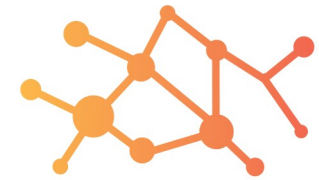


Open Source COVID19 Medical Supplies: Our Intent, Needs, and Your Role

Summary of COVID19 Situation & Supply Needs

~~Version 1.0, last updated 3/18/2020 @ 7:45 AM Pacific Time~~
Version 1.1, last updated 3/20/2020 @ 5:06 PM Pacific Time.

- Updated FAQ significantly, added a link to medical-grade 3D printing standards.

The Problem

COVID19 is currently spreading exponentially, in a mostly-unchecked fashion, throughout the world. Infection doubling rates are currently as high as 2-3 days. In basic models, such unchecked growth means the disease infects most of the world in just a few months. Current statistics indicate that 15-20% of people who get the disease require hospitalization for respiratory failure for multiple weeks, and often need intense and attentive care from medical professionals. These medical professionals are at severe risk while treating these highly infectious patients, and have an order of magnitude higher mortality rate than the patients themselves as a result. Treatment and care looks like oxygen therapy or intubation for weeks in highly-specialized ICUs.

If infections proceed at their current pace across the globe, **we will not have enough medical supplies to prevent the higher mortality rates (8+%) Italy is seeing as of 3/17/2020.**

Treating COVID19

(Mostly synthesized from 200312 Medical Practitioner Interview - New England; additional primary source interviews and supporting testimonials can be found here.)

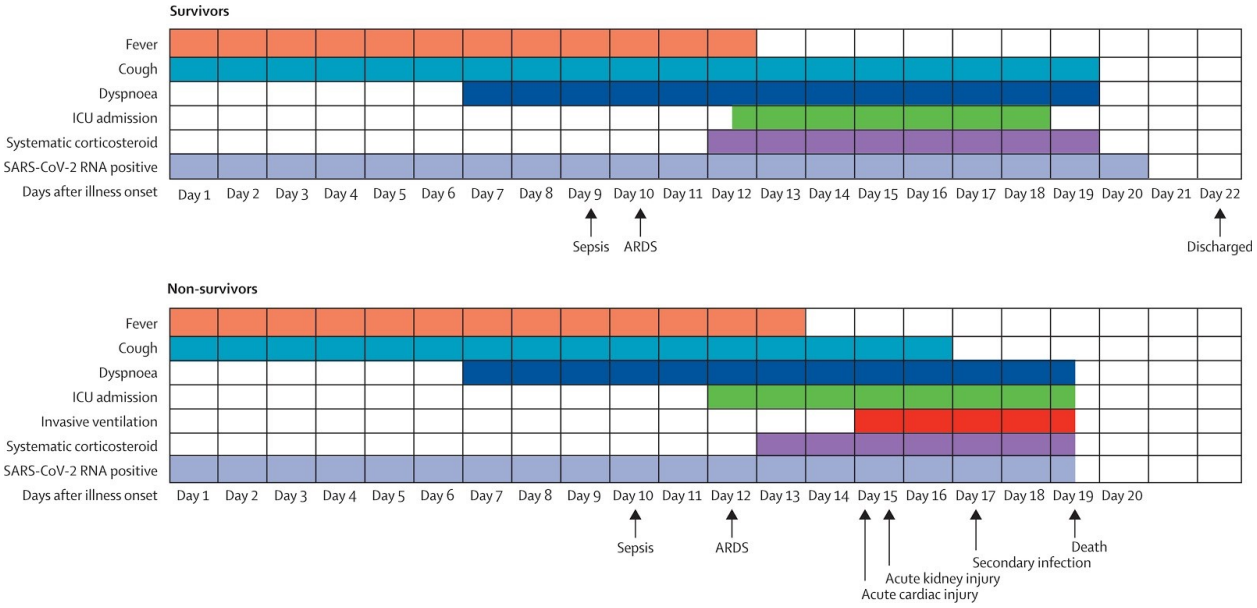
A COVID patient usually arrives at the hospital when they develop significant shortness of breath, on day 9-10 of the illness. At this point, it is decided whether the patient needs further testing, inpatient hospitalization, or ICU care. In the early stages of the disease, the patient is given predominantly symptom based treatment and supportive care, for example medications to reduce fever and cough and adequate hydration. Non-critical inpatient hospitalizations for respiratory failure are currently given oxygen via nasal cannula, with faces covered in N95 masks to prevent aerosolized virus spread from exhalation (non-invasive oxygenation methods such as CPAP and BiPAP are avoided due to severe risk of aerosolization of virus particles).

