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Review

COVID-19: The Use of 3D Printing to Address PPE Shortage during a Pandemic—A Safety Perspective

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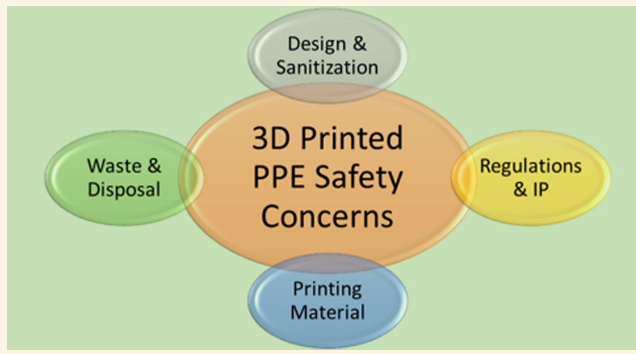
ABSTRACT: The COVID-19 pandemic created a global health crisis that impacted the supply of personal protective equipment and created a shortage of much-needed face shields and masks for essential workers. During this time, a community of manufacturers, academic institutes, and hobbyists came together and tried to address the supply shortage by providing 3D-printed face shields and masks. Although the Secretary of U.S. Department of Human and Health Services and the Food and Drug Administration relaxed some of the liability and product regulations regarding 3D-printed medical supplies during the pandemic, the safety of 3D-printed face shields and masks is still a concern. In this Review, we have highlighted some of the safety concerns related to printing materials, design consideration, waste generation and disposal, intellectual property and manufacturing regulations, and the sanitization of 3D-printed personal protective equipment.



KEYWORDS: *3D printing, PPE, face shield, face mask, safety*

■ INTRODUCTION

The emergence of the COVID-19 pandemic created a world health crisis in the form of a shortage of highly essential medical supplies that are critical to first responders and health care professionals to fight against the pandemic.[1] Along with social distancing, personal protective equipment (PPE) is one of the protective measures in place for the improvement of occupational safety and is used as a shield by medical professionals to protect themselves against COVID-19. The shortage of PPE was experienced worldwide. Nearly half of the doctors in the UK struggled and were forced to find protective equipment on their own.[2] Doctors in Australia were lined up in front of hardware stores to procure PPE.[3] To counter the PPE shortage, the rapid prototyping community came to the rescue. Big manufacturers, local maker communities, institutes, and hobbyists worked collaboratively to find a timely solution to address the PPE supply shortage.[4] Around the world, makers worked together with government agencies to ease the approval process of 3D (three-dimensional) printed products.[4,5] During this process, some important concerns were raised on the safety of 3D-printed PPE, regulatory requirements, intellectual property, liability risk, and other safety issues.

As the 3D printing community showed great promise in playing an important role in addressing this shortage of medical supplies during the current pandemic, government agencies have eased regulatory requirements and liability risks to mobilize the 3D printing community to manufacture medical supplies.[5,6] Earlier this year, the Secretary of the U.S. Department of Human and Health Services (HHS) announced a new declaration under the existing Public Readiness and Emergency Preparedness Act (PREP Act) that addressed some of the liability risks associated with 3D-printed medical supplies.[5,6] The initial declaration moderated liability risks and provided immunity to individuals engaged in certain activities related to 3D printing medical supplies and PPE. It included devices used in the diagnosis, treatment, cure, or mitigation of COVID-19.[6] In April 2020, the Secretary of HHS announced an amendment to the initial declaration of the PREP Act and extended immunity to respiratory devices approved by The National Institute for Occupational Safety and Health.[7] In addition to the PREP Act's immunity, an executive order from the U.S. President's office in March 2020 invoked the Defense Production Act (DPA) of 1950, which provided additional protections to certain business manufacturing medical supplies like 3D-printed PPE.[8] Regardless of manufacturing methods or techniques, the Food and Drug

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Administration (FDA) regulates medical products intended to diagnose, treat, prevent, or mitigate a disease. Due to the dire shortage of PPE for healthcare workers and to fill the gaps in the supply chain of medical supplies, the FDA acted proactively and took various actions to ease regulations regarding 3D-printed medical supplies and PPE manufacturing.[5] To leverage this opportunity, makers and hobbyists used freely available designs from resources such as the National Institutes of Health (NIH) 3D print exchange.[9] The NIH 3D print exchange is an online design repository of 3D designs, uploaded by the design creator/owner using Creative Commons license terms, and supported by the National Institutes of Health.[9] A recent article studied the use of social media and explored how the community used it to share the 3D printable design to tackle the PPE shortage (Figure 1).[10]

