., 2018).

Collectively, these cases illustrate the effective use of additive manufacturing in surgical planning, eliciting many benefits for this area of healthcare. Therefore, these benefits support the decision to select surgical and preoperative planning as a healthcare area to focus on for the AM hub.

However, while utilising medical models elicit many benefits to improve practice and patient care, there are various unintended consequences that must be considered. Current turnaround times for manufacturing medical models are often inadequate to support emergency situations. While having a physical model is more beneficial than exclusively utilising 2D imaging, current 3D models are often unable to exactly replicate the texture and anatomical intricacies of an actual human organ. However, there are various research initiatives that are attempting to utilise 3D bioprinting to replicate human tissue, such as skin (Yan et al., 2018).

2.4 AM in training

Another major area for AM in healthcare is training and education. Many medical students and residents interact with models to fully understand surgical concepts and the human anatomy of specified regions. Leveraging AM to manufacture these models will elicit many benefits for medical training. Similarly, not only students, but experienced professionals who need additional training and practice in an extremely complex region before operating on the patient will also benefit from utilising AM models within surgical training specifically.

An article within Volume 3 of the *Annals of 3D Printed Medicine* navigates the use of AM models as a simulation tool for trauma surgery of the pelvis. Surgical treatment for pelvis fractures is extremely complex, due to "the proximity of neighbouring vessels and organs", After transforming CT scans into a tangible 3D printed model, a 1:2 model of the entire pelvic region was developed, as seen in part C and D of Figure 2.

Figure 2 3D printed training model for pelvic surgery (see online version for colours)

This provides an educational simulation model that shows the complex anatomy surrounding pelvic fractures. Some limitations of this model include an absence of certain nerves and a variance in the anatomical position of certain organs based on slight differences of the patient's position within the scanner (Le-Nail et al., 2021). Nonetheless, this model will not only provide a tangible perspective the pelvic area but also give students hands-on practice and training in performing surgery on this complex anatomical region.

Additionally, congenital heart disease, a common heart complication among children, provides another area where practitioners and trainees may leverage AM models for surgical training. Due to the heart being a complex organ, analysing 2D imaging for this disease poses several possibilities for error and potential inefficiencies in the surgical process. Thus, having 3D models that replicate the heart eliminates these potential complications. Regarding experienced surgeons, these models can be used to develop new procedures and improve skills on more rare cases of congenital heart disease that they have little to no experience operating on. For students or trainees, due to the small size of a child's heart and the rarity of certain cases, there are very few accessible resources to train those learning how to operate on patients with congenital heart disease. However, 3D models allow these trainees to accumulate unlimited repetitions of handson practice until they are assured in their operative abilities (Yoo et al., 2016). Standardising practice on 3D models as a mandatory component within congenital heart disease surgery programs will reduce the inefficiencies within current surgical training. Adopting AM to create 3D models within the realm of congenital heart disease allows for greater knowledge on and increased possibilities for training on this complex condition.

AM models also have benefits for radiology trainees learning about the neuroanatomy of the middle ear. This area of the ear has a complex and intricate anatomy, and its structure has historically been taught using dissections and figures. While this method has been sufficient for training, 3D printed models provide an enhanced method of learning. To test the claim that these AM models improve radiology education for the middle ear, a group of researchers conducted a study on the efficacy of 3D models for teaching radiology trainees. In their article within the *Annals of 3D Printed Medicine*, they explain their development of a 3D printed middle ear model to test its efficacy on education. This model was used in a small group teaching session, and the trainees completed a survey pre- and post-intervention that indicated their level of knowledge on the subject. Figure 3 depicts the results of the study, which indicate that regardless of the year of training, each group had a statistically significant increase in knowledge post-intervention compared to pre-intervention.

Figure 3 P-values for post- and pre-intervention middle ear model education

A survey conducted at the study's conclusion yielded quantitative data that indicated the trainees found the model beneficial and want it integrated into the existing curriculum (Fleming et al., 2022). This study provides additional statistical and quantitative reasoning for AM's use within training.

Overall, these studies and cases prove the benefits additive manufacturing has for providing more holistic and tangible training methods, which further supports the selection of training models for the AM hub.

