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Chapter 19

PERSONAL PROTECTIVE EQUIPMENT IN THE COVID-19 PANDEMIC

Kevin Pineda*[*], *Geoffrey Nasuti*[2] *and Jaqueline Darcey*[3,†], *MD
[1]Kessler Institute for Rehabilitation Physical Medicine and Rehabilitation,
Rutgers New Jersey Medical School, West Orange, New Jersey, US
[2]St. George University School of Medicine, Grenada
[3]Department of Medicine, Morristown Medical Center,
Morristown, New Jersey, US

INTRODUCTION

Personal Protective Equipment (PPE) in 2020

When COVID-19 arrived in the United States in late February 2020, the country boasted approximately 12 million N95 respirator masks in its stockpile. At that time, it was projected that the United States would require approximately 3.5 billion N95 masks to meet the demands of the COVID-19 pandemic [1], meaning the country had fewer than 1% of the total number of the N95s needed. Those calling it a shortage were grossly understating the deficit. This chapter serves as both a comprehensive guide of PPE and an archive of the evolution of PPE measures taken during the pandemic.

Before 2020, most of the N95 production for the United States was outsourced to China. At the outset of the pandemic, the supply chains were significantly impaired. Many hospitals, with their small N95 stockpiles, found they had expired masks which were nonviable due to degradation of the elastic straps, further increasing demand. American companies such as Honeywell® converted their facilities for N95 production but were unable to keep up with demand. N95 respirator masks were only one category of the many PPE types in extreme shortage, which included face shields, surgical masks, powered air-purifying respirators (PAPRs), gowns, and mechanical ventilators. In some institutions, even surgical masks were at

[*] Corresponding Author's Email: oscms.northjersey@gmail.com.
[†] Corresponding Author's Email: jmdarcey@optonline.net.

a shortage resulting in healthcare workers being provided one disposable surgical mask in a brown paper bag and were instructed to keep and use mask continuously for 1-2 weeks.

Due to the dire scarcity of PPE, the Open Source Medical Supplies (OSMS) global group was created on March 16, 2020 as a grassroots group [2]. The original mission of OSMS was to make an open-sourced, low-cost mechanical ventilator to meet demand. This was in response to the prediction, based on European experiences, that the United States would not have enough ventilators to care for its most ill citizens. Shortly after, OSMS expanded its scope to source ideas for other much-needed PPE, including face shields, surgical masks, PAPRs, ear savers, and gowns.

This chapter will review PPE and the innovations that rapidly developed due to necessity during the COVID-19 pandemic. While some designs were approved by National Institutes of Health (NIH) under the Emergency Use Authorization (EUA), many of the designs listed below from OSMS and the larger 'maker' community merit further exploration for medical/peer review, National Institute for Occupational Safety and Health (NIOSH) validation, and Occupational Safety and Health Administration (OSHA) approval.

Case Report

In mid-March 2020, a middle-aged man with a medical history of chronic obstructive pulmonary disease and diabetes mellitus presented to the hospital for a one-week history of dyspnea and fever. He was intubated in the emergency department due to respiratory failure. The patient's first COVID-19 test, performed on admission, was negative. Nonetheless he was admitted to the COVID ICU as a person under investigation (PUI). His chest radiograph revealed bilateral ground glass opacities concerning for a superimposed pneumonitis. After a second negative test for COVID-19, he was transferred to the regular intensive care unit (ICU). He was treated, stabilized, and extubated 36 hours after transfer, requiring high flow nasal cannula oxygen supplementation for refractory hypoxia. While in the ICU, multiple medical residents, nurses, respiratory therapists, and critical care attendings cared for the patient, wearing only a surgical mask as per protocol at that time due to PPE shortages. Due to persistent hypoxia and abnormal chest radiography, the patient was retested. A third repeat COVID-19 test resulted as positive, and he was transferred appropriately to a COVID floor. The staff members exposed to the patient were required to monitor for symptoms of fever, cough, and shortness of breath over the next 2 weeks.

Discussion

Face Shields and Masks - Figure 1A

When trying to identify a substitute face shield to use in a healthcare setting, it is important to consider the total protective properties of the shield. COVID-19 has airborne properties, placing those working near ill patients at high risk for contracting the virus. The risk is greater if a COVID-19 positive patient produces aerosols such as during talking, coughing, or sneezing, among other acts [3]. An effective face shield design should decrease the user's risk of droplet

exposure from a patient. Ideally, the top of the head should be covered and there should be no room for droplets to run down the forehead. Conversely, no droplets should be able to reach the face from beneath the shield. The design of the face shield should have full coverage of the face from above the head to below the chin and from ear to ear. It should also be easily adjustable to fit a wide range of individuals' faces [4]. Figure 1 top left shows an example of a face shield where there is a closed top and extension of the shield drops below the chin and covers the ears with a mask as well. The face shield also features a strap to easily adjust to the wearer's face.

Not only is the shape of the shield important, but also the type of material used to create it can affect its protective properties. Many medical supply companies, such as 3M®, use a polycarbonate material to create their face shields. Polycarbonate is a versatile thermoplastic sheet which can be used for different functions. It absorbs minimal moisture and is durable, making it resistant to impact as well as water damage. Additionally, it is flame retardant and chemically-resistant. It is 30 times stronger than acrylic and 200 times stronger than glass [5]. This makes polycarbonate's surface hard to scratch. Because of these properties, polycarbonate is easy to clean and makes an excellent choice for medical grade equipment.

Although these materials are superior to others, there is limited public accessibility. Often, makers must improvise and use other supplies to achieve an acceptable level of protection for healthcare workers in times of urgent need. The following sections will highlight ideas and designs which have been used and tested in clinical practice.

Do-It-Yourself (DIY) "Olesya Design" Face Shield - Figure 1B

As the medical supply chains in the United States dwindled quickly, face shields became scarce. Many different communities produced their own face shields using various materials and methods, but all aimed to comply with the standards listed in the previous paragraph. For example, one easily-assembled shield which required no intricate equipment was designed by the open-source community, using a rubber sealing gasket easily purchased in stores or online. Additionally, 16- to 20-gauge marine-grade vinyl offers superior protection as the shield portion. This marine grade vinyl is waterproof, and thus droplets which encounter it cannot pass through the shield. It is very flexible and can be mended and cut with scissors to fit around the user's face with ease.

