How Standards Can Facilitate the Global Fight against Pandemics and Improve Preparedness

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Abstract

The medical community encountered enormous challenges during COVID-19, including facing significant shortages of emergency medical supplies such as nasal swabs and personal protective equipment that are critical for testing and treating patients. When COVID-19 shattered the global manufacturing supply chain, and hospitals and caregivers were overwhelmed, many turned to additive manufacturing (AM), also known as 3D-printing, for rapid development and mass production of critical medical products. Designs of these conventionally fabricated products were revised on an ad-hoc basis to suit the additive manufacturing requirements. The crisis-response additive manufacturing efforts helped us to tackle disruptions in manufacturing supply chains and transportation. However, many of these efforts faced challenges from a lack of standard approaches in the selection of design, material, process, and equipment. Appropriate use of the existing standards and development of some missing additive manufacturing-specific standards can enable us to exploit the full potential of additive manufacturing in tackling future production needs during emergencies. These standards include product and material specifications, performance requirements, design, process selection, quality control, and testing and evaluation of final products. We can transform the lessons we have learned with the shortages of medical supplies during COVID-19 into better preparedness for future pandemics. In this work, we investigate how standards can enable agile production of emergency medical supplies using additive manufacturing. We also identify some available standards that can be leveraged in designing, producing, and evaluating medical products. Finally, we recommend some additional standards for AM to ensure secure and responsive manufacturing operations, assure product quality and performance, and support rapid production of on-demand medical supplies for future pandemics.

1. Introduction

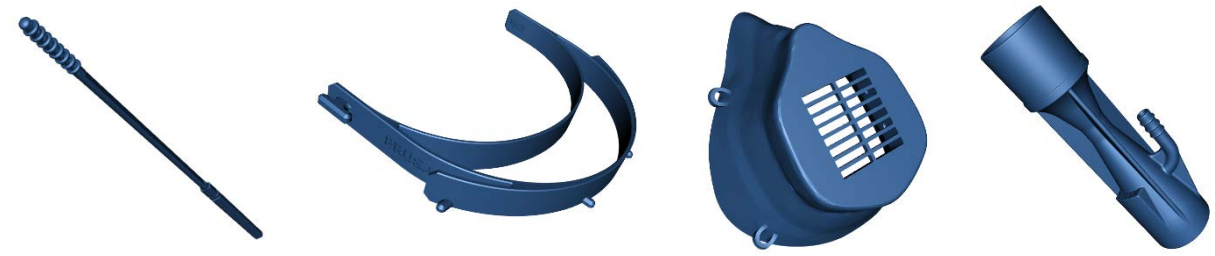
During COVID-19, there were shortages in test kits, protective gear, and other critical medical devices in the United States [1]. Additive manufacturing (AM) has proven its potential in rapid product development and scaling-up production of these products [2]. For example, efficient designs of nasal test swabs were developed using AM, and within a short period, millions of kits were printed [3]. Several tests by federal agencies ascertained that 3D-printed nasal swabs perform the same as or better than traditionally manufactured swabs [2]. Additionally, different 3D-printer manufacturers, companies, and universities designed and printed personal protective equipment (PPE) such as face shields and face masks for protecting caregivers against the virus (some instances are listed in Table 1) [2]. As some of these PPE designs were made publicly available online, many makerspaces, hospitals, and medical professionals stepped forward to ramp up local productions of PPE through 3D-printing. Other 3D-printed medical supplies included ventilator valves, ventilator splitters, and mask adjusters. Figure 1 shows examples of 3D-printable designs of medical equipment. When the Defense Production Act was invoked, large manufacturers such as General Motors also relied on AM for pivoting overnight to medical device and PPE production [4]. Thus, AM helped us tackle the strain of supply shortages in our fight against COVID-19 and save human lives.

Table 1: Some AM initiatives to meet the supply shortages during COVID-19 [5].

