







Physicians as Manufacturers:

The Rise of
Point-of-care
Manufacturing





COVER: Dr. Kevin Arce works with biomedical engineer, Amy Alexander, in the Mayo Clinic 3D Printing Lab to place osteotomy (surgical cut) planes which will be used to digitally cut and then reconstruct the jaw bone in preparation for 3D printing quides.

Bioresorbable tracheal splint developed at the University of Michigan working with CS Motts Children Hospital for patient with tracheobronchimalacia (TBM).

Patient holding her heart model used by physicians at Nicklaus Children's hospital to aid in planning for a double aortic arch surgery.

Photos courtesy Mayo Clinic, SME & Stratasys

Technology Keeps Patient First

Healthcare providers operate in an evolving environment influenced by policy, regulations, and changing technology. Yet, the number one priority remains patient care.

In a recent survey¹, nearly half (49%) of healthcare provider executives said revamping the patient experience is one of their organization's top three priorities over the next five years.

This focus is helping fuel the rise of point-ofcare (POC) manufacturing enabled by additive manufacturing (AM), commonly known as 3D printing.

From anatomical models to prosthetics, the use of 3D printing at hospital sites is providing benefits for patients and physicians/institutions including:

- Better patient outcomes
- Less time in the operating room
- Reduced costs

The POC model is especially noteworthy due to the collaboration between hospitals, device manufacturers, U.S. Food and Drug Administration (FDA), and partners such as SME.

These partnerships drive efficiency through best practice sharing as well as accelerate innovation for applications such as bioprinting and tissue fabrication. They also lay the groundwork for 3D printing of organs and scaling up production of tissues which are still decades away.

This white paper, developed by SME, discusses the factors leading to a rise in POC manufacturing as well as existing challenges. In addition, the paper unveils results from SME's Medical Point-of-Care Manufacturing Survey and presents case studies of successful 3D printing models created within a clinical setting.

What is Point-of-Care Manufacturing?

POC is a non-traditional form of manufacturing referring to the just-in-time creation of anatomical models, surgical instruments, prosthetics, scaffolds, and other 3D printed applications at the place of patient care, based on their personal medical imaging data (MRI, CT, or surface scans).

Larger research hospitals may have their own in-house 3D printing laboratories while smaller hospitals may work with contract manufacturers.

Medical "hubs," such as the 150 hospitals and over 800 outreach centers run by the U.S. Department of Veterans Affairs (VA), are standardizing 3D printing best practices across its locations.



3D-printed osteotomy guide to correct a double forearm malunion; shown on patient's anatomical model.

Hospitals connected to university engineering departments Hospitals - Government - Non-profit - For-profit **Contract Manufacturers**

Types of POINT-OF-CARE Manufacturers

- Non-profit hospital
- For-profit hospital
- University engineering department working with hospital
- Government hospital / Hub (i.e., Veterans Affairs System)
- Contract manufacturers working with hospitals

At-a-Glance: POC Manufacturing

In late 2017, SME asked those involved in the POC manufacturing area to provide feedback on practices and applications through its first-ever Medical Point-of-Care Manufacturing Survey². The results provide a compelling snapshot of how emerging 3D printing technology is impacting medical care.