The "Olesya Design" Face Shield seen in Figure 1 top middle (named after our colleague who pioneered it) is an example of one community variation on the overarching design. It is easy to create, as the rubber sealing gasket strips come with adhesive tape and the gasket strips are laid on and adhere to the vinyl sheet. Lastly, elastic straps can be fashioned to the side of the sheet to adhere to the user's head. This provides excellent protection to the user as there is no route for droplets to get under the longer shield. An additional advantage of this design is its closed top, limiting droplets entering from its caudal aspect. Many earlier face shield designs did not have this added layer of protection (such as the Prusa face shield, discussed later). The shield portion of the design can also be made of many materials, meaning that makers can easily create this face shield even if they are unable to obtain higher grade material. One limitation of using non-polycarbonate materials is increased fogging; after several weeks of hospital use, the shield demonstrates increased fogging, suspected to be due to poor venting of airflow around the shield and the face shield's close proximity to the user's face.

3D Printers and Face Shields - Figures 1C, 1D, 1E, 1G

Among the many diverse methods for producing DIY face shield frames during the acute scarcity of PPE, three-dimensional (3D) printing was the most promising. 3D printers are typically small, safe, easy to use, and operate similarly to ink printers connected to a computer using computer-aided design (CAD) programs. 3D printers build 3-dimensional models from the bottom up, printing one layer at a time, repeatedly going over the same area in a method called fused depositional modeling (FDM; Figure 1C) [6]. Instead of using ink like conventional printers, 3D printers use molten plastic or filament and fuse the layers together using adhesive or UV light [7].

3D printing confers many advantages over manually creating and assembling face shields by hand. Such printers have the flexibility to produce prototype designs in hours rather than over days to weeks for more complex devices. In addition, due to increased speed, 3D printers are capable of printing more complex designs than industrial-scale manufacturing processes. Using this method, production generates little or no waste compared to typical manufacturing methods using large chunks of non-recyclable materials. Not only does the process save on resources, but it also reduces cost.

The multitude of printers available allows for makers (the term applied to operators of 3D printers) to pick and choose which type of product they would create. Each printer type has specific properties according to the type of filament or resin it uses. Stereolithography (SLA) printers (Figure 1C*)* use a process known as photo-solidification, in which a chemical reaction adheres multiple layers. The photons focus on a specific point, making the SLA resin solidify. Because SLA printing can be so precise, one can expect smooth, high-quality prints with extremely fine detail [7]. Digital light processing (DLP) is very similar to SLA style printing. Both use vat polymerization to create each layer of the object. When light targets a point in the resin, the polymers react by hardening into place. Objects printed on a DLP printer are very smooth compared to items printed on an FDM machine. Selective laser sintering (SLS) printers create new layers by focusing a laser to a point inside a vat of powder. The powder solidifies as the laser moves to the next location [7, 8]. This process is ideal for printing complex industrial parts and detailed objects.

Resin printers, like SLA and DLP, use liquid resins to create objects. The options vary between manufacturers, and models but are typically categorized depending on the type of resin being used. Standard resin often comes in several colors to fit the needs of the maker. This makes it excellent for the creation of prototypes or miniatures. However, because the resin does not hold tightly together for an extended period of time, it can be difficult to use for mass production. Tough resin is more physically resistant than standard resins and is ideally used for making products which must withstand a greater impact force. Lastly, medical-grade resin is used to create many different products, from hearing aids to dental prostheses. It can be used for longer periods of time compared to standard resins as it does not denature as easily. They are also transparent (or very nearly so), which makes them an excellent substitute for glass. However, medical-grade resin is expensive, and, in many cases, other resins would produce an acceptable–and less expensive–product [9].

Filament printers use spools of filament made from a wide variety of materials, including flexible and wood-based filaments. Polylactic acid (PLA) is a plant-derived thermoplastic polymer with a melting temperature which ranges from 130°C to 180°C. Its use is limited due to rapid deterioration on exposure to excessive moisture or sunlight. This filament is useful for

indoor use such as hospitals, but can become compromised if used for long periods outside. Polyethylene terephthalate glycol (PETG) is a food-safe plastic. Because this material forms a crystalline lattice as it slowly cools, layers are created which can easily trap moisture, food and bacteria. Its heat-resistant properties make it more favorable than other filamentous plastics depending on the device need. Acrylonitrile butadiene styrene (ABS) is a notoriously sturdy plastic. It requires a high temperature to properly set thus works best with an enclosed 3D printer to keep the ambient temperature warm [10]. The material is amorphous thus does not have a true melting point, making it a great material for injection molding. It is very lightweight and can be sterilized in multiple ways, even withstanding gamma-rays [11].

Figure 1. PPE. A: Commercial face shield and hand sewn mask. B: "Olesya" DIY face shield. C: A PRUSA SLA printer. D: An FDM printer. E: A 6-hole Verkstan with an acetate sheet to protect the face. It is easily adjustable to fit many faces and has a closed top design. A strap can be added to the back of it for a tighter fit. F: DtM design face shield. This shield's design enables superior protection compared to others but has a longer print time. G: The Prusa design face shield. Its major drawback is an open top which allows respiratory droplets to enter from above. H: A 3D printed mask frame. Cloth, string, or elastic ties secure it to the face. It provides a tight seal to prevent spread of the user's respiratory droplets. I: Examples of different hand sewn masks.

In the early stages of the pandemic when medical supply shortages were becoming increasingly apparent, the NIH implemented a community-driven 3D printing initiative. Along with makers from the OSMS community and others, the NIH approved certain designs for use within healthcare settings. The following are examples which are cost-effective and easy to print.

The Prusa face shield (Figure 1G) was one of the first designs widely circulated. Early iterations were an effective stopgap measure when the need was high and supplies were scarce. This shield's frame was relatively easy to print but used more filament than other shields such as the *Verkstan* (Figure 1E). Although many hospitals accepted these face shields solely out of need, as newer iterations were developed and became available, many hospitals stopped using the Prusa shield. Newer designs like the Verkstan, *DtM* (Figure 1F), and Budmen (not pictured) shield frames had closed tops while maintaining an appropriate distance from the face and were generally preferred. The NIH reviewed these designs and approved them for use in hospital settings, facilitating contributions from maker communities. Hospitals have generally been more willing to accept donations of NIH-approved face shields.

As described earlier in this chapter, polycarbonate remains the ideal material to use for the transparent portion of the face shield, but it requires a laser cutter for mounting to the shield frame. Laser cutters are not available to most makers, so acetate or projector transparency sheets are readily accessible and cut easily with a 3-hole paper punch. Acetate offers inferior protection compared to polycarbonate but is easy to obtain and offers adequate protection in emergency situations where standard industrial PPE cannot be obtained.

