

# *Open Source COVID-19 Medical Supply Guide*

Open Source Medical Supplies opensourcemedical supplies.org

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### Epidemiology of COVID-19

The COVID-19 pandemic has exploded since the disease was first identified in China in December of 2019. As of December 9, 2020, more than 68 million cases of COVID-19 have been reported globally, including more than 1.5 million deaths. It is estimated that approximately 44 million people have recovered [1]. Individuals of all ages are at risk for infection and severe disease. However, the probability of serious complications and fatal disease is highest in people over the age of 65 years and those living in long-term care facilities or nursing homes. Others at particularly high risk for COVID-19 are people of any age with existing underlying conditions, especially when not well-controlled [2,3].

### Transmission of COVID-19

The onset and duration of viral shedding and period of infectiousness are not completely defined. Asymptomatic or pre-symptomatic individuals infected with COVID-19 may have viral

RNA detected in upper respiratory specimens before the onset of symptoms [4]. Additionally, transmission from asymptomatic individuals has been described [5].

The time from exposure to onset of symptoms is typically around five days but may range from two to fourteen days [6]. The virus is primarily spread between people during close contact, [7] often via small droplets produced by coughing, sneezing, or talking [8]. Additionally, these droplets fall to the ground or onto surfaces where people may also become infected by touching a contaminated surface and then touching their face, nose, mouth, or eyes [9].

Smaller respiratory droplets, known as aerosols, have the ability to remain suspended in air for a longer amount of time and can transmit the virus if they are inhaled by others. There have been reported outbreaks of COVID-19 in closed settings (such as restaurants, bars, and places of worship) where people were shouting, talking, or singing. These likely crowded and poorly ventilated spaces facilitated the spread of infectious aerosols [10].

It appears that the virus that causes COVID-19 can spread from people to animals in some situations. The USDA previously confirmed COVID-19 infection in one tiger at a zoo in New York after several large cats began to suffer from respiratory illness [11]. The CDC is aware of a small number of pets, including cats and dogs, reported to be infected with the virus that causes COVID-19. These infections occurred after the animals had close contact with people actively infected with COVID-19 [12]. Infected pets may show signs of illness or they may not have any symptoms. Of the pets that have been infected, most only had mild illness and fully recovered [13].

### **Clinical Presentation of COVID-19**

The spectrum of illness from COVID-19 can range from asymptomatic infection to severe pneumonia with acute respiratory distress syndrome (ARDS) and death. In a summary of 72,314 persons with COVID-19 in China, 81% of cases were reported to be mild, 14% were severe, and 5% were critical [14]. Symptoms may appear anywhere from 2-14 days after exposure to the virus. The most common symptoms of COVID-19 include: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, body aches, headache, loss of taste or smell, sore throat, runny nose or congestion, nausea or vomiting, diarrhea [15].

Common laboratory findings of COVID-19 include leukopenia and lymphopenia. Other laboratory abnormalities have included elevations in aminotransferase levels, C-reactive protein, D-dimer, ferritin, and lactate dehydrogenase [16]. Critically ill patients were found to have elevated inflammatory markers with an increased risk for thrombosis (blood clots) secondary to an increase of inflammatory cytokines and activation of coagulation (clotting) factors [17].

Abnormalities in chest X-ray vary, but typically reveal bilateral multifocal opacities. Chest x-rays obtained early during the course of infection may not reveal significant changes [18]. Abnormalities seen in computed tomography (CT) of the chest also vary, but typically reveal

bilateral peripheral ground-glass opacities with the development of areas of consolidation later in the clinical course [19].

### **Diagnosing COVID-19**

The diagnosis of a COVID-19 patient requires detection of SARS-CoV-2 RNA by reverse transcription polymerase chain reaction (RT-PCR). Detection of viral RNA is best when collected from nasopharynx samples compared to throat samples. Lower respiratory samples may have better yield than upper respiratory samples [20,21]. The detection of SARS-CoV-2 RNA in blood may be a marker of severe illness [22].

Viral RNA shedding may persist over longer periods among older persons and those who had severe illness requiring hospitalization [23]. Infection with both SARS-CoV-2 and with other respiratory viruses has been reported, and detection of another respiratory pathogen does not rule out COVID-19 [24].

Antigen tests for SARS-CoV-2 were recently authorized. This new category of tests can detect fragments of proteins from the virus when samples are collected from within the nasal cavity. This type of test was developed for the rapid identification of acute COVID-19 infection and provides faster results than the RT-PCR method [25]. Antibody testing is available to detect a previous infection with COVID-19. Most people will produce antibodies 1-3 weeks after exposure to the virus, but it is unclear how long these antibodies will remain with the person or if any future protection against COVID reinfection is offered [26].