2.5 AM in custom orthotic insoles

According to the American Podiatric Medical Association (APMA), prescription custom orthotic insoles are "specially-made devices designed to support and comfort your feet" that are only manufactured "after a podiatrist has conducted a completed evaluation of your feet, ankles, and legs" (Advancing Foot and Ankle Medicine and Surgery). These insoles have a high success rate when used as an intervention for a wide variety of lower extremity problems (Zifchock and Davis, 2008).

Moreover, with current progress in AM innovation, 3D printed custom orthotic insoles are becoming more commonplace. According to the orthotic insole manufacturing company Superfeet, they offer *ME3D*™ insoles, which are personalised 3D printed custom insoles (Superfeet, n.d.). These orthotic insoles are customised through a scan of the patient's foot, and the appropriate material and insole structure is manufactured according to the scan. In general, custom orthotic insoles have the benefit of targeting patient-specific ailments that provide the most optimal conservative treatment.

Although orthotic insoles are an extremely low-risk and historically highly effective fix to podiatric-related problems, with custom orthotic insoles utilising AM technology, these devices become extremely high in price. These insoles can cost \$100 to \$400, and most insurance plans do not cover these fees (Zifchock and Davis, 2008).

2.6 Workflow process for medical models

After defining and comprehending the applications of AM in healthcare, the next steps involve understanding existing workflow and manufacturing process parameter inputs for the AM hub location model. Figure 4 provides the typical workflow of developing medical models.

Here, the AM process to develop these medical models begins with 2D imaging, which includes computed tomography (CT) scans, magnetic resonance imaging (MRI), and ultrasounds (Salmi, 2021). These medical images follow the Digital Imaging and Communications in Medicine (DICOM) format, which is "the international standard to transmit, store, retrieve, print process, and display medical imaging" (Digital Imaging and Communications in Medicine). Next, the 2D images undergo various types of segmentation algorithms, which involve stacking multiple layers of 2D scans to transform the images into a realistic, virtual 3D model (Bucking et al., 2017). During this step, the virtual model may also be adjusted to ensure its accuracy to patient-specific cases. Following segmentation, the virtual 3D model is converted into an additive

manufacturing file format (AMF) and printed with additive manufacturing on a 3D printer; the most used AMF for solid image processing is stereolithography (STL) (Gokhare et al., 2017). Lastly, the physical 3D model receives postprocessing, which involves tasks such as removing the support structures (Salmi, 2021).

2.7 Workflow process for custom orthotic insoles

According to Superfeet, Figure 5 represents the high-level workflow of how they manufacture their custom insoles.

Figure 5 Superfeet's *ME3D*™ custom orthotic insole workflow (see online version for colours)

Through this company, patients will visit their nearest retailer. At these retailers, a machine will take a 2D scan of the patient's feet, which is then sent to the manufacturer to print. After printing, the insole is sent directly to the patient's home (Superfeet, n.d.). At a deeper level, the 2D scan along with the patient's pre-indicated dispositions (e.g., wanting soft vs. firm insoles) determine how the insole is manufactured. Like medical models, the imaging is segmented into layers to transform the scan into a 3D image, which allows the additive manufacturing to initiate. Unlike most other healthcare-related 3D printed devices, there is no required post processing following the additive manufacturing process (Superfeet, n.d.).

2.8 Additive manufacturing methods for medical models

The additive manufacturing process behind the development of medical models is extremely complex. There are varying methods of additive manufacturing types and materials used to develop these AM models. According to an article titled "Future of additive manufacturing in healthcare", Table 1 presents the potential AM methods used specifically for surgical planning and training models and their respective category and processing descriptions.

A medical model can be developed utilising any of these methods, but certain methods are more applicable to specific cases. Table 2 provides a list of medical model examples and the specific AM material and method used to generate it.