During the COVID-19 pandemic surge of early 2020, many hospitals in the northeastern United States preferred the 6-hole Verkstan shield over other models. It is quick to print as the frame does not use much filament material during production. It has a closed top design which is favorable due to safety concerns. The shield portion can be made from a sheet of acetate, which can be hole-punched twice by turning the sheet 180 degrees if the original holes become stretched and the shield becomes loose. Other designs like the Prusa or DtM use much more filament with significantly longer print times. Design-for-design, the Verkstan shield frame is safer and cheaper to use and is more rapidly and efficiently produced.

3D Printed Face Masks - Figure 1H

Surgical masks have been a cornerstone of preventing disease spread during the COVID-19 pandemic. Like face shields, surgical masks were in high demand when treating patients who were infected with COVID-19. However, when states mandated face mask use for the general population outside the home, surgical mask supplies diminished even further. The maker community designed an effective 3D printed variant (Figure 1H) which was relatively cheap and easily produced.

PLA (polylactic acid) is the preferred material for these 3D printed face mask frames due to its durability. PLA has a very high tensile strength at 61-66 MPa as well as a very high melting point at 130-180 °C, allowing it to be heated up while maintaining its structure. Mask frames made from PLA can be briefly placed in hot or boiling water to make the material more malleable, allowing the wearer to mold the mask frame to their face for a superior fit. The food-safe plastic PETG is readily available, but has a lower melting point. Heating the object may cause its structure to be compromised, and the frame may fail [12].

A 3D printed mask frame can be used with a variety of fabrics and materials. Cotton or flannel was a very early solution as it was easily-obtainable and inexpensive. Cotton and cotton-

polyester hybrids are better filters than expected due to their ability to form an electrostatic barrier. As a result, smaller particles which are not typically stopped by a physical barrier are unable to pass through a charged one. Therefore, combining materials together, such as any cloth with a flannel sheet, on a 3D printed mask frame, will prevent up to 90% of particles with a size of 300 nm or more from passing through the mask. Filter materials with a higher minimal efficiency reporting value (MERV) such as MERV13 will guarantee removal of 90% of particles size 300-1000 nm [13]. Ultimately, if industrial filter material is not available to the maker, a cotton-polyester substitute can still provide excellent protection.

Handsewn Masks - Figure 1I

Limiting the public spread of SARS-CoV-2 has been of utmost importance. With PPE shortages affecting the entire world, recommendations for wearing cloth face masks have been an important tool for public safety. Cloth masks do not prevent all COVID-19 disease. Their strength lies in minimizing the wearer's ability to transmit it. Droplets and respiratory secretions from talking have been implicated in the spread of disease from person-to-person. A normal healthy person can expel droplets anywhere from 20-500 micrometers [3]. However, a cloth covering the face can nearly eliminate all droplets being expelled from a person's mouth, emphasizing the importance of wearing a mask. Cloth masks are easy and efficient to make, taking experienced makers only 10-20 minutes to complete. Very few materials are needed: two layers of tightly woven cotton (such as a dress shirt or bed sheet) for the mask and ⅛ inch elastic for the ear holders. Some makers effectively used soft fabric tie straps during an elastic shortage. Cloth face masks can be made in a variety of sizes to fit adult and child faces, and there are several mask styles and tutorials available on the internet for DIY use.

N95 Respirator Masks – Figure 2

The N95 filtering facepiece respirator (N95) is the most critical component of PPE for healthcare workers (Figure 2). N95s protect healthcare workers from airborne droplets and aerosolized viruses, including SARS-CoV-2. Pre-pandemic, China had been the main worldwide supplier of N95 masks. The United States and much of the world had a critical shortage of N95s due to stockpile inadequacy as well as supply chain deficits due to COVID-19's effects on China. Makers scrambled to find ways to make N95 replacements which would be approved by OSHA, the certifying body. N95 stands for *N*: not resistant to oil, and *95*: 95% filtration of airborne particles [14]. The unique component of the respirator material is the nonwoven electrically charged melt-blown polypropylene fibers which give it both mechanical and electrostatic filtration properties [15]. An adequate seal to the wearer's face is necessary to ensure appropriate filtration, which is affected by facial size, shape, and the presence of facial hair. The N95 filtering efficiency can be degraded after extended use, causing breathing difficulties for the wearer, and the elastic straps can fail [16]. Prolonged and repetitive N95 use can also cause skin breakdown in areas of friction.

A significant challenge to the use of N95 respirators is finding the appropriate fit for available mask types. Healthcare workers are required to complete a fit test annually, which is most often a subjective process using the OSHA-recommended saccharin fit test. Simply put, if the wearer cannot smell aerosolized saccharin while wearing a certain-sized mask, then that fit size is confirmed. More objective measures utilize a sensor to analyze the number of

particulates passing through a filter [17]. N95s are meant to be single use only, but under the FDA's Emergency Use Authorization, reuse was permitted if the integrity of elastic and filtration was preserved. Sterilization techniques were investigated at the outset of the pandemic in attempts to safely increase the number of uses of each N95 before replacement and will be discussed in the sterilization section. The addition of a surgical procedure mask over the N95 is another strategy to prolong the life of the N95 and provide another layer of droplet protection.

N95s with an exhalation valve (also known as cool vent or cool flow valves) were created for use by construction workers to prevent inhalation of aerosolized debris during demolition or construction projects. Due to their initial easier accessibility, the public sought out use of these respirator masks, causing significant public health concerns. Although these respirators offer protection for the user with improved breathability, the exhaled air is not filtered, potentially putting people around the user at risk should the user actively have COVID-19 infection. It is recommended to wear a surgical mask over a N95 with an exhalation valve.

KN95 masks were historically used in China before the COVID-19 pandemic, and many are an acceptable alternative to N95s if availability is lacking. It is imperative to use a fit test to verify effective filtration, and due to multiple counterfeits, all KN95s must be verified on the CDC/FDA website matched to the specific model and maker. Efficacy of some masks can be as low as 20-30% filtration. The CDC website has an updated list of approved and non-approved N95s and KN95s [17].