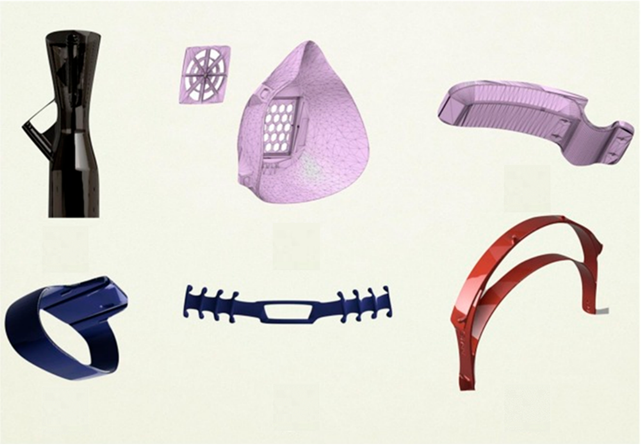

Figure 1. 3D designs of PPE and parts of medical equipment. Reprinted with permission from ref 10. Copyright 2020 Elsevier.

Despite the regulatory requirement relaxation for 3D printing medical supplies, it is important to prioritize the safety of 3D-printed articles. Although these potential immunities make it easier for manufacturers to mitigate liability risks and produce PPE for essential workers, it should not be taken for granted, and extreme care should be practiced. Manufacturers need to avoid unproven claims, provide proper labeling, provide safety precautions, and indicate the intended use of products. The present Review aims to highlight some of the safety concerns of 3D-printed face shields and masks, to ensure that manufacturers are aware of these safety risks, and to provide the 3D printing community an overview of potential safety concerns and liabilities. This review also provides a brief overview of common 3D printing technologies and the safety risks related to 3D printing materials, design consideration, waste generation and disposal, intellectual property and the manufacturing process, and sanitization of 3D-printed face shields and masks.

■ 3D PRINTING: BACKGROUND AND INTRODUCTION TO THE TECHNOLOGY

3D printing, also called rapid prototyping, is an emerging technology that has captured the attention of educators, inventors, and entrepreneurs around the world and has become increasingly useful. The history of 3D printing goes back to the 1960s. It mostly stayed behind the scenes until the 1980s, when it was called additive manufacturing. In 1988, Chuck Hull launched the first commercial additive manufacturing machine, named the stereolithography apparatus.[11] It was the start of "the revolution" as manufacturers took an interest in this technology. The term "3D Printing" was used by Prof. Cima from MIT for the first time in 1993 for a printer that could print a model using several printing materials such as plastic, metal, or ceramics.[12] In the past 25 years, 3D printing technology has made remarkable progress and has been credited as the fourth industrial revolution.[13]

In recent years, 3D printing technology has gained attention from different sectors of society and has shown a wide range of applications in various fields of human engagement.[14] It provides an innovative outlook for many manufacturing industries, disciplinary education, and research. 3D printing has been used to design prototypes and models of new machines.[15] It has also been used in architecture, construction, aerospace engineering, and robotics engineering to prepare prototypes and structural models. It shows great potential in medicine and health sciences in fabricating several prosthetic, bone grafting, implants, and machine components.[16] 3D printing also made strides in printing artificial body parts and organs using biotissues and cell printing material, and fabricated heart tissues and bionic ears.[16,17] Fabricated tissues and organs are used for pharmaceutical and drug toxicity testing, as it is seen as a replacement of drug toxicity testing on animals.

3D printing allows the creation of a physical object from a digital design by applying a printing material layer by layer.

