SYM-AM-22-033



EXCERPT FROM THE PROCEEDINGS of the Nineteenth Annual Acquisition Research Symposium

Acquisition Research: Creating Synergy for Informed Change

May 11-12, 2022

Published: May 2, 2022

Approved for public release; distribution is unlimited.

Prepared for the Naval Postgraduate School, Monterey, CA 93943.

Disclaimer: The views represented in this report are those of the author and do not reflect the official policy position of the Navy, the Department of Defense, or the federal government.



Acquisition Research Program **Department of Defense Management** Naval Postgraduate School

The research presented in this report was supported by the Acquisition Research Program at the Naval Postgraduate School.

To request defense acquisition research, to become a research sponsor, or to print additional copies of reports, please contact any of the staff listed on the Acquisition Research Program website (www.acquisitionresearch.net).



Acquisition Research Program **Department of Defense Management** Naval Postgraduate School

Exploring the Potential for 3D Printing in Medical Logistics for Medical Supplies in Operational Environments

Lieutenant Elena Williams, USN—graduated from the Naval Postgraduate School in Monterey, California, earning a Master of Business Administration degree with a concentration in Operations and Logistics Management. After graduation, LT Williams reported to Naval Medical Readiness and Training Command, Camp Lejeune, where she serves as the Material Management Department Head, and was responsible for the medical logistics supporting the COVID-19 vaccination effort. [elena.v.williams.mil@mail.mil]

Bryan Hudgens, Lt Colonel (Ret), USAF—is a Senior Lecturer in Logistics and Operations Management at the Naval Postgraduate School, Monterey, California. Hudgens's early professional experience spans the field of government contracting, from supporting front-lines contracting in the Persian Gulf, to serving as a contracting officer on major weapon system contracts for the United States and its allies. Hudgens's teaching, research, and consulting focus on interorganizational relationships, within the end-to-end supply chain and among first responders. [bryan.hudgens@nps.edu]

Kathryn Aten—is an expert in organization science focusing on the adoption and use of emerging and information technologies. She draws on her expertise using surveys, behavior observation, focus groups, and individual interviews to help Navy leaders reduce technology acquisition and transition costs, design innovative systems for manning, and develop resilient warfighters and systems. Her research and publications investigate how individuals and organizations adopt and transition technologies as well as how technology implementations influence work and communication. Aten teaches strategic management and change, strategic management of information technology, research design, and qualitative and applied research methods. [kjaten@nps.edu]

Abstract

Medical supply shortages occur in mass casualty events in operational military environments. These challenge environments both lead to and exacerbate medical supply shortages. This study answers the research questions: Does 3D printing have the potential to positively affect medical logistics operations in these challenging environments, and if so, which Class VIII(a) consumable medical supplies show high potential? A qualitative case analysis investigates the challenges of medical logistics in austere, deployed environments, particularly in mass-casualty scenarios, and the implications of additive manufacturing to medical logistics operations in these environments. The analysis and findings suggest that some Class VIII(a) medical supplies are not good candidates for 3D printing, but others meet characteristic requirements to be 3D printed in operational environments. The study results in initial insights, propositions, and recommendations on how to proceed with 3D printing to support medical logistics operations in operational environments.

Introduction

Mass casualty events in operational military environments consume medical supplies very quickly, leading to or exacerbating life-threatening supply shortages in an environment where refilling those supplies can be difficult or impossible. Our study explores this problem and assesses the potential for 3D printing to help medical logisticians address this challenge.

Medical logistics in operational military environments must deal with challenges very different from those facing so-called garrison military treatment facilities that operate in more stable, non-combat locations, and typical civilian hospitals, even those specializing in trauma care. Some challenges are obvious, such as the risks of adversaries attacking either the operational locations themselves, the resupply deliveries, or both. Less dramatically, locations can be difficult to reach, both in terms of distance and the supporting infrastructure (e.g., roads) that might not support normal delivery vehicles, requiring delivery by aircraft. Unlike large



civilian trauma centers, medical facilities in operational environments can experience no trauma cases for weeks at a time; conversely, given the unpredictable nature of war zones, multiple mass casualties can occur in a very short time, rapidly depleting critical supplies for which resupply is difficult or impossible. Compounding the effects of mass casualty events, even modestly prolonged patient stays can drastically exacerbate shortages of Class VIII(a) consumables. Accordingly, military facilities in operational environments must expect to operate without resupply for an indeterminate time (Eyer & McJessy, 2019).