### Treatment of COVID-19

Patients with a mild clinical presentation (without viral pneumonia and hypoxia) may not require hospitalization, and many patients will be able to manage their illness at home. The decision to monitor a patient in the inpatient or outpatient setting should be made on a case-by-case basis [27]. This decision will depend on the clinical presentation, requirement for supportive care, risk factors for complications, and if the patient is able to self-isolate at home. Patients with risk factors for severe illness should be monitored closely given the possible risk of progression to severe illness during the second week following symptom onset [28,29].

No specific treatment for COVID-19 is currently FDA approved; however, in accordance with preliminary clinical trial data, the COVID-19 Treatment Guidelines Panel (NIH) have recommended the investigational antiviral drug remdesivir for the treatment of COVID-19 in hospitalized patients with severe disease ( $O2 \le 94\%$  on room air), requiring supplemental oxygen or mechanical ventilation. Remdesivir is not approved by the FDA, and is only available through an FDA emergency use authorization, in clinical trials, or through an emergency access program for children and pregnant patients [30][31].

While corticosteroids have been widely used in hospitalized patients with severe illness in China [32], the benefit of corticosteroid use cannot be determined based upon uncontrolled observational data. The use of corticosteroids may be indicated for other reasons, such as management of chronic obstructive pulmonary disease or septic shock [33]. The COVID-19 Treatment Guidelines Panel (NIH) recommends using dexamethasone for the treatment of COVID-19 in patients who are mechanically ventilated and in patients who require supplemental oxygen but who are not mechanically ventilated [34].

The majority of inpatient management revolves around the supportive management of the most common complications of severe COVID-19: pneumonia, hypoxemic respiratory failure/ARDS, sepsis and septic shock, cardiomyopathy and arrhythmia, acute kidney injury, and complications from prolonged hospitalization including secondary bacterial infections, thromboembolism, gastrointestinal bleeding, and critical illness polyneuropathy/myopathy [<u>35,36,37,38</u>].

### Home Care for COVID-19

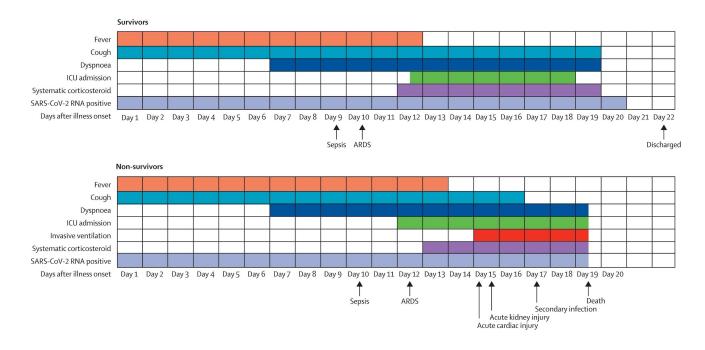
In patients where only mild symptoms are present, supportive measures and in home care are recommended with the appropriate guidelines and precautions being adhered to [<u>39</u>].

# The <u>OSMS Home Care Guide</u> is a repository of current recommendations, guidance, and research for the management of COVID-19 at home.

### **Clinical Resources**

Information for Healthcare Professionals about Coronavirus (COVID-19) (CDC) ADA Coronavirus (COVID-19) Center for Dentists (ADA) Question and Answers Hub COVID-19 (WHO) Coronavirus Disease 2019 (COVID-19) (FDA)

#### Visualization of Symptoms of COVID19 Over Time, ~5 Days After Exposure



### A Note About Safety and Liability

There are engineering and manufacturing risks around medical devices. Though the FDA has issued Emergency Use Authorizations (EUA) (<u>Coronavirus Disease 2019 (COVID-19)</u> <u>Emergency Use Authorizations for Medical Devices</u>, FDA), to avoid doing more harm than good, it is recommended to attempt to the best of your ability and circumstances to follow regulations, which may seem cumbersome, but exist for good reason.

Regulatory standards that apply to the supplies and devices in question: <u>eCFR: QUALITY SYSTEM REGULATION</u> (especially Identification and Traceability, Production and Process Controls, and Labeling) <u>eCFR: GENERAL HOSPITAL AND PERSONAL USE DEVICES</u>

#### Resources

<u>Technical Considerations for Additive Manufactured Medical Devices</u> (FDA) <u>General Controls for Medical Devices</u> (FDA) <u>Recommended Content and Format of Non-Clinical Bench Performance Testing Information</u> (FDA) <u>Counterfeit Respirators / Misrepresentation of NIOSH-Approval | NPPTL | NIOSH (CDC)</u>

### Good Samaritan Laws in the United States

In the United States, Good Samaritan laws offer legal protection from civil lawsuits to people who voluntarily provide reasonable aid to those who are injured, ill, in danger, or otherwise incapacitated. A claim of negligent care can also be raised if the injuries or illness were made

worse by the volunteer's negligence. Laws generally do not exempt a Good Samaritan who acts in a willful, wanton or reckless manner in providing care, advice, or assistance.