Table 1. Most Common 3D Printing Technologies

technology	description	compatible with material
stereolithography (SLA)	uses a computerized laser beam to build the required structure from a liquid polymer	photopolymers
selective laser sintering (SLS)	uses a high-power laser to form a 3D model by fusing the plastic powder layer-by-layer	thermoplastics, metals
fused filament fabrication (FFF) or fused deposition modeling (FDM)	produces a 3D object by extruding melted thermoplastic, adding layer upon layer, working from the bottom to top	thermoplastics or material with thermoplastic binders
digital light processing (DLP)	uses photopolymers, conventional sources of light, and digital micromirrors placed on a semiconductor chip	photopolymers
selective laser melting (SLM)	uses a high-power laser beam to fuse the metallic powder to form a 3D object	thermoplastics, metals
electron beam melting (EBM)	uses an electron beam for building a model using the metallic powder bed fusion technique	metals
material jetting (MJ)	uses photosensitive material droplets that solidify using ultraviolet light	photopolymers
laminated object manufacturing (LOM)	uses normal printer paper and adhesive to glue material together and cut the shape with a knife or laser cutter	paper, polymer, or metal sheets

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Digital designs can be produced using 3D modeling software such as SolidWorks or Tinkercad (an open-source software). Currently, various 3D printing technologies are available with various printing material options including plastics, metal powders, and resins. Table 1 summarizes the most common 3D printing technologies and their compatible materials.[18]

Recently, 3D printing is becoming affordable, and the cost of a common 3D printer can range from $300 to $5,000, depending on the technology and functionality of the printer. A simple 3D printer (Figure 2) is one of the most popular lower-range printers. Commercial grade printers are more expensive. 3D printing provided a great boost to the small manufacturing, education, research, and hobbyist markets and made a great impact on the manufacturing economy.[19] Current estimates suggest that the global 3D printing market's revenue will reach $34.8 billion by 2024, and it will be one of the fastest-growing industries.[20]

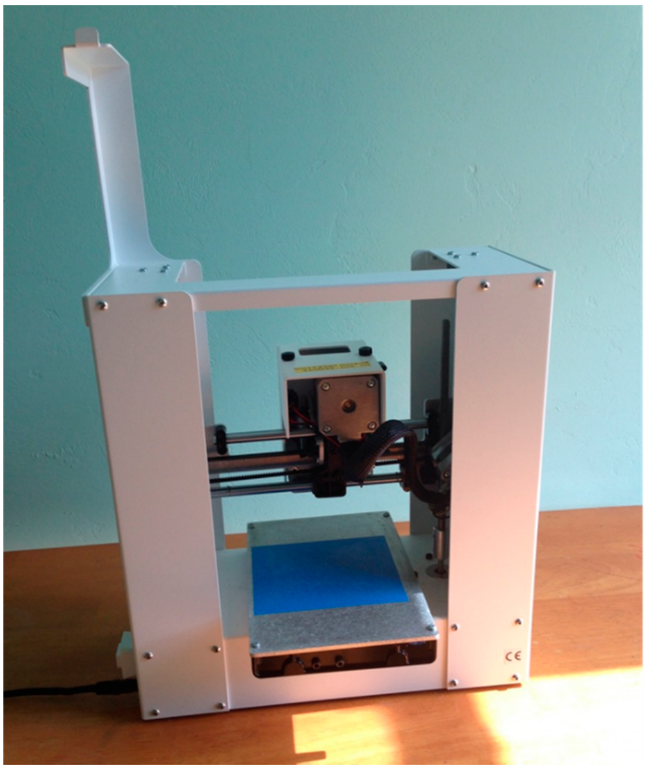

Figure 2. Lower-end FDM 3D printer.

■ 3D PRINTING APPLICATIONS DURING THE COVID-19 PANDEMIC IN PPE MANUFACTURING

During the pandemic, 3D printing technology has been used to fill the gap between PPE supply and its demand. The printing of face shields, goggles, medical accessories, surgical masks, and ventilator parts has become very common during the past few months.[10,21,22] Most makers use freely available designs of face shields and masks, downloaded from online resources or social media.[9,10] Hundreds of models are available online for face shields, masks, and other accessories on several websites. Although none of these models are regulated or endorsed by any agency, the 3D printing community in the USA collaborated with the FDA and the Department of Veterans Affairs (VA) in validating 3D face shield designs from freely available resources such as the NIH 3D Print Exchange.[9] The NIH website states that "the NIH, FDA, VA, America Makes, and the contributing creators cannot ensure the quality, safety, and efficacy of these designs when manufactured without proper quality controls and processes."