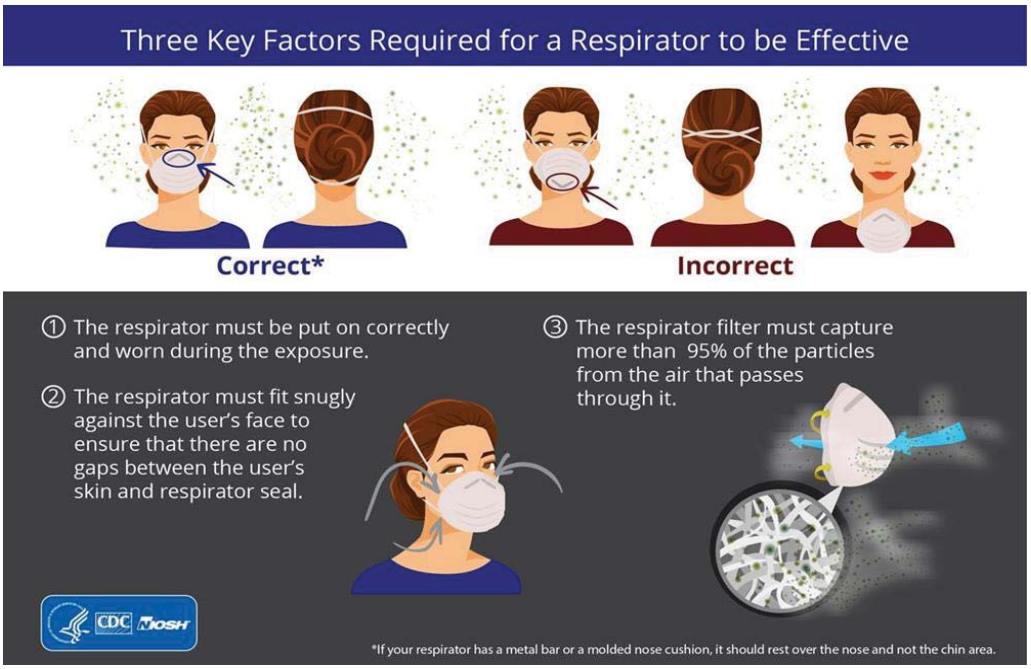


Figure 2. Anatomy of N95 mask regarding proper fit per CDC.

Innovations for Consideration as N95-Stopgaps

The next section covers N95 stopgap solutions to consider for use in the event of critical shortage of supplies of N95s. Designs are subject to change based on multiple factors such as

feedback, funding, and demand. Although there are many other designs submitted every day, these solutions have been evaluated and/or considered during the COVID-19 surge.

The Platypus Mask (Figure 5A) sold by Rydgetech is a N95-style mask like a duckbill [18]. It uses a combination of Filti© fabric for filtration and Halyard H100 fabric for the moisture barrier. Filti© is an American-made, spunbond nonwoven polypropylene with a nanofiber fine filtration layer and surface layer of nonwoven polyester. It has a MERV 16 rating rated at 95% efficiency for aerosols measuring 0.3 microns (300 nm) according to its material data sheet [19]. Halyard H100 fabric is widely used as sterilization wrap for surgical and dental instruments and is an additional effective filtration material considered when supplies are limited [20]. Heat and ultrasonic welders are used to combine the laser-cut materials together without sewing, minimizing any compromise to filter integrity. The platypus mask has passed qualitative fit tests. A TSI PortaCount® Respirator Fit Tester device was used for quantitative fit testing, showing fit factor results above 100, which is the average for manufactured N95s. The Platypus Mask is intended for use for a single day's use. There are no current guidelines for sterilization and reusability. The Rydgetech website features a tutorial for users to create their own platypus-style N95 mask [21].

Montana Mask - Figure 3A

Two doctors and their son realized how critical the N95 shortage was at the start of the COVID-19 pandemic. They created a 3D printable filtration mask called the *Montana Mask* (Figure 3A) which can be heat-molded to custom fit a health care worker's face and sanitized between uses [22]. This technique describes cutting one N95 mask into 2.5 x 2.5-inch swatches to insert into the mask's filter casing with a gasket. Sanitization tests on the mask frame itself revealed that after a full day in a clinic with appropriate wipe down, no bacterial growth was found. Theoretically, at the minimum, this can quadruple a facility's supply of N95 masks to support more workers. The Montana Mask passed a fit test if the seal was correct using an appropriate cut N95 swatch. It was recommended to use one swatch for up to six unique patient encounters before needing to replace it.

At the time of publication, the Montana Mask has been validated for use in major hospitals in Montana, Texas, California, Georgia, and Colorado, although it has not been approved by OSHA or state authorities. It was not intended to replace standard PPE such as N95 masks, but to ration the existing critical supply. Although the mask was one of the first successful N95-style 3D print masks in the open source community, some of its limitations from feedback with healthcare workers were reduced breathability and speaking volume. Standard N95s exhibit this consequence in extended use, although not to the extent of the Montana Mask; this is speculated to be due to the decreased filtration surface area in the gasket as well as CO_2 retention. Some makers have tweaked the design to increase the filter's surface area for improved breathability.

When the Montana Mask became available in the open-sourced community, many makers and designers modified and improved the concept. Some offshoots had dual gaskets to increase the filter size or made use of alternate filter attachments such as those created by 3M®. Buildpl8 in New Jersey is a company that specializes in additive manufacturing, and they sought to help facilities hit hardest at the outset of the COVID-19 pandemic: nursing homes. They supplied their 3D printed version of the Montana Mask to long term care facilities in the region enabling healthcare workers and patients increased protection when faced with a critical shortage of NIOSH-approved N95s [23].

A: The original Montana Mask, with a cut N95 swatch in the gasket.
Source: https://www.makethemasks.com/. B, C: Two mask drivers. D: JI-1500, with the N95 swatch in the cage, in the 1st stage, followed by larger thicker filti material behind (stage 2). E: The mask driver, with JI-1500 in hand to demonstrate the ease of taking it off to swap between a clean JI-1500. F: Combination of mask driver and JI-1500 with filtration material. G, H, I: represents the latest iteration with premium silicon to improve skin contact, with a new JI-1500.

Figure 3. Evolution of the Montana Mask as the skeleton for Mask as a Service, or MaaS.

Mask as a Service- Protect, Conserve, Persist- Figure 3 Middle and Bottom Rows

During the process of meeting with healthcare workers by the open-sourced community, a cycle of prototyping, field testing, and feedback began which culminated in the creation of *Mask as a Service, or MaaS*. Using a subscription model, MaaS is a cloud-based mask management platform to protect individuals from mask shortages. It can be conceptualized as a Netflix© for masks, with the mask akin to software requiring upgrades over time. The platform consists of two parts: The mask driver and *filtration insert* (Figure 3E).

