Open-Source COVID19 Medical Supplies Requirements

Link to document / Link al documento actualizado:
https://docs.google.com/document/d/15kqUPPI7bYL6dnCetOeDSyE8IG5pHVmtg8Ju4yzGlF8/edit#heading=h.elyq59vqxfyb

Introduction

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 low numbers of 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 (7%) Italy is seeing now.**

Treating COVID19

(Mostly synthesized from 200312 Medical Practitioner Interview - New England)

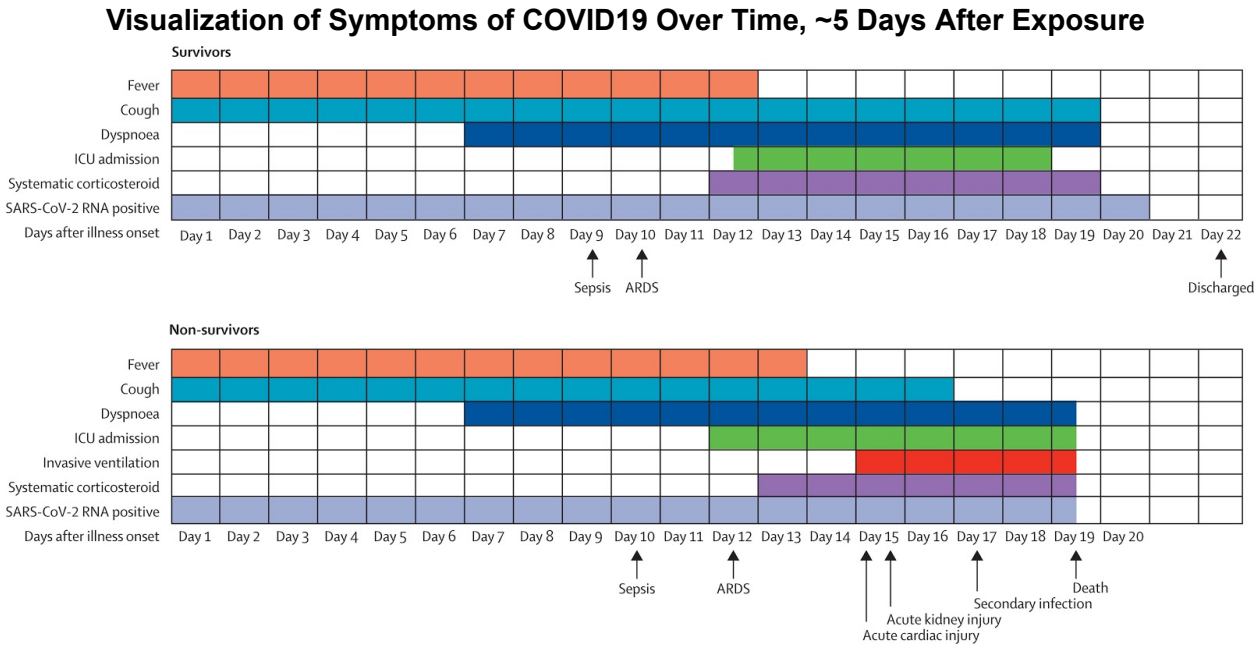
A COVID patient usually arrives at the hospital when they develop significant shortness of breath, on day 9-10 of the illness. At this point, it is decided whether the patient needs further testing, inpatient hospitalization, or ICU care. In the early stages of the disease, the patient is given predominantly 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.



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.

Interviews - Medical Practitioners

The following are primary source interviews with doctors, nurses, and other medical professionals directly treating COVID-19. If you want to familiarize yourself further with the disease and the issues surrounding treating it, read below.

- Living Location Folders
    - External Folder for Interviews
    - Google Form COVID-19 Questions for Medical Professionals

- 20 March 10- High ranking medical practitioner in San Francisco
    - 10% of infected go to the hospital for respiratory failure - via nasal cannula with masks on patients on top of the nasal cannula. This is the only non-invasive ventilation allowed. Other forms will aerosolize the virus. 1/3 of hospitalized people are intubated, ~10 days after infection. Intubation aerosolizes the virus, so takes a lot of resources (negative pressure room, CAPR suit, powered respirator, up to 4 people) The fatality rate is 4-5x higher for healthcare workers, and takes out people for up to a month to recover.
    - In Extreme Short, 1/3 of patients will be in critical care and will need to be intubated FAST, and that process is dangerous and exposes everyone, in particular the respiratory therapists we desperately need.

- 20 March 11 - Reddit Thread - Dr. Ali Raja, Vice Chair of the Department of Emergency Medicine at Mass General Hospital

- 20 March 12- Pulmonary and critical care physician working in critical care in the Northeast
    - Around day 8-9 of infection, a decision is made with an emergency physician if needs further testing, inpatient hospitalization and whether or not they need ICU. Most patients fail to oxygenate adequately and require invasive mechanical ventilation. Early stage care is symptom based, fever reducers and cough suppressants. Critical patients moved to ICU and move to intubation. ARDS (acute respiratory distress syndrome) involves fluid filling interstitium of lungs, leading to reduced lung compliance (difficulty breathing). Treated in parallel with antibiotics, but is falling out of practice. Minority of patients develop florid shock and need vasopressor support. Patients are hospitalized for up to three weeks in critical condition. Major Institutional changes at the hospital include a huge increase in PPE (personal protection equipment) including footwear- increasing preparation time to see patients and is cumbersome for performing invasive procedures due to reduced dexterity and heat exhaustion.
    - Main fear for running out of supplies is PPE supplies, PAPR, CAPR, N95 masks. There doesn't seem to be a concern for turning away patients unless they

weren't sick. Unfamiliar equipment may be more detrimental but on-the-job training is possible. Each ICU bed has a ventilator with a few spares in the back (inference meaning running out of ICU beds is tied to ventilator shortage)

- 20 March 12- Frontline medical practitioner in Seattle
    - Patients seem to be of all ages, 15% of infected need to be hospitalized, another 8% are critically ill. ⅓ require face masks (or oxygen non-rebreather masks). ⅓ are intubated, having high fevers off and on. Respiratory failure happens after 7-10 days in, but usually requires patients be intubated within 24 hrs. Patients are mostly dying from cardiac arrest, usually later in the course(after they are weaned off Flolan and ventilator cause they look like they're doing well) Consensus is steroids, in particular inhaled steroids should x.
    - This one in general has a lot more technical medical details, re: white blood cell for patients seem normal, with low lymphocytes. It seems more relevant to what tests are useful to show which patients may be at higher risk, please refer to full interview for more detail.