Manufacturing healthcare products on-site to treat battlefield injuries and medical conditions presents a possible solution—or at least a partial mitigation—for this challenge. Our study explores this problem and assesses the potential for 3D printing to help medical logisticians address this challenge, by printing necessary medical supplies on-site to mitigate critical supply shortages. While other studies have explored the utility of 3D printing in humanitarian assistance environments (Corsini et al., 2020; Savonen et al., 2018), the literature on 3D printing in combat zones is "scant" (Yu & Khan, 2015). Our study investigates the challenges of medical logistics in austere, deployed environments and the potential of 3D printing to address those challenges. We seek to answer the question, "Can 3D printing positively affect medical logistics operations for existing austere operational environments?" Specifically, we focus on what the U.S. military calls Class VIII(a) medical supplies, which have both a high risk for short-notice depletion and a high potential for 3D printing.

We focus our study specifically on what the Navy refers to as Class VIII(a) consumable items, or simply medical supplies, which are medical materiel—equipment and consumables used in military medical communities, including repair parts peculiar to medical equipment. We focus on these items, because they are critical to survivability and quality-of-life outcomes but can rapidly deplete in a single mass casualty event, leading medical professionals (e.g., doctors, nurses) to resort to nonstandard workarounds to care for patients in operational medical facilities. To further scope our exploratory study, we restricted our focus to medical resupply for Naval medical units at operational medical facilities.

Our findings are exploratory, based on a single setting, and are not generalizable to all settings. However, our study's focus on 3D printing for specific (Class VIII(a)) consumable supplies in one DMO environment provides initial insights, propositions, and recommendations on how to proceed. Our findings suggest that, while some Class VIII(a) medical supplies are not good candidates for 3D printing, other potential Class VIII(a) consumables do appear to be candidates to be 3D printed in operational environments.

Background

Medical Logistics

The United States military, and particularly the United States Navy, manages medical supplies through a network of organizations. The Defense Logistics Agency (DLA), Naval Supply Systems Command (NAVSUP), and Naval Medical Logistics Command (NMLC) provide total logistics support to military facilities (Defense Logistics Agency, 2020). Within this broad network of organizations, however, thee resupply process for Class VIII(a) material differs from the other classes of material because Navy Medicine acquires medical materials from a designated Prime Vendor under a ten-year contract (Cardinal Health, 2020; Defense Logistics Agency, 2020). This so-called prime vendor is a single distributor of brand-specific medical supplies and provides next-day delivery to military medical facilities in the continental United States (CONUS). The designated prime vendor fills all orders for its material; if the primary prime vendor cannot fill the order timely, the customer can place the order with a secondary prime vendor (Cardinal Health, 2020). Class VIII(a) medical supplies are purchased based on



recurring demand using a continuous review ordering system (http://www.navybmr.com/study%20material/NAVEDTRA%2014295B.pdf))

Medical Logistics In Operational Environments

The U.S. military calls its hospitals Military Treatment Facilities (MTF). Operational MTFs are typically situated in combat areas or hostile environments. The MTFs place orders with the prime vendors, which are located within the United States. The Defense Logistics Agency, located in the CONUS, receives classes of supply from manufacturers and prime vendors, and ships the supplies through a series of overseas distribution centers to the end-user MTFs (Resnick et al., 2014). One of those MTFs is NATO's Role 3 Military Medical Unit (MMU) in Kandahar, Afghanistan. NATO Role 3 MMU is far removed from prime vendors in the United States and relies heavily on two intermediate distribution centers in its region to restock Class VIII(a) medical supplies.

Applying standard logistics processes for all medical supplies in an operational environment creates gaps due to remote locations separated by time and distance. Unpredictable demand makes it difficult to identify recurring orders to manage inventory levels, set reorder points, or stock the right products in the right quantity. Inconsistent demand can lead to MTFs failing to designate otherwise critically-needed items as recurring orders; a critical item may be used one month and not used again for several months or used four times in three days. Storing large amounts of inventory as an inventory buffer is challenging due to the varying shelf lives of Class VIII(a) medical supplies, limited storage capacity, and the erratic nature of demand. Varying shelf lives of items creates issues. because an item can arrive expired or can expire before being used. Patient influx can vary greatly, based on the erratic operational environment, resulting in prolonged patient care that rapidly depletes inventory; also, buffers can be exhausted during a single event.

Research Approach

As we noted previously, we focus our study specifically on what the Navy refers to as Class VIII(a) consumable items, or simply medical supplies, which are medical materiel equipment and consumables—used in military medical communities, including repair parts peculiar to medical equipment. We focus on these items, because they are critical to survivability and quality-of-life outcomes but can rapidly deplete in a single mass casualty event, leading medical professionals (e.g., doctors, nurses) to resort to nonstandard workarounds to care for patients in operational medical facilities. To further scope our exploratory study, we restricted our focus to medical resupply for Naval medical units at operational medical facilities. Additionally, because Class VIII(a) consumables must be resupplied through contracts awarded to so-called prime vendors and located in the United States, fulfillment lead-times can extend significantly; this leads to loss of patient life or patient quality of life, further emphasizing the importance of these supplies.

This study explores the potential of 3D printing to positively affect medical logistics operations for Class VIII(a) consumables in operational environments through a case analysis (Baxter & Jack, 2008; Eisenhardt, 1989; Gibbert & Ruigrok, 2010; Yin, 2018). Our study focuses on cases that are extreme, and thus the processes that influenced events and outcomes are likely to be transparently observable (Flyvbjerg, 2006; Pettigrew, 1990). Because of the nature of combat situations, however, the cases represent similar extreme situations. Our approach is appropriate because 3D printing is an emerging technology and extant research is largely focused on non-medical repair parts, with medical, and especially surgical, supplies being under-researched (Yu & Khan, 2015). We focus on three mass casualty events that occurred between October 2018 and April 2019; within those events, we analyze shortages of six critical



Class VIII(a) consumable medical supplies during the mass casualty events: syringes, IV tubing, central lines, cranial kits, suction valves, and canisters.

This qualitative, exploratory research focuses on how logistics processes for Class VIII(a) consumables differ from the processes for other classes of materials, and how 3D printing might help mitigate challenges in resupplying those materials. MTFs in operational environments must use prime vendor contracts to resupply Class VIII(a) consumables (Cardinal Health, 2020). This study's focus on Class VIII(a) medical supplies is derived from one author's field experience, where constraints with resupply strained the medical care system. Class VIII(a) supplies are important because these consumables have a unique purpose: to save lives.

Interviews were the principal data source for each phase of analysis. We also collected operational documentation from the NATO MMU and reports of research on 3D printing of medical supplies. To understand how a shortage of medical supplies affects a Role 3 MMU during a mass casualty event, as well as the resupply process for Class VIII(a) consumables, we conducted semi-structured initial interviews with intensive care unit (ICU) nurses who served at the Kandahar NATO Role 3 MMU. Our initial interviews lasted one to three hours and follow-up interviews lasted 30 minutes to two hours. We asked medical professionals to describe their experience during October 2018 to April 2019, including how shortages of medical supplies affected the Role 3 MMU during mass casualty events which occurred in this timespan. Interviewees described the patient medical conditions, the number of patients, and the effects the mass casualty events had on Class VIII(a) medical supplies. They described insufficiencies in the resupply chain of Class VIII(a) and improvised actions taken to supplement shortages during long order fulfillment lead-times between acquisition and receipt.

These medical professionals identified Class VIII(a) items that were rapidly depleted during mass casualties. We used these items as inputs to subsequent interviews of 3D subject matter experts. To gather information on the potential of 3D printing for Class VIII(a) consumable items and to identify high potential consumables, we reviewed documents and conducted interviews with experts from Uniformed Services University (USU) and Walter Reed National Military Medical Center (WRNMMC) who have successfully researched and tested 3D printing medical supplies.

The medical professional interviewees identified Class VIII(a) consumables that were rapidly depleted during mass casualties. We shared this information with the 3D printing subject matter experts to solicit their expertise on the potential of 3D printing Class VIII(a) medical supplies and to get their recommendations on which Class VIII(a) medical supplies show the highest potential. Interviewees described the characteristics of 3D printing materials and types of printers with potential to print Class VIII(a) medical supplies in an operational environment and shared their thoughts on the feasibility of 3D printing Class VIII(a) medical supplies in an operational environment. Interviewees also shared their knowledge of field tests of specific medical supplies.

The so-called seven rights of logistics framework (Swamidass, 2000) provided an overall framework to guide our analysis. These so-called rights are "to deliver the right product, in the right quantity and the right condition, to the right place at the right time for the right customer at the right price" (Swamidass, 2000). Our analysis emphasized four of the rights: product, place, time, and quantity. These four rights reveal constraints most relevant to this study's research findings within the operational environment. The other rights, while important to the framework, do not provide value-added contributions to this study. For example, while logistics and 3D printing experts would argue generally that it is more cost effective (the right cost or price) to ship in bulk, this study places more emphasis on having the right product at the right time for unpredictable demand environments.



We analyzed the data in phases. First, we analyzed the case data to develop an understanding of the challenges of medical logistics in operational environments. Next, we drew on initial findings and the seven rights of logistics framework and analyzed the 3D printing data to develop an understanding of the current state of the art in 3D printing related to medical supplies. Finally, we integrated these analyses to answer the study's research questions.

Case Context

Since 2010, NATO Role 3 MMU, a 70,000 square foot trauma care facility, has been the primary trauma care facility for all combat casualties and inpatient care in Southern Afghanistan. It is a rocket proof structure staffed by military and contract support personnel from NATO nations.

The MMU experienced unpredictable demand during the mass casualty events of our case study (October 2018 to April 2019). The unpredictability of demand, number of patients, and unknown patient lengths of stay complicated demand calibration, made identification of recurring ordered items challenging, and setting reorder points more challenging. It was challenging to identify items as recurring or non-recurring because of limited storage space, obsolete consumables, previously stockpiled supplies, the needs of the local populace, and the varying shelf lives of Class VIII(a) medical supplies. Time and distance compounded by rotational deployments further complicated projecting logistics requirements.

To mitigate the long delivery times and distance from prime vendor, NATO Role 3 MMU relied on partnerships with other hospitals within the same geographical area to meet unexpected demand. These partnerships included Kandahar Regional Medical Center and Craig Joint Theater Hospital (CJTH) at Bagram Airfield, and Landstuhl Regional Medical Center in Germany, which provided longer-term care to NATO patients once stabilized. Kandahar Regional Medical Center had limited capacity, which caused NATO Role 3 MMU to face unanticipated patient demand and longer patient stays for stabilized patients. CJTH experienced similar long lead time constraints and mass casualties as NATO Role 3 MMU which made resource sharing difficult. Finally, while NATO Role 3 MMU cared for trauma victims among local Afghan partnered forces, these personnel were required to stay in country rather than being transported to Germany for longer-term care or rehabilitation as is the case with NATO forces, which, when combined with Kandahar Regional Medical Center's limited capacity, exacerbated demand for medical supplies at NATO Role 3 MMU.

Increased hostilities during this time resulted in compounded mass casualties that strained medical equipment. Long patient stays require excessive use of Class VIII(a) medical supplies such as syringes to deliver medicine, IV tubing, IV fluids, needles, bandages, and any surgical interventions that are used to treat battle injuries, adding to the strain on Class VIII(a) stocked medical supplies and medical equipment. Increased hostilities and attacks led to increased base threat conditions, grounding all incoming flights. This delayed the resupply of items depleted during the mass casualty event. Mass casualty patients required multiple surgeries and then admission to the Intensive Care Unit (ICU). Finally, NATO Role 3 MMU had limited storage capacity. There was not enough space for the right product because the warehouse was filled with obsolete products The facility therefore had little room for building buffers of critical items identified by a new rotation.

Case Findings

The medical professionals we interviewed described critical events they experienced, which provide insight into the burn rate during mass casualties and that caused shortages in Class VIII(a) medical supplies commonly used and rapidly depleted. Table 1 describes how



these critical events influenced logistics. The critical event the MMU experienced was a shortage of medical supplies, which led in turn to subsequent deviation from standard medical practice. This had the potential to have negative effects on patient care. The same interviews identified items most likely to be depleted during mass casualty events (see Table 2).

Four major constraints causing shortages emerged from this analysis: time, distance, mass casualties, and facility space. These constraints resulted in long patient stays, delays, reuse, and stock/storage. The process for ordering supplies is constrained by unpredictable demand while the delivery process is constrained by time and distance.

Time

Our analysis suggests both long patient stays and resupply delays depleted resources and strained the inventory of medical supplies. Resupply for items stored at nearby distribution centers could arrive in seven to ten days; however, non-recurring items took two to four weeks to transit from the prime vendor in the continental United States just to the first distribution center in Europe, much less to the end user in the NATO Role 3 MMU.

Distance

NATO Role 3 MMU is far from the mandated sources of supply in the CONUS. As with time, prime vendor items ship from CONUS to a first stop distribution center. There is no direct delivery to NATO Role 3 MMU (Resnick et al., 2014), which is within a landlocked operational environment. Prime vendor items must first stop at a distribution center in Europe, adding to the distance it takes to resupply. The distance from prime vendors to intermediate distribution centers to NATO Role 3 MMU caused shortages and impacted availability of Class VIII(a) medical supplies. This led to limited resources and improvised actions not practiced in civilian or stateside hospitals.

Mass Casualties

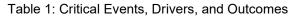
Mass casualties are uncertain within operational environments and can occur rapidly or not at all. Mass casualties compounded with shortages, patient influx, and length of stay rapidly depleted resources impacting the availability of the right product, in the right quantity, at the right time (Swamidass, 2000). Mass casualties create unpredictable demand that makes it difficult to identify the right products in the right quantity to maintain in inventory. Stocked items in MEDLOG rapidly depleted during a single event. Unpredictable demand with uncertain types of medical conditions and number of patients caused significant challenges in identifying items that should be recurring to establish an order history. Recurring items were rapidly depleted because of long patient stays because of surgical interventions and intensive care requirements. The facility is only set up for 72-hour trauma care support. Afghan partnered forces remained in NATO Role 3 MMU the longest. Critical items required to treat a medical condition from a mass casualty event were often non-recurring items. Non-recurring items were the ones typically exhausted during extensive surgeries. When mass casualties occurred, it was often from an attack which then increased threat conditions for the base. Communication during high threat levels is challenging within a landlocked operational environment. Kandahar has one airfield that experiences limited inbound flights during high threat levels which delay receiving resupply shipments.

Facility Space

NATO Role 3 MMU was constrained by limited storage space. Supply catalogs had duplicate items, items that would never be used and inconsistencies from rotation to rotation in recurring ordered items and levels of inventory. Some items ordered incorrectly, cases instead of boxes, took up storage capacity. Unfortunately, the MMU also stocked too many supplies that would never be used and carried too many of the wrong items and not enough of the right items.



Critical Event	Driver	Outcome	Sample quotation
Critical Event 1: Placement of tracheostomy in Afghan patient. Tracheostomy is not expected care in an operational trauma facility.	Providing intensive care beyond 72 hours. More time and intensive care than facility was intended to provide. Local facilities were not capable to care for patient.	Caused personnel to go through supply of suction valves incredibly quickly.	"The suction valves are a one-time-use item; however, due to the necessity of their use for the patient, and our rapidly dwindling supply of the valves in our stock and inability to get replacements quickly, we had to reuse the valves repeatedly."
Critical Event 2: U.S. patient with abnormal heart rhythm, a medical condition not expected in an operational environment.	More time and intensive care than facility was intended to provide.	Medical condition required more rapid use of flushes, which depleted supply of flushes. Personnel was required to improvise flushes.	"We had a patient with an abnormal heart rhythm and no flushes. I had to send a nurse to run and make flushes."
Critical Event 3: Patient with extreme and highly contagious infection came in along with mass casualties.	Facility and supplies are not designed for highly contagious patients, with an open ward and limited PPE.	Personnel were forced to break infection control protocol because of rapid depletion of PPE and secondary resources (e.g., linen, pillows, and cleaning supplies that had to be destroyed).	"Forced to break infection control protocol to take care of him. This is significant because our infection protocols are followed as strictly as possible to keep both the patients and staff safe, but in this case, we were forced to put them aside to ensure keeping the patient alive."
Critical Event 4: Surgery on Afghan patient with ruptured brain malformation, a procedure not typically conducted in a deployed environment.	Supplies not adequate for this type of procedure. More time and intensive care than facility was intended to provide. Local facilities were not capable to care for patient.	Items available were not the right size and thus personnel improvised use of surgical clips during trauma care.	"We treated one medical condition, a ruptured brain malformation. The clips the surgeons had to use in surgery to stop the bleeding were bigger than what neurosurgeons would have used if in the United States."
Critical Event 5: Multiple patients with GSW to the head over short period of time. This number of similar cranial injuries in this short period of time was unprecedented.	Not stocked with the number of cranial kits needed to treat the specific injury, because event was not anticipated. Condition necessitated prolonged care.	Facility ran out of cranial kits and was forced to request kits from other facilities. These limitations delayed patients going into surgery. Also, facility was not stocked with sufficient items needed to treat the patients over the necessary length of stay.	"During our 5 days receiving GSWs to the head we ran out of cranial kits."





Rapidly Depleted	Depleted in Critical Events	Depleted in Critical Events	
10 cc Syringes	Cranial Kits	Cranial Kits	
Suction Tubing	Central Lines	Central Lines	
Flushes	Surgical Clips	Surgical Clips	
Suction Canister	Craniotomy Flaps	Craniotomy Flaps	
Primary Tubing	Central Lines	Central Lines	
Secondary Tubing	Surgical Clips Scalpel	Surgical Clips Scalpel	
Alaris Tubing			
Trac Holder			
Arterial Line Set Up			

Table 2: Ra	pidly De	pleted Class	VIII(a) Items
		pioloa olabo	v	,

Case Observations

Our findings revealed problems with product, place, and time specific to the operational environment's unique characteristics and challenges. The three rights that were most problematic shape the subsequent sections: problems with product, problems with place, and problems with time.

Problems with Product

This section discusses problems with products identified within the embedded case. Shortages led to limited resources and improvised actions not practiced in civilian hospitals. For example, there was a shortage of IV tubing and secondary IV tubing for medical equipment pumps. The driver for problems with product was the influx of patients resulting in high burn rates of certain Class VIII(a) medical supplies. The consequence was extending the life of the item and reusing tubing that would not be done stateside. If this were practiced in stateside U.S. hospitals, medical professionals would lose their license.

Medical equipment is a challenge and strains the delivery of patient care. Medical equipment was broken, required replacement, or needed repair parts. The glide scope in the ICU was old, outdated and even recalled. Components needed to operate the scope were missing. The ICU and ER had a few of the components required and between the two units the parts could be compiled to create one good working glide scope, but it was not standardized. The ultrasound machines were past life expectancy and had to be kept plugged in or they would shut down. If the machine was not near a transformer (converter), patient care was more challenging. IV pumps were past life expectancy, and new pumps were acquisitioned. The pumps were delayed due to a software updates and contract modifications. When they arrived, the IV tubing was not compatible further delaying the use of the new pumps.

One issue with medical equipment was the need for transformers. Transformers are required to run all medical equipment delivering patient care. Medical equipment is procured from United States manufacturing companies that require 140-watt voltage. NATO Role 3 MMU was built with European outlets at 240-watt voltage. All medical equipment to deliver patient care had to be plugged into a transformer that was plugged into the wall. Transformers only had two outlets compatible for U.S. voltage. Outlets were in short supply and could easily be all occupied on a single patient. The transformers were unsafe and would be turned off to prevent overheating. However, if the units did not keep the medical equipment plugged in, the equipment would shut off during patient care. The medical equipment and transformers required



unscheduled preventive maintenance and experienced significant delays in receiving replacement parts.

Problems with Place

This section discusses problems with place identified within both cases which described the operating environment. The situations provide an understanding to why the operational environment must be viewed differently. Normal medical logistics practices are constrained within the operational environment. The operational environment causes anxiety, and supply shortages lead to more anxiety of the medical professionals, resulting in improvised actions and rationing supplies. Certain types of medical conditions can deplete resources rapidly due to patient demographics shaped by the increase in Afghan partnered relationships, unpredictable demand, and erratic mass casualties. The medical professionals interviewed stated that medical conditions arriving would not typically stay in a trauma care facility set up for only 72 hours of care. NATO Role 3 MMU did not just treat U.S. military and coalition forces. All interventions done within the NATO Role 3 MMU for Afghan police, army, or CG patients would guarantee they stay longer than 72 hours, because of the capacity constraints at the local Kandahar hospital.

Problems with Time

Problems with time were also identified within the embedded case. The extended time to receive supplies and the extended time patients stayed within NATO Role 3 MMU are just a few of the differences from a similarly classified civilian or stateside military treatment facility. There are long lead times affiliated with prime vendor within the United States, which delays the arrival of resupply to operational environments. An item can stock out within while new inventory is being shipped. Such long lead times required medical professionals in the operational environment to take actions, whether improvised or not. They were required to adapt and reuse medical supplies in ways not practiced by stateside hospitals. If an item is necessary to save a patient's life, measures beyond the typical scope of practice, whether improvised or reactionary, are taken. This is an understanding of medical professionals within operational environments. The problem with time is long lead times, intermediate stops, unpredictable demand, and prolonged patient stays.

3D Printing Analysis and Findings

3D printing involves building a "three-dimensional object using a computer-aided design" (Saptarshi & Zhou, 2019). Medical devices can be produced "using a range of media, including metals, plastics, hydrogels, or vein biological materials" (Manchanda, 2020). Medical companies have embraced 3D printing to create "personalized devices for patients or provider specific tools" (Kondor et al., 2013). The nature of the raw materials melted and restructured into a plastic or metal object, however, limits some medical supplies from being safe for patient care.

All medical supplies are "highly regulated by the U.S. Food and Drug Administration" because they encounter humans (Resnick et al., 2014). Medical supplies come in direct contact with patients making the nature of the structural integrity of specific items important to understand. Medical supplies have specific characteristics such as a plastic material that delivers medication. That material must be intact and must not introduce any other material into the patient. Our initial findings showed the following Class VIII(a) medical supplies were rapidly depleted: syringes, IV tubing, central lines, cranial kits, suction valves, and cannisters. This section describes the analysis of interviews with experts in 3D printing and identifies potential limits and constraints to 3D print the six items in an operational environment.



Our interviews identified five characteristics key to 3D printing the rapidly depletable items. Table 3 summarizes those characteristics. These characteristics influence the potential for printing the six items.

	Table 3: Key characteristics to 3D print critical items
Internal/External	"An implant is printed with materials sustainable within a patient,
	approved by the FDA." (Interview 5).
Material and Use	"It's not just being in the patient, it's the material of the object that matters." (Interview 4)
Watertight	Syringes or IV tubing require being "watertight."
Flexibility	"Material/objects that are rigid (like scalpel handles) are easier to print than flexible materials (like IV tubing). From an engineering perspective, 3D printing flexible materials is not impossible but more difficult, and R&D required." (Interview 4)
Technology Requirements	"3D printing 'watertight' objects requires specific printing technologies, which are bulky and take longer to print therefore, they are not practical in operational environment." (Interview 5)
	"Some polymers can leach harmful compounds over time." (Interview 5) Testing to determine if this occurs with 3D printed plastics delivering liquids through IVs to patients' blood stream likely will not happen soon.
	"Printing implants on-site in operational environment would require a larger foot-print. Million-dollar printer to print implants, very costly." (Interview 5)

Syringes

Syringes are vital to administering medicine, blood, nutrition, and other fluids. In trauma care syringes are vital to gain access to internal blood streams through IV flushes and ensuring patency. Syringes are a critical item. As shown in the case analysis, when syringes are not available, medical professionals deviated from standard practice to treat patients. Syringes are used outside of the body and thus are not subject to regulation for internal use. The syringe does not have to be flexible. However, the seal must be watertight. Interviewees suggested that it may be possible to 3D print syringes, but there are some challenges. Syringes include a rubber stopper and there is currently there is no material to print rubber. One interview participant said:

Some biomaterials available could aid in printing the plastic of a syringe but there remains the concern about leaching. A syringe has a rubber stopper and SME's do not know any material that could print the rubber stopper. (Interview 5)

Overall syringes exhibit moderate potential for 3D printing in an operational environment.

IV Tubing

IV tubing provides the continued flow of fluids whether blood, normal saline, or medicine to keep patients alive during trauma and prolonged care. There is concern regarding the potential to 3D print IV tubing. One interview participant recommends it is better currently being manufactured by companies because it is a thin plastic. Thin plastic materials holding a substance are a concern to 3D printing experts because there is no feasibility testing on the potential to leach 3D printed material into the solution. More biocompatible research is required to determine if the printed material will leach undesirable materials from the plastic into the liquid



and thus into the patient. Specific characteristics are not compatible with 3D printing. Interview participants said:

IV tubing may not be feasible due to the construction of the plastic tubing being fine and thin. However, it is possible to print medical equipment replacement parts. (Interview 4)

One must consider what is being printed. Consider that face shields printed by FormLabs for COVID are thin and take two hours to print. A thicker material will take longer; therefore, in a mass casualty it may not be a logical expectation that one can print an item rapidly. (Interview 5)

Overall, IV tubing exhibits low (to none) potential for 3D printing in an operational environment.

Implants

As mentioned previously, the production and reconstruction of implants are currently better served within WRNMMC. One interview participant made this point:

Printing implants on-site in operational environment would require a larger footprint. This would be a million-dollar printer to print implants, very costly. Overhead and the materials alone would be expensive plus the printer and power requirements. WRNMMC handles all DoD implant requests and is suitable to maintain all requests. (Interview 5)

Overall implants exhibit high potential for 3D printing in an operational environment; however, better to 3D printed within WRNMMC.

Suction Canisters, Valves, and Instruments

One interview participant noted that suction canisters, valves, and surgical instruments, which are used during both trauma care and prolonged patient care, could be a candidate for 3D printing, though not without some possible constraints. They said,

Suction canisters could be printed; however, there would be concerns about water tightness. Some materials printed can absorb or leach materials. This is a complication with 3D printing IV tubing because of the thinness of the tubing, potential for leaching and the lumen within the tubing. (Interview 5)

Overall, and given these constraints, suction canisters appear to exhibit moderate potential for 3D printing in an operational environment.

Antibiotic Bandage

Although the medical professionals did not mention antibiotic bandages, one interview participant did note they had potential to be 3D printed in an operational environment. As another interviewee noted:

The USU research teams are looking at leaching antibiotics and antifungals from the bandage. The leaching time of the compounds within the bandage allows the bandage to administer antibiotics over days to weeks. (Interview #4)

The ability to 3D print an antibiotic bandage, which could deliver antibiotics for days or weeks, is significant; it could—at the risk of dramatization—mean life or death to a warfighter, in bridging the gap from point of injury to care at a military trauma center.



Discussion, Limitations, Conclusions, and Recommendations

Our study sought to explore whether 3D printing has the potential to impact medical logistics in operational environments. Our findings, limited and exploratory as they are, suggest it does.

Analysis of the interviews identified the size of the printer, safety concerns (explosion from materials), and the types of materials required limit the potential to 3D print in an operational environment. Larger capacity printers are not suitable for operational environments. Printing metal in an operational environment may be challenging because those printer types have a larger throughput but in turn have a large footprint and may not be ideal for operational environments. Some plastics will be challenging because there is not enough research and testing done currently regarding whether the 3D printed plastic object is watertight. If the 3D printed material holds a liquid, there is concern with delivering the liquid through a plastic object directly to a patient. There may be leaching from the plastic materials into the liquid, however, at this time, no feasibility testing has been conducted.

An effective 3D printer within an operational environment would be a small plastic printer that can do multiple small items including repair parts and non-critical parts. Generally, the materials for small printers are stable and could be successful in Kandahar. There is also the added benefit of little concern in the personnel running it and the maintenance requirements. There is little training and operation skills required in advance.

This research found that while 3D printing can do many things, some things are logistically better served by manufacturers in bulk, such as IV tubing. Not a lot of Class VIII(a) medical supplies have been researched or tested using a 3D printer at this time, but some medical supplies are being tested in studies and field cases. While this study focused on two specific cases with shortages of Class VIII(a) relevant to that deployment, the analysis and findings have provided additional medical supplies that have the potential to be 3D printed in operational environments. More testing in the field should be done in the future to discover the benefits and potential of Class VIII(a) medical supplies rapidly depleted during mass casualties, but not enough data is currently available on those specific Class VIII(a) medical supplies. The analysis and findings from both cases did identify medical equipment repair parts with significant problems in receiving them due to backorder.

References

- Baxter, P., & Jack, S. (2008). Qualitative case study methodology: Study design and implementation for novice researchers. *The Qualitative Report*, *13*(4), 544–559.
 - http://nsuworks.nova.edu/tqr/vol13/iss4/2/?utm_source=nsuworks.nova.edu%2Ftqr%2Fvol13%2F iss4%2F2&utm_medium=PDF&utm_campaign=PDFCoverPages
- Cardinal Health. (2020). *DoD prime vendor program.* https://www.cardinalhealth.com/en/productsolutions/medical/laboratory-products/resources-for-laboratory-products/governmentlaboratories/dod-prime-vendor-program.html
- Defense Logistics Agency. (2020). *The nation's combat logistics support agency*. Electronic Catalog (ECAT). https://www.dla.mil/
- Eisenhardt, K. M. (1989). Building theories from case study research. *The Academy of Management Review*, *14*(4), 532–550. http://doi.org/10.2307/258557
- Eyer, K., & McJessy, S. (2019, March 5). Operationalizing distributed maritime operations. Center for International Maritime Security. http://cimsec.org/operationalizing-distributed-maritimeoperations/39831
- Flyvbjerg, B. (2006). Five misunderstandings about case-study research. *Qualitative Inquiry*, *12*(2), 219–245. http://doi.org/10.1177/1077800405284363



- Manchanda, G. (2020). 3D printing applications and workflows: Insights from the top ranked U.S. hospital [Webinar]. Radiology Today. https://3d.formlabs.com/medical-3d-printing-insights-from-the-mayo-clinic-recording
- Gibbert, M., & Ruigrok, W. (2010). The "what" and "how" of case study rigor: Three strategies based on published work. *Organizational Research Methods*, *13*(4), 710–737. http://doi.org/10.1177/1094428109351319
- Pettigrew, A. M. (1990). Longitudinal field research on change: Theory and practice. Organization Science, 1(3), 267–292.
- Resnick, A. C., Wesler, W., & Yoho, K. D. (2014). Sourcing and global distribution of medical supplies (Document No. RR-125-A). RAND Corporation.

https://www.rand.org/pubs/research_reports/RR125.html

- Savonen, B. L., Mahan, T. J., Curtis, M. W., Schreier, J. W., Gershenson, J. K., & Pearce, J. M. (2018). Development of a resilient 3-D printer for humanitarian crisis response. *Technologies, 6*(1), 30. http://dx.doi.org/10.3390/technologies6010030
- Swamidass, P. M. (Ed.). (2000). Seven "rights" of logistics. In *Encyclopedia of production and manufacturing management.* SpringerLink.

Yin, R. K. (2018). Case study research and application: Design and methods. Sage Publications, Inc.

Yu, A. W., & Khan, M. (2015). On-demand three-dimensional printing of surgical supplies in conflict zones. *The journal of trauma and acute care surgery*, *78*(1), 201–203. https://doi.org/10.1097/TA.00000000000481





Acquisition Research Program Naval Postgraduate School 555 Dyer Road, Ingersoll Hall Monterey, CA 93943

WWW.ACQUISITIONRESEARCH.NET