We are providing you with the specifications you will need to manufacture items which are much-needed during this pandemic; however, you are responsible for your creations, so please practice due diligence (the care that a reasonable person exercises to avoid harm to other persons or their property). We want your contributions to help, not harm!

If you are familiar with similar laws in other countries, please reach out to us with relevant references.

References: Good Samaritans (US Legal)

# Social Action, Responsibility and Heroism (SARAH) Act in the United Kingdom

Effective in England and Wales, the Social Action, Responsibility and Heroism (SARAH) Act seeks to provide protection to individuals who act voluntarily to provide reasonable aid to those who are injured, ill, in danger, or otherwise incapacitated. The Bill contains language to make clear its overarching purpose: to "take a range of measures to encourage volunteering and involvement in social action".

# Access to Medical Treatments (Innovation) Act 2016, the United Kingdom

This Bill, applicable to England and Wales, was enacted "...to promote access to innovative medical treatments (including treatments consisting in the off-label use of medicines or the use of unlicensed medicines) by providing for (a) the establishment of a database of innovative medical treatments, and (b) access to information contained in the database."

We are providing you with links to designs for items that are much-needed during this pandemic; however, you are responsible for your creations. Please practice due diligence (the care that a reasonable person exercises to avoid harm to other persons or their property). We want your contributions to help, not harm! If you are familiar with similar laws in other countries, please reach out to us with relevant references.

References: <u>SARAH Act</u>; <u>Access to Medical Treatments (Innovation) Act 2016</u> (UK Legal)

# Design, Manufacturing, & Engineering Projects

PPE (Personal Protective Equipment) is critical to the protection of healthcare workers, acting as a barrier and therefore controlling exposure to COVID-19. Some of the most fundamental

items comprising PPE include gloves, goggles, surgical masks, respirators, protective gowns, and disinfectant. Many of these crucial PPE items are now in short supply due to interruptions in the supply chain, and also from the massive demand as the number of patients infected continues to grow exponentially.

Numerous medical devices are required to treat the COVID-19 patient and will also fall into short supply (e.g. ventilators). Shortages of necessary PPE and medical devices will continue to pose a significant problem for healthcare workers and patients around the globe. Anyone with production capabilities should carefully consider the manufacture of known designs and development of new designs for the following items.

# PPE Use Guide

OSMS has compiled research from twelve sources to give the public a comprehensive view of what kinds of personal protective equipment (PPE) should be used to minimize the risk of COVID-19 infection during different types of activities. Please reference our <u>OSMS PPE Use Guide</u> for more information.

# **Supply Categories**

OSMS lists the included reference materials in service to the ongoing development of global COVID-19 response efforts. The inclusion of any reference or resource should not be construed as endorsement, promotion, or support of any organization. Since medical developments occur daily, this page may contain outdated material. While reasonable efforts are made to present current and accurate information, no guarantee of any kind is made and OSMS is not liable for any damage or loss related to the accuracy, completeness or timeliness of any information contained on or linked from this page.

### Protective Gear

Full Document Face Shields (33 links to projects) N95 Respirators (1 link to projects) Face Masks (Fabric) (25 links to projects) Powered Air Purifying Respirators (PAPR) (8 links to projects) Gowns (17 links to projects) Aerosol Box (8 links to projects) Goggles (4 links to projects) Ear Savers & Nose Bridge Supports (12 links to projects) Scrub Caps (8 links to projects)

Partial Document (empty sections) Examination Gloves <u>Scrubs</u> <u>Shoe Covers</u> (2 links to projects) <u>Face Masks (3D Printed, Injection Molded, etc.</u> (10 links to projects) <u>Hands-Free Door Openers</u> (3 links to projects) <u>Sneeze Guards/Transparent Partitions</u> (2 links to projects)

Not Released Suits- Available soon Testing Booth

#### Assessment

*Full Document* <u>Pulse Oximeters</u> (7 links to projects)

Partial Document (empty sections) Non-Contact Thermometers Stethoscopes (1 link to projects) Testing & Lab (5 links to projects)

### **Patient Treatment**

### Airway support

Full Document
<u>Ventilator Machines</u>
<u>Noninvasive Helmet Ventilation</u> (4 links to projects)

