Contingency planning for the large-scale delivery of negative pressure ventilation in a severe COVID-19 pandemic

This document describes a ventilator concept intended for use as a last resort in a catastrophically-overloaded healthcare system, where the alternative is denial of ventilation due to lack of equipment and a significant probability of death. Any design work, construction and most of all use must be carried out by qualified experts and medical professionals. This includes testing. Lung tissue is among the most delicate in the human body, and mis-application of assisted ventilation (either positive or negative pressure) can result in serious injury or death, even to healthy people.

No safety or efficacy studies have been carried out, and no authority has provided regulatory approval. Without this, any device built around this concept should be considered inherently dangerous. Bluntly, if you put a medical device into service without following the proper procedures, you should assume you will probably kill people – so don't do it unless the alternative is worse. Any such device will also almost certainly contravene a number of laws and regulations in your jurisdiction unless appropriate approvals are obtained first.

This document is released to support emergency preparedness, and so the concept can be developed further by the broader community. Anyone building and/or operating a device based on the concepts provided here takes full responsibility for any and all negative outcomes. No liability is accepted by myself or by the University of Calgary.

Hopefully none of this will ever be needed.

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Background.

This document is a preliminary technical response to a fast-moving situation, and will evolve as we acquire a greater understanding of potential needs from clinicians and emergency planners. The anticipated use-case is an acute shortage of ventilators caused by rapid disease propagation where patients are dying due to an immediate lack of equipment,[1] justifying the use of systems that have not been through the full regulatory approvals process. Current data from the outbreak in Italy appears to suggest as many as one in ten patients will require ventilation (although presumably this statistic is significantly inflated by selection bias, with more serious cases more likely to be detected), and guidelines have been issued regarding rationing of care in the face of overwhelming demand.[2]

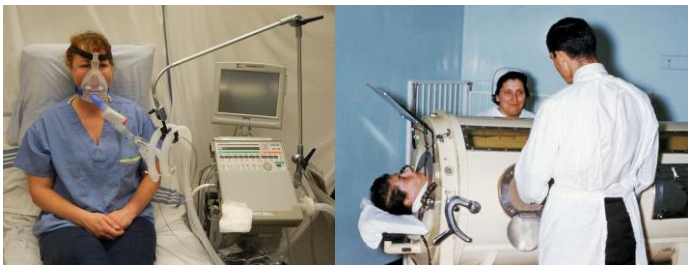

Fig. 1: Noninvasive positive pressure ventilation system (left); "iron lung" negative pressure ventilation system (lower). Both negative and positive pressure ventilation systems can also incorporate devices inserted into the airway in order to keep it open if needed.

Polio outbreaks in the 20th century provide a model for the use of technologies that would be considered fairly basic by modern standards to maintain respiratory function in patients who have lost the ability to do so on their own. While many modern systems employ positive-pressure ventilation (PPV - where air is forced into the lungs by pressures above atmospheric), the system stereotypically associated with polio is the "iron lung" tank respirator, in which the pressure around the patient's chest and abdomen is reduced, and normal atmospheric pressure causes air to flow into and inflate the lungs (Negative Pressure Ventilation – NPV) (**Fig. 1**). There is literature suggesting NPV can provide improved oxygen delivery and cardiopulmonary circulation in some situations,[3,4] including treatment of ARDS.[5]

In response to an acute ventilator shortage in Australia in 1937, the Both cabinet respirator was developed, specifically designed for rapid, low-cost manufacture (**Fig. 2**).[6] Subsequent development[7,8] led to a range of devices including cuirass-style units and softer "poncho" or "jacket" designs (**Fig. 3**).

Fig. 2: The Both cabinet respirator was built of plywood, an order of magnitude cheaper, easy to manufacture, and lighter than previous devices. Note air pump at right, and the pivot point on the support legs that allows patient angle to be adjusted to drain fluid from the lungs.

Concept

Fundamentally, these systems are composed of three modules. A **chamber** around the patient allows lung expansion in a negative pressure environment; a **pressure sink** provides the pressure reduction as needed; and a **control system** determines the degree, duration, and frequency of the patient's exposure to negative pressure.

Chamber: Jacket-style ventilators appear most promising for rapid production, needing only the chest arch, which could be fabricated from a variety of materials such as partial pipe sections, and the envelope, which could be rapidly formed using e.g. low-cost mattress bags, layflat tubing, or polyethylene vapour barrier used in the construction industry. From personal experience mattress bags with rolled edges sealed with duct tape will seal adequately for this application, although mechanical closure with a stapler first may make the process easier and faster. An additional benefit is that to access the patient in an emergency, the jacket can be easily cut open, and subsequently repaired with tape or replaced as needed. Historically, jackets have been sealed either at the collar or at a hood around the face; limbs can be entirely within the jacket, or can penetrate the