- 20 March 14 - Testimonial from frontline medical professional in SF
    - NO MEDICAL UPDATES. Testimonial about SF hospital preparedness which includes noting that masks are almost out of stock for the month (on the 15th), and masks have not been used proactively in treating potential COVID19 patients.

This Document

The purpose of this document is to clearly **SCOPE** (NOT SOLVE; that comes later) the medical necessity, design requirements, engineering requirements, and fabrication requirements involved in creating the medical equipment necessary to care for COVID19 patients in both ideal hospital environments and improvised home environments. Our goal here is to set the guard rails for a distributed design and fabrication effort to create open source emergency medical supplies using both conventional and unconventional materials, in the **very likely** case that supplies run out and traditional supply chains/manufacturers fail. Once this requirements document is complete and reviewed by medical professionals, engineers and makers around the world can then use it to develop appropriate medical supply solutions to COVID-19 treatment if necessary.

The goal is to aggregate, distill into layman's terms, and write up as much accurate information about:

- The latest, most up-to-date COVID-19 treatment procedures
- All the medical supplies needed to treat it in both ideal hospital environments and improvised home environments
- All the design requirements around using and making those supplies (including relevant medical standards distilled into useful layman's principles)

- How many of each type of supplies are needed, and where we might be short

Please add distilled, helpful information (in layman's terms) to the appropriate sections of this document. Please avoid deleting information unless you have added it - comment instead if you take issue with something. If you are a medical professional, please review the layman's descriptions you see and offer additional nuance or insight (or requests to delete content) as appropriate. If you have questions about assertions, please comment appropriately.

Work Requests:

Please take on one or more of these tasks and update the document accordingly. If you're working on a section, note it in comments. If the request has been fulfilled, add a strikethrough.

- **Review the sections under Devices and Supplies/PPE. Then, fill in as much information about medical summaries of what that supply does, what its intended purpose is, what standards apply to it, what supply chain information we have about it, what engineering and assembly/fabrication requirements apply to it, and provide links and/or summarized information about healthcare standards and best practices about it.**
- Look up standards on intake filtering for ventilators and exhaust filtering for negative pressure rooms
- Look up standards for powered air purifying respirators that doctors will need as part of their PPE, that share similar characteristics to respirators.
- Look up WHO recommendations for how much PPE/ventilators/etc. we need for the coming wave of illnesses (see this story for reference), pull out information on listed shortages and list them in the Assembly/Fabrication requirements section. We can format them later.
- Pull out information on ISO connectors for ventilators/respirators from a link posted in the comments on the engineering section, put summaries into the engineering requirements and link the source Common Information Repository

Medical & Standards Information

- INTERNET BOOK OF CLINICAL CARE FOR COVID-19, a public health resource being used widely for medical advice on treating COVID-19
- WHO Clinical Management of 2019-nCOV, 28 January interim guidance
- This is the revised version 1.2 of the WHO Clinical Management of 2019-nCOV report from 13 March 2020
- FDA notice (on 3/11/2020) that there will be a shortage of medical supplies
- The clinical needs for mechanical ventilators are outlined by the NIH here.

- Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19) Interim guidance - 2/27/20 (has table of PPE for given setting/activity to optimize PPE use)
- [Please throw other medical information, project BOMs, and links here]
- WHO recommended management of patients with COVID19
- https://www.dynamed.com/condition/covid-19-novel-coronavirus - Medical resource for care of patients
    - Management and diagnosis is most useful to this group
- Lancet paper on Wuhan severe case mortality - discusses what treatments were used on patients that survived and did not. Covers 200 patients who had serious enough symptoms to be hospitalized and have either died or recovered. Twitter commentary.

Supplies / PPE

NOTE: *Request from Physicians dealing with COVID19: "Please focus on consumer directed PPE to reduce demand from the private sector, allowing them to maximize supply among the medical community (where there is regulation, and to be clear, even with Exemptions basic testing and utilization is not going away)"*

"The current global stockpile of PPE is insufficient, particularly for medical masks and respirators; the supply of gowns and goggles is soon expected to be insufficient also. Surging global demand − driven not only by the number of COVID-19 cases but also by misinformation, panic buying and stockpiling − will result in further shortages of PPE globally. The capacity to expand PPE production is limited, and the current demand for respirators and masks cannot be met, especially if the widespread, inappropriate use of PPE continues." (WHO, 2/27/20)

N95 Respirators

The Problem:

- The role of facemasks is for patient source control, to prevent contamination of the surrounding area when a person coughs or sneezes. Patients with confirmed or suspected COVID-19 should wear a facemask until they are isolated in a hospital or at home. The patient does not need to wear a facemask while isolated. CDC
- Healthcare professionals are fitted at least once per year.

- Note: N95 respirators are generally unnecessary for the general public for prevention, especially when not fitted properly to produce a tight seal. ***To prevent a shortage of N95 respirators, they should be used primarily by patients and healthcare workers. There have been reports of N95 shortages at hospitals due to mask overuse by the public. [citation to SF medical practitioner interview]***

Current US Resources:

- **Strategic National Stockpile:** 12,000,000 N95 respirator masks (HHS officials, Time)

Worst Case Expectation:

- **HHS:** "HHS estimates the U.S. could need up to 3.5 billion N95 respirator masks" over the course of a year in a pandemic (HHS estimate, Time)

Why We'll Need It:

- "85 million N95 respirators" were distributed during the H1N1 pandemic in 2009 (WP, 3/10/20)
- "Washington state initially received only half of the 233,000 respirators and 200,000 surgical masks that authorities urgently requested from the stockpile." (WP, 3/10/20)
- "In California, expired N95 masks are being distributed from a state stockpile to ease hospital shortages. The CDC has approved the use of several models of N95 masks beyond their expiration date "due to the potential urgent demand." (WP, 3/10/20)
- 3M produces 35 million a month (WP, 3/10/20)
- Unknown respirators in hospitals; already shortages in California, Washington, Massachusetts (WP, 3/10/20)
- "the H1N1 influenza pandemic triggered the largest deployment in SNS history when ... 19.6 million pieces of PPE, 85.1 million N95 respirators [were deployed]" (The Nation's Medical Countermeasure Stockpile, NAS, 2016)
- SNFs, nursing homes, dialysis clinics, and outpatient clinics typically do not stock N95 masks at least in California, but SNFs and nursing homes have already had multiple outbreaks in the US.
- Anecdotally, San Francisco Bay Area hospitals are already running low on N95 masks

Why We Won't Need It:

- China can produce 116 M masks a day (source). This includes surgical masks.
- WHO advocates consideration of ad hoc measures to reduce PPE needs:
    - Telemedicine to minimize the number of individuals who go to healthcare facilities for evaluation
    - Using physical barriers to reduce virus exposure, such as glass or plastic windows, including areas where the patients will first present in a healthcare setting (e.g., triage area, registration desk, pharmacy windows)

    - Bundling activities to reduce the number of times a room is entered and pre-planning which bundle of activities will be performed
    - Restricting individuals from unnecessarily entering the rooms of COVID-19 patients

Engineering Requirements:

- https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks
- Proper fit to face
- Light weight
- High particulate removal down to required PM size
- Low cost and/or ability to sanitize
- Typical US hospital practice would be to discard N95 after each patient contact. CDC (Q&A in conference call) is suggesting in shortage to use same the mask for a series of respiratory patients. Chance of transmission is low from the mask to patient, but care has to be take to avoid contact transmission by HCP from handling the mask.