Partial Document (empty sections) Oxygen Masks (1 link to projects) Oxygen Concentrators Laryngoscopes Valves & Adapters (4 links to projects) Oxygen Flowmeter (1 link to projects)

### **Drug Delivery**

Partial Document (empty sections) Infusion Pumps

Not Released Spacers

### Hospital Expansion/Conversion

Partial Document (empty sections) Hospital Beds Negative Pressure Rooms

### Decontamination/Sterilization

Full Document <u>Hand Sanitizer</u> (2 links to projects) <u>Hand Washing Stations</u> (8 links to projects) <u>UV-C Decontamination</u> (5 links to projects)

Not Released Sterilization Tunnel Heat Sterilization Sanitizer Dispenser Bracelet

### Manufacturing Infrastructure

Full Document Bias Tape Makers (7 links to projects)

Partial Document (empty sections) <u>Mask Pleaters</u> (5 links to projects) <u>Mask Fitters</u> (2 links to projects)

# **Manufacturing Processes**

	Key	vy: www.opensourcemedicalsupplic												lies.c	ang .	3/28	2020	)	v1.	1								
- • · · -		N - unlikely to be used in manufacturing any design																										
	Y	- strong likelihood that process could be used in manufacture of a design (not every design)																										
- <b>X</b>	M												catio	n, ar	sem	bly (e	.g. g	love	s)									
OSCMS	?	- 0	<ul> <li>not sure if process would be used in designs</li> </ul>																									
	Rapid Prototyping				High Volume Production Processes								Cra	fts		Fabrication and Assembly									Primary Construction Materials			
	3D Printing (FDM)*	3D Printing (SLA)*	Machining/CNC MilliRouting	aser Cutting	Die Cutting	Injection Molding	Compression Molding	Blow Molding	Dipping	Film Casting	Extrusion	Thermoformingireflow	Glass Blowing	Sewing	Wood Working	Gluing/Bonding	astening	Sheet Motal Working	Fabrication	Electronics	Assembly	Formulation	Distillation	Chemicals/Solvents	Mutalis/Alloys	Elastomers	Thermoplastics	Soft Materials
Customization per Part	H	H	H	Ē	L	1	L	L	L	L.	L	Ē	н	н	н	н	H.	H	H	M	M.	M	M		-		1	
Supplies	-			-	-	-	-	-	-	-	-	-			-	-	-	-			-			-	-	-	-	
Hand Sanitizer	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y	N	N	2	N
N95 Respirators	Y	Y	in.	N	v	v.	N	N	N	N	N	N	N	v.	N	v	N	IN N	N	N	v.	N	N	N	N	2	Y	Y
Surgical Face Masks	N	N	i.	Y	Ý	N	N	N	N	N	N	N	N	Ŷ	N	Ŷ	N	N	N	N	i.	N	N	N	N	2	Y	÷
	Y	Y	Y	Ý	÷.	V.	N	N	N	N	N	N	N	Y.	N	Y.	N	N	N	N	Y	N	N	N	N	Y	Y	÷
Goggles / Masks	Y	Y	Y Y	Y	Y Y	2	2	N	N	N	N	2	N	Y Y	N	Y V	Y	N	2	Y	r	N	N	N	Y	2	Y	ţ
Powered Air Purifying Respirators	Ŷ	ľ	ľ	ľ	ľ	Ĺ	ŕ	N	N		Ĩ	ŕ		ľ		1	ľ	N	ŕ	۲		Ň	~	~	ľ	ŕ	*	ľ
Examination Gloves	M	Ν	Ν	N	N	М	Ν	N	Y	N	N	Ν	N	N	Ν	?	N	N	N	Ν	N	N	N	N	N	Y	Y	Y
Gowns	N	Ν	?	2	Y	N	N	N	Ν	Ν	N	Ν	N	Y	N	Y	N	N	N	Ν	N	N	N	N	N	?	?	Y
Face Shields	Y	м	Y	Y	Y	Y	М	N	N	N	N	м	Ν	N	N	Y	N	N	N	N	Y	N	N	N	?	?	Y	?
Nasal Cannulas	м	м	м	N	N	Y	Y	N	N	N	N	Y	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	Y	N
Catheters	м	м	?	N	N	Y	N	N	N	N	Y	Y	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	Y	N
Oxygen Masks	M	м	м	2	N	Y	м	Ν	Ν	N	N	м	N	N	N	?	N	N	N	N	Y	N	N	N	N	Y	Y	N
Venturi Masks	м	м	м	?	N	۲	м	N	N	N	N	м	N	N	N	?	N	N	N	N	Y	N	N	N	N	۲	۲	N
Elow-Splitters for Oxygen. Supply	м	м	?	N	N	Y			Γ	Γ	Γ		۲	N	N	?	?	Г	N	N	Y	N	N	N	N	Y	۲	N
Thorpe Tube Flowmeter	Y	2	?	N	N	?		-	-	-	-	-	Y	N	N	?	?	N	N	N		N	N	N	?	N	Y	N
Devices																			-	-							-	-
Negative Pressure Rooms	N	N	Y	Y	v	N	N	N	N	N	N	N	N	Y	Y	v	v	v	v	N	v	N	N	N	v	Y	Y	Y
Ventilator Machines	Y	Y	Ŷ	Y	2	N	Y	N	N	N	N	M	N	N	Ŷ	2	Ŷ	÷,	v	v	Y	N	N	N	Y	Y	r.	7
Hospital Beds	N	N	Ý	Y	Ý	Y	M	N	N	N	N	M	N	Y	Ý	Y	Ý	Y	Y Y	N	Y	N	N	N	Y	N	+	Ý
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Oxygen Concentrators	Y	Y	2	· ·		Y	-	-	-	-	-	-				2	· ·	2	<u> </u>	<u> </u>	Y				· ·	2	-	-
Pulse Oximeters	-	Y	· ·	?	N	Y	-	-	-			-	N	N	N	<u> </u>	Y	2	N	Y	· ·	N	N	N	Y	?	-	N
Non-Contact Thermometers	Y	· ·	Y	<u> </u>	N	<u> </u>		-					N	N	N	N	· ·	<u> </u>	N	· ·	Y	N	N	N	· ·	· ·	-	N
Non-Heated Humidifier	?	?	?	?	N	?	-						Y	N	N	?	?	?	?	?	?	N	N	N	Y	?		N
Laryngoscopes	Y	Y	Y	м	Ν	Y	N	N	N	Ν	Ν	N	Y	N	N	м	Y	?	м	Y	Y	N	N	N	Y	?	Y	N
Infusion Pumps	Y	Y	Y	?	N	Y							N	N	N	?	Y	M	?	Y	Y	N	N	N	Y	?		N