Recently, Amin et al. described a method to print face shields using a 3D printer. The process included design selection, digital preparation, printing, and the assembly of the final product (Figures 3 and 4).[21] In short, a design was selected, and the parts were printed on a 3D printer using polymer printing material. The shield was assembled using Velcro, adhesive foam, and transparency films on the shield frame.

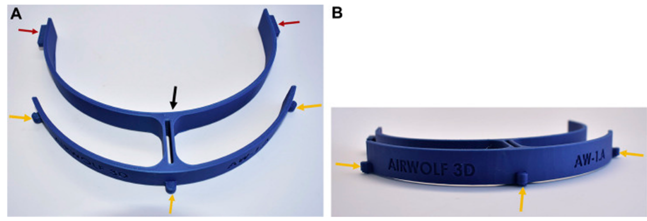

Figure 3. (A) Superior and (B) frontal views of a 3D-printed frame of the face shield. Note the inner circumference (black arrow), lateral projections (red arrows), and rounded projections (yellow arrows). Reprinted with permission from ref 21. Copyright 2020 Elsevier.

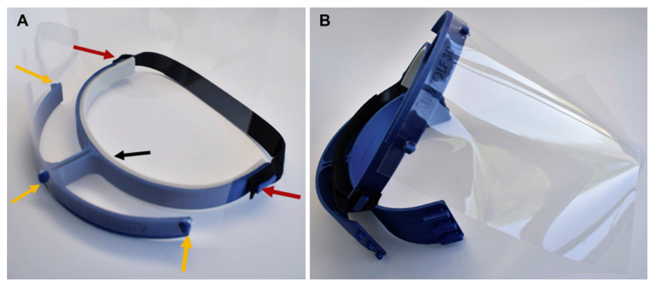

Figure 4. (A) Inferior and (B) lateral views of the assembled face shield. Note the position of Velcro on the lateral projections (red arrows), foam at the inner circumference to improve comfort (black arrow), and transparency film on the rounded projections (yellow arrows). Reprinted with permission from ref 21. Copyright 2020 Elsevier.

Belhouideg explored several designs of 3D-printed medical equipment including masks to analyze their printability and use (Figure 5).[22] Swennen et al. printed face masks using plastic polymers.[23] The face mask was printed in two components and was assembled using Velcro and textile materials. The study suggested a disinfecting protocol, but the masks were not tested for leakage and virologic flow testing in real-life scenarios.[23]

■ CONCERNS WITH THE 3D-PRINTED FACE SHIELDS AND MASKS

As 3D-printed PPE is making news around the world, there are several concerns regarding the safety and use of 3D-printed face shields and masks by health care workers.[24] As people are trying to combat PPE shortage by printing their protective equipment, this raises concern as there is not enough guidance on how to do it safely. As the article mentioned, "Medical grade face masks and shields must be fit for purpose, and some hospitals are having to turn away much of the equipment because it is of poor quality, badly designed, or assembled

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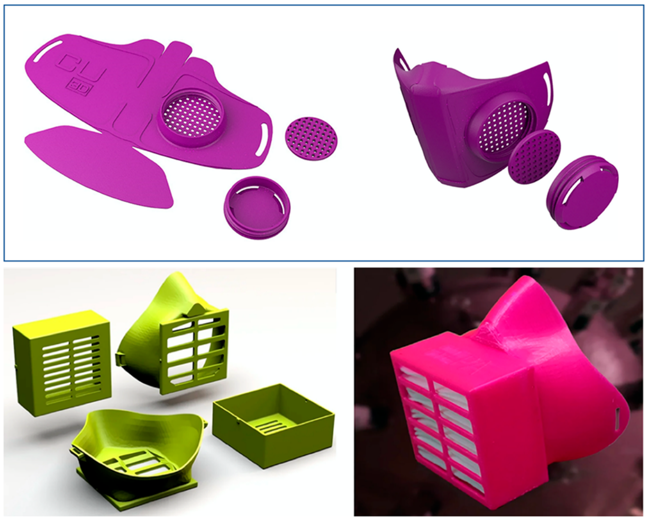

Figure 5. 3D-printed protective face mask. Reprinted with permission from ref 22. Copyright 2020 John Wiley & Sons.