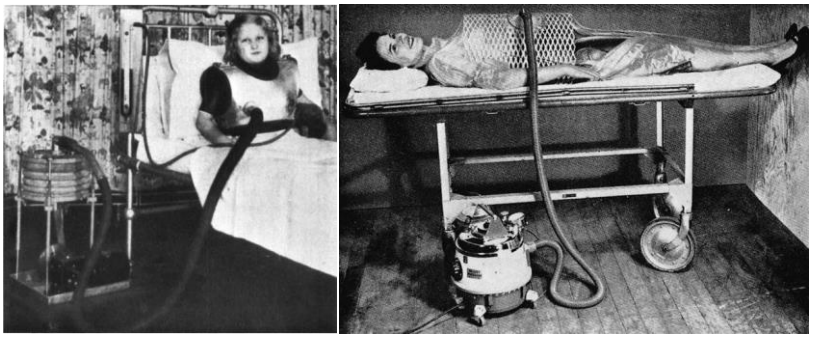

Fig. 3: Cuirass NPV systems (left) are lighter and more portable than prior tank designs, but historically encountered problems with reduced efficacy, as well as chafing at the seals, and needed some degree of custom fitting. "Poncho" or "jacket" NPV designs (right) are simpler, with the patient's body sealed into a plastic envelope (transparent here), and a rigid arch preventing it from collapsing and thereby allowing the lungs to expand.

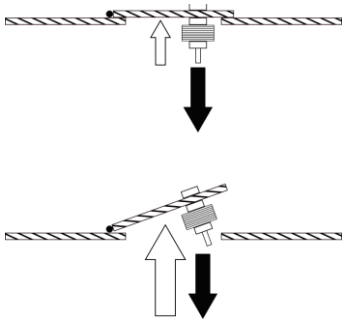

Fig. 4: A flap with an adjustable weight (shown here as a bolt with a variable number of washers) will remain closed (upper) while the force due to the pressure differential (white arrow) is less than the force of gravity (black arrow), and will open (lower) if the pressure exceeds the set point. A spring with adjustable preload could also be substituted here.

jacket with an adequate seal around them, as can tubing and monitoring equipment.

Pressure sink: Initial conversations with respirologists indicate negative chamber pressures required (down to -50 or 60 cm H_2O or around 5-6 kPa, similar to numbers in the literature[4,5,9]) are well within the range obtained by household vacuum cleaners,[10] however equipment will need to tolerate continuous operation. Flow requirements will be largely determined by leakage rates, with actual lung displacement on the order of 500 mL per breath. Options could include individual blowers, as well as centralized dust-collection type systems serving multiple patients – other approaches (bellows) etc could also be examined if needed. Consideration will need to be given to durability, reliability, simplicity and failure modes (for example can it be hand-pumped during a power failure?). While modern equipment incorporates lightweight, highly responsive computer-controlled motors that can quickly reverse direction, a constant negative pressure to which the chamber is connected and disconnected will be easier to obtain with widely-available machinery. *Local HVAC suppliers will likely have suitable equipment in stock, and the expertise to assemble it rapidly*. A bleed valve could be used to adjust pressure; a simple weighted flap opening in response to pressure differential would provide adjustable feedback control (**Fig. 4**) and stabilize sink negative pressure. One medical professional suggested that in some cases a positive pressure of up to +10 cm H_2O may be useful during the exhale phase.[9,11] This could potentially be obtained from the output port of the air handling system, however it would require a more rigid and complex chamber (e.g. Both cabinet). Unless a widespread need is anticipated, it is likely preferable to reserve more advanced equipment for these patients, rather than adding it here.

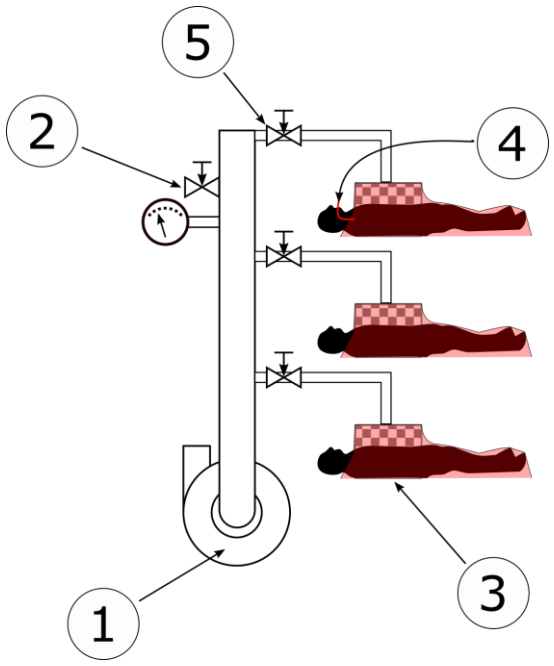

Fig. 5: Concept emergency negative-pressure ventilation system. Pressure sink (1) - in this example a central blower serves multiple patients. Ideally located away from patient (or even outside building) to reduce noise. Redundancy and generator backup if possible. Negative pressure level set at blower and/or via bleed valve (2). Patients in jacket-type chambers (3) may be intubated (4) if necessary to prevent airway collapse. Valves (5) to pressure sink and room air open and close mechanically or electronically to control respiratory cycle timing and pressure. Note that patients will be breathing (and exhaling into) room air, so contamination issues may need to be addressed. If blower exhaust is directed somewhere appropriate, the same ducting could also be used to provide removal of exhaled air.