Product Type	**Product Description**	**Manufacturer**	**Production Capacity (units/day)**	**Material**	**Manufact-uring Process**
Nasopharyngeal Swab	A flexible stick with a bristle at the end used to collect COVID-19 test sample from the patient's nose	Formlabs	112,000	Surgical Guide resin	SLA
		Nexa3D	75,000	Nexa3D material	SLA
		Markforged	10,000	Nylon base and Rayon	FDM
Face Shield	Protective equipment usually made of clear plastic to protect the entire face from large splashes	Prusa3D	10,000	PETG	FDM
		Stratasys	700	ABS	FDM
		Ford Motor	300	ABS 3D-FC	SLS/SLA

Face Mask	A device covering a person's nose and mouth to prevent contamination	Maker Mask	1500	PLA	FDM/SLA
		Formlabs	50	Formlabs Draft Resin	SLA
		Essentium	700	TPU74D	High-Speed Extrusion
Ventilator parts	Ventilators are mechanical devices that provide breathing support to patients	Isinnova, Lonati	100	PLA	SLS
		Weerg	500	PA 12 Nylon	Powder Bed Fusion
		3D Systems	N/A	Medical Grade Nylon	SLS

While the U.S. Federal and Drug Administration (FDA) temporarily relaxed regulatory requirements for 3D-printed medical supplies during COVID-19, regulatory bodies did not approve all parts, as their clinical effectiveness was not verified. A key impediment was the lack of standards for design, manufacturability, material, process, machine, and quality and testing specifications of 3D-printed medical devices. In essence, most of the 3D-printing efforts, especially from local 3D-printing community members, faced significant challenges.



(a) (b) (c) (d)

Figure 1. 3D-printable designs of various medical equipment: (a) nasopharyngeal testing swab, (b) face shield head-band, (c) face mask, and (d) venturi valve [6]

We can only exploit AM to its fullest potential during future pandemics through the well-planned incorporation of AM either as a stop-gap solution or a critical product development tool. To do that, we need standards for both rapidly growing AM technologies as well as for the applicability

of AM in producing critical medical devices. Table 2 lists some major challenges and limitations of AM applications during COVID-19.

Table 2: Major challenges and limitations in AM applications during COVID-19 [3], [5], [7]–[9].

Area	**Specific limitation/challenge**
Design and functionality	Most of the printed respirators performed poorly, with almost all providing less than 60% filtration efficiency (significantly below the requisite 95% efficiency of an N95 respirator).
Material	Increased risk for virus transmission during use or reuse of unregulated PPE, as many FDM filaments retain ambient moisture.
	Many materials used for 3D-printing are not ideal for long-term skin contact. Also, disinfecting printed materials can be challenging.
	Unavailability of detailed data on relevant raw materials for the medical applications in time of need.
Quality	Quality issues such as warping of printed parts, stringing.
File-format	No print specifications for prototype development with the standard tessellation (STL) files that are available for download.
The expertise of manufacturers	Inadequately assessed safety or functionality of locally fabricated products (mainly due to lack of expertise in product testing) makes those products inappropriate for use in health care settings.
Testing and validation	No validation and hypothesis formulation before open distribution and propagation of PPE prototypes during this pandemic.
Copyright issue	Complex copyright and legal issues in producing the emergency items in mass volumes.
AM technologies	The disparity between developing and developed countries in case of availability of 3D-printing technologies.

The above-mentioned areas demonstrate where standards are essential. The efforts of the makerspaces, hospitals, and hobbyists would be more successful in terms of design, quality, testing, and reproducibility through proper utilization of existing standards and development of the missing standards. In this work, first we will briefly discuss the importance of standards in manufacturing and AM, especially for medical applications. Next, we present some relevant standards for producing medical supplies during COVID-19. Finally, we recommend some standards that should be developed for 3D-printing emergency medical supplies in future pandemics.

2. Importance of standards in manufacturing, AM, and medical applications

In the manufacturing industry, a well-defined set of guidelines and practices can help organizations to achieve reliability, consistency, and predictability in their processes, systems, and products. If standardization and regulations are ignored in manufacturing, there is a risk of increased waste, compromised quality, and uncertain process performance. AM technologies are recent additions to the manufacturing industry. AM offers various benefits such as rapid prototyping, part consolidation, part customization, complex geometric features, and distributed manufacturing. However, the layer-by-layer part-building nature and its numerous process variables (e.g., scan speed, build orientation, laser power) make this technology prone to various defects or quality issues. For example, variability in parameters of metal powder bed fusion processes leads to different microstructures in 3D-printed metallic parts, which eventually may result in different material properties and product performance.