Assembly/Fabrication Requirements:

- MERV 13 or higher FILTRETE filters can be used to make DIY N95 masks

Projects/Resources:

- HHS pursues reusable respirator to better protect medical providers during pandemics 2017

Hand Sanitizer

The Problem:

Provides sanitation when soap and water are not available.

Current US Resources:

Isopropyl/Ethanol supply chain status

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

- As shutdowns take place, people who stay home will presumably use soap and water instead, which may reduce demand.

Engineering Requirements:

See WHO guidelines below.

Assembly/Fabrication Requirements:

- WHO guide to DIY sanitizer
- Calculator for WHO Sanitizing Handrub
    - Revision Requests

Projects/Resources:

Surgical Face Masks

The Problem:

N95 masks are in short supply, and people who don't need them are using them. Surgical masks can serve lighter duty uses.

Current US Resources:

- HHS Strategic National Stockpile:
    - 30,000,000 surgical face masks in Strategic National Stockpile (HHS officials, Time)
    - “"U.S. Department of Health and Human Services intends to purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile " (HHS, 3/4/20)

Worst Case Expectation:

- **World Health Organization:** “89 million medical masks will be required for the COVID-19 response” (each month, globally) (CNBC, 3/4/20) (WHO 3/3/20)

Why We'll Need It:

- ""Facemasks are an acceptable alternative when the supply chain of respirators cannot meet the demand," the CDC said in a statement that is expected to unsettle health care workers who have been trained to use the more protective gear during contagions." (WP, 3/10/20)
- "Among the general public, persons with respiratory symptoms or those caring for COVID-19 patients at home should receive medical masks." (WHO 2/27/20)

Why We Won't Need It:

- China can produce 116 M masks a day (source).
- WHO advocates consideration of ad hoc measures to reduce PPE needs:
    - Telemedicine to minimize the number of individuals who go to healthcare facilities for evaluation
    - Using physical barriers to reduce virus exposure, such as glass or plastic windows, including areas where the patients will first present in a healthcare setting (e.g., triage area, registration desk, pharmacy windows)
    - Bundling activities to reduce the number of times a room is entered and pre-planning which bundle of activities will be performed
    - Restricting individuals from unnecessarily entering the rooms of COVID-19 patients

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

https://www.appropedia.org/Simple_masks

Goggles / Mask

The Problem:

- [insert 1 paragraph description of the problem]

Current US Resources:

Worst Case Expectation:

- World Health Organization: “1.6 million goggles” (each month, globally) (CNBC, 3/4/20) (WHO 3/3/20)

Why We’ll Need It:

Why We Won’t Need It:

- Goggles are cheap and easy to clean and reuse
- WHO advocates consideration of ad hoc measures to reduce PPE needs:
    - Telemedicine to minimize the number of individuals who go to healthcare facilities for evaluation
    - Using physical barriers to reduce virus exposure, such as glass or plastic windows, including areas where the patients will first present in a healthcare setting (e.g., triage area, registration desk, pharmacy windows)
    - Bundling activities to reduce the number of times a room is entered and pre-planning which bundle of activities will be performed
    - Restricting individuals from unnecessarily entering the rooms of COVID-19 patients

Engineering Requirements:

- Masks: Found out that these are usually 0.2-0.5mm PET or PETG, which is a very cheap plastic. About $20 for a 4x8 sheet. Which will make 20-30ish shields

Assembly/Fabrication Requirements:

Mask: the simplicity of the shape allows to obtain the object very quickly even from 20mm polystyrene sheets (better XPF) without needing to print it in 3D: template file "visiera_Template.pdf" for laser cutter, foam cutter, cnc cutters has been loaded. (Luca, 3/15/20)
DISCLAIMER:
-an ineffective protection can be more dangerous than having nothing because it tends to reduce the level of prudence: make a responsible use of it. Use suitable materials and glues to reduce the risk of breakage and therefore exposure during use.

Projects/Resources:

https://www.thingiverse.com/thing:4222407
https://www.thingiverse.com/thing:4223144

MAXAIR CAPR® Suits

The Problem:

- Source Interview
- **Quote:** “Current CAPR systems are awkward and difficult to use, and there aren’t enough of them to deal with the outbreak. Something lighter and quickly mass-producible would be ideal.”

Current US Resources:

Worst Case Expectation:

Why We’ll Need It:

Why We Won’t Need It:

- WHO advocates consideration of ad hoc measures to reduce PPE needs:
    - Telemedicine to minimize the number of individuals who go to healthcare facilities for evaluation
    - Using physical barriers to reduce virus exposure, such as glass or plastic windows, including areas where the patients will first present in a healthcare setting (e.g., triage area, registration desk, pharmacy windows)
    - Bundling activities to reduce the number of times a room is entered and pre-planning which bundle of activities will be performed
    - Restricting individuals from unnecessarily entering the rooms of COVID-19 patients

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

- https://www.maxair-systems.com/index.php?option=com_k2&view=item&id=197:capr-series
- CAPR personal protective equipment

- Dinosaur themed CAPR
    - Would need a way to put an N95 on the input

PAPR (Powered Air Purifying Respirators)

The Problem:

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

- PAPR Use in Healthcare 2014
- Powered Air-Purifying Respirators (PAPR)

Examination Gloves

The Problem:

- [insert 1 paragraph description of the problem]

Current US Resources:

Worst Case Expectation:

- World Health Organization: “76 million examination gloves ” (each month, globally) (CNBC, 3/4/20) (WHO 3/3/20)

Why We’ll Need It:

Why We Won’t Need It:

- WHO advocates consideration of ad hoc measures to reduce PPE needs:
    - Telemedicine to minimize the number of individuals who go to healthcare facilities for evaluation
    - Using physical barriers to reduce virus exposure, such as glass or plastic windows, including areas where the patients will first present in a healthcare setting (e.g., triage area, registration desk, pharmacy windows)
    - Bundling activities to reduce the number of times a room is entered and pre-planning which bundle of activities will be performed
    - Restricting individuals from unnecessarily entering the rooms of COVID-19 patients

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Devices

Ventilator Machines

The Problem:

COVID-19 causes fluid build up in the lungs, which then requires use of ventilators for the patient to have sufficient oxygen. An insufficient supply of these will lead to increased mortality.