The mask driver is the 3D printed shell which uses the foundation of the Montana Mask with two options for customization: heat molding with boiling water to custom fit to the user's face, or uploading a selfie on the website and using the site's Visual Mask Designer for customization. The filtration gasket inserts, known as the JI-1500, fits into the center of the mask driver. It uses Bernoulli's principles to increase air volume down the filtration channel, resulting in improved breathability. The insert consists of a 2-stage filtration system, with a 2.5 x 2.5-inch N95 swatch in the cage for stage 1 combined with an additional filter medium with excellent filtration efficiency such as *Filti© for stage 2.* (Figure 3D).

In conjunction with the customizable sizing options, the electrostatic principles of the N95 in the first stage, followed by the mechanical principles of the Filti© material for the second stage combine together to create a respirator device which passes clinical fit tests and offers improved breathability. This respirator option can potentially reduce CO_2 accumulation, thus allowing the user to comfortably wear it for longer periods of time. During field tests, users were able to wear it for at least 4 to 6 hours. Both the mask driver and filtration insert can be fully sanitized and reused. The filters in the JI-1500 can be replaced as often as needed per site-specific recommendations.

MaaS offers subscription models for both individuals and businesses to be used as a firewall for shocked supply chains when NIOSH-approved N95s are in short supply. With the subscription, users can receive replacement masks, as well as monthly filtration shipments. MaaS continues to innovate to improve comfort, decrease skin breakdown and even improve functionality with an integrated fan to improve breathability.

Mask Brace - Figure 5 Top Middle

Former Apple engineers looked to N95s as the gold standard and attempted to see if it was possible to improve the fit of medical grade, surgical masks [51]. Early on, they used rubber bands and paper clips to enhance the seal for a better fit. Initial results showed that it passed a qualitative fit test, but it was uncomfortable to wear. Building upon the idea, they created a mask brace made of rubber silicone material that goes around the mouth to create a seal over a surgical mask. When applied properly using the correct size, it passed both a qualitative and quantitative fit test. This means that in the setting of critical supply of N95s, medical grade surgical masks can have improved protection. However, one should be prudent to use medical grade surgical masks, ideally level 3 rated by ATSM (American Society for Testing and Materials), as some masks will not pass a fit test due to inherently poor filtration materials. The website does not recommend using the mask brace with cloth masks at this time. Healthcare facilities should perform fit testing with their existing surgical mask inventory to determine which masks would be appropriate to apply the mask bracing.

There are a number of advantages using a mask brace. The most obvious advantage is that it lessens the demand for N95s and augments the existing supply of medical grade surgical masks. The mask brace allows virtually the same level of breathability which would make it more comfortable to breathe through compared to an N95. It is also easily reusable because the mask brace itself can be washed with soap and water or hand sanitizer between uses.

There are some disadvantages of the mask brace. Due to the mask brace hooking along the top of the nose bridge, those with certain nose sizes may be unable to have a proper seal. Those wearing small sized N95s may be more prone to have this issue. The mask brace can be uncomfortable for long periods because of the increased pressure it applies on the nose, leading to skin breakdown.

Elastomeric Respirators

Traditionally, N95s are rated for one-time use before proper disposal. Half/full non-powered air-purifying half facepiece respirators, or *elastomeric respirators* (Figure 4 and Figure 5F), are devices made from synthetic or natural rubber material which can safely be sanitized between uses with soap and water, bleach, or other EPA-registered household disinfectants [24].

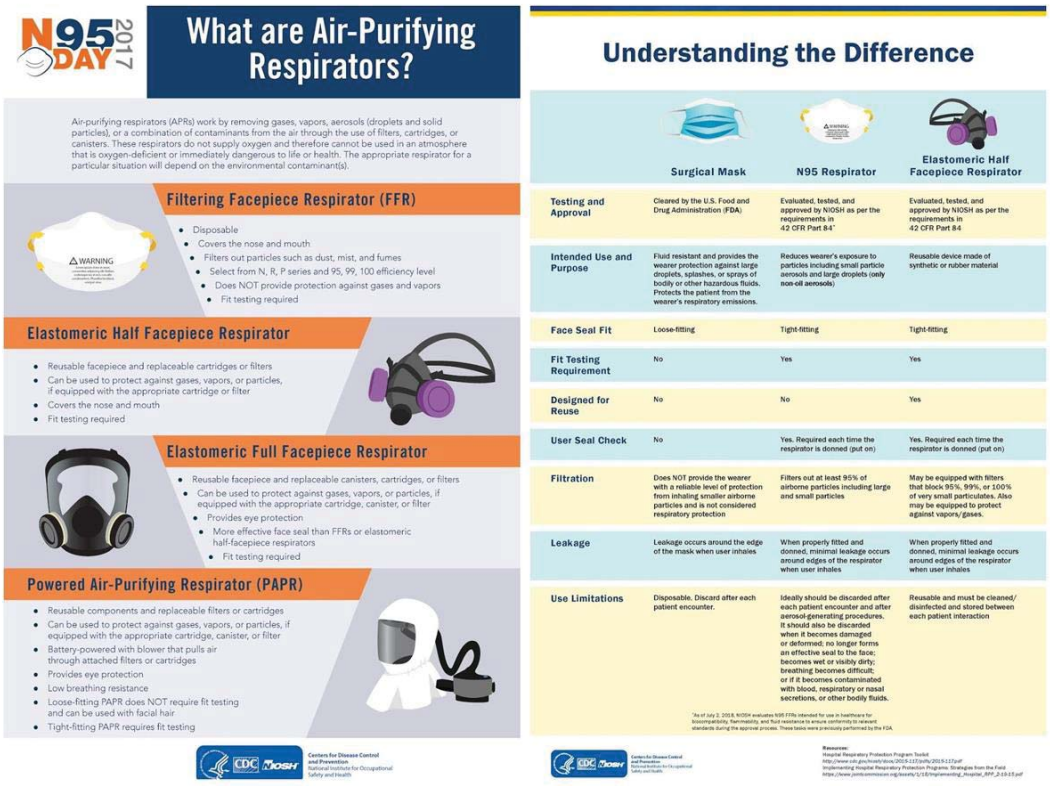


Figure 4. CDC's visual representation of elastomeric respiratory protection; including N95s, elastomeric half, full face respirators, and PAPRs.