incorrectly or in insanitary conditions."[24] If 3D-printed PPE is not efficient or sanitized properly, or does not fit correctly, it might give a false sense of security and may do more harm than good. In some cases, 3D-printed face masks were rejected due to serious questions about their efficacy in preventing COVID-19 transmission, lack of proper fitting, or other potential issues.[24] Ben Johnson, Director of Product Development at the 3D Systems Healthcare explained, "Face shields likely can be printed in FDM just fine and serve the need of a health care provider just fine, where you can disinfect them. Other types of applications, like face masks or diagnostic tools or other medical device components are likely not acceptable to be manufactured from those types of materials and processes because they wouldn't meet the essential requirements of those parts."[25] 3D-printed face masks are likely to not be acceptable because they would not meet stringent manufacturing requirements for health workers and would be hard to wear, sanitize, and disinfect. Other concerns are stability, the texture of the material, design safety and sanitization, intellectual property rights and manufacturing guidelines, along with waste generation and disposal during the process. All these concerns are described below in detail.

Stability Safety and Texture of 3D Printing Material.

- Most of the face shields and masks printed by hobbyists use plastic polymers such as polylactic acid (PLA), acryl butadiene styrene (ABS), or polypropylene (PP). These thermoplastics generate ultrafine particles and volatile organic material during the printing process which can impact surrounding air quality and makers' health.[26−29] Some of the 3D printing materials have a specific smell such as PLA and ABS, which could be a cause of concern to some users and makers.[26−29]
- 3D printing materials are polymers or chemicals that are not fully tested for human use, so they can have unintended consequences, and chemical injury to the users may be possible.[26−29]
- Picking an appropriate material for 3D printing, which can be easily sanitized by the users for sustainable reuse, is critical. It is also important for the makers to know if the material used for printing is approved for medical device manufacturing and is environmentally sustainable.[30] According to the National Personal Protective Technology Lab, ideal materials for face shield fabrication are polycarbonate, propionate, acetate, polyvinyl chloride, and polyethylene terephthalate glycol.[30,31]
- FDA does not regulate materials or manufacturing processes for 3D-printed PPE, but it is a matter of concern that 3D-printed devices could potentially introduce toxic materials into the user's body. FDA recommends that all materials used must be identified by the makers, including the source and purity.[5,6] The material's Safety Data Sheet (SDS) should be consulted, and the hierarchy of controls should be considered before using them for printing PPE.
- During 3D printing, the material is melted and solidified multiple times, which could introduce undesirable chemical effects by changing the material's chemistry.[32] Makers need to ensure that it does not create any unintentional chemicals that could pose a potential health risk. For PPE printing, only noncytotoxic and nonallergenic materials should be used. It is recommended to use skin approved materials and work in sanitary and clean conditions.
- Oskui et al. studied the toxicity of 3D-printed parts on the Zebrafish embryo.[33] During the study, Zebrafish embryos were exposed to 3D-printed parts, which were printed with polymers using two different techniques, STL and FDM. It was found that parts from both types of printers were measurably toxic to Zebrafish embryos and created hatching and developmental abnormalities. The study found that STL-printed parts were significantly more toxic than FDM-printed parts.[33]
- De Almeida et al. also studied the toxicity of commonly used 3D printing polymers on bovine embryos and found toxic effects of the polymers on embryo development.[34]
- Since 3D printing has become more widespread, and there have been some reports on the toxicity of 3D-printed parts, the effects of 3D printing materials and printed objects on human health should be explored.[33,34]

Design Safety and Sanitization of 3D-Printed PPE.

- Many practitioners rejected 3D-printed face shields due to the concerns of not being tested for efficiency against COVID-19, improper ventilation through the face shield, other buildups, and improper filling.[24] Other concerns were the sanitary conditions of these materials and how to sanitize them after each use.
- There are many designs available freely online. None of them is a one size fits all solution, and most of them are not tested or validated.[35] It is best to consider who is the user and what the intended use of the product is before choosing the model and adjusting it to their need. There is a significant difference between a 3D model and a printable 3D model. Just being available on the website does not mean it is printable. Make sure to follow the recommended slicing setting for any given model.
- Although the FDA has issued a guideline previously as the Technical Consideration for Additive Manufactured Medical Devices, this guides regular device process validation and accepted activities of a finished device but does not include 3D-printed face shields and masks. The FDA admitted that 3D-printed PPE may provide a

physical barrier but are unlikely to provide the same protection and air filtration as FDA approved surgical masks and N95 respirators.[5,6] The FDA stated that 3D-printed masks may look like conventional PPE, but they may not provide the same level of barrier protection, fluid resistance, filtration, and infection control.[5,6]