Note: Based on doctor interviews the pre-intubation procedure is oxygen therapy via nasal cannula while putting a mask over the person's mouth so they don't aerosolize virus when they exhale or cough.

Non-invasive ventilation machines like CPAP, BiPAP, and hi-flo oxygen are discouraged on the west coast because they aerosolize the room with virus during exhalation.

Intubation (invasive ventilation) happens when patients go critical after long enough (intubation may happen immediately or after deterioration; rapid shallow breaths, high CO2 levels, low O2 levels and heavy use of chest muscles are indicators for potential intubation). The vast majority of patients require sedation for successful initial intubation (reviewed by Midwest Medical Practitioner, Cards).

Current US Resources:

- ~62,000 “full-featured” ventilator machines in hospitals - exclusive of Strategic National Stockpile (["Mechanical ventilators in US acute care hospitals." 2010.])
- ~98,000 other ventilator machines in hospitals (["Mechanical ventilators in US acute care hospitals." 2010.])
- ~30,000 in the Strategic National Stockpile (interview with Dr. Irwin Redlener)

- Unknown number already in use
- “Officials at another manufacturer...just received an order for 10,000 ventilators from the German government. “The delivery of the order will stretch across the entire year and requires a substantial increase of the production capacity,” (ABC News, 3/14/20)
- “Hospitals are saying “we’ll take them all,” (ABC News, 3/14/20)

Worst Case Expectation:

“The report cited...a 2009 survey...indicating that hospitals could use both existing machines and pull older devices from storage, as well as the 8,900 sitting in emergency stockpiles. Combined,... roughly 200,000 devices, but that the number of available medical staff able to operate them at any one time would lower that number significantly. With some worse-case estimates showing **more than 900,000 people** could need ventilators, according to the American Hospital Association” (ABC News, 3/14/20)

Why We’ll Need It:

“We could increase production five-fold in a 90- to 120-day period,” says Chris Kiple, chief executive of Ventec Life Systems, a Bothell, Wash. firm that makes ventilators used in hospitals, homes and ambulances.

Why We Won’t Need It:

Hospitals might be bottlenecked on respiratory therapists instead of ventilators, meaning that the marginal ventilator is pretty much useless. (source). With that said, non-invasive methods are not recommended due to aerosolization of COVID-19 - and these are the methods typically used by respiratory therapists. The bottleneck may be more related to training - respiratory therapists and other medical professionals (e.g. nurses) may need training on ventilator management (MD - Midwest).

Invasive methods require medical training for the intubation process (source). Intubations are within the scope of any trained physician. Most commonly this includes anesthesiologists, emergency medicine doctors and critical care doctors (MD - Midwest). Local protocols vary, but EMT training and practice may include intubation; this is more likely at the paramedic or advanced level.

Staffing:

“A typical ICU ventilator requires three primary operators: a critical care doctor, respiratory therapist, and a nurse.” (ABC News, 3/14/20)

“A report yesterday by the critical-care society postulated an emergency staffing that has one ICU doctor overseeing 96 patients on ventilators. That doctor would command a staff of four non-ICU MDs brought in from other assignments, each of them looking after eight respiratory therapists, four ICU nurses and 12 non-ICU nurses (again, repurposed from other wards, like elective surgery)...there would be a role for quick courses in how to set up a particular model of ventilator and help the MD get the desired output. In a test run of emergency preparedness several years ago, Branson says, instructions in machine operation were given to medically trained people who had never seen the machine before: nurses, physicians, physical therapists and veterinarians. After a two-day, 16-hour course, the veterinarians scored the best.” (Forbes 3/14/20)

Engineering Requirements:

Rebreather Mask

- Source Interview
- **Quote**: “Nasal cannula-based oxygen therapy with a surgical mask or re-breather mask is the current gold standard for pre-critical patients, and all hospitalized patients will use it based on current practices.”

Types of Ventilation (RC 2011)

Negative Pressure Ventilation (e.g. Iron Lung)

Note: this type of ventilator appears to be not indicated for COVID-19 - it was useful in polio cases were muscles were weakened, which is not the case with COVID-19 [TO BE REVIEWED BY A MEDICAL PROFESSIONAL]

Positive Pressure Ventilation

Positive-Pressure Noninvasive Ventilation (NIV) (risk of aerosolized particles)

CPAP

BiPAP

Hi-Flo Oxygen

Positive-Pressure Invasive Ventilators

Intubation (Invasive Ventilation)

Ventilator Standards

Standards relating to ventilator use, operations and design

- ASTM F 1100-90 (Standard Specifications for Ventilators Intended for Use in Critical Care) (Withdrawn without replacement in 2004)
- ASTM F 1246-91 (Standard Specification for Electrically Powered Home Care Ventilators, Part 1-Positive-Pressure Ventilators and Ventilator Circuits) (LINK)
- IEC 6061-2-12(Standard for Critical Care Ventilators)
- ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

- ICS 11.040.10 (ANAESTHETIC, RESPIRATORY AND REANIMATION EQUIPMENT INCLUDING MEDICAL GAS INSTALLATIONS)
- ISO 10651-3:1997 (Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators)
- ISO 10651-4:2002 (Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators)
- ISO 10651-5:2006 (Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators)
- ISO 19223:2019 (Lung ventilators and related equipment — Vocabulary and semantics)
- ISO/TR 21954:2018 (Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator)
- ISO 80601-2-72:2015
- Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
- ISO 80601-2-79:2018
- Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
- ISO 80601-2-80:2018
- Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
- ISO/DIS 80601-2-87 (Medical electrical equipment — Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators)
- ISO/FDIS 80601-2-84 (Medical electrical equipment — Part 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment)

Connectors for Respiratory Devices

ISO/AWI 27427 Nebulizing systems and components (Under Development)
ISO/AWI TR 22175 Connectors for respiratory devices (Under Development)

Related Technical Committees

ISO/TC 121/SC 2 - Airways and related equipment (Link)

Assembly/Fabrication Requirements:

Projects/Resources:

Medical:

