



# Recommendations for the Strategic Response to the Global Ventilator Shortage

Breathing Life into the COVID-19 Pandemic Response

## ***Authors***

Harvey Hawes, MD, MSc, FRCSC  
Abdullah Saleh, MD, FRCSC  
David Evans, AB, MD, CM, MSc, FRCSC, FACS  
Nancy Paris, MASC, PEng, FEC  
Andrew Sutton, PhD  
Rohith Malya, MD, MSc, FACEP  
Joanna Hart, MD, MSHP  
James McKay, MBChB, MSC, FRACS, FCICM  
Chantalle Grant, MD  
Hasan Hamze, MPH

## ***With the support of***

Karan D'Souza, MD  
Keir Martyn  
Blake Birnie  
Helen Kang, PhD

## ***Contact***

Harvey Hawes, MD, MSc, FRCSC  
Trauma Services,  
Department of Surgery,  
Vancouver General Hospital,  
Vancouver, Canada  
[harvey.hawes@vgh.ca](mailto:harvey.hawes@vgh.ca)

Abdullah Saleh, MD, FRCSC  
Director of Global Surgery,  
Department of Surgery,  
Faculty of Medicine and Dentistry,  
University of Alberta,  
Edmonton, Alberta  
[assaleh@ualberta.ca](mailto:assaleh@ualberta.ca)

April 14, 2020

# Table of Contents

<b>Table of Contents</b>	<b>1</b>
<b>Executive Summary</b>	<b>2</b>
<b>Infographic</b>	<b>3</b>
<b>Disclaimer</b>	<b>4</b>
<b>1. Introduction</b>	<b>5</b>
<b>2. Recommendations</b>	<b>7</b>
<b>3. Discussion</b>	<b>10</b>
A. Public health considerations	12
B. Clinical capacity considerations	14
C. Ethical considerations	15
D. Technical considerations	17
E. Manufacturing considerations	19
F. Regulatory considerations	20
G. Health economics considerations	22
<b>4. Conclusion</b>	<b>25</b>

# Executive Summary

The coronavirus disease (COVID-19) pandemic is expected to infect up to half of the world's population and result in death in approximately 2-3.4% of cases. A major challenge is the global shortage of mechanical ventilators, which provide life-saving respiratory support for patients with moderate to severe COVID-19. Without more ventilators, preventable death will be in the tens of thousands in well-resourced countries, and millions in low- and middle-income countries (LMIC).

The global ventilator shortage is a complex problem. Across the globe, there are frenzied efforts to scale-up ventilator production and expedite regulatory processes. However, without a coordinated international response, there is a high risk of causing harm, duplicating efforts, depleting limited resources, overwhelming manufacturing capacities, backlogging regulatory systems, and producing substandard ventilators that could lead to deaths.

As a collective of concerned clinicians, engineers, ethicists, and medical device manufacturers, we recommend the following to avoid the pitfalls of uncoordinated action:

- 1) Establish an international framework for collaboration between stakeholders, sectors, and industries to coordinate efforts, with aims of safety, transparency, and equity of access;
- 2) Establish evidence-based standards for minimum ventilation capacity in providing respiratory support for different stages of COVID-19 disease;
- 3) Redirect high-capacity ventilators currently in use for non-critical patients toward patients with severe COVID-19 lung injuries;
- 4) Develop a coordinated strategy to scale-up global production high-capacity ventilators by existing ventilator manufacturers, utilizing economic incentives, particularly for LMICs;
- 5) Engage other industry manufacturers (i.e. automotive) to produce ventilators, with appropriate regulatory rigor;
- 6) Engage in the spirit of open-source collaboration with organizations and manufacturers to develop new ventilators;
- 7) Develop and mass produce two additional classes of ventilators:
  - a) Low-capacity, low-cost ventilators suitable for light to moderate ventilatory needs, or requiring short-term respiratory support, or in low-resource settings; and
  - b) High-capacity, moderate-cost ventilators for COVID-19 patients with severe lung injuries;
- 8) Engage private-sector firms to innovate solutions, mobilize resources and facilitate global production, training and support;
- 9) Streamline international regulatory and licensing processes to fast-track manufacturing and distribution, while maintaining safety and product standards; and
- 10) Produce efficient just-in-time culturally appropriate training for the end user (i.e. clinicians).

It is absolutely possible to respond to the current COVID-19 crisis with many thousands of new ventilators in record time. This complex problem will require a massive coordinated response and reasoned, strategic implementation. We believe what we have outlined in this report is the shortest and safest path to saving the most lives.

# Infographic

## Recommendations

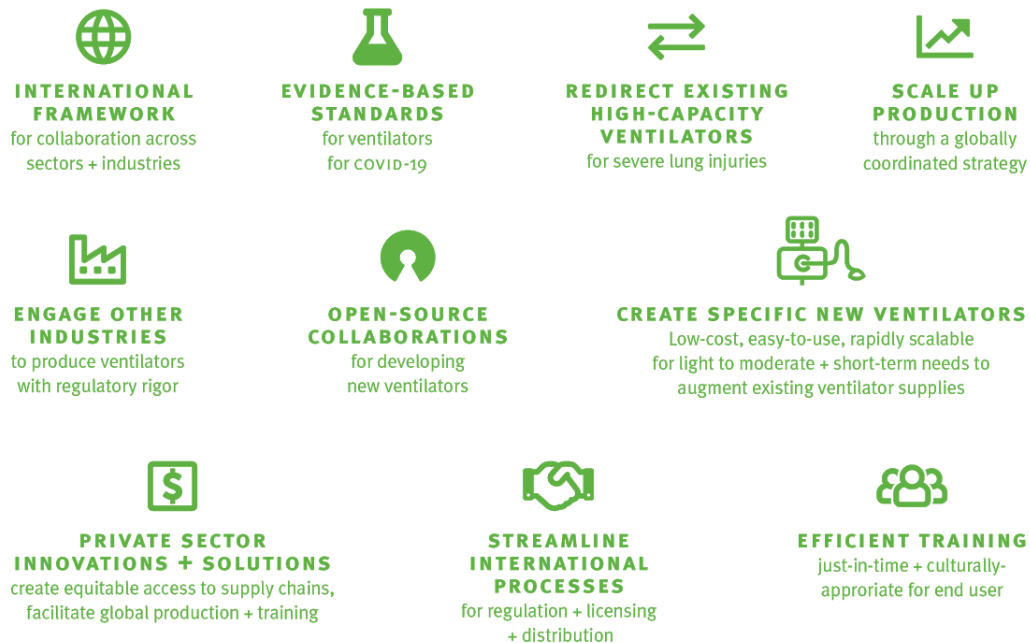
for the Strategic Response to the Global Ventilator Shortage