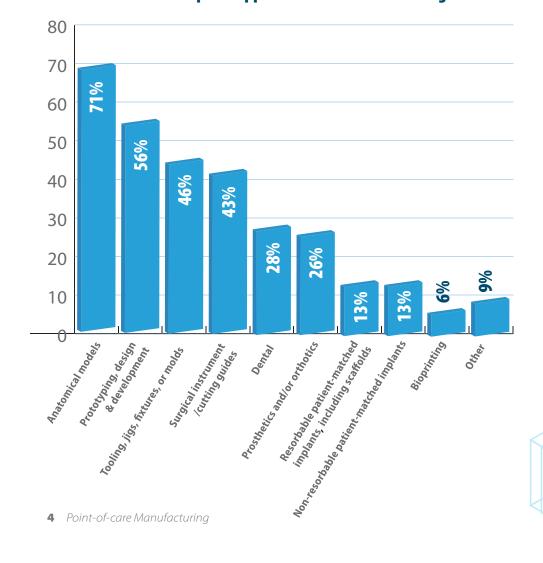
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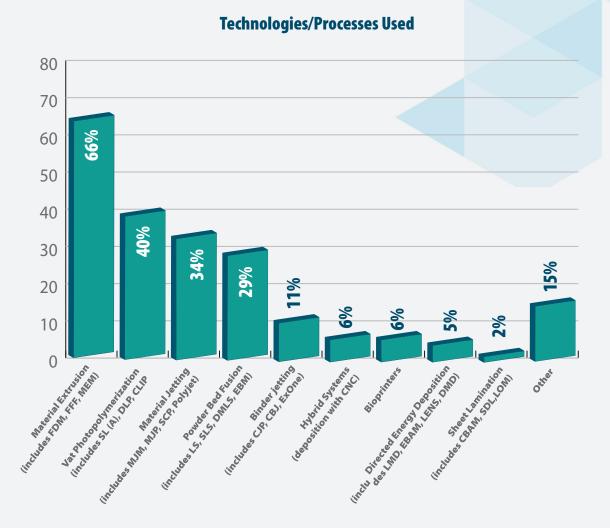
Have used 3D Printing for three years or more



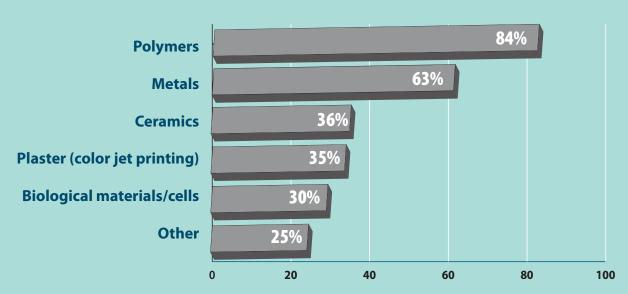
Anatomical model of conjoined McDonald twins with guides developed via virtual surgical planning for separation and then 3D-printed.

Most Popular Applications of POC 3D Printing





POC Manufacturers expect increase in use of these materials, both POC and traditional manufacturing



POC Benefits

Early success stories show the benefits of POC manufacturing which are driven by increased accessibility to the technology by innovative clinicians and enabling greater interdisciplinary collaboration. These advantages lead to a number of positive effects, from reducing operating room times to lower readmission rates. Often these benefits directly translate to cost-savings for the institution.

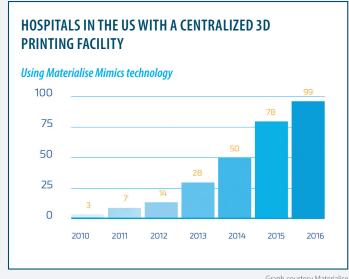
Another advantage of implementing 3D printing in a POC setting is that clinicians can regularly visit the manufacturing lab and provide iterative feedback during the process of anatomical modeling. This team approach successfully blends expertise in biology, engineering and 3D printing.

With more successes and precedents for this model, there will be a greater shift to POC. Already, in the last decade, hospitals with a centralized 3D printing facility have increased significantly, according to Materialise.

The trend is forecast to strengthen as software and hardware/materials continue to improve, and regulatory guidelines become clearer.



Todd Pietila, Materialise, works with Dr. David Morales, Chief, Pediatric Cardiothoracic Surgery, Cincinnati Children's Hospital to review digital images and a patient's cardiac model before surgery.



Graph courtesy Materialise

"Forward looking hospitals are implementing on-demand 3D printing service lines and, in turn, are reaping benefits of an improved patient experience, better training of physicians and growth in innovation which can drive non-traditional revenue streams in addition to the inherent cost saving that can be realized," said Todd Pietila, Global Business Development, 3D Printing for Hospitals, Materialise.

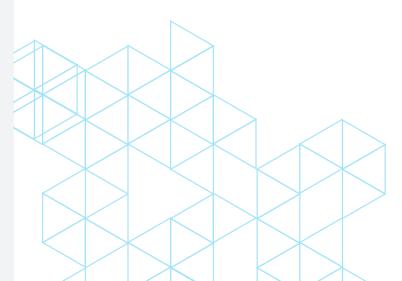
Pietila continued, "I'd put about 2 to 3 percent of hospitals in the early innovator category that are making significant investments in this technology. This will continue to expand as the body of evidence grows. There is tremendous momentum in the industry to address challenges and move forward collectively into the future."