Download PDF

# FAQ

How can I help?

First, educate yourself and your community on <u>what COVID-19 is</u>, <u>how to care for those who</u> <u>have it</u>, and to understand the supply chain problems at hand, before you start designing, building, or ideating anything.

Second, help us continue to grow our network. Join the <u>Open Source COVID-19 Medical</u> <u>Supplies Facebook group</u> and find out what makers are talking about. The goal of our Facebook group is to be a discussion forum, while our <u>Open Source Medical Supplies</u> <u>website</u> is our megaphone to the world. If you're a maker, <u>find a Local Response group</u> in your area and join up with them. If you are seeing a need in your area and don't find a group, you can create one using our <u>Local Response Guide</u>.

Third, is to go out and find as many existing solutions as possible to the supply problems we've highlighted, and focus your design work on the gaps that haven't been solved. Read the documentation in our <u>Categories Library</u> to find current solutions and needs the medical community is facing in each section. From there, check out our expansive <u>Project Library</u> and start making based on the need in your area and your capabilities. If you have an original design or an improvement on an existing one in our library, you can submit it using our Project Submission Form.

#### What should I make?

Before diving in, figure out what your community needs! That answer differs from region to region, and even between facilities within the same region. The best way to find out the needs of your local community is to use our <u>Local Response Map</u> to find a group in your area and partner with them - usually they will have contacts at hospitals, nursing homes, dentists offices, schools, and others and will know what their needs are.

#### How can I find out about local response efforts near me?

We are thrilled to see the upswell in local organizing efforts to help fill the gaps in medical supply chain disruptions. Dozens of Open Source COVID19 Medical Supplies (OSCMS) regional Facebook groups are cropping up, and are gathering volunteers to share information, best practices, local needs, supplies and manufacturers. You can use our Local Response map to find a group near you. If you are running a group and don't see it listed, click here to learn about the benefits of listing your response effort, and then register!

#### How can I start a Local Response group?

If there is not a local response group near you and you are interested in starting one, please <u>read our Local Response Guide</u> to learn more about what is involved and <u>register</u> <u>your group with OSCMS</u>.

#### How can I find people or places that need help in my area?

Visit our <u>Local Response Map</u> and make sure "Add Dataset: Requesters" is checked. You can then search for your local area and will see hospitals and other locations that have put in requests from <u>FindTheMasks.com</u>. If you have commercially manufactured PPE available, we recommend using a matching resource from the list below to find locations near you that are requesting PPE donations.