### CHALLENGES



### SOLUTIONS



For more information, please contact Harvey Hawes or Abdullah Saleh at [info@ventsforall.com](mailto:info@ventsforall.com). <https://www.ventsforall.com/>

# Disclaimer

This document is intended to be a starting point for comprehensive discussion, and thus has been contributed by authors from a variety of backgrounds and training. As this document pertains to medical device creation by collaborative groups, universities, and medical device companies, it is recognized that there could be some inherent conflicts. However, we have endeavoured to be as transparent and as objective as possible regarding this issue. We, therefore will not be promoting an identifiable design, product, or service in the text, nor are we endorsing any of these. It is perhaps a strength of this document that we have sought to include comment from the breadth of the actors and groups responding to this crisis.

# 1. Introduction

The coronavirus (COVID-19) pandemic currently devastating communities in every corner of the planet is expected to infect up to half of the world's population. Already, the case numbers are alarming, and increasing exponentially. Moreover, COVID-19 will cause severe respiratory illness requiring ventilation in approximately 5% of cases and result in death in estimated 3-4% worldwide.<sup>1</sup> The world's existing capacity to respond to a respiratory pandemic is agonizingly inadequate. As China and Italy have already experienced, the unthinkable need for life-or-death rationing of advanced care resources leads to enormous loss of life. This, of course, is on top of the typical day-to-day demands on healthcare systems.

A key feature of the current global inadequacy to respond to COVID-19 is the severely limited capacity to provide mechanical ventilation to critically ill patients. In addition to staffing, ancillary equipment, and space, without prompt access to many thousands more ventilators, vast numbers of people will die in the year ahead. In high-income, well-resourced countries, preventable death will be in the thousands. In low- and middle-income countries, the preventable deaths could be in the millions due to already inadequate healthcare systems.

Though difficult to quantify with precision, the global gap between the supply of mechanical ventilators and their demand is considered to be enormous. In the U.S. alone, there are an estimated 160,000-200,000 ventilators,<sup>2,3</sup> but not all are capable of treating COVID-19 patients with severe lung injuries. The need for additional ventilators is currently estimated at 20,000 in the U.K. and 740,000 in the U.S.<sup>4,5</sup> In low- and middle- income countries, the deficit is so severe that inestimable mortality is predicted and, in worst-case scenarios, set back recent economic gains that some of these countries have made by years or decades.

With greater awareness of the current ventilator shortage, there has been an effort to liberate current stockpiled ventilators and to increase and expedite production of new ventilators to meet needs. In addition, designs are underway in various countries to spur development and mass

---

<sup>1</sup> World Health Organization, Coronavirus disease 2019 (COVID-19) Situation Report - 46, 6 March 2020 [cited 24 March 2020]. [https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200306-sitrep-46-covid-19.pdf?sfvrsn=96b04adf\\_2](https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200306-sitrep-46-covid-19.pdf?sfvrsn=96b04adf_2)

<sup>2</sup> Center for Health Security, Ventilator Stockpiling and Availability in the US, Bloomberg School of Public Health, Johns Hopkins University, 14 February 2020 [cited 24 March 2020]. <http://www.centerforhealthsecurity.org/resources/COVID-19/200214-VentilatorAvailability-factsheet.pdf>

<sup>3</sup> United States Resource Availability for COVID-19, Society of Critical Care Medicine, 19 March 2020 [cited 24 March 2020]. [https://sccm.org/Blog/March-2020/United-States-Resource-Availability-for-COVID-19?\\_zs=jxpid1&\\_zl=w9pb6](https://sccm.org/Blog/March-2020/United-States-Resource-Availability-for-COVID-19?_zs=jxpid1&_zl=w9pb6)

<sup>4</sup> Gompertz S, Carr E. Coronavirus: Plan to ramp up ventilator production 'unrealistic.' BBC News [Internet], 16 March 2020 [accessed 26 March 2020]. <https://www.bbc.com/news/business-51914490>

<sup>5</sup> Hurtado C, Ventilator Stockpiling and Availability in the US and Internationally, Johns Hopkins Center for Health Security, 3 May 2018 [cited 20 March 2020]. [http://www.centerforhealthsecurity.org/our-work/events/2018\\_clade\\_x\\_exercise/pdfs/Clade-X-ventilator-availability-fact-sheet.pdf](http://www.centerforhealthsecurity.org/our-work/events/2018_clade_x_exercise/pdfs/Clade-X-ventilator-availability-fact-sheet.pdf)

production of rudimentary, low-cost ventilators. However, these efforts are currently uncoordinated and unregulated, which will result in duplication of efforts, competition for limited supply of parts, and unnecessary bottlenecks in regulatory systems to approve new devices for mass production. The inefficiency of this process will increase deaths due to the delay in deployment.

The authors of this document represent a diverse multidisciplinary group of individuals and organizations, including clinicians, ethicists, researchers, health economists, and product developers, who are experienced in socially responsible collaboration to address urgent real-world problems. The need for easily produced, reliable, low-cost mechanical ventilators has long been recognized. While the technology currently exists, a significant number of development challenges will need to be overcome and key pitfalls avoided to meet this time-critical challenge. Clinical safety and effectiveness is paramount. Design simplicity is also essential to avoid failure and obsolescence. Production that is possible across a multiplicity of manufacturers will assure scalability and access. The cost per unit must be affordable and justified.

Meeting the current and imminent need for life-saving ventilators is a complex problem requiring a coordinated effort between stakeholders and across sectors, including clinical medicine, engineering, design, manufacturing, government regulation, and product innovation. This will require a system-level strategy based on evidence, consensus, expert knowledge, and a spirit of cooperation that addresses system-level complexities, as well as suspending intellectual property and granting zero-dollar temporary licensing to expedite the production of life-saving ventilation equipment.

Our aim in developing these white paper recommendations is to guide responding agencies and actors to come together now to solve the current global crisis of mechanical ventilator shortage. We believe our recommendations point to the shortest path to saving the most number of lives. We envision this white paper to act as a living document that will continue to be edited, strengthened, and guided by various stakeholders as we all respond to this COVID-19 pandemic and prepare for future public health crises we will likely face.