3D PRINTING IN HEALTHCARE

Increase in the number of hospitals in the U.S. with a centralized 3D printing facility between 2010 and 2016*

Number of hospitals out of the top 20 as ranked by U.S. News and World Report that have implemented a medical 3D printing strategy

*Using Materialise Mimics technology



Benefits of POC

While POC may not be for every hospital due to the investment in equipment and staff, for those that are considering this business avenue, there are a number of benefits:

- Quicker Turnaround: Traditionally, models, prosthesis, instruments and more were 3D printed at remote production facilities and sent back to the hospital. POC manufacturing significantly improves turnaround time by the eliminating shipping step.
- Team Approach: Clinicians and engineers can collaborate onsite. Radiology is most often the home of 3D printing within the hospital. Providing needed anatomy and imaging knowledge, radiologists are the facilitators, leaders, and champions of POC.
- Onsite Quality Control: High quality standards at an internal lab are easily monitored.
- Improves Patient Consultation: Patientmatched anatomical models allow better patient communication and education.
- Pre-surgical Planning, Intraoperative Planning: Clinician involvement through each step helps with planning. On-site printing allows for quicker adjustments if needed. This preparation also saves time in the operating room, lowering costs.
- Improved Outcomes: Surgeons and engineers pool knowledge and skills to address issues and create innovative patient solutions.
- Potential to Impact More Patients: Ultimately, 3D-printed POC applications will be nearly as common as off-the-shelf and available to a wide range of patients.

Traditional Manufacturer Partnerships

Traditional manufacturers, which often supplement hospital POC projects, are a valuable part of the partnership. Whether providing anatomical models for use in the operating room, a sterile field, or handling overflow projects, these partners work closely with surgeon groups and clinicians, bringing years of industry experience to the table.

Katie Weimer, VP of Medical Devices, Healthcare, 3D Systems, which provides 3D printing and patient specific design services for anatomical models, virtual surgical planning and also contract manufacturing for plastics and metals, said, "We are excited about the trend of 3D printing at the hospital level so clinicians can begin to utilize patient specific modeling and 3D printing on their own. It can be a really nice counterpart with a local service center at the hospital and a centralized service center outside the hospital – those two models can work well together into the future."



Katie Weimer and Joe Fullerton, 3D Systems Healthcare, work with medical images to segment and prepare files for 3D printing.



Katie Weimer, 3D Systems Healthcare, works with the surgical team in the operating room with both digital and 3D-printed anatomical model for the McDonald twins separation surgery.

Weimer said that software, printers and materials will continue to evolve. Specifically for material development, Weimer said, "Today, the healthcare 3D printing industry largely uses legacy industrial prototyping materials. As the industry evolves, I believe we will have a bigger impact on patient care when our materials better replicate the human body. I believe we will see a revolution into more biomimetic materials for 3D printing in the healthcare industry."

She added that when it comes to point-of-care 3D printing, "Ultimately, it has to be a plug and play system. As an industry, we need to better deliver a suite of products (software, hardware, materials) and I think the industry will get better at delivering this to hospitals and offices as we continue to evolve together."



Case Study: Hub Model — VA Hospitals

The U.S. Department of Veterans Affairs (VA), which runs 150 hospitals and more than 800 outpatient clinics, is on the forefront of standardizing 3D printing best practices.

The Veterans Health Administration (VHA) has established a new 3D Printing Advisory Board to oversee and advices VHA on 3D printing activities for the entire healthcare system. Through this "hub" model, a diverse group of VA employees share a vision of improving the health of Veterans through 3D printing technologies.

Beth Ripley, Chairman for the VHA 3D Printing Advisory Board, explained, "We are located across the country and we come



Ben Salatin, Albuquerque VA Hospital, pulls 3D-printed smart phone mounts for a veteran's power wheelchair, from the printer.