To ensure consistent quality, safety, and performance of 3D-printed products, proper standardization is needed. Safety-critical applications of AM, especially in the medical industry, demand appropriate standardization. For medical applications, standards provide guidance for specifying and evaluating the design and performance requirements of biomedical materials, tools, and equipment to ensure the health and safety of people. To realize the potential of AM as a responsive and flexible technology in delivering emergency medical supplies, efforts should be made to promote the usage of existing standards. Additionally, we can develop some missing AM-specific standards to fully utilize AM during pandemics.

3. Relevant standards for 3D-printing emergency medical supplies during COVID-19

Organizations including the American National Standards Institute (ANSI), the International Organization for Standardization (ISO), and ASTM International allowed public access to necessary standards used in the production and testing of medical equipment to facilitate the fight against COVID-19. Different product and quality standards are helpful to benchmark product specifications and establish quality requirements for 3D-printing medical supplies. For example, ASTM F2299/F2299M-03(2017), ASTM F2100-19, ASTM F2101-19, ASTM F1862/F1862M-17, and ASTM F3407-20 are standards for material properties, performance

specifications, and testing of medical face masks. ISO/TS 16976-8:2013 offers considerations for ergonomic factors of respiratory protective devices. Additionally, ANSI Z.87.1–2010 covers the drop-test requirements for protective eyewear. These standards can be adopted in designing 3D-printable masks and eye PPE, and to assess their effectiveness.

Apart from those product-specific standards, some available AM-specific standards include the terminology for AM coordinate systems and test methodologies (ISO/ASTM 52921:2013), performance criteria, quality characteristics, and corresponding test methods for AM processes (ISO 17296-3:2014), and geometric capability assessment of AM systems (ISO/ASTM 52902-19). Most of the AM efforts during COVID-19 used extrusion-based AM processes with plastics [2]. Some available standards for such AM processes include specifications for feedstock materials (ISO/ASTM 52903-1) and process equipment (ISO/ASTM 52903-2:2020). However, it is unclear to what extent these standards were utilized in different AM responses. Some companies shared details of their development process, including the use of specific standards. For example, a company named Structo 3D-printed nasopharyngeal testing swabs following the ISO 13485 QMS requirements, and packaged them following ISO 11135 [10]. However, most small responses were only described in press releases, which did not provide technical details. The informal nature of small responses and lack of expertise of involved personnel may have prevented heavy usage of standards.

From the manufacturing supply chain perspective, standard practices can enable better coordination between facilities and teams, allowing agile manufacturing for emergency needs. Organizations can adopt standard additive manufacturing file formats (e.g., ISO/ASTM 52915) and model-based applications for designs (e.g., ASME Y14.47 and SOLIDWORKS MBD). The usage of standard document control systems will streamline information sharing and improve responsiveness. In addition, for collaborative product design and development during pandemics, organizations should use standard software packages (e.g., for design, slicing). A seemingly insignificant inconsistency in the CAD package version used for product design previously caused a billion-dollar production delay [11]. Standard design file formats and software packages can eliminate such delays and improve productivity.

4. Required standards for 3D-printing emergency medical supplies in future pandemics

First, we need a standard approach to identify which medical equipment we can 3D-print. This approach should acknowledge potential AM-specific defects and update the performance specifications and testing of 3D-printed parts. For example, some 3D-printed parts can have porosity, a potential breeding ground for viruses, rendering them unsuitable for certain medical applications. We should incorporate porosity in performance specifications and modify testing standards accordingly, where applicable. Without a standard approach, people could end up with defective or even useless 3D-printed parts, wasting resources.