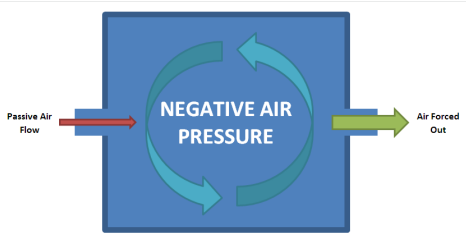
- Short video on how ventilators interact with Acute Respiratory Distress Syndrome (which this article claims is common in COVID19 patients)
- Article describing difference between Non-Invasive Ventilation (NIV) and CPAP
- Short presentation on evolution of NIV practices
- Textbook "Principles and Practice of Mechanical Ventilation"
- Short article published this week describing how NIV can endanger healthcare workers before the patients have viral clearance
- Review of state of the art Mechanical Ventilation (Mayo 2017)
- Overview video of ventilation techniques in respiratory medicine https://www.youtube.com/watch?v=6Bdv7QhNNy4
- https://www.mcgill.ca/criticalcare/teaching/files/intubation
- Mechanical Ventilation- Ventilation Screen, what do some of those numbers mean?
-

Engineering/Design:

- The Mechanical Ventilator: Past, Present, and Future (Respiratory Care, 2011)
- Bench testing simple ventilators for emergency usage, with medical write-ups of what works and what doesn't
- Commercial Off-The-Shelf
    - https://www.hayekmedical.com/about-bcv
    - pNeuton's model A (fully pneumatic)
        - Expired patent
        - System diagram
    - CareFusion's LTV 1200
    - CareFusion's masks, around page 30
    - Philips devices specifically the portable Trilogy Evo
    - OneBreath (seems to be in trials, but good design description here)
    - Trilogy
        - "There's a machine called a Trilogy that a lot of BiPAP or CPAP users have at home. This device is also a ventilator, full stop. If you were to look into machines to be modified for use with ET tubes, you should start there." (M.D. on FB, 3/14/20)
    - **Ambubag**
    - **CPAP Machines / Components**

        - Adjustable mask on Amazon
        - **CPAP Teardown**
            - https://www.youtube.com/watch?v=uRHwZFa6XI0&fbclid
            - Potentially find where these fans are purchased or 3d print one.
- Open/Low Cost Designs
    - Project OpenAir : https://www.projectopenair.org/ - slack channel has >330 participants
        - Also see Gdrive, reference docs : https://drive.google.com/drive/folders/1qtQlHXeLzfgIWJPnlad803tzfmr0Z_7_
    - Open Source Negative Pressure Respirator
    - MIT Hack (anyone know the makers?) https://github.com/nikaiser/openVentilator
    - And Electric Blower Based Portable Emergency Ventilator
    - Low cost ventilator designs from previous design competitions
    - Pandemic Ventilator Project Blog
        - Pandemic Ventilator Instructable
    - Sloan Health Care Prize awarded for low cost ventilator designs from student teams
    - TogVentilator not much here yet.
    - Panvent (Specifications for a Pandemic Ventilator for Coronavirus COVID-19)
    - Pumani BubbleCPAP (from Rice University, started as a maker engineering project)
    - https://www.instructables.com/id/The-Pandemic-Ventilator/
    - https://web.mit.edu/2.75/projects/DMD_2010_Al_Husseini.pdf
    - https://3dprint.com/45352/3d-printed-ventilator-manifold/
    - https://www.3dprintingmedia.network/covid-19-3d-printed-valve-for-reanimation-device/
    - https://docs.google.com/.../1uF6VbxwtKA2iuQtYNQJ.../edit
    - https://gitlab.com/TrevorSmale/low-resource-ambu-bag-ventilor
    - COVID-19 How to Use One Ventilator to Save Multiple Lives (CDC, 3/14/20)
        - Based on: A Single Ventilator for Multiple Simulated Patients to Meet Disaster Surge (ACADEMIC EMERGENCY MEDICINE 2006)
- Adjacent Technologies
    - SCUBA
        - SCUBA Regulator Design Paper
        - Compressor Filter System Theory
        - “Dead” Space in Breathing
    - Emergency Escape Breathing Apparatus
        - Honeywell Emergency Escape Breathing Device Family
        - Allegro Full Mask Supplied Air Respirator

Negative Pressure Rooms (Airborne Infection Isolation Room - AIIR)



The Problem:

- Source Interview
- **Quote:** “Deployable rooms that could draw negative pressure could also help significantly, allowing intubation in place.”

Current US Resources:

Worst Case Expectation:

Why We’ll Need It:

Why We Won’t Need It:

"Health Departments (CDPH and OCHD) state the Airborne Infection Isolation Room (AIIR) is the least important of all the suggested measures to reduce exposure." (source)

Engineering Requirements:

- Negative flow rooms - Purpose of negative pressure, rooms that require negative flow, and creating negative flow rooms

Assembly/Fabrication Requirements:

- **Product Requirements:**
  - https://www.berriman-usa.com/negative_pressure_isolation.htm
  - Negative pressure: https://airinnovations.com/negative-positive-pressure-rooms-hospital-infection-control/
    - Negative pressure of 0.01 inch water column required (2.5 Pa)
  - Flow Rate:
  - Pressure Measurement
    - Inclined Manometers (0.01 inch water column precision)

        - Digital Manometer

Projects/Resources:

- Existing Products:
    - collapsible SARS tent
    -
- **Design References:**
    - manual for tuberculosis

Hospital Beds

The Problem:

If growth of cases continues unabated, hospital beds will be in short supply. Hospital beds allow for patient care with COVID-19 by...

Current US Resources:

- 900,000 Hospital beds (OECD)
    - 2/3rds of these are occupied at any given time (source)
        - Note: these are averages; many hospitals in city centers and suburban areas regularly operate with higher occupancies.
- ICU bed estimates vary, in part because there are many types of ICU beds.
    - According to the AHA, there are 97,776 total ICU beds in community hospitals.

Intensive Care Beds in Community Hospitals	97,776
Medical-Surgical Intensive Care Beds in Community Hospitals	46,825
Cardiac Intensive Care Beds in Community Hospitals	14,439
Neonatal Intensive Care Beds in Community Hospitals	22,860
Pediatric Intensive Care Beds in Community	5,131

Hospitals	
Burn Care Beds in Community Hospitals	1,198
Other Intensive Care Beds in Community Hospitals	7,323

- According to CMS cost reports, there are about 62,000 (Modern Healthcare - Analysis of CMS Cost Reports;). However, some hospitals do not report data to CMS.
    - Large regional referral centers have many more beds than the “average” urban hospital, which has about 10 ICU beds.