San Antonio VA staff are actively exploring opportunities for 3D printing. While 3D printed, weight-bearing prosthetics are not in routine clinical use within the VHA system, this is an area of active research focused on quality, safety, comfort, and durability of 3D printed prosthetics.

from different backgrounds, but we all see how 3D printing can help us do our jobs better, whether that is creating a customized splint for a patient, designing a modification for a wheelchair to improve a Veteran's ability to manipulate that chair, or converting a CT study into a physical model of a patient's anatomy to help the surgeon plan a safer procedure."

Today, there are 35 subject matter experts (SMEs) and 30 3D printers across the VHA system. Thanks in part to collaboration with Stratasys, one of the major manufacturers of 3D printers, the network is growing. Five new Mojo 3D printers from Stratasys are being strategically placed to maximize the reach of the network. These include the VA medical centers in Seattle, Albuquerque, San Antonio, Orlando and Boston.

Ripley said that a lot of 3D printing efforts are around orthotic and prosthetic devices due to their applications with combat Veterans. Recently, one VA team used 3D printing to improve



The VA system 3D printing hubs connect experts and machines across the country to better serve patients.

a hand orthosis, which is traditionally custom made by a hand therapist who would bend and shape it on the patient at the time of the appointment.

"There are two problems. The first is that the orthotic often breaks after about three months," said Ripley. "The second is that the Veteran has to come back to the hospital each time so the hand therapist can recreate the brace."

Hand therapist Mary Matthews-Brownell and rehabilitation engineer Ben Salatin teamed up to use 3D printing to address those problems. Salatin made a digital copy of a hand orthosis created by Matthews-Brownell, enhanced it by removing the seams and removing some of the weight, and then 3D printed it.

The hub model allows this knowledge to be shared. To date, they have created 3D printed orthotics based on the initial custom-fabricated versions for five Veterans.

"The Veteran likes the 3D-printed orthosis much more as it is lighter and more comfortable," said Ripley. "Also, the Veteran doesn't need a new appointment for a replacement. We just print and send a new one. This saves time for both the Veteran and the hand therapist."



A Veteran tests out his new 3D printed hand orthosis while certified hand therapist Mary Matthews-Brownell looks on.

Top 3 Challenges to Increasing Use

Reimbursement

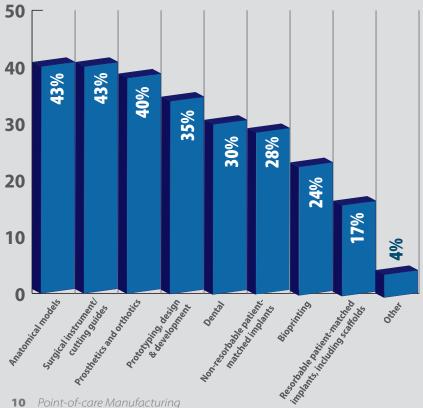
36%

26%

Funding/Capital

Regulatory Environment 18%

Greatest growth areas in 2018



GROWTH POTENTIAL

96% of POC professionals say they expect to see an increase of the use of AM/3DP medical applications in 2018.



Case Study: Mayo Clinic Committed to POC Manufacturing

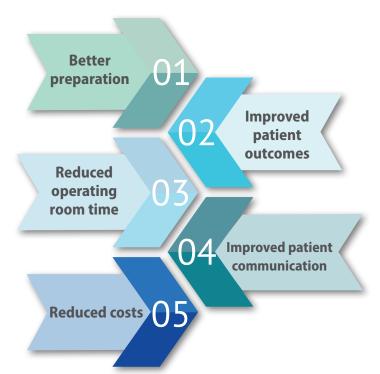
Mayo Clinic in Rochester, Minn. has fully embraced its role as a POC manufacturer for anatomical modeling, virtual surgical planning, and some Class 2 medical devices such as an osteotomy guide.

The institution has invested more than \$1 million for a lab and equipment to cover the entire enterprise. Staffing is robust with one full time radiologist, two engineers, full time segmenters and others onsite which leads to valuable collaboration.

Jonathan M. Morris, MD, Associate Professor of Radiology/ Co-director of the 3D Anatomic Modeling Lab, Mayo Clinic, said that the major benefit to in-hospital 3D printing is allowing the clinical teams, engineering, and radiology to interact where the medical care is being delivered. This close relationship helps them "innovate on the fly" and collaboratively solve complex medical and surgical problems in a way not possible if they worked in silos.

"Engineers working inside the hospital can take a doctor's idea to fruition due to their different skillset," said Dr. Morris.

Top 5 Benefits of Anatomical Models





Dr. Jane Matsumoto and Dr. Jonathan Morris, co-directors of Mayo Clinic's 3D Printing Lab, work with biomedical engineer, Amy Alexander, to prepare files for 3D printing.

One of the big advantages of point-of-care manufacturing is turnaround time," he said. "We can go from a clinical problem to an idea, to protocoling a radiology study tailored to 3D printing, with DICOM transfer to lab as soon as the patient leaves the CT scanner. We can work on segmentation and get the model to the printer pretty quickly on a regular basis."

He added, "We have tried to provide patient specific anatomic models through 3D printing in real time."

An example of a successful turnaround was the first 3D printed aorta they did for a patient specific simulation. The surgeon came in on Thursday with a patient who was not operative and no stent was on the market to fix the issue. The doctor discussed this with a stent company that said they could have something the next week.

The Mayo team said they'd have a working, patient specific prototype that could be hooked up to physiologic flow pumps by Monday. In four days, the stent was created, tested on a patient specific simulator and on the fifth day, it was put into the patient.



"Without this collaboration with the physician-run 3D print lab, radiologist, engineer, and medical device company, there would be no way to get the stent to the patient in this timeframe," said Dr. Morris.

Mayo surgeons across multiple specialties regularly use accurate 3D printed models based on patient CT or MRI scans to plan complex surgeries. This has led to improved care and better outcomes through innovative approaches, less time under anesthesia and in the operating room (OR), shorter hospital stays, smaller incisions, and a more efficient use of overall resources.

Dr. Morris said that although costs are not typically reimbursed, The Mayo Clinic absorbs the cost since it can saves money in the long run while increasing value.

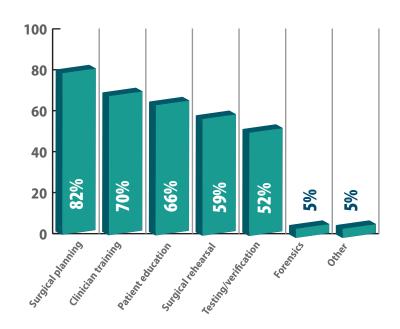
"When it comes to point-of-care manufacturing, the answers are not simple," said Dr. Morris. "Every hospital is different. If you are only printing 10 or 20 models a year at the beginning, it may not make sense to buy a printer for hundreds of thousands. It might be better to outsource or start with low cost, single material printers."

Mayo creates 500 to 700 models per year. "That number barely scratches the surface of the number of patients we see or surgeries we perform," he said.

"At Mayo, we're a destination medical center committed to giving our patients the highest level of care and one of the ways we are doing that is with 3D printing. We are a large enough organization to do it."

ANATOMICAL MODELS use 3D printed anatomical models

How POC Manufacturers Use Anatomical Models



Case Study: Long Distance Collaboration — **Hospital & University**

In 2015, Adam Jakus, PhD, was working for Ramille N. Shah's Tissue Engineering and Additive Manufacturing (TEAM) Lab at Northwestern University's Simpson Querrey Institute for BioNanotechnology in Chicago. Dr. Shah received an email from Duke University Hospital in Durham, N.C., requesting help with a four-month premature infant with a tracheoesophageal defect.

"The Duke surgeons generally knew how to fix it but they didn't have the right tools or the right implants and no one could make something fast enough or make the needed designs," said Jakus, now Chief Technology Officer, Dimension Inx, LLC.

"Through comprehensive discussions with them, and after reviewing patient data, we developed a new variation on an existing material for 3D printing. We designed several devices, 3D-printed and shipped them, all within 2 to 3 days. The shipping itself was the worst part. Even with the fastest shipping, it still took more than a day to get there, and there was no guarantee that the shipment wouldn't be lost or delayed."