## 2. Recommendations

Adhering to the principles of avoiding harm, we recommend the following strategic responses to the current global ventilator shortage:

- 1) Engage organizations, stakeholders, sectors, and industries in a spirit of international open-source collaboration in order to ensure safety, transparency, efficiency, and equity of access.
- 2) Establish evidence-based clinical standards for intubated COVID-19 patients that specify minimum and preferred ventilation capacity for patient transport, bridge to care, and intensive care. Only a fully capable ventilator, with advanced pressure and volume controls, and industry standard infection controls should be used for patients affected by the most serious forms of COVID-19 lung injury.
- 3) Redirect non-critical use of fully capable ventilators toward patients with serious forms of COVID-19 lung injury. There are ventilators already in use and that are COVID-19-capable within many hospitals and health systems. A significant percentage of these are being used on patients only requiring lower-capability ventilators for non-COVID-19 related procedures and illnesses
- 4) Increase global production of existing models of ventilators by medical device manufacturing companies. This priority strategy ensures reliable, safe, known devices to be produced quickly. The implementation strategy should be multi-pronged, including government incentives, purchase of surge supply, and shared manufacturing resources, in order to support and encourage existing ventilator manufacturers.
- 5) Engage manufacturers of other industries to work with regulated medical device manufacturing companies that produce medical ventilators to produce necessary parts. This would work well with automotive manufacturers that work under their own quality systems. Efforts from medical device manufacturers or compliance testing agencies to develop rapid verification and validation testing should be encouraged.
- 6) Engage in the spirit of open-source collaboration with organizations and manufacturers to develop new ventilators aimed at addressing the cost and clinical expertise gaps.
- 7) Accelerate the production of two classes of ventilators along a tiered basis. Design should incorporate readily fabricated component parts amenable to local production as proximal as possible to inventory to minimize servicing turn-around intervals and mitigate supply chain interruptions. We suggest two classes of ventilator designs:



- Rapidly-producible high-acuity limited-operability (HALO) class of ventilators capable of delivering automated volume and pressure cycled positive pressure ventilation, with or without enriched oxygen. Integrated safety triggers for pressures, disconnect with alarms are at minimum mandatory. HALO ventilators may be quickly distributed to populations with immediate and imminent need. Design for safe operability, particularly in low- and middle-income countries with limited training and experience in operating and servicing sophisticated devices due to historical access limitations. HALO ventilators can be transport-adapted and serve a rescue function and bridge to more complex ventilator support if needed. Final requirements for HALO class ventilator could mimic current Transport Ventilator guidance as a first approximation, but further definitive guides should be rapidly formalized and published. Low cost production, and safety are primary design points, and full regulatory compliance is mandatory.
- Mass-producible cost-contained higher-end multi-mode ventilators able to augment modern ICU capacity for respiratory support on a temporary and scalable basis. These devices would fill current cost and operability gaps left by existing ventilator designs. They should offer added functionality over HALO devices, including graphic display, spontaneous breathing support, reduced work of breathing strategies, and advanced ventilatory control modes suitable for COVID-19 lung injury. These interfaces should be designed to expedite training for faster uptake of the ventilators in a broader range of health care facilities and may expand use-cases in low- and middle-income contexts where previously there were none available. Standardized manufacturing with readily producible components will help ensure universal usability and simplified servicing. For more detailed specifications of a fully capable, high-capacity ventilator, see the [U.K. Department of Social and Health Care guidelines](#) for rapidly manufactured, COVID-capable ventilators.

We suggest early guiding thinking around new designs using the following checklist:

- What clinical indications are you using this for? [user needs]
- What does your device need to do to meet these indications? [requirements]
- What is your device capable of? [specifications]
- Does your device work? [verification]
- Can healthcare providers use it to treat patients? [validation]

Expert input for each of these steps should be sought by designers. Risk assessments on design and manufacturing processes need to be performed and documented.

Guidelines for conducting these steps to comply with local and global regulatory standards need to be developed and made available globally and for free with associated training. For devices provided by non-standard manufacturers, the manufacturers must provide enough information and labeling to allow medical professionals to assess the risks associated with rapidly manufactured mechanical ventilators. This includes a list of risks and benefits associated with the use of the

unlicensed device, how the benefits obtained would outweigh the risks, and a summary of known safety and effectiveness information in respect of the device (see ECRI Institute's guidance on [Minimum Requirements for Ventilator Testing](#)). These steps are important as they speak to the issues of liability, ability of healthcare facilities to adopt new technologies and reporting and handling of adverse events.

- 8) Engage private-sector firms to innovate solutions, mobilize resources, and facilitate production global distribution, training and support.
- 9) Streamline internationally compatible regulatory and licensing processes to fast-track manufacturing and distribution of mass produced ventilators, while ensuring basic regulatory requirements are met to ensure that ventilators are safe, reliable, and serviceable. Many regulatory bodies are now starting to produce documents outlining expedited processes, and these should be reviewed early by any organization designing new ventilators.
- 10) Provide simple just-in-time training with cross-cultural language support for health care providers and equipment managers to ensure ready usability, maintenance and repair of any devices.

### 3. Discussion

Worldwide, COVID-19 has shown an alarmingly rapid increase in new cases daily, taking just three months to reach 100,000 confirmed cases and only twelve days to reach the subsequent 100,000.<sup>6</sup> Early evidence shows 5-10% of cases develop severe lung deficiencies and require critical care with mechanical ventilation.<sup>7,8,9,10</sup> Experiences in China show, despite urgent mobilization of critical care resources, only 25% of patients who died from COVID-19 had received mechanical ventilation.<sup>11</sup>

Italy can be seen as an example of COVID-19 entering into a healthcare system in a high-income setting. Italy is highly-resourced, with 3.2 hospital beds per 1000 individuals (compared to 2.8/1000 in the US),<sup>12</sup> and had implemented public health measures to assuage the outbreak. Yet, within the first two weeks, 10% of COVID-19 patients required intensive care treatment with assisted ventilation.<sup>7</sup> Early in the epidemic, Italian authorities requested 4,000 ventilators and were only able to receive one tenth of that number from one company.<sup>13</sup> The country's Intensive Care College issued a statement to triage limited ventilator resources to those who stand to benefit most and have the greatest chance of surviving.<sup>7</sup> Healthcare professionals in Italy face a horrifying reality of having to decide who receives life-saving ventilation and who does not, with one hospitals having to lower the age cutoff from 80 to 75 years.<sup>14</sup>

---

<sup>6</sup> World Health Organization. Coronavirus disease (COVID-2019) situation reports.