Worst Case Expectation:

Why We’ll Need It:

“Consider, too, that hospitals in many areas are already near capacity (UW Madison is at something like 90% full and COVID19 is only starting here).” - A.F. 3/15/20

Why We Won’t Need It:

re literal hospital beds the problem, or is the limiting factor hospital space? Also, this strikes me as a pretty inelastic supply so the constraint may be in manufacturing rate unless there is a big inventory of unused beds somewhere. Can manufacturing even ramp up in time? Counterpoint: any reasons (legal, practical, etc.) why other types of beds couldn’t be converted to hospital use?

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

helpfulengineering.slack.com #hardware-hospital-beds

Oxygen Concentrators

The Problem:

- Problem: “The WHO had sent 40,000 testing kits to Iran but there was still a shortage of ventilators and oxygen.”
- Brief description of high level problem statement/goal can be found here.

Current US Resources:

Worst Case Expectation:

Why We’ll Need It:

Why We Won’t Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Pulse Oximeter

The Problem:

Compact portable device to monitor haemoglobin oxygen saturation and calculate the pulse rate of a patient; finger tip or tabletop; battery

powered or line powered. SpO2 detection to include the range 70–100% SpO2 resolution: 1% or less Pulse rate detection to include the range 30–240 bpm Pulse rate resolution: 1 bpm or less Complies with ISO 80601-2-61:2011, or equivalent.

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Commercially available on amazon.

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

helpfulengineering.slack.com #hardware-oximeter-prototype
https://www.instructables.com/id/Pulse-Oximeter-With-Much-Improved-Precision/

Flow-Splitter for Oxygen Supply

[insert image]

The Problem:

Flow splitter for diversification of oxygen delivery. Each outlet with an independent flowmeter for independently controlled oxygen flow rates. Full scale is graduated in litres per minute (L/min). The device is connected to a single oxygen supply (e.g. concentrator). Input pressure: 50–350 kPa.

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Flowmeter, Thorpe Tube

[insert image]

The Problem:

The Thorpe tube flowmeter is composed of inlet and outlet ports, a regulator, a valve and a clear tapered measuring tube. It is suitable for connection to various medical gas sources, such as a centralized system, cylinders, concentrators or compressors; standard (absolute, non-compensated) and pressure-compensated flowmeter versions; suitable for specific flow ranges.

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Humidifier, non-heated

[insert image]

The Problem:

The humidifier is inserted in the inspiratory line of a breathing circuit to add moisture to the breathing gases for administration to a patient. The bubbling bottle humidifier is a sealed container filled with water and connected inline into the breathing circuit. The medical gas mixture flows through the water inside the bottle and is enriched in humidity.

This type of humidifier does not heat the gas. Should be compatible with oxygen concentrator, including necessary hose connectors.

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

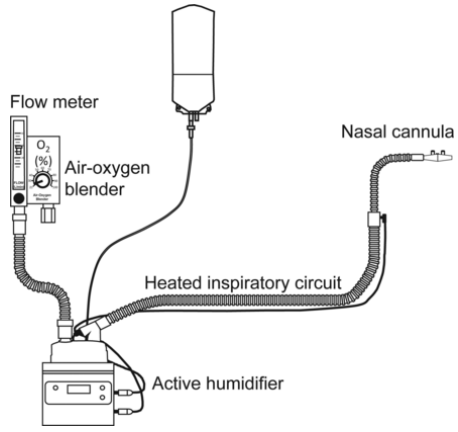
Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Nasal Prongs / Nasal Cannulae

[insert image]



The Problem:

Oxygen cannulae (nasal prongs) are plastic tubes shaped as two prongs delivering air/oxygen mixture into the nasal cavities and connected to an oxygen administration circuit; cannulae can be designed for low-flow applications (0–15 L/min range in general) or high flow (> 15 L/min typically). Oxygen and air/oxygen mixture compatibility, as per ISO 15001; different sizes: adult, paediatric, neonatal

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Catheter

[insert image]

The Problem:

> Flexible nasal catheter with multiple holes (6 to 12 lateral eyes) at distal end. Oxygen and air/oxygen mixture compatibility, as per ISO 15001. Proximal end with connector. Sterile, single-use. Diameter: 8 Fr. Length: 40 cm with lateral eyes, sterile, single-use

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131410.pdf
http://rc.rcjournal.com/content/61/4/529

Assembly/Fabrication Requirements:

Projects/Resources:

Example:
https://www.esutures.com/product/1-expired/43-medtronic/1106-ent/46255905-medtronic-ent-epistat-nasal-catheter-1527031/

Example device: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131410.pdf

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Oxygen Mask

[insert image]

The Problem:

> Connection tube, reservoir bag and valve, high-concentration, non-sterile, single-use; different sizes: adult, paediatric

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Venturi Mask

[insert image]

The Problem:

Venturi mask, w/percent O2 Lock + 2.1 m tubing, non-sterile, single-use; different sizes: adult, paediatric

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Laryngoscope – adult/child

[insert image]

The Problem:

Instrument used to expose and view the larynx and surrounding areas during orotracheal and nasotracheal intubation. Consists of a large cylindrical, hollow, slightly ribbed handle with a threaded head compatible with different blade types and sizes. Each blade has fibre optics or a single bulb; bulb is at least a 2.7 V halogen light and is removable for cleaning. Handle is 28 mm diameter and battery powered with two standard alkaline dry-cell batteries (1.5 V, type C (LR14)). Blades, Macintosh type (curved): • No. 2, length 90–110 mm, for child • No. 3, length 110–135 mm, for small adult • No. 4, length 135–155 mm, for adult Blades, Miller type (straight): • No. 1, length 100 mm Heavy-walled plastic or metal case Instructions for use, troubleshooting and maintenance (English, French, Spanish) Supplied with six compatible batteries in total Four extra halogen bulbs

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Why We Won't Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Non-Contact Thermometer

The Problem:

Current US Resources:

Worst Case Expectation:

Why We'll Need It:

Help test for cases/symptoms

Why We Won't Need It:

Exists at market, and can test many people.

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

Infusion Pump

The Problem:

> “We often need more than 3 per patient, especially for dobutamine, and they are not complex.”