Jakus explained that by the time the samples arrived, the baby's physiology and condition had changed – the baby was growing – and so the devices didn't fit as intended. The team made changes, printed and shipped samples the same day. The shipping took more time than the design and fabrication, and even sterilization.

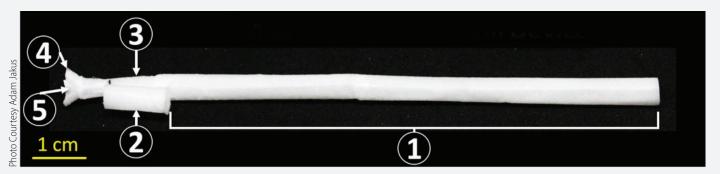


Adam Jakus, Dimension Inx, working on the next generation of 3D-printable materials.

The device was ultimately designed in a modular fashion, such that independently 3D-printed parts/components could be rapidly assembled in real time as more information from the surgeons was received. With the baby weighing less than two pounds, and with such a complex tracheoesophageal defect, the device had to go inside the trachea/esophagus. It also had to be trackable via X-ray and had to be able to be quickly removed if necessary.

This technical knowledge, in conjunction with the expertise and skills of the surgical and support teams at Duke University, resulted in a working device that restored the baby's lung function and separated esophagus and trachea. Ultimately, the infant passed away due to other complications.

Continued on next page



Modular device to treat premature infant with a tracheoesophageal defect produced at Northwestern University for Duke University Hospital. Parts 1-4 were fused together as needed to create a device that would ultimately match the ever changing situation/patient anatomy. Part 5 was printed of Hyperelastic Bone™, normally used for bone regeneration, but used for its highly radio opaqueness and use as a means to monitoring device placement via X-ray.

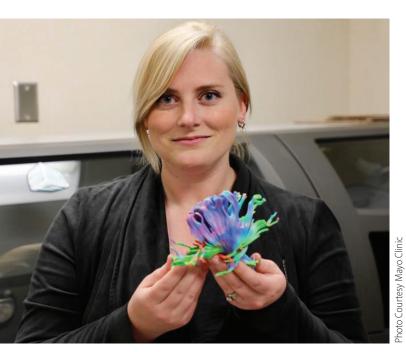
Jakus said there are several lessons to be learned here. The first points to the importance of communications between clinicians and engineers to make something new to solve a problem.

"The ability for engineers to be able to effectively communicate with clinicians, and vice versa, is paramount to the success of these kinds of cases," Jakus said.

The second lesson, he said, is that even if these types of events and activities do not have the best endings, they should still be discussed, as "lessons learned can be communicated to others in the medical 3D printing and surgical communities, hopefully aiding others when similar situations arise, while simultaneously highlighting need for Point-of-Care manufacturing."

He continued, "If we, as the engineering and 3D printing team, had been in the hospital, at least near the hospital, the process would have been faster, much more efficient, and potentially there may have been a much higher likelihood of success overall although I can't say that with absolute certainty."

Jakus said, "Until teleporters are invented and become commonplace, there are limiting factors if manufacturing is not onsite," especially for emergency cases like this.



Amy Alexander, Mayo Clinic, with a model of brain neurons

Challenges: Hospitals are successfully setting up 3D printing labs for POC and learning much along the way. As part of the SME Medical Additive Manufacturing/3D Printing Workgroup, leaders in this area including clinicians, researchers, medical device manufacturers, and technology providers, have identified the following challenges, and are working to address them:

Logistics of engineering within a hospital

- Manufacturing infrastructure (in-hospital GMP)
- · Using a printer within hospital footprint (speed, reliability, materials3)
- · Identifying types of technologies that are hospitalfriendly, considering the best materials, speed, etc. Understanding the trade-off between machines and materials, which will be addressed with future innovation.
- Communication and understanding outside of the 3D lab of the complexity of the process
- Establishing protocols
- Sterilization processes
- Acknowledging differences between types of 3D printing applications whether producing models, guides, implants — and one day, tissues.

Supply Chain

- This Just-in-Time approach to manufacturing requires an ordering system that assures supplies are available as needed. Integrate into Electronic Medical Records (EMR), Radiology Information Management Systems (RIMS), etc.4
- Secure, on-demand transportation from lab to clinical setting must be considered.

Technology and Materials

 Faster processes capable of micro and nano-level precision are need to expand the applications. The number of materials that can be printed needs to expand, whether for strength, biocompatibility, and/or sterilization. What can be printed today is limited when compared to traditional manufacturing methods.



Feline knee implant developed by Dr. Denis Marcellin-Little and Professor Ola Harrysson, North Carolina State University.

Regulatory Environment

- In December 2017, the FDA released guidance⁵ on 3D printed medical devices, "preparing for a significant wave of new technologies that are nearly certain to transform medical practice," according to a statement. The guidance, focused on safety and effectiveness of the products, provides FDA thinking on various approaches to 3D printing, including device design, testing of products for function and durability, and quality system requirements. This "leap-frog" guidance will continue to evolve along with innovation in this area.
- There are discussions in the industry about regulatory oversight. Would you have a POC center certified by a regulatory agency? How do you certify people on the machines?

Funding/Capital/Business Model

- To continue innovation in this area, hospitals must determine how to make the venture financially sustainable.
- Currently, hospitals cover the cost as it saves time/ costs later. For surgical planning, for instance, it's cheaper in the long run since it saves time in the operating room.

POC Capital Investment⁶

Space

Personnel

Facilities

Upkeep

Materials

Scanners

Printers

IT Infrastructure

Sterilization

GMP

Storage

Reimbursement

• Costs are not reimbursed through health insurance. The industry is building guidelines to support standards of care that will become reimbursable. For instance, the Radiological Society of North America (RSNA) 3D Printing Special Interest Group (SIG) is leading a collaborative effort to develop appropriateness guidelines for the use of anatomical models by condition and treatment plan including surgery as well as developing CPT codes.

Quality Control

• Protocols must be in place to ensure quality standards are met between designed and printed models, whether products are manufactured inhouse or outsourced.

Oualified Workforce

- The growth of 3D printing in medicine requires the collaboration of medicine and engineering with bioengineers trained in 3D printing, playing a key role.
- Educators, industry, and medical institutions are working together to make recruiting and training a priority.

Complex Regulatory Process

With the concept of making medical devices at a hospital, everyone needs to understand that the regulatory process is complex. There are a number of steps outside of manufacturing like cleaning and sterilization, which need to be validated. It's not so simple.



Patient-specific kidney tumor model used for surgical planning at NYU School of Medicine as part of an ongoing clinical trial being led by Nicole Wake, to study the ability to enable surgeons to more effectively conduct pre-surgical planning, collaborate in the operating room, and communicate with patients.

Factors Leading to POC Manufacturing Increase

- Precision Medicine: Better patient outcomes and lower costs from developing treatment plans and devices precisely for the patient. 3D printed drug therapies are also being developed.
- Word-of mouth, success, good clinical outcome: The body of evidence related to POC/medical 3D printing continues to grow, leading to optimism about this burgeoning technology.
- Transition from central production to distributed and point-of-care: Seeing the benefits of POC, hospitals are creating their own laboratories. Offers opportunities for bioengineers, blending an expertise in biology, engineering and 3D printing.
- Dental labs use is supported by FDA cleared dental materials.7
- Additive manufacturing/3D printing: More accessible and affordable AM technology becomes mainstream. Innovation around hardware, software, materials, and processes improve speed, flexibility, accuracy, and lifelike qualities of end product.
- Resource sharing: The industry is enthusiastic about sharing best practices and body of knowledge to bring POC to the next level.
- Potential for growth: With nearly \$9 trillion spent each year globally on healthcare⁸, POC manufacturing enabled through 3D printing can help address medical needs.

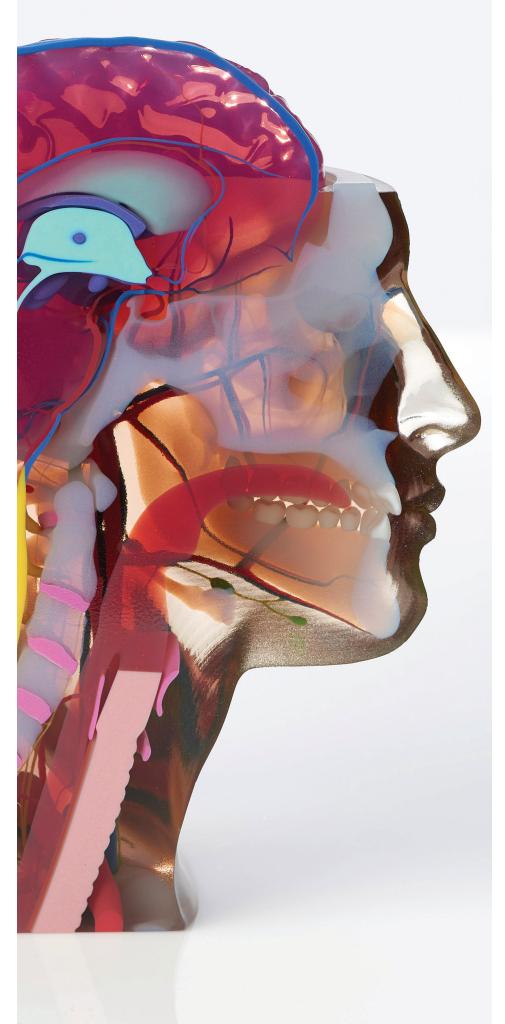
A Look Toward the Future

POC manufacturing, enabled by 3D printing, will continue to play an important role in the healthcare industry. Success to date shows that this emerging technology will improve patient outcomes and create more efficient and cost-effective practices.

Further industry collaboration, additional clinical studies, and regulatory guidance will help ensure in-hospital manufacturing becomes the standard of care. Collaboration will also encourage innovation, by moving 3D printing beyond anatomical models and surgical guides to bioprinting, tissue fabrication and, perhaps one day, even 3D printed organs.



Pediatric cardiac model produced by Materialise for examination of congenital defects.



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- 3. Jonathan M. Morris, MD, Division of Neuroradiology, Co-Director Anatomic Modeling Lab, Department of Radiology, Mayo Clinic and Foundation, "Introducing 3D Printing into a Clinical Setting at Mayo Clinic: 8 Years of Progress and Innovation," May 2017, p. 35.
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- 7. "Process of Printing Medical Devices," US Food & Drug Administration.
- 8. Deloitte's 2017 Global Health Care Outlook report

About SME

SME connects all those who are passionate about making things that improve our world. As a nonprofit organization, SME has served practitioners, companies, educators, government and communities across the manufacturing spectrum for more than 85 years. Through its strategic areas of events, media, membership, training and development, and the SME Education Foundation, SME is uniquely dedicated to the advancement of manufacturing by addressing both knowledge and skills needed for the industry. Learn more at sme.org, follow @SME_MFG on Twitter or facebook.com/SMEmfg.

Building a community of practice

Creating a home for additive manufacturing/3D printing users

More than 25 years ago, SME's rich history of supporting manufacturers led the pioneers and innovators of 3D technologies to make SME the home for their new Rapid Prototyping technical group.

Today, SME connects some 200,000 people in additive manufacturing, continuing the original group's vision of — and commitment to creating an extensive community. www.sme.org/3D

Medical additive manufacturing/3D printing

Making a difference through collaboration

The SME Medical Additive Manufacturing/3D Printing Workgroup supports users of medical and biomedical application technology. Members represent medical device manufacturers, clinicians, technology providers and more, including Mayo Clinic, Biomet, University of Michigan, Smith & Nephew, Materialise, nScrypt, Leuven Medical Technology Centre, DePuy Synthes, Stryker Orthopaedics, Phoenix Children's Hospital, Johnson & Johnson and Northwestern University. By providing content to address the latest industry developments, identify gaps in standards, and build evidence for additive manufacturing applications in medicine, the group helps drive technology to improve and save lives. To find resources and to get involved visit:

www.sme.org/medical-am3dp-workgroup

Contact

For more information about Point-of-Care Manufacturing/Medical 3D Printing, please call Lauralyn McDaniel, Industry Manager, SME at 313-425-3108 or email *Imcdaniel@sme.org* or visit www.sme.org/medical-additive.