- Get Us PPE makers- and manufacturers-to-hospitals
- Project N95 medical equipment and supply exchange
- <u>PPELink</u> research labs-to-hospitals donation
- <u>PPENeeded</u> needs and makers/donors exchange

For other maker-built supplies, we recommend searching for organizers in your region before reaching out to hospitals directly. We need to ensure that hospitals are not overwhelmed with excessive phone calls about donations.

#### Can I make something and bring it directly to a hospital to be used?

Usually, no. For some PPE items (cloth face masks, face shields, head covers, etc.) hospitals may be accepting donations, but this is not universal. We recommend checking with local organizations or finding a local group on the OSMS Map that may already. You can also register as a Maker with <u>GetUsPPE</u>, <u>PPE Needed</u>. or <u>Project N95</u> and they will connect you with an organization in need in your area.

For other supplies, particularly for devices like ventilators, there is not yet a clear pathway for getting items from makers into hospitals. There are a number of safety concerns with medical devices that need to be addressed. Please do not show up at a hospital unannounced with donations.

#### Why (not) make ventilators?

Acute Respiratory Distress Syndrome (ARDS), in which breathing is impaired by fluid buildup in the lungs, is one of the most common and severe complications of COVID-19. Patients with ARDS frequently require mechanical ventilation to survive. Mechanical ventilation requires careful supervision by trained respiratory therapists in order to avoid complications, including permanent lung damage. Without sufficient medical professionals to use them, adding to the supply of ventilators will not improve the treatment of COVID-19 patients.

This does not mean that no one should be working to increase ventilator supply, but it does mean that your energies might be spent better elsewhere, such as familiarizing yourself with the <u>CDC's PPE Strategy</u>, and <u>addressing the PPE shortage</u> for those who are treating patients or for essential workers whose jobs require them to work in close proximity to other people. If you do not have knowledge or experience of mechanical ventilation and are not working with someone who does, you may be better off focusing on other projects.

#### Why (not) 3D print/injection mold/vacuum form medical devices?

3D printing, injection molding, and vacuum forming can be efficient methods of mass-producing needed supplies to prevent shortages. In one example of successful use of 3D printing, <u>respirator valves</u> are already being 3D printed in response to the increased need for mechanical ventilation in Italian hospitals. However, medical devices pose unique problems that require additional precautions in 3D printing.

Medical devices are also subject to strict regulations that vary from country to country. In response to the COVID-19 pandemic, <u>Emergency Use Authorizations (EUAs</u>) exist to allow hospitals more flexibility in the devices they use. However when the EUA expires, any devices that do not meet the normal strict criteria will be discarded.

# FDA UPDATE: FAQs on 3D Printing of Medical Devices and Accessories during COVID-19

#### Are 3D printed parts sterile?

Due to the way in which they are manufactured, 3D printed materials are frequently more porous than typical medical device materials, allowing them to harbor microbes if they are not carefully sterilized. <u>Medical sterilization techniques require heat, radiation, and chemical sterilization processes. Any 3D printed device made for use with patients must be able to withstand repeated exposure to these processes.</u> Most common 3D printing materials will warp, melt, or lose tensile strength when exposed to medical sterilization; see previous link for a list of materials that can be sterilized.

There is some <u>sterile 3D manufacturing</u> but it is rare, mostly proprietary, and usually already located in a hospital or research lab. It is not usually conducive to mass-scale production. Prusa has <u>shared their recommendations</u> for independently lab-tested, methods for disinfecting their face shields.

#### What about using CPAP or BiPAP machines?

Recent <u>updates from the FDA</u> indicate that manufacturers of CPAP or BiPAP machines may submit proposed modifications to be considered for Emergency Use Authorization. This requires the modifications be tested, documented, and formally submitted to the FDA for consideration. These devices would be used to support respiratory therapy but would not be used in lieu of ventilators. Modifications to these devices would be intended to reduce the risk of aerosolizing the virus.

#### What about building a negative pressure ventilator?

A negative pressure ventilator (sometimes colloquially called an "iron lung") is a mechanical ventilator that acts by intermittently lowering the pressure around the patient's abdomen to less than atmospheric pressure, mimicking the natural function of the muscles and diaphragm to allow the patient to take in air. This can be accomplished with either a large tank surrounding the patient's body, or a smaller jacket-like device worn by the patient. These have been widely used for breathing difficulties caused by neuromuscular disorders, but **their safety and effectiveness in pneumonia and ARDS is poorly studied**. In addition, most forms restrict access to the patient's body, and most medical professionals are not familiar with their use.