Current US Resources:

Worst Case Expectation:

Why We’ll Need It:

Why We Won’t Need It:

Engineering Requirements:

Assembly/Fabrication Requirements:

Projects/Resources:

https://www.open-electronics.org/guest_projects/openpump-an-open-source-hardware-syringe-pump/

ICU Kit

GOLDEN RULE ABC-AIRWAY, BREATHING ,CIRCULATION
(adapted from Anand Singh to FB group, 3/14/20)

- 1) Devices:
    - 6 lead alive cor ekg (portable smartphone ekg device made by alive cor)
    - defibb machine
- 2) Ambubag
- 3) cpap machine with filters attached to exhalation points
- 4) pulse oximeter
- 5) ORS (oral rehydration salts) packets for fluids (can make your own)
- 6) stethoscope, BP monitor, thermometer
- 7) DIY N95 respirators:
    - FILTRETE merv 13 or higher rating filters
- 8) DIY PPE:
    - large size garbage bags
    - duct tape
- 9) Medications
    - Antibiotics
    - Guaifenesin (aka mucinex)
    - Nsaids
    - Phenyleprine (sudafed)
    - Dobutamine
    - basic essential meds list
- 10) grain alcohol >150 proof (isopropyl alcohol alternative)
- 12) DIY alcohol
    - Sugar
    - Brewers yeast
    - Appropriate glassware
- 13) Books
    - where there is no doctor by david werner

Human Factors

Please limit this section to requests coming from health care providers and other subject matter experts. There is a significant pushback against medical devices being a useful avenue for the non-medical community to assist with, but some valid technical and organizational challenges remain. Those go here

- **Digital infrastructure among providers**: A lot of healthcare was not remote or online and suddenly are. Can you assist and help set up this infrastructure for hospitals, clinics, and providers to rapidly share and disseminate information
- **Education among the population**: can you find ways to decrease barriers to understanding and maximize responsible actions like social distancing, hand hygiene, and self-quarantine? For example, we have a database of random lingo. Can someone make an API/chrome extension that translates things to plain english, or beyond? https://doctorlingo.com/covid-19-terminology/
    - Good tool for comprehension: https://www.washingtonpost.com/graphics/2020/world/corona-simulator/
- **Issues with self quarantine**: Can you assist with technology that can make self quarantine more tolerable, humane, easy for those most vulnerable in the population? (homeless, etc). The truth is the most vulnerable in our society will not be able to self quarantine, perpetuating infections.
    - https://techagainstcoronavirus.com/
    - www.goodify.co
- **Childcare**: Schools are closed and many healthcare providers have families. If healthcare providers cannot care for their children, they cannot go to work. This is a major issue being discussed in healthcare right now (See the UCSF Infectious disease panel: they actually advocated NOT closing schools for this very reason. This will have a REAL impact on healthcare providers.

Supply Chain Agencies

“The Biomedical Advanced Research and Development Authority (BARDA, a component of ASPR)...BARDA’s specific mission is to develop and procure MCMs *[medical countermeasures]* that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, **pandemic influenza, and emerging infectious diseases.** Through its programmatic initiatives, BARDA supports the SNS by leading the advanced devel- opment and procurement of drugs, vaccines, and other products considered to be priorities for national health security.” (The Nation’s Medical Countermeasure Stockpile, NAS, 2016)

“...BARDA provides a range of stockpiling options for the SNS. They can deliver...pandemic influenza products to the SNS if there is not a commercial market. Vendor-managed inventory can be used when there is a commercial indication and market that can be leveraged to decrease life-cycle management costs. In such cases the product is stored at the vendor in a cage that is owned by the U.S. government. As it nears expiration, it rotates into the commercial mar- ket and then new product comes into that cage. This means that the product is available to the U.S. government at any time; however, this method for managing and storing pharmaceuticals is not possible for all MCMs.” (The Nation’s Medical Countermeasure Stockpile, NAS, 2016)

“EUA [Emergency Use Authorization] opened the door for mass preparedness planning...Emergency-use legal mechanisms allow expanded access to investigational drugs and devices...in certain circumstances, clinical trials under an IND/IDE may be the most ethical and fairest means to provide access, given limited supplies and need to assess products. EUA was established by the Project BioShield Act (2004) and amended by PAHPRA in 2013...under EUA authority, FDA can authorize for use in CBRN emergencies the unapproved MCMs (despite lacking the amount of data necessary for approval) and the unapproved use of approved MCMs (e.g., for a new indication). When scientific evidence is available to support MCM use in a CBRN emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act of 1938, as amended. The DHS, DoD, or HHS Secretary makes a specific type of determination regarding requirements for EUA issuance. The HHS Secretary issues a declaration that circumstances exist to justify EUA issuance based on one of the four determinations, and FDA ensures that EUA criteria for issuance are met (e.g., based on totality of scientific evidence, the known/potential benefits outweigh known/potential risks; no adequate, approved, available alternative). Conditions of authorization are put in place as safeguards for use of the product under EUA.” [Disposable N95 respirators EUA was issued 2009-10 for H1N1 by HHS (CDC) and terminated as of 2016 - Table 2-1] (The Nation’s Medical Countermeasure Stockpile, NAS, 2016)

FDA EUA Information

Division of Strategic National Stockpile (DSNS)

Open Source Engineering Resources

- Open Knowhow Data Standard
- Wikifactory
    - Wikifactory is a social platform for collaborative product development. Designed for open source communities, designers and product companies.

- Makernet.org
- helpfulengineering.slack.com

Ventilators/Respirators

Medical Summary [TO BE CHECKED BY A MEDICAL PROFESSIONAL]

Source: WHO Clinical Management of 2019 nCOV

Patients arriving at hospitals with COVID19 are sorted by mild, moderate, and severe illness. The latter includes pneumonia, acute respiratory distress syndrome, sepsis, and septic shock. Patients with severe acute respiratory infection (SARI, an acute respiratory infection with measured temperature >38°C and cough) and respiratory distress need immediate oxygen therapy at 5 liters per minute to reach target levels. All patients with SARI should be equipped with pulse oximeters, functional oxygen systems, disposable single-use oxygen-delivery interfaces (nasal cannula with a simple face mask or mask with reservoir bag).

Critical cases (showing hypoxia (not enough O2), hypercapnia (too much CO2), or tachypnea (rapid breathing)) require intubation and mechanical ventilation. The process of intubation aerosolizes the virus and is a significant airborne hazard to healthcare workers.

Potential Open-Source Need [TO BE CHECKED BY A MEDICAL PROFESSIONAL]

Ventilators/respirators are used by a significant number of hospitalized patients. Oxygen therapy is used initially for mild cases via nasal cannula, and mechanical ventilation is used later. Reports from Italy indicate that their hospital systems have run low on respirators/ventilators, and are one of the limiting factors.

Interviews with current practitioners indicate that several types of respirator/ventilator systems other than mechanical intubation are discouraged, because they aerosolize the virus during operation. Current accepted practice for mild patients is oxygen therapy via nasal cannula, covered by a face mask. CPAP, BiPAP, and high-flow oxygen machines are specifically discouraged due to virus aerosolization.