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports> (accessed March 22, 2020)

<sup>7</sup> Guan W-J, Ni Z-Y, Hu Y, Liang W-H, Ou C-Q, He J-X, et al. Clinical Characteristics of Coronavirus Disease 2019 in China. *N Engl J Med*. 2020 Feb 28.

<sup>8</sup> Cao B, Wang Y, Wen D, Liu W, Wang J, Fan G, et al. A Trial of Lopinavir-Ritonavir in Adults Hospitalized with Severe Covid-19. *N Engl J Med*. 2020 Mar 18.

<sup>9</sup> Yang X, Yu Y, Xu J, Shu H, Xia J, Liu H, et al. Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study. *The Lancet Respiratory Medicine* [Internet]. 2020 Feb 24 [cited 2020 Mar 24]. Available from:

[https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30079-5/abstract](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30079-5/abstract)

<sup>10</sup> Vergano M, Bertolini G, Giannini A, Grstina G, Livigni S, Mistraletti G, et al. (2020). SIAARTI - Clinical Ethics Recommendations for the Allocation of Intensive Care Treatments in exceptional, resource-limited circumstances - Version n. 1. 16 March 2020.

<http://www.siaarti.it/SiteAssets/News/COVID19%20-%20documenti%20SIAARTI/SIAARTI%20-%20Covid-19%20-%20Clinical%20Ethics%20Reccomendations.pdf>

<sup>11</sup> Li R, Rivers C, Tan Q, Murray MB, Toner E, Lipsitch M. The demand for inpatient and ICU beds for COVID-19 in the US: lessons from Chinese cities. *medRxiv*. 2020 Mar 16 [preprint].

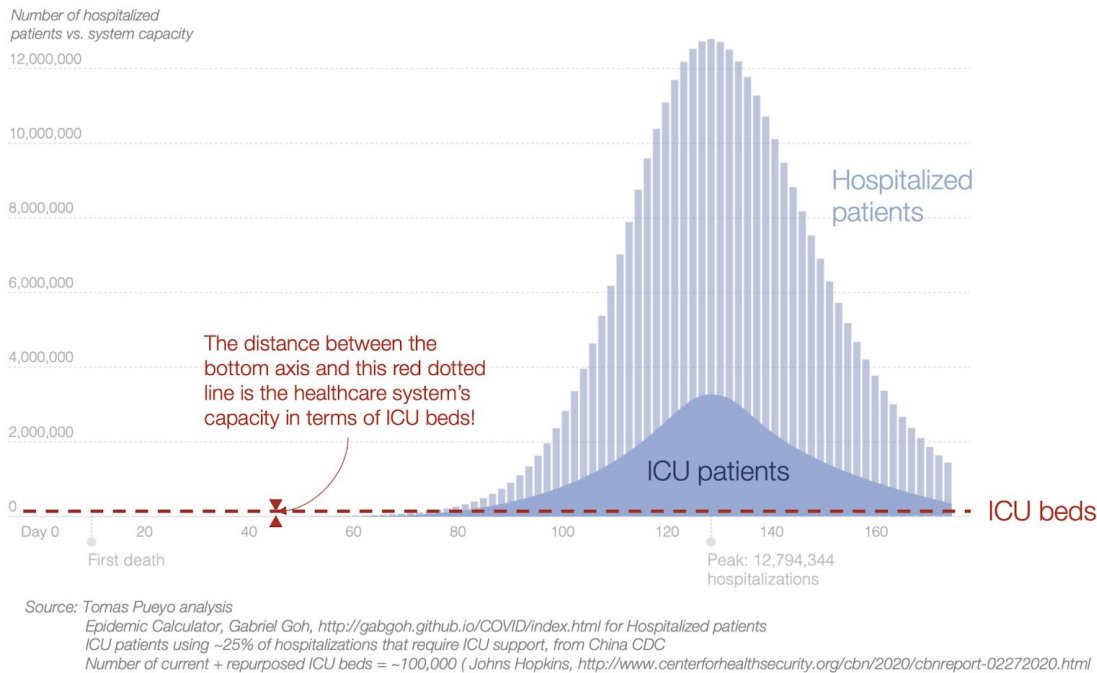
<sup>12</sup> Fowler RA, Abdelmalik P, Wood G, Foster D, Gibney N, Bandrauk N, et al. Critical care capacity in Canada: results of a national cross-sectional study. *Crit Care*. 2015 Apr 1;19:133.

<sup>13</sup> Kliff S, Satariano A, Silver-Greenberg J, Kulish N. There Aren't Enough Ventilators to Cope With the Coronavirus. *The New York Times* [Internet]. 2020 Mar 18 [cited 2020 Mar 20]; Available from:

<https://www.nytimes.com/2020/03/18/business/coronavirus-ventilator-shortage.html>

<sup>14</sup> Rosenbaum L. Facing Covid-19 in Italy — Ethics, Logistics, and Therapeutics on the Epidemic's Front Line. *New England Journal of Medicine*. 2020 Mar 18;0(0):null.

**Figure 1.** Number of hospitalized patients vs. system capacity in the U.S.<sup>15</sup>



Projections using public health mathematical models show intensive care requirements will exceed 8-fold current capacity in the U.S. and the U.K., even with aggressive public health measures and conservative estimates of infection rates (see also Figure 1).<sup>16</sup> The surge capacity will likely be lower in low- and middle-income settings where health care resources are already at low capacity.

According to a model projection published in Bloomberg, a global pandemic of COVID-19 could lead to an estimated \$2.7 trillion in global loss of output and zero growth in the global economy for 2020.<sup>17</sup>

The problems are challenging, complex, and multifactorial, and they are now well and truly upon us. The best solutions now are not what were suggested even just five years ago. To understand the current problem, it will be useful to briefly summarize the public health, clinical capacity, ethical, technological, regulatory, manufacturing, and health economic context in which we find ourselves. These considerations will then lead to a set of suggestions for how to

<sup>15</sup> Pueyo T. Coronavirus: The Hammer and the Dance. Medium, 19 March 2020 [accessed 25 March 2020]. <https://medium.com/@tomaspueyo/coronavirus-the-hammer-and-the-dance-be9337092b56>

<sup>16</sup> Ferguson NM, Laydon D, Nedjati-Gilani G, Imai N, Ainslie K, Baguelin M, et al. Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand. London Imperial College, Medical Research Council, 16 March 2020. DOI: <https://doi.org/10.25561/77482>

<sup>17</sup> Orlik T, Rush J, Cousin M, Hong J. Coronavirus Could Cost the Global Economy \$2.7 Trillion. Here's How. Bloomberg, 6 March 2020. Accessed: <https://www.bloomberg.com/graphics/2020-coronavirus-pandemic-global-economic-risk/>

proceed from here collectively and collaboratively. This document, either during or after the pandemic subsides, could form the basis for a multidisciplinary, comprehensive discussion on how to respond for the inevitable future respiratory pandemics to come, and to the chronic global inequity in ventilator access.