#### Is there a Slack/Jira/Wiki/Discord for this group?

We have a team of over 800 volunteers from all over the globe who are collaborating in a Slack workspace that supervises the Open Source Medical Supplies effort. This group includes moderators, administrators, medical professionals, transcriptionists, engineers, communications specialists, marketing teams, philanthropists, scientists, points of contact for makerspaces and globally distributed manufacturers, and more.

The explicit goal of our group is to not design anything ourselves. We believe there are tens of thousands of engineers all over the world already working on the problems we present, and our job is to research, catalog, present, and act upon those solutions. If you would like to join this narrowly scoped and tightly focused team, please send an email to info@opensourcemedicalsupplies.org.

#### Will I get sued for making things?

In the United States and Canada, <u>Good Samaritan laws</u> offer legal protection from civil lawsuits to people who voluntarily provide reasonable aid to those who are injured, ill, in danger, or otherwise incapacitated. We are providing you with the specifications you will need to manufacture items which are much-needed during this pandemic; however, you are responsible for what you make, so please practice due diligence.

If you are in the United States, we recommend reading familiarizing yourself with current <u>FDA Emergency Use Authorizations (EUAs)</u> and how your creations are affected by these proclamations and their eventual expirations. Other countries have similar orders issued by governing bodies, and you should become familiar with what your country is doing. When in doubt, consult a lawyer who can advise you on legal matters.

OSMS: 3D Printing - Getting Started, Safety, and Designs.

#### Are cloth masks safe?

The efficacy of any mask depends on the materials used, proper donning and doffing techniques, and proper wear and disinfecting of the mask. Generally speaking though, cloth masks are safe and offer better protection than nothing. You can find a variety of mask patterns in the <u>OSMS Project Library</u> (Fabric Face Masks and 3DP Face Masks)

In a <u>randomized trial</u>, it was found that cloth face masks were associated with higher rates of respiratory infection than wearing medical masks (N95 respirators); however, this study did not test whether cloth masks were better than no masks at all. The original results of this study have been widely misinterpreted, however the authors sought to <u>clarify their findings in this recent addendum</u> to the original article. Cloth face masks are an appropriate choice for members of the general public, for healthcare workers to wear over other types of mask, or as an emergency alternative when no other PPE is available.

#### I only have a sewing machine - is sewing cloth face masks helpful?

Making cloth face masks is a great way to start helping your community, as <u>many places</u> are requiring people to wear masks in outdoor public places where appropriate social distancing cannot be maintained, and inside public buildings. Start by reading the OSMS <u>fabric face masks documentation</u> for information on materials selection, filtration efficacy, and a list of projects.

#### I am out of raw materials - where can I find them?

We suggest first reaching out to more specific groups for your craft - 3D-printing, sewing, injection molding, etc - and find out where they are getting their materials. Please make sure you trust the source. There have been occurrences of bad actors/scammers taking advantage of buyers.

My local community is set with the thing I am making, but I still want to help! What can I do?

Reach out to other places in your network you may not have thought of (dentists, hair salons, nursing homes, restaurants, etc) and then neighboring communities. You can also use the <u>OSMS map</u> and roster to find maker groups near you who may have connections to businesses or individuals in need.

I am seeing a lot of PPE being made from materials such as Halyard and Tyvek. Are these materials OK to use?

OSMS recommends always following the manufacturer's specific guidance on their products. If no public statement has been made, we suggest reaching out to the manufacturer directly for a safety statement to determine if their product is safe for your intended application.

# Glossary

Many of the medical terms pertaining to COVID-19 may be unfamiliar to you- please review our glossary below. For a more comprehensive glossary, visit the Bundessprachenamt's (Federal Language Agency, Germany) recently-released glossary of terms related to COVID19. Their glossary is available in 7 different languages- German, Dutch, English, French, Polish, Russian and Spanish).

#### Acute Respiratory Distress Syndrome (ARDS)

A condition in which fluid collects in the alveoli (air sacs) within the lungs. Oxygen capacity is severely reduced and patients may suffer organ damage. ARDS occurs in those who are critically ill. These patients require mechanical ventilation.

#### **References:**

ARDSnet (NIH-NHLBI ARDS Network)

#### Barotrauma

Barotrauma refers to injuries caused by increased air or water pressure, such as during airplane flights or scuba diving. In the case of mechanical ventilation, alveoli (air sacs) in the lungs may be ruptured or scarred due to high air pressure in the lungs.

#### **References:**

Barotrauma (Havard)

#### FiO2

"Fraction of inspired oxygen" is the percentage of oxygen in the air mixture delivered to the patient.