Patients are determined to be critical if their oxygen requirements increase (hypoxemia) and they develop severe shortness of breath. In critical patients, significant deterioration in oxygenation abilities occurs within 24 hours. For the vast majority of illnesses, this results in hypoxemic respiratory failure (also known as acute respiratory failure), requiring the initiation of invasive mechanical ventilation. A minority of patients develop cardiac failure due to shock, usually from overwhelming sepsis.

The hypoxemic respiratory failure associated with COVID19 is acute respiratory distress syndrome (ARDS). This involves fluid in the interstitium of the lungs, that is not from heart failure (noncardiogenic pulmonary edema), and leads to increased stiffness in the lungs (reduced lung compliance), resulting in difficulty in ventilation. These patients respond favorably to aggressive ARDS treatment, including proning and high positive end-expiratory pressure ventilation (high PEEP ventilation). Most patients are treated early with **antibiotics** for suspected secondary infections (an infection acquired at the hospital), but this is discontinued based on clinical status (how the patient is doing). A minority of patients develop septic shock and require vasopressors to increase blood pressure. A subset of patients also develop heart failure.

The time course of COVID19 patients is extremely variable, but patient one from Italy was hospitalized from 02/21 to 03/11, a period of 19 days. The chart below (Lancet paper on Wuhan severe case mortality) offers guidance for development of symptoms for survivors and non-survivors.

Visualization of Symptoms of COVID19 Over Time, ~5-14 Days After Exposure



While patients are hospitalized but in non-critical condition, healthcare workers typically wear N95 masks, gowns, and gloves and sometimes face masks to prevent undue droplet-based

virus contact. When patients become critical, they are moved to negative-pressure rooms in ICUs, and healthcare workers need to wear positive-pressure CAPR suits with purified regulators, because the risk of aerosolized virus is very high during intubation and critical care.

A Note About Safety and Liability

There are engineering and manufacturing risks around medical devices. Though the FDA has issued Emergency Use Authorizations (EUA) (Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices, 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:
eCFR: QUALITY SYSTEM REGULATION (especially Identification and Traceability, Production and Process Controls, and Labeling)
eCFR: GENERAL HOSPITAL AND PERSONAL USE DEVICES

References:
Technical Considerations for Additive Manufactured Medical Devices (FDA)
General Controls for Medical Devices (FDA)
Recommended Content and Format of Non-Clinical Bench Performance Testing Information (FDA)

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)

Feedback

Our mission is to provide transparent, accurate, medically-reviewed content that will help communities around the world develop open source medical supplies. At the same time, recent cyberattacks on American health institutions and disinformation campaigns have shown that there are state-level actors who do not want accurate information shared. Thus, for the sake of information security, we have locked all of our public-facing content to read-only.

We welcome your feedback on the factual information presented here, and especially welcome links to new projects that we can share to the global community. If you have feedback you would like to share, or have an addition to make to our content (whether more information, or projects that should be added), **PLEASE USE THIS FORM TO SUBMIT THAT FEEDBACK.** This will allow our medical team to vet incoming supply design suggestions, and let us process feedback in a centralized way that is not prone to being taken down by malicious actors.