## A. Public health considerations

Effective preparedness planning and whole system adaptability are key in the management of a public health emergency (PHE). This is especially invaluable in an infectious disease pandemic where events play out over weeks to months. The current pandemic is preceded by Severe Acute Respiratory Syndrome (SARS) in 2003 and the Influenza outbreaks of 1918, 1957, and 1968, as well the 2009 influenza A (H1N1), all of which have produced analyses that have been acted upon. While the virulence, transmission, and pathogenicity of this current COVID-19 virus pandemic are startlingly different from the previous influenza outbreaks, there are many lessons to be applied with respect to a ventilator response.<sup>18</sup>

The US Centers for Disease Control and Prevention (CDC) and the US Department of Health and Human Safety developed a framework of how existing ventilator supplies could be managed and deployed during a large-scale crisis, such as an influenza pandemic. A key feature of this model is the differentiation between phases of response: conventional, contingency, and crisis, ranging from business as usual to a PHE.<sup>19</sup> This U.S.-based model demonstrates the number of additional patients who could be ventilated at each phase of response: 8,200-16,400 patients at conventional capacity (using approximately 82,000 critical care beds available), 26,000-52,400 at contingency capacity (using approximately 260,000 intermediate care beds available), and 88,600-177,300 at crisis capacity (using approximately 886,000 general ward beds available) (Table 1).<sup>16</sup>

**Table 1.** Number of additionally mechanically ventilated patients that can be treated at the peak of an influenza epidemic (adapted from Ajao et al., 2015)

Response Level	Type of Hospital Beds	Total # in U.S.	% bed availability	# of patients treatable
Conventional	Intensive and critical care bed (adult & pediatric)	81,790	10%	8,179
			20%	16,358
Contingency	Intensive and critical care bed (adult &	261,790	10%	26,179

<sup>18</sup>Phua G-C, Govert J. Mechanical Ventilation in an Airborne Epidemic. Clinics in Chest Medicine. 2008 Jun 1;29(2):323–8.

<sup>19</sup> Ajao A, Nystrom SV, Koonin LM, Patel A, Howell DR, Baccam P, et al. Assessing the capacity of the healthcare system to use additional mechanical ventilators during a large-scale public health emergency (PHE). Disaster Med Public Health Prep. 2015 Dec;9(6):634–41.

	pediatric) and intermediate care beds (step-down, post-operative, emergency care)		20%	52,358
Crisis	Intensive and critical care bed (adult & pediatric) and intermediate care beds (step-down, post-operative, emergency care), general ward beds	886,262	10%	88,626
			20%	177,252

Modeling for large scale PHEs like an influenza pandemic that would generate overwhelming demand for mechanical ventilators underscores the need for a multi-faceted and tiered response.<sup>16,20</sup> Unlike planning for conventional surge capacity (which places mild demand on existing infrastructure without requiring reconfiguration) or contingency planning (which sees expanded capacity exploiting existing adjacencies), crisis planning requires bold, innovative strategies to drastically extend available resources and capabilities without provoking excessive reduction in care standards, particularly with regard to safety. This is first and foremost applicable to ensuring sufficient availability of mechanical ventilators.

Based on 2015 estimates of mechanical ventilators in use across the U.S., it was estimated that hospitals can absorb 26,200-56,300 additional ventilators during an influenza epidemic.<sup>16</sup> The U.S. federal government supports maximum surge capability of each component by stockpiling supplies and equipment (including ventilators), planning distribution methods, supporting industry upscaled production, and determining projections on manufacturing surge capacity.<sup>21</sup> Models suggest that in a severe pandemic (such as the 1918 influenza outbreak), the U.S. stockpiles could fall short. A 2017 article indicated that there were approximately 8,900 ventilators in America’s “Strategic National Stockpile” (4,400 in 2002 and 4,500 added in 2009 and 2010),<sup>22</sup> with many likely to be simpler versions suitable only for more stable patients or for providing basic functions in an emergency.<sup>19,23</sup>

The need for crisis-level response must be anticipated with the present COVID-19 pandemic. This definitionally implies a fundamental systemic change in which care standards will be significantly altered to accommodate treatment of the greatest number of patients.<sup>16</sup> There are four components to a crisis response that all require successful strategic management to optimize outcomes: equipment, space, staff, and systems for decision-making and resource allocation.<sup>16,18,24</sup> While, as discussed, ventilator supply is a crucial and a major threat in the

<sup>20</sup> Corcoran SP, Niven AS, Reese JM. Critical care management of major disasters: a practical guide to disaster preparation in the intensive care unit. *J Intensive Care Med.* 2012 Feb;27(1):3–10.

<sup>21</sup> Zaza S, Koonin LM, Ajao A, Nystrom SV, Branson R, Patel A, et al. A Conceptual Framework for Allocation of Federally Stockpiled Ventilators During Large-Scale Public Health Emergencies. *Health Secur.* 2016 Feb;14(1):1–6.

<sup>22</sup> Huang H-C, Araz OM, Morton DP, Johnson GP, Damien P, Clements B, et al. Stockpiling Ventilators for Influenza Pandemics. *Emerg Infect Dis.* 2017 Jun;23(6):914–21.

<sup>23</sup> Meltzer MI, Patel A. Stockpiling Ventilators for Influenza Pandemics. *Emerg Infect Dis.* 2017 Jun;23(6):1021–2.

<sup>24</sup> Institute of Medicine (US) Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations. *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report* [Internet]. Altevogt BM, Stroud C, Hanson SL, Hanfling D, Gostin LO, editors. Washington (DC): National Academies Press (US); 2009 [cited 2020 Mar 24]. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK219958/>

current COVID-19 situation, a parallel supply of upscaled clinical personnel with sufficient space, tools, skills, and system support is required to deploy a comprehensive intensive care.