#### **References:**

Ventilator Management (NIH)

#### Flow (Ventilation)

The rate, in liters per minute, that the ventilator delivers breaths. **References:** 

#### Ventilator Management (NIH)

Hypoxia

Not enough oxygen. References: <u>Hypoxia</u> (Wikipedia)

Hypercapnia

Too much carbon dioxide. **References:** <u>Hypercapnia</u> (Wikipedia)

#### Intubation

A procedure in which a tube is placed into the airway. This is performed so that a patient can be placed on a ventilator to assist with breathing.

#### References:

Tracheal Intubation (Wikipedia)

#### Atelectasis

Complete or partial collapse of the lobe, or part of the lobe, of the lung. It occurs when the alveoli (air sacs) become deflated or filled with fluid.

#### **References:**

Atelectasis (Mayo Clinic)

#### Negative Pressure Ventilation

Mechanical ventilation in which negative pressure is generated on the outside of the chest and transmitted to the interior to expand the lungs and allow air to flow in (e.g. "Iron Lung").

#### **References:**

Negative Pressure Ventilation (ATS Journals)

#### Oxygenation

The process of treating a patient with oxygen. This can be accomplished by increasing the **fraction of inspired oxygen** (FiO) or the **positive end-expiratory pressure** (PEEP). **References:** 

Ventilator Management (NIH)

#### Peak Pressure

The highest level of pressure achieved during inspiration when air is being pushed into the lungs. It increases with airway resistance.

#### **References:**

Peak inspiratory pressure (Wikipedia)

#### Plateau Pressure

The static pressure achieved at the end of a full inspiration, and is a measure of alveolar pressure and lung compliance. Normal plateau pressure is below 30 cm H20 (**.43 psi**), and higher pressure can generate <u>barotrauma</u>.

#### **References:**

Plateau pressure (Wikipedia)

#### Pneumonia

An infection that inflames the alveoli (air sacs) in one or both lungs, which may fill with fluid or pus. The infection can be life-threatening to anyone, but particularly to infants, children, and people over 65. Symptoms include cough with phlegm or pus, fever, chills, and difficulty breathing. It can occur secondary to a primary infection.

#### **References:**

Pneumonia Symptoms and Diagnosis (American Lung Association)

#### Positive End-Expiratory Pressure (PEEP)

The pressure in the lungs, above atmospheric pressure (the pressure outside of the body), that exists at the end of expiration.

#### **References:**

Ventilator Management (NIH)

#### Sepsis

Sepsis is a potentially life-threatening condition caused by the body's response to an infection. This can cause a cascade of changes that damage multiple organ systems, leading them to fail, sometimes even resulting in death. Symptoms include fever, difficulty breathing, low blood pressure, fast heart rate, and mental confusion. Treatment includes antibiotics and intravenous fluids. **References:** 

#### Sepsis (Wikipedia)

#### Septic Shock

A severe and potentially fatal condition that occurs when sepsis leads to life-threatening low blood pressure and abnormalities in cellular metabolism.

#### **References:**

Sepsis and Septic Shock - Critical Care Medicine (Merck Manual)

#### Severe Acute Respiratory Infection (SARI)

Defined as an **acute respiratory** illness of recent onset (within seven days) manifested by fever (≥38°C/100.4F), cough and shortness of breath or difficulty in breathing requiring hospitalization

References: <u>Viruses Causing SARI</u> (NIH)

Tachypnea

Rapid breathing. **References:** <u>Tachypnea</u> (Wikipedia)

Tidal Volume

Volume of air moved in and out of the lungs every respiratory cycle.

#### References: Ventilator Management (NIH)

#### Ventilation

Moving air in and out of the lungs to facilitate gas exchange - bringing in oxygen and flushing out carbon dioxide. Ventilation occurs naturally (breathing), or in cases of respiratory failure, via mechanical ventilation (ventilators).

#### **References:**

Ventilator Management (NIH)

## Acronyms

AIIR - Airborne Infection Isolation Room **ARDS** - Acute Respiratory Distress Syndrome BARDA - Biomedical Advanced Research and Development Authority **CPAP** - Continuous positive airway pressure **COTS -** Commercial off-the-shelf **BiPAP** - Bilevel positive airway pressure **BVM** - Bag valve mask **EMS** - Emergency Medical Services **EUA** - Emergency Use Authorization **FDA** - Food & Drug Administration **FiO** - Fraction of inspired oxygen FFP - Full face protection HCP - Healthcare professional HHS - Health & Human Services **IPPV** - Tracheostomy, intubation SARI - Severe Acute Respiratory Infection **SNS** - Strategic National Stockpile **MCM** - Medical countermeasure **NIV** - Noninvasive ventilation

**NPV** - Negative pressure ventilation

**PEEP** - Positive end-expiratory pressure

**PPV** - Positive pressure ventilation

Rr - Respiratory rate

Vt - Tidal volume