Frequently used medical products should be designed with interchangeable components to allow easy replacement during emergencies and/or shortages. And although many products were developed during the COVID-19 crisis, most of those designs lacked quality and were not regulated. So standard design and specification of 3D-printable parts or components should be created and updated regularly for future emergencies. Moreover, with the improvement of technology and materials, product designs should be optimized for better manufacturability and product quality. Upgrading one standard design (e.g., for face shields) is easier than improving several designs. Besides, better innovation is possible from a collaborative approach when many people use the same design. User feedback should be integrated during the product development if the demand for new products is related to customers' comfort.

Generally, manufacturers have to go through frequent iterations to find a suitable combination of printing parameters to ensure product quality and reproducibility. Optimal process parameters can vary depending on the material, process, and machine. One combination of process parameters could work best for extrusion-based processes but fail in stereolithography. Recent experiences during COVID-19 show that some people downloaded design files from online repositories without considering the compatibility with their equipment and material, and iteratively used different process parameters on a trial-and-error basis. Consequently, many printing attempts failed or resulted in bad quality. Standard methods to specify process parameters for a particular design when transmitting the design to the manufacturer can help to avoid time-consuming iterations and improve future pandemic preparedness with agile production capabilities.

Standards pertinent to the quality aspects of additively manufactured parts, especially medical devices, need further development. During COVID-19, achieving sterility, adequate cleaning, and biocompatibility of parts produced using AM processes raised concerns across the community. The existing sterility standards should be modified for AM applications. Process-specific in-situ quality inspection and control standards should be developed.

For in-process quality monitoring in AM, the operator's expertise and experience in capturing and relating the process data with the physical output is also important. During COVID-19, people of different levels of expertise printed PPE and other accessories. They often tried to optimize the printing process (e.g., to reduce the print time), which resulted in various quality issues. If the operator is not aware of such issues, it can pose a major problem for the caregivers. Therefore, the required expertise to print emergency medical equipment should be standardized (similar to ISO/ASTM 52942:2020). There can also be standard training programs for operators.

Finally, standards should be developed to ensure safe and secure manufacturing operations. During the supply shortage of emergency medical equipment in COVID-19, people downloaded publicly available design files for these components from organizations like Thingiverse, Prusa3D, and GrabCAD. These design files are accessible via various cloud storage platforms. However, due to the lack of standards for secure file sharing and storing, adversaries and malicious actors can alter design files and printing commands to tamper with the design intent of a product [12]. Design files and printing commands can be intercepted and modified in cloud storage and during file transferring [12]. When someone downloads such altered design files, it can lead to the production of defective products.

Additionally, adversaries can exploit the internet connectivity in modern 3D-printers to inflict physical damages to the equipment. For example, hackers leveraged the Wi-Fi connectivity of a FlashForge 3D-printer, modified the firmware of the printer, and removed the temperature constraint in the heater [13]. It caused the printer to heat to a point of catching fire. These security threats can not only disrupt emergency production but also endanger human lives. Appropriate cybersecurity standards could come in handy to minimize the risk of cyber-attacks. Standard encryption methods such as Advanced Encryption Standard (AES), Triple Data Encryption Standard (3DES), and Digital Signature Standard (DSS) should be used for securing

the design files during sharing/transferring. In addition, guidelines from the National Institute of Standards and Technology (NIST) on security and privacy, recommended practices for improving industrial control system cybersecurity, and the framework for identifying cybersecurity risks in manufacturing for developing proper standards should be followed.

5. Conclusion

During the unprecedented shortage of emergency medical equipment, AM emerged as the stop-gap solution in the global fight against the pandemic. However, appropriate design, process, performance, and testing standards are essential to ensure the efficacy of additively manufactured medical supplies. Standards can eliminate unnecessary production iterations, reduce material wastage, and improve responsiveness and preparedness for emergencies. According to our observation, it is unclear to what extent the AM efforts during COVID-19 utilized the available standards. For future pandemics, we should make standards widely available and accessible, promote the use of standards, and offer education and training programs to people on how to make the best use of existing standards. Also, as technologies progress and new needs and use cases emerge, it is imperative to update standards to address new challenges.

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