## B. Clinical capacity considerations

The U.S. Society of Critical Care Medicine Ventilator Task Force has estimated that 20% of the 160,000 ventilators currently available in the U.S. under extreme circumstance will be unused due to shortfalls in skilled staff, a proportion of which will be eliminated as the medical workforce becomes afflicted itself.<sup>25</sup> Competent staffing with effective oversight is thus a genuine concern, without which an increase in physical critical care resources will be ineffective, if not harmful. With the estimated U.S. need for performing mechanical ventilation on nearly 1,000,000 patients in a major epidemic, mass production of these devices requires a concurrent clinical strategy to support their use in an excessive number of critically ill patients.

Mechanical ventilation is virtually the sine qua non of intensive care medicine. These devices are one component of a whole care delivery bundle incorporating specialty qualified physicians, nurses, respiratory therapists, pharmacists and other health and service professionals employing an array of physiologic support and monitoring, laboratory and imaging diagnostics, and pharmacological therapeutics. In conventional and contingency response modes of increased patient demand, these necessary adjuncts are generally adequately provided in advanced health systems.

In crisis mode, extraordinary system-level adaptive strategies in intensive care are crucial, particularly for providing the manpower and skills required to assure a minimum level of advanced care. Without this, a full supply of stockpiled mechanical ventilators will still be unusable. The principles of Emergency Mass Critical Care (EMCC) response are called into play.<sup>26</sup> This mandates that contingencies be in place for facility expansion, supply management, staffing augmentation with training and supervisory support, resource triage, ethical care rationing, and the provision of palliative care. The assurance of adequate clinical expertise goes hand in hand with site and system management. Sound clinical decision making must be applied in the implementation of triage rules that marshal appropriate patients from the community, through acute care facilities and to bedside care. Deficiencies here will overrun the expanded system and culminate in significant preventable mortality.<sup>27</sup>

---

<sup>25</sup> Halpern NA, Tan KS, Society of Critical Care Medicine Taskforce. U.S. ICU Resource Availability for COVID-19, Version 2. Society of Critical Care Medicine, 25 March 2020 [accessed 25 March 2020]. <https://sccm.org/Blog/March-2020/United-States-Resource-Availability-for-COVID-19>

<sup>26</sup> Devereaux A, Christian MD, Dichter JR, Geiling JA, Rubinson L; Task Force for Mass Critical Care. Summary of suggestions from the Task Force for Mass Critical Care summit, January 26-27, 2007. *Chest*. 2008;133(5 Suppl):1S-7S. doi:10.1378/chest.08-0649

<sup>27</sup> Subbarao I, Bostick NA, Burkle FM, Hsu EB, Armstrong JH, James JJ. Re-Envisioning Mass Critical Care Triage as a Systemic Multitiered Process. *CHEST*. 2009 Apr 1;135(4):1108.

It has been estimated that the U.S. has fewer than 30,000 certified intensive care specialists, far short of the number required to manage a major respiratory infection epidemic, and there exists a similar shortage in nurses and technicians.<sup>22</sup> The deficit of qualified clinicians would be orders of magnitude worse in low- and middle-income countries.

Any plan to expand clinical capacity in a pandemic by the stockpiling or up-scaled manufacture of physical resources such as ventilators must be paired with a clinical implementation strategy to assure competent clinical care through training, safety, quality assurance, and oversight. Manufacturers of surge response ventilators must fully anticipate this requirement and design mitigation strategies into the devices produced. New models will need to be user friendly and supplemented with instructions and training modules that are quick and accessible for frontline providers who are already working beyond capacity. Further, there are entire health regions and countries that have never had access to or have used a ventilator. Even in high-income countries, rural and remote regions may not have an ICU but will need to ventilate patients. Clinicians in these settings may not have seen a modern ventilator or be familiar with current evidence-based critical care guidelines, even if they were trained in ICUs previously. As such, developers will need to work closely with clinicians to ensure that the end product is both usable and acceptable for end-users.

## C. Ethical considerations

The provision of health care in most international systems is centered on the goals of maintaining patients' right to self-determination and maximizing benefit to the individual patient. Much of the care during critical illness is preference-sensitive, or based on patients' own values and goals.<sup>28</sup> How an individual patient defines acceptable and unacceptable outcomes, tolerates risk, and conceptualizes meaningful quality of life determines the care that a patient should receive within the limits of medical appropriateness. Therefore, the goal of critical care is to rescue and restore through the provision of goal-concordant care. Shortages in available resources during a pandemic undermines the very basis of these ethical systems. Instead, the ethical framework used during scarcity maximizes societal benefit over self-determination and individual benefit.<sup>29</sup>

The first principle of allocation of scarce resources is to avoid scarcity whenever possible. Reliance on allocation systems, even when thoughtful and representing broad views, degrades public trust in health care systems and clinicians, creates moral distress for clinicians, and may worsen or institutionalize existing disparities.<sup>30,31</sup> Therefore, the first ethical obligation of

---

<sup>28</sup> Turnbull AE, Sahetya SK, Needham DM. Aligning critical care interventions with patient goals: A modified Delphi study. *Heart Lung*. 2016 Dec;45(6):517–24.

<sup>29</sup> Ozge Karadag C, Kerim Hakan A. Ethical Dilemmas in Disaster Medicine. *Iran Red Crescent Med J*. 2012 Oct;14(10):602–12.

<sup>30</sup> Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, et al. Fair Allocation of Scarce Medical Resources in the Time of Covid-19. *N Engl J Med*. 2020 Mar 23; DOI: 10.1056/NEJMs200511.



governmental and health systems when facing a pandemic is to provide sufficient resources to meet the demand when possible.<sup>32</sup>

Rapidly expanding capacity may also carry ethical concerns if that increased capacity does not provide a minimum standard of care. Expanding critical care capacity, given its complexity and multidisciplinary care context, requires increasing resources consisting of materials, space, and expert clinicians. Providing one component without sufficient support for other necessary components will lead to substandard and potentially harmful care. Therefore, design and implementation of novel technologies and equipment to expand material capacity in times of scarcity should also expand rather than decrease or place additional demands on existing available expertise. These materials should also be designed with space and other physical considerations so as not to worsen existing strain or scarcity in those domains. For example, mechanical ventilators deployed to expand capacity could use default options and settings based on evidence-based ventilatory strategies, such as lung-protective ventilation.<sup>33,34</sup> Thus, inexperienced or over-extended clinicians would be more likely to provide care that meets the standard of care.