Glossary

- **Acute Respiratory Distress Syndrome (ARDS)**
    - what medical professionals call it when pneumonia has gotten really bad. There is a 2 page write up on treatment. http://www.ardsnet.org/files/ventilator_protocol_2008-07.pdf Just making sure the

protocol is followed would save a lot of lives. Right now, E.D. staff are way over worked and prone to making mistakes. People are rendered unconscious for ARDS treatment by an anesthesiologist, then ventilated. Making cheap, fast to produce, respiratory and cardio sensors to let people know if someone is responding poorly to anesthesia would also be really useful. There are systems to monitor anesthetized patients, but there are far fewer monitoring systems than projected people who will need ARDS treatment.

- **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 (mechanical air sacs) in the lungs may be ruptured or scarred due to high air pressure in the lungs.
  - WARNING: “It takes only about 2 psi to cause barotrauma (overpressure damage to your lungs) which can lead to pulmonary edema and death. CPAP machines are usually limited to about 0.5 psi to prevent this. Don't go over that!”
- **FiO2** (Ventilator Management, NIH)
  - fraction of inspired oxygen
  - Percentage of oxygen in the air mixture delivered to the patient
- **Flow (Ventilation)** (Ventilator Management, NIH)
  - Liters per minute that the ventilator delivers breaths
- **Hypoxia**
  - not enough oxygen
- **Hypercapnia**
  - too much CO2
- **Intubation**
- **Microatelectasis**
  - partial lung collapse
- **Negative Pressure Ventilation**
  - e.g. “Iron Lung” - air is drawn in by reducing pressure around the patient's body
- **Oxygenation** (Ventilator Management, NIH)
  - Supply greater oxygen supply to the lungs
  - You can either increase **fraction of inspired oxygen** (FiO) or the **positive end-expiratory pressure** (PEEP)
- **Peak Pressure**
  - the pressure achieved during inspiration when the air is being pushed into the lungs and is a measure of airway resistance.
- **Plateau Pressure**
  - the static pressure achieved at the end of a full inspiration. Plateau pressure 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.
- **Pneumonia**
  - Pneumonia decreases lung compliance (COVID19 kills via pneumonia - Lancet)

        - "common causes of death that I have seen discussed are viral pneumonia, or ARDS, and sepsis/septic "
    - "The problem with stiff lungs is that small increases in volume can generate large increases in pressure and cause barotrauma. This generates a problem in patients with hypercapnia or acidosis as there may be a need to increase minute ventilation to correct these problems. Increasing respiratory rate may manage this increase in minute ventilation, but if this is not feasible, increasing the tidal volume can increase plateau pressures and create barotrauma."
- **Positive End-Expiratory Pressure (PEEP)** (Ventilator Management, NIH)
    - Amount of pressure that remains in the airways at the end of the respiratory cycle, above atmospheric pressure (15 psi)
- **Sepsis**
- **Septic Shock**
- **Severe Acute Respiratory Infection (SARI)**
    - an acute respiratory infection with measured temperature >38°C and cough
- **Tachypnea**
    - rapid breathing
- **Tidal Volume** (Ventilator Management, NIH)
    - Volume of air moved in and out of the lungs every respiratory cycle
- **Ventilation** (Ventilator Management, NIH)
    - moves air in and out of the lungs, and mechanical ventilation is measured in "Minute Ventilation"
    - The most important effect is removing carbon dioxide from the body, not increasing blood oxygen content
    - **Minute ventilation** is measured as respiratory rate (Rr) times tidal volume (Vt)
    - "Mechanical ventilation with positive pressure significantly decreases the work of breathing. Decreasing the work of breathing decreases blood flow to respiratory muscles and redistributes it to critical organs, and reduces generation of CO2."
    - Overview video of ventilation techniques in respiratory medicine https://www.youtube.com/watch?v=6Bdv7QhNNy4

Acronyms

AIIR - Airborne Infection Isolation Room
ARDS - Acute Respiratory Distress Syndrome
BARDA - Biomedical Advanced Research and Development Authority
CPAP -
COTS - commercial off-the-shelf
BiPAP -
BVM - bag valve mask (e.g. Ambubag)
EMS -
FDA - Food & Drug Administration

FiO - fraction of inspired oxygen
HCP - healthcare professional
HHS - Health & Human Services
IPPV - tracheosomty, intubation
SARI - severe acute respiratory infection
SNS - Strategic National Stockpile
MCM - medical countermeasure
NIV - non-invasive ventilation
NPV - negative pressure ventilation
PEEP - positive end-expiratory pressure
PPV - positive pressure ventilation
Rr - respiratory rate
Vt - tidal volume

Ventilator Requirements

Engineering Requirements

[Derive raw engineering requirements such as flow rates, filtration, power sources, timing, and the like from medical requirements.]

PowerInput: 100V - 240V AC. IEC plug. Earth stud present on ventilator

It is assumed an external medical isolation transformer is upstream and cleans the power.

A medical isolation transformer is different from an isolation transformer. In a medical transformer, the earth pin is connected to mains earth to allow all E.D. equipment to be connected to a common earth via an earth stud. A medical isolation transformer usually has a double pole switch with current in-rush limitation. The ventilation device need worry about those requirements as long as the device is clearly labeled as requiring them.

Output: ? V DC (based on other requirements),

Assembly/Fabrication Requirements

Research

Scenario 1: Kitting As Many As Possible With Functional Supply Chains

Scenario 2: Making One As Quickly As Possible With Functional Supply Chains

Scenario 3: Making One From Local Supplies

Scenario 4: Making Ideal Tools For High-Needs Patients

Biocompatibility (Health & Safety) Requirements

- Ensure materials do not contain substances at levels that are acutely harmful. Time will likely not be sufficient to do all required biocompatibility testing so only acquire materials used in inhalation medical devices which are likely to pose a low toxicological risk. Substances to avoid:
    - Polyurethanes which are made up of isocyanates that can cause respiratory sensitization (allergy)
    - ...

ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

ISO 18562-1: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

Legal/Compliance Requirements

[What context is this operating in regarding rules that must be observed, procedures to be followed, design rights, etc.]

Quality

https://www.qualio.com/blog/quality-management-initiative-for-coronavirus-and-covid-19

https://www.ecdc.europa.eu/en/covid-19/all-reports-covid-19

Communal Resources

Purpose	First Name	Last Name	E-mail	Phone
Aero/Mech Engineering Business Operations	Matthew	Lee	mjlee177@gmail.com	530-219-3312
Expedited FDA Approval (in Japan)	Matthew	Lee	mjlee177@gmail.com	530-219-3312