Compared to N95s, these respirators have reusable and replaceable cartridges for filtration that can be used up to a year with proper sanitation. Like any respirator device, it should be replaced sooner if cartridges become clogged or directly contaminated. The cartridges are typically rated for P100 filtration (*P* = oil proof), the highest level of respiratory protection preventing inhalation of 99.9% of aerosol sizes of at least 0.3 microns. Elastic straps enable custom fit for each user with optimal comfort [14]. These respirators are equivalent if not superior alternatives to N95s. An additional advantage is that in times of crisis, these devices can be shared with other healthcare workers for reuse if absolutely necessary. Elastomeric respirators have some disadvantages. Due to the size of the device and requisite tight fit, communication can be more difficult compared to N95s. These devices also have an unfiltered exhalation valve, possibly posing a risk to others should the user have active COVID-19 infection. To alleviate this risk, some healthcare providers wear a surgical mask over the exhalation valve.

The Snorkel Face Shield - Figure 5D

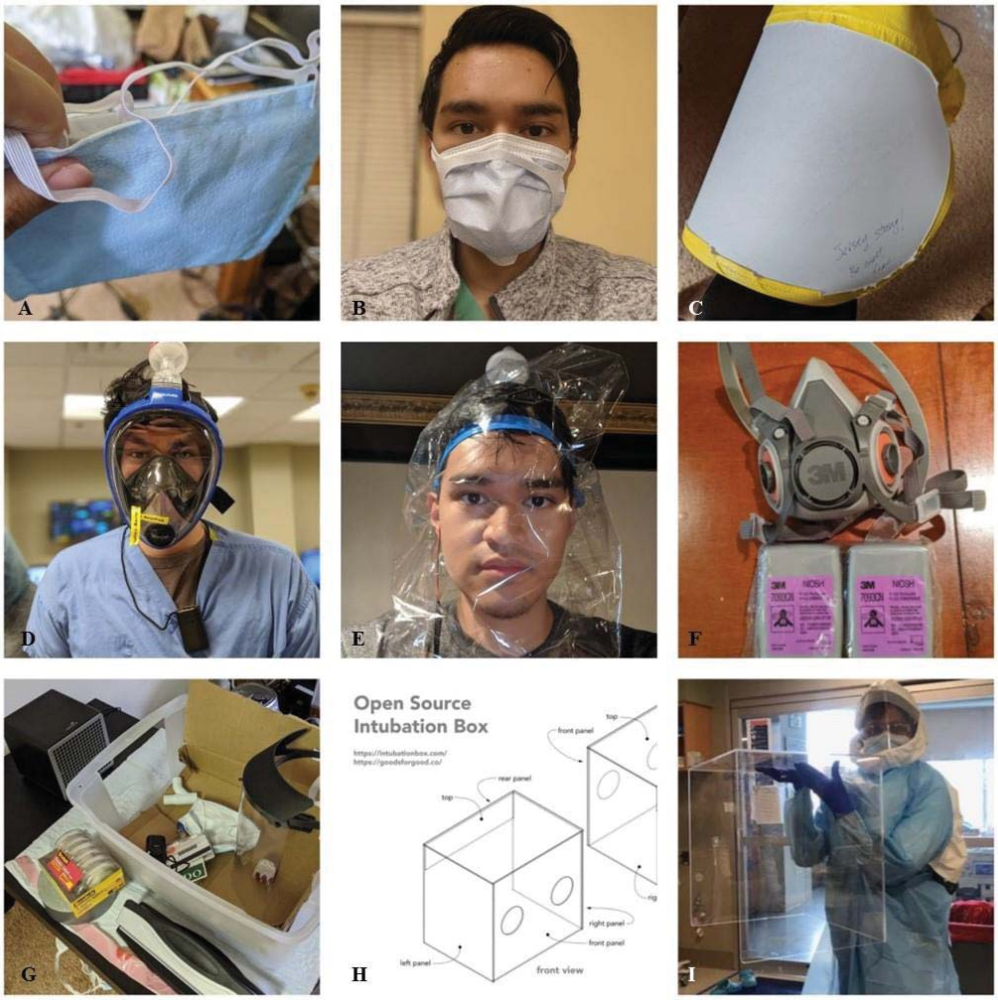
The mask kit uses a conventional full-face snorkel mask with an injection-molded adapter to interface with a standard 15 mm bacterial/viral filter providing up to 99.99% filtration [25]. Each filter is recommended for use up to seven days, depending on institutional recommendations [26]. The snorkel mask covers the entire face unlike a typical N95, providing the benefits of both an N95 and a face shield. Side straps help secure a tight seal around the face. The kit has instructions on proper reuse and sanitation using soap or bleach solution in a bucket. Tests to validate its performance include: Bitrex respirator fit test, OSHA saccharin fit test, extended clinician exertion testing using a 3-mile run or 45-minute spin bike session, capnography testing, and NIOSH exhalation leak assessment. It is available for use under the FDA's EUA when NIOSH-approved N95s are unavailable.

There are several advantages of wearing a Snorkel Face Shield compared to a N95 and face shield combo. It is simpler to don and doff due to only having to put on a single PPE item instead of two, potentially limiting errors with contamination during the process. Its simplicity means it may be faster to don in emergent situations when a patient is decompensating or coding. While reused, autoclaved, or expired N95s are at higher risk for elastic breakdown during patient encounters, the Snorkel Face Shield avoids this limitation. Like elastomeric half/full respirators it can be sanitized in soap and bleach solutions, and thus it may be used by multiple healthcare workers during critical PPE shortages.

There are disadvantages of the Snorkel Face Shield kit. Communication becomes more difficult due to the nature of the seal on the entire face. Although the kit was validated with extended clinician exertional testing, some healthcare workers may be uncomfortable wearing it for prolonged periods of time and may experience dizziness or lightheadedness. Healthcare workers with claustrophobia may have difficulty tolerating the kit due to the full-face seal. Viral filters can be difficult to source due to their primary use in multiple healthcare settings for other respiratory devices when supply chains are broken.

Powered Air-Purifying Devices (PAPRs) - Figure 4 Bottom Left, Figure 5I

Powered Air-Purifying Respirators, or PAPRs, (Figure 4 bottom left, Figure 5I) are enclosed devices that use battery-operated fans to deliver continuous filtered air through a tube into a hood cover for healthcare workers. Air is circulated in the hood, affording improved breathability, thus enabling extended time for patient encounters. PAPRs are regarded as one of the superior forms of protection for healthcare workers [7, 27]. PAPRs have a higher assigned protection factor (APF) and fit factor compared to N95s or reusable elastomeric non-powered air-purifying half face masks. According to OSHA, assigned protection factor is defined as "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section [28]." Fit factor is defined as "a quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn." Simply put, higher numbers translate to better protection and fit [28].