Deploying or rapidly implementing novel or experimental treatments and technologies can be one component of mitigating a public health crisis. However, this rapid deployment often necessitates bypassing or speeding typical research, quality, and safety regulatory mechanisms.<sup>35</sup> The reason these regulatory processes exist is to ensure the reliability of a treatment or device, but more importantly, reduce or prevent harm to patients and other users. Therefore, an inherent tension exists between the benefit of rapid deployment and the potential for harm due to unknown or unclear risks of use. Use of new technologies without regulatory oversight becomes particularly appealing in times of scarcity with a high risk of morbidity. Often processes for providing such newly developed technologies or treatments for compassionate use are done on an individual basis, rather than at the population level. During a pandemic response, this instead occurs on a population level, thus reducing the ethical justification for compassionate use based on self-determination.<sup>36</sup>

Steps can be taken to mitigate the risk an individual patient assumes as a result of this population-based strategy. First, notifying patients or their legal decision makers of the state of the technology being used, and that safety and efficacy may be unknown, is important to protect

---

<sup>31</sup> Truog RD, Mitchell C, Daley GQ. The Toughest Triage — Allocating Ventilators in a Pandemic. *New England Journal of Medicine*. 2020 Mar 23;0(0):null.

<sup>32</sup> Papadimos TJ, Marcolini EG, Hadian M, Hardart GE, Ward N, Levy MM, et al. Ethics of Outbreaks Position Statement. Part 1: Therapies, Treatment Limitations, and Duty to Treat. Read Online: *Critical Care Medicine | Society of Critical Care Medicine*. 2018 Nov;46(11):1842–1855.

<sup>33</sup> Mehta M, Veith J, Szymanski S, Madden V, Hart JL, Kerlin MP. Clinicians' Perceptions of Behavioral Economic Strategies to Increase the Use of Lung-Protective Ventilation. *Ann Am Thorac Soc*. 2019 Dec;16(12):1543–9.

<sup>34</sup> Halpern SD. Using Default Options and Other Nudges to Improve Critical Care. *Crit Care Med*. 2018 Mar;46(3):460–4.

<sup>35</sup> Caplan AL, Ray A. The Ethical Challenges of Compassionate Use. *JAMA*. 2016 Mar 8;315(10):979–80.

<sup>36</sup> Walker MJ, Rogers WA, Entwistle V. Ethical Justifications for Access to Unapproved Medical Interventions: An Argument for (Limited) Patient Obligations. *The American Journal of Bioethics*. 2014 Nov 2;14(11):3–15.

self-determination. Second, establishing monitoring systems for adverse events and patient outcomes should be in place prior to deploying new technologies or equipment to enable concurrent safety reviews and risk mitigation strategies. Third, the use of novel technologies should be deployed in a manner that promotes justice within a particular society. For example, use of a new mechanical ventilator that had bypassed typical regulatory processes primarily in low-income communities or among incarcerated individuals would be ethically unjustifiable during a pandemic. Ventilator allocation should instead be equitable across communities and populations based on need rather than pre-existing resources.<sup>37,38</sup> Fourth, manufacturers and developers should recognize their inherent conflict of interest and not use a pressing societal need to bypass appropriate safety and regulatory steps, nor should they promote technologies or treatments known to be unsafe to the general public to increase demand for their product.

## D. Technical considerations

Modern mechanical ventilators are costly, sophisticated machines that require complex maintenance and skilled physicians and/or competent respiratory therapists to operate them. There has been long-standing interest in the production of simpler ventilatory support devices suitable for regular use in low-resource settings and to periodically augment capacity in well-resourced settings. The design and manufacture of safe, affordable, functional, reliable, and effective mechanical ventilation devices on a short timeline is achievable with strategic and committed collaboration.

These include simplifying current technology to deliver a minimal, but standardized set of functions, incorporating durable, accessible, and maintainable components, assuring safety and effectiveness in sustained clinical use, meeting regulatory standards, addressing licensing and liability, opening distribution networks, ensuring efficient just-in-time training, and doing all of this at low cost.

The basic necessities for a medical ventilator are:

1. A source of input energy to drive the device;
2. A means of converting input energy into output energy in the form of volume or pressure to create airflow and regulate the timing and size of breaths;
3. A means of monitoring the output performance of the device and the condition of the patient;<sup>39</sup>

---

<sup>37</sup> White DB. Allocation of Scarce Critical Care Resources During a Public Health Emergency. Department of Critical Care Medicine, University of Pittsburgh. 23 March 2020 [accessed 25 March 2020]. <https://pre.ccm.pitt.edu/content/ethics-and-decision-making-critical-illness>

<sup>38</sup> White DB, Katz MH, Luce JM, Lo B. Who Should Receive Life Support During a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions. *Ann Intern Med*. 2009 Jan 20;150(2):132–8.

<sup>39</sup> Chatburn RL, Mireles-Cabodevila E. Chapter 3. Basic Principles of Ventilator Design. In: Tobin MJ, editor. *Principles and Practice of Mechanical Ventilation* [Internet]. 3rd ed. New York, NY: The McGraw-Hill Companies; 2013 [cited 2020 Mar 25]. Available from: [accessmedicine.mhmedical.com/content.aspx?aid=57061171](https://accessmedicine.mhmedical.com/content.aspx?aid=57061171)

4. A reliable and titratable source of medical Oxygen (O<sub>2</sub>) that can generate sufficient flow to enable adequate ventilation requirements; and
5. Sufficient airflow system filtration to ensure protection from device contamination and safety for current and subsequent patient use.

A number of types of ventilators and ventilatory assist devices exist that range from extremely low performance and low-cost (manual resuscitators such as a bag valve mask) up to full-feature ventilators with costs ranging in the tens of thousands of dollars.<sup>40</sup> At the low-end of the spectrum are the purely pneumatic portable ventilators, with prices estimated to range from US\$700 to US\$1000; however, these require external pressurized air which may not be available in many low-resource settings. It should be made clear that none of these pneumatic ventilators will be capable, nor are they designed to be used for the stresses of ventilating COVID-19 patients with significant lung disease over an extended period of time, though there may be a limited, capacity-building role for these devices.

Current clinical experience shows that COVID-19 patients ventilation may not be the same as what is considered “classical” Acute Respiratory Distress Syndrome (ARDS), but there are similarities. For COVID-19 patients, ventilators need to be capable of generating at least moderate mean airway pressure to support breathing, have advanced functions to control for volume and to regulate/sense pressure, and ensure a titratable and controlled use of Positive End Expiratory Pressure (PEEP). The latter plays a particularly important part of the ventilation strategy. COVID-19 acute pulmonary presentations are characterised by significant and often profound and precipitous hypoxemia. As a consequence, any ventilator would require an adequate and reliable O<sub>2</sub> source that would ideally be titratable and, as a minimum standard, be able to deliver close to 100% fractional inspired oxygen (FiO<sub>2</sub>). Lastly, filtration systems applied to the ventilators would need to be able to adequately filter COVID-19 viral particles.