- The cleaning of the parts after printing is also critical. Some 3D printing methods use secondary support material that need to be washed with alkaline and corrosive chemicals. 3D-printed parts should be rinsed properly to remove any alkaline residue before sanitization if an alkali soluble support material was used during printing.[14] PPE printed parts need to be free of chemicals on the surface and be properly sanitized.
- 3D-printed PPE can be fragile and cause injury to the user if a fracture occurs. The strength of 3D-printed parts needs to be tested before use, and polymers that have high tensile strength and low friction should be used. They can also have very sharp edges depending on the printing process and after print processing.
- While printing PPE on 3D printers, the emission of UFPs should be considered, and the printer should be operated only in a properly ventilated area.[14]

Intellectual Property and Manufacturing Guidelines.

- While printed freely available 3D designs, there is always a third-party intellectual right that needs to be taken into consideration.
- Printing setup and workflow is different for hobbyists and expert 3D printing users. With hobbyists or nonapproved manufacturers, the FDA warrants that, for printing PPE, they need to have a quality control and management system in place.[5]
- There is no clear federal guidance on designs for 3D-printed PPE. According to the FDA regulations, a 3D face mask should not be used by a health care provider, except some exceptions where government agencies are working with the manufacturer, and a quality control method is in place.[5]
- Regulations are specific for devices used in health care settings. Hobbyists do not have the testing and rigor required for specific types of devices. Some devices may need to be sterilized in an autoclave at 121 °C under pressure for 15−20 min. Certain 3D printing materials are not stable at this temperature and pressure and will become deformed.[36]

Waste Generation and Disposal.

- Decentralized efforts of 3D printing PPE during a pandemic created a huge concern about the amount of plastic waste generated and released into the environment. Since the toxicity of most 3D-printed materials is not explored in detail, waste management of 3D printing material is a challenge.
- 3D printing has contributed to PPE availability, but it may be difficult to scale 3D printing production due to the time-consuming printing process. Although 3D printing is a practical and temporary workaround, there are sustainability concerns.[37]
- For specific print processes that use an alkaline bath to dissolve support materials, it should be handled with care, and the waste should be disposed of properly using appropriate lab attire, corrosive resistant rubber gloves, and splash goggles.[14] When the alkaline bath is emptied, it must be disposed of as hazardous waste per Environmental Protection Agency regulations and cannot be poured down the drain because some components of the dissolved material are harmful to aquatic life.[14]

A few years back with the expansion of 3D printing, it was predicted that this technique would have a potential to disrupt industrial applications and would influence the supply chains in the future. It came true during the recent pandemic: 3D printing is being used to print PPE to close the gap in the PPE supply chain. 3D-printed PPE should be printed in a safe environment, and clearly labeled for the intended use. In each case, compliance needs to be maintained, and regulations should be followed. The FDA assists manufacturers by providing specific guidelines and addressing questions regarding the 3D printing of medical supplies during a pandemic. This includes FAQs on the 3D printing of medical supplies, accessories, components, and machine parts.[5] The FDA provides more detailed guidelines and recommendations on technical considerations for 3D-printed medical supplies, but information on 3D-printed face shields and masks was not clearly stated. While 3D printing has the potential to address this PPE shortage, the safety of their use should be seriously considered.

■ CONCLUSION

3D printing technology has displayed tremendous potential in playing an important role in the global crisis by filling the PPE supply gap during the COVID-19 pandemic. The FDA and NIH came together to provide some guidance to the maker community on 3D-printed face shields and masks. Although the FDA has relaxed some of the liability risks and provided guidance to the maker community, it is still important to consider safety risks. It is important to include adequate labeling, not make unproven claims, and indicate the intended use of the product. The product manufacturer should consider the intellectual rights of the designer, especially if the designs are downloaded from freely available resources, and provide proper credit to the designer. Finally, printing PPE is a great use of technology, but people should research the design, materials, other components, how to sanitize or disinfect the product, who are the users, and how to dispose of the waste before printing. By keeping safety in mind, this technology can be a part of the solution to many problems and do wonders.

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Notes

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