OFFICE OF
INFORMATION
AND TECHNOLOGY

3D Printing at the Department of Veterans Affairs

White Paper

October 2018| Enterprise Program Management Office

U.S. Department of Veterans Affairs
Office of Information and Technology

Table of Contents

1 Introduction

The future is filled with endless technical possibilities. Among them is the evolutionary movement of creating three-dimensional (3D) objects from computer-assisted designs by successively joining or solidifying materials from a printer, layer by layer. 3D printing, also known as additive manufacturing, has advanced from spewing toner on a white sheet of paper to building layers of plastic until an object is formed; to now using specialized printers to print a body part, airplane engine parts, or a 500-square-foot barracks room for soldiers, all in a timely, efficient, and cost-effective manner.

The Office of Architecture and Engineering Service (AES), within the Department of Veterans Affairs' (VA) Office of Information and Technology (OIT), developed this high-level white paper to address the initiatives of 3D printing across healthcare at VA. This document provides examples of the benefits and constraints of 3D printing, thought leadership on 3D printing at VA, and plans to enhance customer service and improve product satisfaction for the benefit of our nation's Veterans.

2 Overview of 3D Printing

In 1984, Chuck Hull, an American businessman, received a U.S. patent for stereolithography, one of 3D printing's earliest recorded uses. Stereolithography enabled designers to create 3D models using digital data, which could then be used to create a tangible object. Hull was inducted into the National Inventors Hall of Fame in 2014 at a time when widespread uses for the technology began, following the creation of the first prototype of an affordable large-format 3D printer by the National Aeronautics and Space Administration (NASA) engineers. The 3D printing industry is estimated to continue to grow by more than 31 percent annually through 2020, and generate more than $21 billion in revenue, according to an insights report.

3 Usage at VA

In March 2017, the VA Center for Innovation (VACI) partnered with Stratasys, a manufacturer of 3D printers and 3D production systems, to translate 3D printing into "point-of-care" manufacturing by implementing a 3D printing initiative for VA patients. The plan was to serve more than eight million Veterans each year and change the dynamic of how VA hospitals function. Five 3D printers were installed in five VA hospitals in Seattle, Albuquerque, San Antonio, Boston, and Orlando. The plan was built upon the 3D printing work already completed at other VA hospitals, including the McGuire VA Hospital in Richmond, Virginia, where printers print custom assistive technology devices for Veterans. VA Puget Sound Health Care System in Seattle and the San Francisco VA have both utilized 3D printing for pre-surgical planning work for cases including mandibulectomies, renal surgeries, and orthopedic surgeries.

One of the fastest growing areas of the 3D printing industry is point-of-care medical applications. For example, a hospital's radiology department uses medical imaging data to manufacture life-size tangible anatomical models that are used for surgical planning and guidance, simulations, diagnoses, and patient education. For instance, a radiologist, who is an expert with 3D imaging, can image patients that might need surgery and create a 3D model of the site where the surgery will be performed. Afterwards, the radiologist can give that 3D model to the surgical team, who can then use it to operate.

Gary Brayshaw,[1] a Veteran in Washington State, is devoted to outdoor sports and recreational activities. His regular routine consisted of chopping wood until his Dupuytren's contracture, a condition pulling fingers into a bent position, made that nearly impossible. An occupational therapy hand specialist, Mary Matthews-Brownell, reached out to Seattle VA 3D printing leadership to help her create a custom-made 3D printed splint for Brayshaw. Matthews-Brownell joined Ben Salatin, a clinical rehabilitation engineer at the Albuquerque VA hospital, to collaborate in creating a 3D printed orthotic that allowed Brayshaw to pick up an axe again.

Ismael Baca, a Veteran from Albuquerque, New Mexico, was in a tragic accident, where he sustained a spinal cord injury that left him bound to a wheelchair. When Salatin observed that Baca had a difficult time turning on the toggle switches on his wheelchair joystick, due to loss of finger function, Salatin sought a 3D printing solution for the Veteran. Salatin used 3D printing to create a press-on adapter to widen the toggle switch. This allowed Baca to use and maneuver his wheelchair with great ease. The toggle design was shared with other VA hospitals to enable other Veterans to take advantage of the solution. A design can be customized to fit the different needs of any Veteran and configured to the wheelchair joystick.

These success stories show how experts from various specialties have worked together at VA to utilize 3D printing technology to improve the quality of life for Veteran patients.

4 Thought Leadership

The Veterans Health Administration (VHA) 3D Printing Advisory Committee has representatives from VHA National Program Offices (i.e. Radiology, Surgery, Bioengineering, Rehabilitation and Prosthetic Services, etc.), Veteran Integrated Service Networks, VA medical centers, VACI, the Information and Access Privacy Office, OIT, and ex officio members to collectively grasp firsthand knowledge of the current stature of existing 3D printing technology and its utilization across the country in VHA facilities.

[1] https://www.blogs.va.gov/VAntage/36409/vas-center-innovation-using-3d-printing-create-devices-help-veterans-feel-whole/

Collectively, this VHA 3D Printing Advisory Committee serves as the group of subject matter experts (SMEs) that advise VHA to facilitate a network of VHA sites with 3D printing capabilities, providing guidance, coordinating best practices, and contributing to policy regarding the quality, safety, standardization, and utilization of 3D printing technology within the VA healthcare system.

Dr. Beth Ripley[2], a radiologist and chair of the VHA 3D Printing Advisory Committee at VA, states that 3D printing supports VA's vision to "provide Veterans the world-class benefits and services they have earned - and to do so by adhering to the highest standards of compassion, commitment, excellence, professionalism, integrity, accountability, and stewardship." Ripley sees 3D printing as a rapidly emerging tool to accomplish VA's primary vision to care for Veterans in ways that are more personalized. The strategy is to place a Veteran first, accept their need, and create the prosthetic, orthotic, or assistive technology device that is necessary. Point-of-care manufacturing is a technology that can enable this process to be performed.

Utilization of 3D printing is similarly being used in medical applications for custom orthotics and braces, dental implants, facial reconstruction, and customizing items routinely used by Veterans with disabilities to accommodate their specific needs (e.g., adaptive sports items, accessories for wheelchairs, etc.). VA healthcare providers want to expand Veterans' access to this new cutting-edge technology, and to modernize VA systems and processes to implement it on site where it is needed. The main goal is to integrate the technology across multiple disciplines with the intent of improving patient care and establishing personalized care.

5 Benefits

The benefits of 3D printing include improving VA's ability to target its efforts toward key mission areas that are focused on Veterans. 3D printing allows healthcare providers to manufacture point-of-care solutions at the Veteran bedside, thereby personalizing treatment, devices, and other solutions.

Dr. Ripley and her team have used 3D printing to create patient braces that are hand-molded, since they often break after three to four months. Instead of the Veteran driving to the nearest VA medical facility to retrieve the brace, the team can digitize the hand brace, print it, and ship it to the Veteran in a timely manner.

Another example where 3D printing has been crucial to success is in repairing the mandible[3], the lower jaw bone. Many patients have tumors of the mandible and chronic injuries and deformities of the jaw bone. The solution is a two-part surgery where (1) the surgeon removes

[2] Interview with Dr. Ripley and Dr. Chandler on 3D printing conducted on August 17, 2018
[3] Interview with Dr. Ripley and Dr. Chandler on 3D printing conducted on August 17, 2018

a portion of the mandible, and (2) the surgeon cuts into the leg to harvest a portion of one of the leg bones, the fibula, which they then cut into the shape of the mandible and use as a replacement. The surgery is time consuming and is very challenging. To improve the process, the patient's mandible can be 3D printed prior to surgery; this allows the surgeon to study it and plan pre-operatively before performing the fibular surgery and creating the mandible. In each of the few cases performed, the patients are under anesthesia two hours less and the surgeon is standing for less time – a factor that can improve the patient's health outcome and reduce surgical fatigue.

Dr. David Chandler, deputy chief consultant of VA Rehabilitation and Prosthetic Services, explained that biological implants represent a large expense to VA. Over 100 million dollars each year is spent on implants. Some implants, such as heart valves and knee and hip replacements, are necessary and are not currently produced by 3D printing. However, in cases such as the examples in which a 3D printing implant can be produced using the patient's natural anatomy, implementation of 3D printing can greatly reduce costs.

The next step in VA 3D printing may be using printers that can 3D print in titanium and other metals for medical and dental implants, as some organizations are already offering purely metal 3D printed parts. Soon, the VHA 3D Printing Advisory Committee will be exploring ways to print new bones for the Veteran patient, as a living part of the patient for long term stability.

6 Challenges

6.1 Understanding the Technology

3D printing for healthcare is still a relatively new concept, and an understanding of the technology is required to implement it. With limited knowledge of this new technology, the purpose of the equipment is often misunderstood when it is placed in hospitals. There are still questions, such as, "Is it a biomedical tool?" and "Can it be connected to the internet?" While there are many SMEs per capita within healthcare organizations, there are few who are trained specifically in utilizing 3D printing.

6.2 Standards

The VHA 3D Printing Advisory Committee recognizes that VA will need to develop appropriate plans for training, onboarding, and certifying employees, and for developing standards for quality and safety for 3D printing programs. Verification and validation procedures for the products created will need to be developed, and lessons learned will need to be borrowed from manufacturing, existing VA medical technology mandates, and other government agencies. For example, existing standards may include Food and Drug Administration (FDA) standards. There also exist Department of Defense (DoD) 5220 standards, which require using a software program for secure wiping, requiring three passes of overwriting with a special numeric pattern and verification.[4]

There are also other standards based agencies that offer existing guidance. The Federal Information Processing Standards (FIPS), for example, is a set of standards that describe document processing, encryption algorithms, and other information technology (IT) standards for use within non-military government agencies and by government contractors and vendors who work with the agencies.[5] To be compliant with FIPS, it is necessary to use cryptographic encryption of data residing on 3D printers when on-premise. Crypto-shredding, a method used to delete data, by encrypting the data and then deliberately deleting the encryption keys, so the data is non-recoverable, may be necessary for compliance.

The VHA 3D Printing Advisory Committee's goal is to understand these standards and concepts, build upon them to provide as a model to help guide VHA hospitals and healthcare system. While Mayo Clinic, Boston Children's Hospital, and a handful of other private hospitals produce the majority of medical 3D printing models, currently, the growth of 3D printing programs to approximately 20 VA hospitals to date puts VA on track to become a major player in this space. Both private and public hospitals, as well as organizations, such as the Society of Manufacturing Engineers, are expected to look to VA for best practices and guidance in 3D printing.

6.3 Implementation of 3D Printing

As a digital technology, 3D printing can be implemented in a digital base or virtually. The ability to share patient imaging scans, surface scans, or specifications across the enterprise to retrieve data points from the correct SME, and then manipulate and create them in a 3D printer, is a process that is vital to the welfare of many Veteran patients. Yet currently, there are unique challenges to delivering this service to all patients at all hospitals.

The VHA Directive 1104 of September 2017 provides policy for establishing and maintaining the Veterans Integrated Service Network (VISN) picture archiving and communication system (PACS) to support storage for the display and interpretation of images to the Veterans Health Information and Systems Technology Architecture (VistA) for non-radiology clinical viewing of images and image sharing beyond the VISN. The VISN includes 23 regional areas that are based on geography. Different VISN regional areas provide different PACS vendors, depending on their preference. This structure impedes the ability to digitally send 3D printing images across the VA network. For example, currently it is not possible for a physician in Seattle WA to retrieve

[4] For additional information, reference the National Industrial Security Program Operating Manual at http://www.dss.mil/documents/odaa/nispom2006-5220.pdf.
[5] The National Institute of Standards and Technology (NIST) provides information on FIPS at https://www.nist.gov/itl/itl-publications/federal-information-processing-standards-fips.

imaging in Orlando FL. In this scenario, the images would need to be mailed on a compact disc (CD). In addition, this structure highlights the need for governance at the enterprise level to ensure 3D printing availability across facilities as opposed to each facility procuring independently. For example, the same medical device should not be deployed with varying software versions and configurations across different facilities at VA, increasing security risks and the complexity of problem resolution.

In addition to accessing images, there is also the need to enable user access to 3D printers from remote locations, maximizing 3D printer utilization and uptime. The goal is to be able to remotely push jobs to the right printer for rapid manufacturing. The VHA 3D Printing Advisory Committee has expressed interest in creating an internal file repository for 3D print files with consideration for cloud access and retrieval. This repository would likely hold files that were de-identified and were made available for sharing (e.g. designs for assistive technology devices or braces). However, there could potentially be the need to be able to store files associated with protected health information (PHI). There is likely a need to validate each 3D medical device profile, including network communications and vulnerabilities, before the 3D device is put into operation. VA has entered into a Cooperative Research and Development Agreement (CRADA) with Underwriters Laboratories to develop a process to certify the cyber security posture of medical devices. There is the potential for this process to result in a kind of testing that satisfies this requirement and provides an acceptable risk profile for devices that are certified.[6]

Risk can be reduced through authentication of 3D printing devices when joining the Local Area Network (LAN) to aid in their identification and tracking, including the use of event logs of audit activity. 3D printing device integrity enforcement is significant since medical devices are more vulnerable to unauthorized access than typical IT assets due to the need to ensure the devices are readily accessible for patient care.[7]

6.4 Future Challenges

Other challenges deal with human health resources needed for medical testing. For example, currently, researchers in a lab in Toronto, Canada are testing a device that could be used in the future to directly print new skin on a patient.[8] Axel Günther, an engineering professor at the University of Toronto, explains that the skin can form the tissues right above the wound. The device prints a “bio-ink” gel filled with collagen, skin cells, and fibrin, a protein that aids in healing wounds. Günther’s vision is to manufacture a model that resembles a regular printer and ink cartridges. He envisions the use of a handheld instrument that can be sterilized, and

[6] For additional information, reference the Mobile Security Enterprise Design Pattern (EDP) at https://www.oit.va.gov/library/recurring/edp/.
[7] Refer to the Mobile Security EDP at https://www.oit.va.gov/library/recurring/edp/.
[8] https://www.design-engineering.com/uoft-3d-bio-printer-creates-skin-grafts-directly-on-wounds-1004030049/

custom cartridges that are single use and in touch with the patient. He suggests creating a small portable printer, instead of a bulky instrument, and ordering more cartridges.

Usually, skin grafts cannot cover a large surface area of skin, due to a lack of skin available. However, the use of 3D printing could produce skin that could cover an entire wound and aid in the process of healing the skin, while fighting off infections.

Currently, however, the research is in its beginning stages and will need more animal testing prior to human clinical trials. A challenge that researchers face is having enough skin cells available to print, due to the time it takes to grow cells. Researchers are working on an alternative method that uses fewer number of cells, with use of “universal donor” stem cells; these stem cells could be mass-produced and would not be rejected by individuals.

7 Conclusion

3D printing is a nascent and rapidly growing technology initiative and moving forward with this innovation is vital for progressing healthcare. There is still a great deal of work to be accomplished in advancing the technology for widespread, dependable use that will best serve the general population and Veterans. The effort at VA can serve as a catalyst to see the approval of 3D printing solutions for patients ranging from pre-surgical planning and implantable bioprosthetics to assistive technology devices, to custom prosthetics and orthotics.

It is crucial for VA medical centers to be connected to the correct 3D tools, and staff who know how to utilize them to provide Veterans the ability to access personalized 3D printed body part replicas, assistive technology devices, and other tools. The overall vision is for 3D printing to be available at all 168 VA hospitals across the nation to provide Veterans with the world-class benefits and services they have earned.

Appendix A. Acronyms

The following table provides a list of acronyms that are applicable to and used within this document.

Acronym	Description
3D	Three-Dimensional
AES	Architecture and Engineering Service
CD	Compact Disc
DMD	Demand Management Division
EPMO	Enterprise Program Management Office
FDA	Food and Drug Administration
NASA	National Aeronautics and Space Administration
OIT	Office of Information Technology
PACS	Picture Archiving and Communication Systems
PHI	Protected Health Information
SME	Subject Matter Expert
VA	Department of Veterans Affairs
VACI	VA Center for Innovation
VHA	Veteran Heath Administration
VISN	Veterans Integrate Service Network
VistA	Veterans Health Information Systems and Technology Architecture