Many of the first prototype devices currently appearing on collaborative open-sourced forums are very rudimentary, and incapable of providing adequate ventilation for any patient except those who are healthy, totally sedated, or chemically paralyzed. To assist new ventilator makers, the U.K.’s Department of Health and Social Care (DHSC) published a set of guidelines for rapidly manufactured ventilator system specification.<sup>41</sup> These guidelines outline minimum and preferred specifications regarding ventilation, gas and electric supplies, infection control, monitoring and alarms, design, durability, and instructions. Further, the DHSC warns that “ventilators with lower specifications than this are likely to provide no clinical benefit and might lead to increased harm.”<sup>39</sup> Inadequate ventilation can result in death, or other complications, including brain hypoxia or anoxia, and ventilator induced lung injury (VILI), namely barotrauma,

---

<sup>40</sup> Al Hussein AM, Lee HJ, Negrete J, Powelson S, Servi A, Slocum A, et. al. Design and Prototyping of a Low-cost Portable Mechanical Ventilator. *J Med Devices*, 2010;4(2):027514. doi:10.1115/1.3442790

<sup>41</sup> Department of Health and Social Care. Guidance: Rapidly Manufactured Ventilator System Specification. 20 March 2020 [accessed 24 March 2020]. <https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification>

volutrauma, atelectrauma and biotrauma.<sup>42</sup> Insufficient design, including improper infection control and electrical or mechanical safety non-compliance, could potentially risk the lives of healthcare provider teams. While it is certainly possible to create new ventilator devices that can meet these necessities, the challenge of trying to compress what is typically years of design and testing into a timeline of weeks to months, seems an impossible challenge.

## E. Manufacturing considerations

Mechanical ventilators as currently used in modern intensive care units (ICUs) are sophisticated machines that are produced by medical device manufacturers. Total worldwide production capability is estimated at 40,000-50,000 units annually, with not all units being suitable for use in ICU patients.<sup>43</sup> The result has been a frenzied competition to acquire ventilators across the globe. Hospitals wishing to purchase new ventilators cannot find them, as manufacturers cannot produce them quickly enough to meet the escalating demand.<sup>44</sup> There is an intense pressure on manufacturers of existing models to expedite production, in some cases with pressure from governments to keep the products within the borders.<sup>33,45</sup>

The British government recently issued a plea to multiple manufacturers in other sectors, such as automobile and domestic appliances industries, to repurpose their production lines to the effort just as the automobile industry did in World War II to meet an overwhelming need for military aircraft.<sup>46,47</sup> Similarly, the U.S. government invoked the *Defense Production Act* to redirect auto manufacturers there to assist in the production of medical equipment such as ventilators.<sup>48</sup> Mechanical ventilators contain multiple carefully calibrated hardware and software components. Their complexity raises concerns whether non-medical manufacturers can quickly adapt their production lines and acquire technological know-how in time to produce these specialized machines.<sup>49</sup>

---

<sup>42</sup> Beitler JR, Malhotra A, Thompson BT. Ventilator-induced Lung Injury. Clin Chest Med. 2016 Dec;37(4):633–46.

<sup>43</sup> Chief Executive of Ventec Life Systems quoted in Baldwin W. Ventilator Maker: We Can Ramp Up Production Five-Fold. Forbes, 14 March 2020 [accessed 20 March 2020].  
<https://www.forbes.com/sites/baldwin/2020/03/14/ventilator-maker-we-can-ramp-up-production-five-fold/#cee81f45e9a5>

<sup>44</sup> Kliff S, Satariano A, Silver-Greenberg J, Kulish N. There Aren't Enough Ventilators to Cope With the Coronavirus. The New York Times [Internet]. 2020 Mar 18 [cited 2020 Mar 20]; Available from:  
<https://www.nytimes.com/2020/03/18/business/coronavirus-ventilator-shortage.html>

<sup>45</sup> Hong J, Lyu D. China's factories work 24/7 to build ventilators for Milan, New York. Bloomberg Business, 23 March 2020 [accessed 24 March 2020].

<https://www.bloomberg.com/news/articles/2020-03-23/china-s-factories-work-24-7-to-build-ventilators-for-milan-ny>

<sup>46</sup> Smith A. Coronavirus: Ventilator rush faces regulatory and logistical obstacles. NBC News, 17 March 2020 [accessed 21 March 2020].

<https://www.nbcnews.com/news/world/coronavirus-ventilator-rush-faces-regulatory-logistical-obstacles-n1161651>

<sup>47</sup> UK Manufacturers Use 3D-Printing to Aid Ventilator Production. Assembly, 20 March 2020 [accessed 21 March 2020]. <https://www.assemblymag.com/articles/95536-uk-manufacturers-use-3d-printing-to-aid-ventilator-production>

<sup>48</sup> Sanger D, Swanson A, Haberman M. Trump Bets Business Will Answer Call to Fight Virus, but Strategy Bewilder Firms. New York Times [Internet]. 22 March 2020 [23 March 2020].

<https://www.nytimes.com/2020/03/22/us/politics/coronavirus-trump-defense-production-act.html>

<sup>49</sup> Lee A. How does a car company make a ventilator? Wired, 19 March 2020 [accessed 21 March 2020].  
<https://www.wired.co.uk/article/car-manufacturers-ventilators>

Exacerbating the availability shortfall are interruptions in the supply chain. The multiple parts contained within each device, such as pressure generators, air flow regulators, sensors, filters, valves, and alarms, are manufactured and shipped from across the globe before they are assembled. Suppliers of parts, such as those located in China, are and will increasingly be affected by COVID-19 outbreaks within their borders, resulting in hindered manufacturing capacities and even factory closures.

If manufacturing capability is going to be brought in from other industries, such as the automotive sector, engagement must be led by existing ventilator companies who have the expertise to assess safety, and regulators, who are tasked with ensuring medical manufacturing compliance. Automotive manufacturers have a wealth of experience in producing products under quality systems, and should be viewed as capable parts providers to experienced ventilator companies, rather than attempting to turn professionals from other industries into medical designers overnight.

## F. