Ontario Health
Quality

3D Printing of N95 Respirators and Face Shields: Supplemental Information

Key Messages

This supplemental information was generated to support decision-making and to provide information on 3D printing of N95 respirators and face shields during the novel coronavirus disease (COVID-19) pandemic.

We examined the recommendations from national and international health authorities and organizations and completed a targeted search of published literature to determine what is known around 3D printing of N95 respirators and face shields. We found the following:

- There is very limited evidence on effectiveness; only some models/designs have been tested in a clinical setting (see table below)
- Guidance from national and international health authorities emphasize that 3D-printed N95 respirators may not provide the same fluid barrier and air filtration protection
- Guidance from national and international health authorities emphasize that 3D-printed face shields need to provide adequate coverage and fit snugly in order to provide protection

ISBN 978-1-4868-4450-0 (PDF)

Background and Context

On April 3, Ontario Health (Quality) received a request from the Ontario Health Secretariat for information around 3D printing of N95 respirators and face shields during the COVID-19 pandemic. In response to that request, this supplementary information provides a summary of recommendations from national and international health authorities, organizations, and grey literature.

Guidance

US Food and Drug Administration

The US Food and Drug Administration (FDA) has provided the guidance document *3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic*.[i] These recommendations are in addition to existing FDA guidance[ii] on technical considerations for manufacturing, testing, and characterization of devices that have at least one part that is made by additive manufacturing, which encompasses 3D printing.

Below is a summary of the FDA's most recent advice relevant to N95 respirators and face shields:

- 3D-printed personal protective equipment (PPE) is unlikely to provide the same fluid barrier and air filtration protection as FDA-cleared surgical masks and N95 respirators
- 3D-printed PPE can be used to provide a physical barrier to the environment
- Health care workers should be aware of and follow these steps with 3D-printed masks:
    - Check the 3D-printed mask's seal for leaks
    - Confirm that they can breathe through any makeshift filter materials
    - Exercise caution in surgical environments where liquid barrier protection and flammability are concerns
    - Recognize that the mask may not provide enough air filtration to prevent the transmission of infectious agents
    - Safely dispose of infectious materials, and disinfect any part they intend to reuse
- Entities wishing to 3D print accessories or components of medical devices should use original parts or those with the same specifications, dimensions, and performance as original parts (i.e., they should work with medical device manufacturers), and they should verify that any 3D-printed products fit and work properly before they are used in a clinical setting
- Some devices and components are more amenable to 3D printing than others. The FDA is willing to discuss these and other issues with manufacturers and facilities

US National Institutes of Health 3D Print Exchange

The US National Institutes of Health (NIH)[iii] has compiled a collection of PPE designs that can be 3D printed. Prototypes can be submitted by researchers to this site for testing and clinical review.

NIH disclaimer: While many of the designs can be printed with a 3D printer at home or at a local makerspace, the NIH and other contributing creators cannot ensure the quality, safety, and efficacy of these designs when manufactured without proper quality controls and processes.

Health Canada

Health Canada[iv] has provided guidance to companies intending to 3D print PPE in response to the COVID-19 pandemic. Specifically, for face shields, these minimum specifications should be followed:

- The face shield must provide adequate coverage (CSA Z94.3 Sections 10.2.1/10.2.2/10.3/10.4)
- The face shield should made of optically clear, distortion-free, lightweight materials (refer to CSA Standard Z94.3.1-16 and Roberge, 2016[v])
- The face shield should be free of visible defects or flaws that would impede vision (ANSI Z87.1 Section 9.4)
- The face shield should allow adequate space between the wearer's face and the inner surface of the visor to allow for the use of ancillary equipment (medical/surgical mask, respirator, eyewear, etc.)[vi]
- The face shield should fit snugly to afford a good seal to the forehead area and to prevent slippage[vii]
- The face shield should withstand impact from sharp or fast projectiles (ANSI Z87.1 Section 9.2 and 9.3, CSA Z94.3 Section 10.1)
- If possible, the face shield should have antifog properties on both sides (CSA Standard Z94.3.1-16)
- Materials that come into contact with the wearer should provide adequate material biocompatibility (skin sensitivity and cytotoxic testing) (ISO 10993-5, 10)

For face masks, Health Canada[viii] has suggested that further caution is warranted: 3D-printed face masks may provide a physical barrier, but they *are unlikely* to provide the same fluid barrier and air filtration protection as licensed surgical masks or N95 respirators.

3D Printed N95 Respirators, Face Shields, and Mask Straps That Have Been Reviewed for Clinical Use or Are Under Review

Type of PPE	Design/Company/ Website	Evidence	Other Considerations
3D-printed PPE that have been reviewed for clinical use			
Face shield (headband)	3DPX-013421 designed by Stratasys	According to the NIH, this design has undergone review in a clinical setting and is recommended when fabricated as instructed.	—
Face shield (headband)	3DPX-013359	According to the NIH, this design has undergone review in a clinical setting and is recommended when fabricated as instructed.	—
Face shield (headband)	3DPX-013309	According to the NIH, this design has undergone review in a clinical setting and is recommended when fabricated as instructed.	—
Face shield	The Canadian Shield	—	This face shield has received a licence from Health Canada.
Respirator	3DPX-013429 Stopgap Surgical Face Mask	According to the NIH, this design has undergone review in a clinical setting and is recommended when fabricated as instructed.	—
Surgical mask tension release band	3DPX-013410	According to the NIH, this design has undergone review in a clinical setting and is recommended when fabricated as instructed.	This product is designed for ear comfort and extended use. It can be printed on an HP 580 out of Nylon 12. It holds elastic straps and rubber bands attached to a mask.
Mask comfort strap	3DPX-013440	According to the NIH, this design has undergone review in a clinical setting and is recommended when fabricated as instructed.	This product is designed to relieve pressure from the mask straps on the ears.

Type of PPE	Design/Company/ Website	Evidence	Other Considerations
3D-printed PPE that are under review*			
Reusable 3D-printed N95-equivalent respirators	George Washington University[ix]	This respirator was developed with PLA (printer filament), a removable cap, a removable filtration unit consisting of two layers of MERV 16 sandwiched between MERV 13, and removable elastic bands to secure the mask. This prototype passed leakage evaluation and a qualitative Bitrix N95 fit test at employee health at George Washington University Hospital.	This respirator prototype is undergoing further development for its seal against the face, comfort, and sizing.
Reusable respirator	Developed by Intermountain 3D Inc in collaboration with the Saint Alphonsus Heart Institute in the United States	This model has not been evaluated by the FDA or any other regulatory agency, and Intermountain 3D makes no warranties as to its efficacy in any specific situation. According to the company website, this respirator has been tested with an N95 filter using the N95 Respirator Fit Test with Challenging Agent at St. Alphonsus Hospital and has passed all tests.	Material/components: 3D-printed mask (nylon 12 material); sealing strip, elastic straps, and filter material made from surgical wrap (polypropylene). Cost: each fully assembled mask is $19.50. For unassembled respirators in bulk volumes, special pricing is available.

*There are many PPE prototypes currently under review on the NIH 3D Print Exchange website that are not listed in this table. As the NIH website provides updates, more designs/prototypes will be clinically reviewed.

References

[i] Food and Drug Administration. 3D printing of medical devices, accessories, components, and parts during the COVID-19 pandemic. Silver Spring (MD): The Administration; 2020 [cited 2020 Mar 26]. Available from: https://www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic

[ii] Food and Drug Administration. Technical considerations for additive manufactured medical devices. Silver Spring (MD): The Administration; 2017 [cited 2020 Apr 3]. Available from: https://www.fda.gov/media/97633/download

[iii] National Institute of Health. NIH 3D Print Exchange. Cited April 3, 2020. Available from: https://3dprint.nih.gov/collections/covid-19-response

[iv] Health Canada. 3D printing and other manufacturing of personal protective equipment in response to COVID 19. Ottawa (ON): Health Canada; 2020 [cited 2020 Apr 3]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html

[v] Roberge RJ. Face shields for infection control: a review. J Occup Environ Hyg 2016;13(4):235–42.

[vi] Roberge RJ. Face shields for infection control: a review. J Occup Environ Hyg 2016;13(4):235–42.

[vii] Roberge RJ. Face shields for infection control: a review. J Occup Environ Hyg 2016;13(4):235–42.

[viii] Health Canada. 3D printing and other manufacturing of personal protective equipment in response to COVID 19. Ottawa (ON): Health Canada; 2020 [cited 2020 Apr 3]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html

[ix] Provenzano D, Rao YJ, Mitic K, Obaid SN, Pierce D, Huckenpahler J, et al. Rapid prototyping of reusable 3D-printed N95 equivalent respirators at the George Washington University. Preprints 2020, 2020030444 (doi: 10.20944/preprints202003.0444.v1).