Role of Additive Manufacturing in PPE Shortage Mitigation

Kirstie Snodderly
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Agenda

• Introduction
• ASTM AM Center of Excellence
• PPE Shortages
• Community, Industry, Government Response using Additive Manufacturing
• ASTM Response
• Collaboration

Responding to COVID-19 with Additive Manufacturing
Introduction

- Additive Manufacturing R&D Project Engineer, ASTM International

- 5 years of experience in additive manufacturing for medical applications

- Former Additive Manufacturing Engineer for the Additive Manufacturing of Medical Products (AMMP) Lab at the US FDA – Food and Drug Administration

- Master of Engineering and Bachelor of Science in Bioengineering from the University of Maryland
• ASTM formed Additive Manufacturing Center of Excellence (AM CoE) in 2018

**Mission**

The Center bridges standards development with R&D to better enable efficient development of:
- Standards
- Education and training and
- Certification and proficiency testing programs

**Vision**

The Center facilitates collaboration and coordination among government, academia, and industry to:
- Advance AM standardization
- Expand ASTM International’s and our partners’ capabilities.

ASTM Committee F42 is dedicated to AM and has technical subcommittees focused on the development of consensus-based standards. This is happening in partnership with ISO TC261.

ASTM AM CoE is a collaborative partnership among ASTM and organization representing government, industry, and academia that conducts strategic R&D to advance standards across all aspects of AM in addition to create E&WD and Certification Programs.
**ASTM AM CoE Focus Areas**

**Research & Development**
Leverage R&D to significantly accelerate standards development.

**Education and Workforce Development**
Addressing standards and standards related program gaps of the AM community via webinars, workshops, symposiums and conferences.

**Standards and Certification**
Benchmarking materials, testing, processes and machinery for standards development.

**Industry Consortia**
Serving as a consortium platform for all industry sectors leveraging AM technologies.
Medical Device Shortages During the COVID-19 Public Health Emergency

- The US FDA has created and maintained a list of US medical device shortages which include PPE such as:
  - Face masks
  - Respirators
  - Medical Gowns
  - Gloves

- Why shortages exist in the US:
  - Hospitals
  - Government
  - Demand Shock
  - Supply Chain
Additive Manufacturing Technologies

**Note:** the following terms/definitions are based on "ISO/ASTM 52900: Standard Terminology for Additive Manufacturing - General Principles - Terminology"

<table>
<thead>
<tr>
<th>Process Feature</th>
<th>Materials</th>
<th>Part Size</th>
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<tr>
<td>Material Extrusion</td>
<td>Metals</td>
<td>S,M,L</td>
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<td>Material is selectively dispensed</td>
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<td>through a nozzle or orifice</td>
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<td>Material Jetting</td>
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<td>Droplets of build material are</td>
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<td>selectively cured by light-activated</td>
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<td>polymerization</td>
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<td>Directed Energy Deposition</td>
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<td>fuse materials by melting as they are</td>
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<td>being deposited</td>
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<td>Powder Bed Fusion</td>
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<td>regions of a powder bed</td>
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<td>Binder Jetting</td>
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<td>A liquid bonding agent is selectively</td>
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<td>deposited to join powder materials.</td>
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<td>Sheets of material are bonded to</td>
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<td>form a part.</td>
<td>Polymers</td>
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<td>Ceramics</td>
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Most Common for PPE fabrication
Why Additive Manufacturing

Benefits of Additive Manufacturing

• Flexibility
• Design Freedom*
• Rapid Prototyping – Short turnaround time
• Part Integration
• **Supply Chain Mitigation**: manufacture parts closer to point of use
  • Reducing impact of disruptions to transportation

* Compared to Traditional Manufacturing
Community and Industry Response

- Individuals began to sew fabric masks and donate them to health care and essential workers

- Community members created social media pages to connect individuals who wanted to help

- Industry, Academia, and other organizations called for community help to address shortages by providing designs or creating design challenges:
  - Open-source designs for door openers, face shields, face makes, etc.
  - America Makes: Fit to Face AM Mask Design Challenge

A Sewing Army, Making Masks for America
With overrun hospitals facing an acute shortage of masks, people are pulling out their sewing machines to fill the void.

3D printed face shields for medics and professionals
Open-source face shields anyone with a 3D printer can help produce. Join the community-driven effort to help professionals in your area.

America Makes Announces Top Designs of Fit to Face—Mask Design Challenge

https://www.prusa3d.com/page/covid-19_379/
https://www.americamakes.us/americamakes-announces-top-designs-of-fit-to-face-mask-design-challenge/
• ASTM International is providing no-cost public access to 29 important ASTM standards, used in the production and testing of personal protective equipment (PPE)
  o Face masks
  o Medical Gowns
  o Gloves
  o Hand Sanitizers
  o Respirators

• Target Audience: Manufacturers, test labs, health care professionals, and the general public as they respond to the global COVID-19 public health emergency
ASTM AM Response

- Development of a design guide for Additive Manufacturing
- Identified devices that could be designed and fabricated using AM including PPE
- **Objective**: Increase the quality of designs and shorten the design review/selection process.
• The design guide covers potential design-related issues in AM and provides recommendations for mitigation of these design issues based on existing Design for Additive Manufacturing Standards (ASTM F42.04)

• Decreases the possibility of receiving low-quality (feasibility) designs for PPE submitted to America Makes portal and the NIH print exchange
Collaborative Effort

- US FDA, VA, and National Institutes of Health (NIH) MoU
- Community members provided the designs
- NIH controls the use of data or model
- VA evaluated and tested the designs: clinical and bench testing

- Challenge America and the Veterans Health Administration Innovation Ecosystem 2nd call, maker challenge – asked the community to submit designs for PPE, specifically, respirators
Additive Manufacturing can provide a stopgap for certain PPE items when traditionally manufactured PPE is limited or unavailable such as:

- Face Masks
- Face Shields

https://assets.researchsquare.com/files/rs-63872/v2/16735c17-bebe-4938-8ac4-064e854c0645.pdf?c=1631862553
Thank you.

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