A: Platypus N95 style mask. Halyard material represented by the blue fabric. Filti material represented by the white fabric. B: Mask brace from fixthemask. C: Hand Sewn PAPR hood. D: Snorkel face shield with viral filter. E: Bunny PAPR with viral filter on top. Schematic source: https://devpost.com/software/bunnypapr-for-jcrmrg-hackathon. F: also known as half/full non-powered air-purifying half facepiece respirators.G: UVC/ozone portable generator for sterilizing equipment at home. H, I: open source intubation box, with a physician demonstrating it wearing a PAPR. Source intubation box: http://www.intubationbox.com.

Figure 5. N95 stopgap solutions, PAPR, Intubation box.

OSHA assigned an APF of 25 to loose-fitting PAPRs [29]. The PAPR hood can be loose- or tight-fitting, the former giving it an advantage over the seal requirement for N95s. Additionally, this also mitigates skin breakdown commonly seen when wearing N95s for extensive periods of time. There is also splash protection due to the full-face coverage, and it additionally does not obstruct vision. Fit tests are typically not required for loose-fitting hoods [27]. Typically, this device is used by healthcare providers during high aerosolization-generating procedures such as intubation, extubation, bronchoscopy, respiratory treatments, and suctioning, among others.

The biggest disadvantage of PAPR use other than limited supply is their cost. According to Novak, a PAPR can cost about $768, compared to an N95 which can cost around $1.50 per unit [30]. Another disadvantage is communication, which is difficult due to the PAPR seal and constant fan blower noise. The PAPR appearance itself has been reported to frighten patients, especially those in the intensive care unit with altered mental status [31].

DIY PAPR -Figure 5C

Innovations for PAPRs have gained traction, especially given the scarcity of equipment. An anesthesiologist in Washington specializing in disaster preparedness and emergency response worked closely with a social media 'Sewcial Distancing' DIY group to reverse-engineer the 3M BE-12® hood cover, using Tyvek® house wrap and shower pan liner [32]. This hand sewn hood (Figure 5C) allows it to interface with an Air-Mate HEP Air Filter Unit® or 3M Versaflo® PAPR blower. There are also options to connect it with a DIY air filter unit using a CPAP filter and air mattress pump developed by a critical care ICU physician. Given the scarcity of PAPRs, these options give healthcare workers the ability to have their own hood cover while rotating air filter units. The University of Washington Field Research and Consultation Group evaluated the handsewn Tyvek® hood version with a TSI PortaCount® Pro+ Respirator Fit Tester 8038 using OSHA's Respiratory Protection standard for a quantitative fit test. It demonstrated that the overall fit factor was 20,975, which is 42-times higher than the fit factor for a full-face elastomeric respirator, and 200-times higher than the fit factor for half-face elastomeric respirators. Healthcare workers who have used this hand sewn PAPR hood reported they were successfully able to use it for patient care with no noticeable difference compared to the 3M BE-12® hood covers. The website has tutorials and a list of materials for DIY use [32].

BunnyPAPR™ - Figure 5E

The bunnyPAPR™ is an open-sourced PAPR developed by a Seattle anesthesiologist (Figure 5E). It is made with easily-sourced components such as a computer fan, USB power pack, clear plastic hood bag, and a 3D printer. It uses an FDA-approved viral filter to create a sealed compliant PAPR [1]. Like other open source designs, it was intended for use by frontline workers without access to NIOSH-approved PPE. It has been tested using qualitative fit tests for N95s, and field tested to be worn for around 11+ hours in a hospital setting. The bunnyPAPR™ won first place at the University of California at San Francisco Hackathon, which was dedicated to designing new, innovative, and technical solutions to address challenges in the COVID-19 pandemic.

The design of the bunnyPAPR™ is as follows. The viral filter is affixed to the top of the head, filtering air. Below it sits the computer fan, which helps to draw air through the viral filter, and disperse purified air throughout the clear bag hood for the user to inhale. As the user exhales, air travels through one-way exhaust vents in the back. The computer fan is powered by a USB interface which can be connected to any portable battery charger. The clear bag hood is sealed using a personal utility strap to maintain positive pressure of at least 20 liters per minute for proper CO_2 clearance. After use, the components inside are sanitized, and the clear bag hood is discarded and replaced with a new hood. The design has been validated with specific computer fans that end-tidal CO_2 levels below 42 mmHg prevent hypercapnia.

The main advantage of this device is its low cost and easy scalability, making it a viable option for use in areas with critical scarcity of PPE at any time, not just during a pandemic.

Frontline workers who fail fit testing for available NIOSH-approved N95s may find this option an alternative solution since there is no tight-fit requirement for this type of hood design. One of the disadvantages of the bunnyPAPR™ is that the device needs to be assembled, which can take up to 30 minutes the first time. Those familiar with making this device can ultimately assemble it in a mere five minutes. An additional disadvantage is that the necessary viral filters have become more difficult to source due to the demand by hospitals.

PPE Sterilization Options

Given the scarcity of PPE—particularly N95s—many novel methods have been introduced to sterilize and reuse existing N95 respirator masks. Some of these sterilization techniques have been used in other industrial settings or with other microbials. This section explores methods which have shown promise and highlights others which may not be as effective for decontamination.

Ozone

Ozone, or O_3, is a colorless gas made of three oxygen atoms, compared to molecular oxygen's two atoms. Studies have shown ozone is an effective oxidant against virus-containing aerosols, with one experiment showing inactivation of more than 99% of viruses sprayed inside a chamber with ozone [33]. Ozone has been used as a water disinfectant for years according to the CDC [11]. It has a characteristic odor at very low concentrations [34]. This is similar to the odor of lightning strikes during a thunderstorm at high concentration, which can be hazardous and cause lung inflammation. Due to its additional oxygen atom, ozone is highly unstable, with a half-life of 22 minutes. It can take up to 4 hours for ozone to convert back to oxygen. Ozone generators are noted to be effective in eliminating bacteria, viruses, mold, mildew, and smoke. Ozone sterilization systems have been tested on both N95 respirators and surgical masks for reuse. Although viral particles are effectively sterilized, the process can degrade the filter's fluid resistance and elastic straps. Because ozone is an oxidant, care should be taken to minimize combustion and explosion risks [35].

Hydrogen Peroxide

Hydrogen peroxide (H_2O_2) is an oxidizing agent used in the medical, food, and environmental industry such as for water treatment [36]. It has broad-spectrum activity against bacteria, viruses, and fungi, with minimum environmental toxicity when degraded. Hydrogen peroxide was found to inactivate SARS-CoV-2 on all N95 mask types [15, 37]. N95s have been found to tolerate 3-5 hydrogen peroxide decontamination cycles before starting to have integrity failure [38]. The Battelle Critical Care Decontamination™ system utilizes hydrogen peroxide vapor and has been deployed in several hospital systems in the U.S., reporting that with its system N95s can go through 20 cycles of decontamination [38]. One disadvantage is that very specific dosages are required for proper decontamination. Using less than recommended dosages can lead to insufficient decontamination [39]. Because hydrogen peroxide is an oxidizer, there are combustion and explosion risks to consider, similar to ozone. Deploying hydrogen peroxide vapor systems like Battelle's can also be expensive, averaging $1 million per system installation [40].

Heat

Heat is a well-known form of decontamination that is generally safe. There is conflicting data about the efficacy of heat decontamination with regard to SARS-CoV-2 regarding temperature and timing. One study revealed that N95 masks can be sterilized and reused by placing them in an oven for 30 minutes at 158°F or 70°C [41]. Another study recommended having N95 masks sterilized at 158°F or 70°C for 60 minutes, arguing that 30 minutes was insufficient [42]. According to the CDC, there are two types of dry heat sterilizers—static-air and forced-air. Ovens are examples of static-air sterilizers, as heat is generated from the bottom through coils, and the heat rises through convection. Air fryers are examples of forced-air sterilizers that utilize a blower to circulate heated air through the space at high speeds [11]. Due to the slower heating process of the static air, forced-air sterilizers such as air fryers are likely better solutions, as the N95s in the chamber will be more uniformly heated. A major advantage of heat decontamination is its relatively low cost. In a crisis, common household items such as ovens and air fryers can be used when in a separate room designated for decontamination. Disadvantages include the multiple variables required for proper decontamination, including temperature, time, and humidity. Heating N95 respirators at higher temperatures or for longer times damages the filtration material and elastic straps. Although heat decontamination can have variable degrees of success, it remains an option in both home and institutional settings when decontamination needs are urgent.

Steam Sterilization

Steam sterilization, also known commonly as autoclaving, is an inexpensive nontoxic method of decontamination traditionally used to sterilize hospital and medical office equipment for reuse [11]. Items are placed in direct contact with steam at specific temperature and pressure settings for a specific amount of time. Common temperatures used for steam sterilization are 250°F or 121°C, and 270°F and 132°C for an average of 30 and 4 minutes, respectively, depending on the type of item being sterilized (rubber, metal, plastic). There are many types of steam sterilizer solutions for different needs. With regards to N95s, research has found that autoclaving can provide up to ten reuses before losing functional integrity [15]. However, in real-world use, the average was closer to 3-5 cycles, primarily due to the degradation of the elastic reported by multiple healthcare workers.

Ultraviolet Light (UV-C)

Ultraviolet light, specifically UV-C light, has been shown to be effective in inactivating microorganisms such as *E. coli* and *Cryptosporidium* [43]. However, there is a distinction between different types of UV light, as UV-C has microcidal effects, compared to UV-A and UV-B which do not. Within the UV spectrum, UV-C has a range of 200-280 nm, with a peak wavelength of 254 nm to guarantee microcidal effects. UV-A and UV-B have ranges of 320-400 nm and 280-320 nm, respectively [44]. Most commercial ultraviolet light products do not exhibit UV-C capabilities, usually only up to UV-A. Commonly available examples mistaken to have UV-C capabilities include nail polish and tanning bed lamps. There are several products on the market that claim to sterilize phones; these products should be carefully reviewed to ensure they use UV-C. Sunlight exposure is not known to have UV-C capabilities therefore has minimal, if any microcidal properties. Hospitals have increased the use of UV-C systems for decontaminating patient rooms over the last three decades, and more recently it has been

deployed outside hospital settings in restaurants and for public transportation. Studies have shown that 1 J/cm^2 of UV-C inactivates viruses similar to COVID-19 [30, 45]. In vitro, N95s retain their fit and filter integrity for up to 10-20 cycles before needing replacement. However, in real world settings, they can last five cycles or less due to reports of elastic degradation. UV-C is damaging to the eyes and skin, so proper care and use is recommended for safe decontamination.

Wait and Reuse, Alternative Methods

Given the scarcity of N95s, there have been multiple methods for sanitation investigated such as soap, alcohol, bleach, and antibacterial wipes to enable the reuse of N95s. However, these methods can compromise filter integrity and reduce the efficiency of N95s according to the FDA and CDC [16]. With regards to surfaces, a study has shown that SARS-CoV-2 is more stable on surfaces such as plastic and stainless steel for at least 72 hours compared to copper and cardboard which found no viable SARS-CoV-2 after 4 hours and 24 hours, respectively [46]. There have been recommendations that storage at room temperature for seven days can significantly reduce SARS-CoV-2 on an N95 respirator mask [18, 47]. Some healthcare workers have resorted to storing N95s in brown paper bags for future reuse.

Alternative Healthcare Provider Protection: The Intubation or Aerosol Box

Intubation and tracheostomy procedures are aerosolizing generating procedures which place healthcare workers at increased risk of contracting COVID-19 infection. Intubation boxes were created by open source makers to create a physical barrier between the patient and the healthcare worker for the reduction of COVID-19 exposure. Intubation boxes are enclosed on four sides and are generally made of transparent Plexiglass (Figure 5 bottom middle and bottom right). One side features two arm holes to allow the performing healthcare provider to access into the box with both arms. The box sits over the patient's head, open to the patient's body and feet. In spite of its popularity when needs were high and PPE was scarce, some studies have argued that due to the arm holes and feet-facing opening, exposure to aerosols may be increased with the intubation box compared to without [48]. It was also reported that the box increases the complexity of the procedure by limiting provider movement, decreasing favor by healthcare workers in certain situations [49]. A sealed intubation with appropriate suction was found to decrease aerosol exposure to the healthcare provider, functioning as a negative pressure room [50]. More research is needed to verify the usefulness and safety of intubation boxes.

CONCLUSION

In a perfect world, there would be adequate personal protective equipment available for all. The supply chain failures, lack of adequate stockpiles, and higher-than-expected needs all served to highlight system inadequacies right at the onset of the COVID-19 pandemic. Understanding the details of NIOSH-approved PPE (Figure 4) enabled open source makers, healthcare workers, and institutions to innovate creative solutions to enable both the safe

practice of medicine and the safety of the public at large. It is important for readers and healthcare providers to not only use appropriate PPE, but also consider various alternatives to appropriate PPE in light of the current pandemic, its subsequent multiple waves, as well as potential future pandemics.

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