Design, Manufacturing, & Engineering Projects

PPE (Personal Protection 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:

Supplies

Hand Sanitizer

PPE

N95 Respirators
Surgical Face Masks
Goggles / Masks
Powered Air Purifying Respirators (PAPR/CAPR)
Examination Gloves
Gowns

Face Shields (Full Face Protection / FFP)

Medical Supplies

Nasal Cannulas
Catheters
Flow-Splitters for Oxygen Supply
Thorpe Tube Flowmeter
Oxygen Masks
Venturi Masks (High Flow)

Devices

Negative Pressure Rooms
Non-Contact Thermometers
Ventilator Machines
Hospital Beds
Oxygen Concentrators
Pulse Oximeters
Non-Heated Humidifier (aka Cool-Mist)
Laryngoscopes
Infusion Pumps

FAQ

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 severe complications of COVID-19. Patients with ARDS frequently require mechanical ventilation to survive. According to the American Hospital Association, it is possible that up to 900,000 people in the United States may need mechanical ventilation during the COVID-19 pandemic. The Society of Critical Care Medicine estimates that approximately 200,000 are currently available, though exact numbers are not known. **If ventilator production could be quickly increased, this would make it possible to care for more critically ill patients.**
- 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 other supplies (e.g. PPE) may be of more direct use to those who are treating patients. **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 (mass production, etc)?

3D printing can be an efficient method of mass-producing needed supplies to prevent shortages. In one example of successful use of 3D printing, respirator valves 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.

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. **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.** 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 sterile 3D manufacturing but it is rare, mostly proprietary, and usually already located in a hospital or research lab. Not usually conducive to mass-scale production.

What about using CPAP or BiPAP machines?

CPAP (continuous positive airway pressure) is a form of non-invasive ventilation in which mild, consistent air pressure is applied through a mask to keep the airway open and maintain oxygenation. BiPAP (bilevel positive airway pressure) is similar to CPAP, but alternates periods of higher and lower pressure to make it easier for the patient to exhale. While these are being used in the treatment of patients experiencing respiratory distress, **these methods have been discouraged for the treatment of COVID-19 patients** due to the risk of aerosolizing the virus and thus increasing risk of infection to other patients and caregivers; the risk can be mitigated, but not eliminated, with optimal mask fit. In addition, these approaches are unlikely to prevent the need for mechanical ventilation, though they may postpone it.

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.

How can I help?

1. Educate yourself and your community on how COVID19 is treated, and understand the entire problem at hand, before you start designing or building or ideating anything.

2. Continue to grow this group. The goal of this Facebook group is to be a discussion forum and megaphone to the world once safe open source supply solutions are found, and it needs to be as large as possible to reach everyone who will be affected.

3. Go out and find as many existing solutions as possible to the supply problems we've highlighted, and focus your work on the gaps. Cataloging existing solutions is just as important as designing anything new.

Are home-sewn masks safe?

They are safe by being better than nothing. Here is a design that has been approved by our medical experts: http://project-cloth-masks.com. You can find other vetted designs for masks and other PPE here.

How can I find hospitals that need help in my area?

You can find hospitals who need help by calling a hospital marketing/PR dept, materials management, or procurement dept. We will also try to post information on this page as we receive it.

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

We have a team of over 180 volunteers from all over the globe who are collaborating on the Slack channel that supervises this group. We have 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 vet, catalog, present, and soon act upon those solutions. If you would like to join this narrowly scoped and tightly focused team, please let us know in the comments.

Can I use coffee filters/vacuum bags/cotton t-shirts/dish towels to make a mask?

You can use those materials to make a mask, but the effectiveness and safety will depend on how well they are constructed and fitted to your face. Make sure you can breath through the mask -- don't suffocate yourself.

A HEPA filter (the ones we use for our AC) can be used (CAUTION while taking apart the filter sheet (white color) from the metal netting to prevent exposure to the fiber glass when cutting) . The particulate size of these filters is the smallest among household items and can be a back up option. Place the HEPA filter sheet between two pieces of cloth and glue with a hot glue gun. Attach two pieces of string on either side to tie them down so it conforms to your face.

Will I get sued for making things?

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. 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. We recommend reading OSCMS: 3D Printing - Getting Started, Safety, and Designs.

Glossary

Many of the medical terms pertaining to COVID-19 may be unfamiliar to you. We're here to help.

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:

Hypoxia (Wikipedia)

Hypercapnia

Too much carbon dioxide.

References:

Hypercapnia (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 barotrauma.
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:
Viruses Causing SARI (NIH)

Tachypnea

Rapid breathing.
References:
Tachypnea (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