AM method	Category	Processing description
Stereolithography (SLA), digital light processing (DLP), multiphoton polymerisation	Vat polymerisation	(1) Platform needs to be immersed in a photopolymer solution
		(2) Light is exposed according to the intended design
		(3) Polymer solidification
		(4) Fabrication is carried out layer by layer
Fused deposition modelling (FDM), Fused filament fabrication (FFF), 3D dispensing	Material extrusion	(1) Polymer heating
		(2) Extrusion through nozzle
Selective laser sintering (SLS), selective laser melting (SLM), electron beam melting (EBM)	Powder bed fusion (PDF)	(1) Power bed preparation
		(2) Layer by layer deposition of powder
		(3) Using laser resource to sinter each layer due to the predesigned structure
Binder jetting, polyjet, inkjet printing, multijet modelling (MJM), wax deposition modelling (WDM), laser-induced forward transfer (LIFT)	Droplet-based printing	(1) Extrusion of viscous solution due to the designed structure
		(2) Fixed pressure
		(3) Layer by layer deposition at a fixed extrusion rate

Table 1 AM methods for medical models

Source: Ghomi et al. (2021)

2.9 Additive manufacturing methods for custom orthotic insoles

Orthotic insoles do not have the same specified AM methods for creation as medical models. Due to the simple and unchanging overall shape of orthotic insoles, multiple AM methods are feasible. For example, a prefabricated 3D printed insole utilised fused deposition modelling (Yarwindran et al., 2017), whereas a custom-made foot orthosis was created with laser sintering (Choo et al., 2020).

2.10 Materials for custom orthotic insoles

Unlike medical models, orthotic insoles have a more standardised material selection. The main parts of many orthotic insoles utilise different types of thermoplastics, such as thermoplastic polyurethane (Choo et al., 2020), thermoplastic elastomers like Filaflex and Ninjaflex (Yarwindran et al., 2016), and EVA material which can be processed like a thermoplastic (Xu et al., 2019). Many orthotic insoles also contain a softer, rubbery material underneath to provide grip. These materials include polyethylene acetate, polylactide, or any general plastic materials.

3 Findings from stakeholder survey

The second method for collecting information to supplement the AM location model was conducting a stakeholder survey. The survey received 19 respondents with varying levels of AM familiarity. The survey included multiple choice questions on the respondent's specialty, type of facility, use/potential use of AM in their practice, and materials used to generate their AM models. Short answer questions included how AM models are used within their practice, information required to send to manufacturer, location of manufacturer, and average/optimal turnaround time for receiving the AM models.

Regarding sourcing, there are multiple methods for medical models. Currently, many utilise in-hospital labs that manufacture these models, such as the Mayo Clinic's '3D Atomic Modeling Laboratories' in Rochester, Minnesota (Mayo Clinic), as well as personalised in-house 3D printers. However, these applications are typically in lower volume for exceptional cases. Furthermore, the AM hub will serve as an outsourcing tool for hospitals and healthcare workers to manufacture their AM models, meaning inhospital manufacturing is not a target area for research. Thus, referencing the survey, the outsourcing for AM models may occur at various stages in the workflow process. For example, those that use the AM models for surgical planning and diagnostics send CT scans to the manufacturer, meaning the manufacturing company is responsible for segmentation, .stl file conversion, and 3D printing the model. However, a certain prosthetic and orthopaedic specialist sent the .stl file, meaning the manufacturer only had to print the model. Therefore, with a focus on medical models and orthotic insoles, the AM hub should have the capabilities to complete the workflow of transforming raw 2D imaging into a 3D printed model.

Additionally, surgeons and physicians are the specialties that would leverage the benefits of medical models and orthotic insoles the most. Furthermore, Figure 6 represents the specialties of the respondents who indicated their current use of AM models within their practice.

Figure 6 Percentage of specialties (see online version for colours)

As shown above, physicians and those working in surgery represent the highest percentages of respondents at 57.89% and 26.32%, respectively. Although the survey was undoubtedly skewed in favour of these specialties, this chart nonetheless shows that physicians and surgeons have an extremely high use of AM models within the healthcare industry. However, as surgery and physicians are an extremely broad category, the uses of the medical models and custom orthotic insoles intended for the AM hub relate most directly to orthopaedic related physicians and surgeons. The survey also indicated an average of 2–3 weeks of required turnaround time for outsourced AM models, which are most relevant to the focus areas.

With the primary goal of erecting an initial AM hub in California, specific areas where these specialties are at a higher density will help define locations for the AM hub. According to Statista, California has the highest number of active physicians that specialise in surgery at 5412 (Michas, 2022). According to the California Health Care Foundation (CHCF), the counties surrounding in the San Francisco Bay Area have the highest population density of physicians with greater than 59 practicing physicians per 100K. Following this area, the county in central California with the highest population density of physicians is San Luis Obispo County and southern California's is Orange, Ventura, and Los Angeles County (Gaines, 2017).

Lastly, the type of facility is another important aspect to fully understand the sourcing methods for medical models. When prompted with the type of facility they work in, respondents from the survey provided answers that included hospitals, clinics, community health centers, and private practices. Figure 7 represents the percentage of facility types that utilised 3D printed medical models within their care.

Figure 7 Percentage of facility types (see online version for colours) What type of facility do you work in? \bullet Clinic

As shown above, healthcare workers that utilise medical models within their practice are exclusively from hospitals and clinics. Thus, the AM hub should serve these facility types to source medical models most effectively.

4 Additive manufacturing hub location model

Combining the literature review analysis with the stakeholder survey feedback, there is now an adequate understanding of the relevant healthcare applications, AM techniques, materials used, workflow process, and sourcing methods for AM applications in healthcare.

4.1 Model inputs

Following this fundamental research, a mathematical model will be generated to optimally locate the AM hub through operations research techniques. To generate the model, specific inputs are necessary.

4.2 Coordinates of healthcare facilities

One of the most important inputs for beginning a sample location model is coordinates of local healthcare facilities. From the findings listed above, the specialties with the highest frequencies of use for the hub are orthopaedic-related. Therefore, an example of coordinates from orthopaedic or similar clinics in the San Luis Obispo County are shown in Table 3.

These coordinates will be used to minimise the distance between facilities and the AM hub location.

Specialty	<i>Facility type</i>	Coordinates
Orthopaedic Surgeons	Multi-Physician Orthopedic Clinic	35.293333022167694, -120.6688035
Orthopaedic Spine Surgeon	Private Practice Clinic	35.33364177881895. -120.6591225405242
Orthopaedic Surgeon	Private Practice Clinic	35.287449733261724, -120.65549241534264
Orthopaedic Surgeons and Sports Medicine	Multi-Physician Orthopedic Clinic	35.28734409152173, -120.65503027989537
Orthopaedic Surgeons	Multi-Physician Orthopedic Clinic	35.14451025574229, -120.63130127782635
Orthopaedic Surgeon	Private Practice Clinic	35.14456403850933. -120.6307227473069
Orthopaedic Surgeons	Multi-Physician Clinic	35.27463027920004, -120.64455931349302
Foot and Ankle Specialists	Multi-Physician Podiatric Clinic	35.29330886753669. -120.66879783841905
Podiatric Surgeon	Private Practice Clinic	35.29318627042111, -120.66879573074783
Podiatric Surgeons	Multi-Physician Podiatric Clinic	35.27438339916223. -120.64374092607913
Surgeons/Specialists (all types)	Medical Center	35.278403791284106, -120.651071155708

Table 3 Orthopaedic and podiatric facility coordinates

4.3 Turnaround time inputs

Another potential input needed for the location model is turnaround times. While geographical proximity is certainly important, varying turnaround times must also be considered. When considering the survey, the general necessary turnaround time for medical models is 2–3 weeks. However, unlike the higher urgency of medical models due to scheduled surgeries, physicians have indicated they can wait up to 8 weeks (about 2 months) for their product.

5 Conclusion

With extensive literature research performed and an inclusive survey conducted, the objectives required to initiate the development of the AM hub location model have been met, which is depicted in the following list:

- 1 The best-known application for AM in healthcare delivery is medical models, with an emphasis on surgical planning and training models, and orthotic insoles.
- 2 Those that benefit the most and would have the highest frequency of use for these AM models are surgeons and physicians for medical models and podiatrists for custom orthotic insoles.

3 The benefits of utilising medical models within healthcare practice are higher tactile and visual perception of patient-specific body parts, making analysis for either training or preoperative planning more efficient and effective. Benefits for orthotic insoles include a short-term relief for specific foot-related diseases and back pain. Certain consequences include inadequacies for emergency situations and lack of accuracy for tactile anatomy for medical models and high costs for orthotic insoles.

The next steps include generating a mathematical model that is supplemented with input information to optimally locate the AM hub, understanding the interconnectivity of the hub with the manufacturing industry, facilitating discussions with healthcare professionals that will use the AM hub, and developing the hub itself.

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Abbreviations