Alternatively, an online report from an ICU anaesthesiologist indicated COVID-19 patients may retain good lung compliance, but exhibit profound deoxygenation.[12] It may therefore be desirable to maintain residual external negative pressure at the end of the cycle, analogous to PEEP (Positive End Expiratory Pressure), sometimes referred to as external PEEP.[13] As would be expected on theoretical grounds, conventional and external PEEP show approximate equivalence in relation to ΔP.[5] Of note, +20 cm H_2O PPV PEEP at 200 m elevation (similar to New Delhi, lower than Calgary, Tehran, Madrid or Canberra as well as many tall buildings in sea-level cities) yields the same absolute internal and external pressures as -20 cm H_2O NPV PEEP at sea level. This could be achieved via a relief valve (**Fig. 4**) limiting atmospheric air intake during the exhale phase. As the patient's face remains free, supplemental oxygen could be delivered via nasal cannula, low- or high-flow masks (including masks with exhalation filters capable of capturing exhaled viral particles), or more invasive intubation strategies.

Control system: Key case-specific parameters to be set by the operator are the level of negative pressure (to compensate for variable stiffness due to inflammation or other conditions); the duration of negative pressure (inhale duration); and the cycle time (inhale plus exhale plus ramp times; breathing rate). A wide variety of approaches are possible, depending on available resources. An adjustable relief valve (**Fig. 4**) could provide patient-specific pressure control. Timing of valve opening to negative and neutral pressure could be controlled mechanically via rotary motion (e.g.

adjustable cam and follower; rotating disk with holes, possibly powered by air flow) or electronically (e.g. Arduino with solenoid valves). *In extremis*, multiple patients could be ventilated quickly using a shared, manually operated system until an automated solution can be arranged.

An illustrative system layout is shown in **Fig. 5**. Feedback from medical personnel with direct ICU experience of COVID-19 ventilation requirements would be valuable, as would up to date predictions by experts with current knowledge of the likelihood of needing such a system in a given setting, and at what scale, and time course. Please email it to mark.ungrin@ucalgary.ca. The most current version of this document will be posted to https://ucalgary.ca/ungrinlab/EPV.

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References

1. Patrone, D. & Resnik, D. Pandemic Ventilator Rationing and Appeals Processes. *Health Care Anal.* **19**, 165–179 (2011).
2. Vergano, M. *et al.* IN CONDIZIONI ECCEZIONALI DI SQUILIBRIO TRA NECESSITÀ E RISORSE DISPONIBILI (https://translate.google.ca/translate?hl=en&sl=it&u=http://www.siaarti.it/SiteAssets/News/COVID19%2520-%2520documenti%2520SIAARTI/SIAARTI%2520-%2520Covid19%2520-%2520Raccomandazioni%2520di%2520etica%2520clinica.pdf; https://www.siaarti.it/SiteAssets/News/COVID19%20-%20documenti%20SIAARTI/SIAARTI%20-%20Covid19%20-%20Raccomandazioni%20di%20etica%20clinica.pdf).
3. Grasso, F. *et al.* Negative-Pressure Ventilation: Better Oxygenation and Less Lung Injury. *Am. J. Respir. Crit. Care Med.* **177**, 412–418 (2008).
4. Corrado, A. & Gorini, M. Negative-pressure ventilation: is there still a role? *Eur. Respir. J.* **20**, 187–197 (2002).
5. Raymondos, K. *et al.* Negative- versus positive-pressure ventilation in intubated patients with acute respiratory distress syndrome. *Crit. Care* **16**, R37 (2012).
6. Item Details | Health Museum of South Australia. http://www.healthmuseumsa.org.au/ehive-object-details/.
7. Woollam, C. H. M. The development of apparatus for intermittent negative pressure respiration (2) 1919–1976, with special reference to the development and uses of cuirass respirators. *Anaesthesia* **31**, 666–685 (1976).
8. Spalding, J. M. & Opie, L. Artificial respiration with the Tunnicliffe breathing-jacket. *Lancet Lond. Engl.* **1**, 613–615 (1958).
9. Corrado, A. *et al.* Intermittent negative pressure ventilation in the treatment of hypoxic hypercapnic coma in chronic respiratory insufficiency. *Thorax* **51**, 1077–1082 (1996).
10. Vacuum Chart. http://www.dpvac.com/chart.html.
11. Mike Soares. Slack | Helpful Engineering | #skill-medical-personnel. https://helpfulengineering.slack.com/archives/CV7K1C6AU/p1584073351122600.
12. Matt Aldridge. Slack | Helpful Engineering | #skill-medical-personnel. https://helpfulengineering.slack.com/archives/CV7K1C6AU/p1584282735208800.
13. Nava, S. *et al.* Effect of Nasal Pressure Support Ventilation and External PEEP on Diaphragmatic Activity in Patients with Severe Stable COPD. *Chest* **103**, 143–150 (1993).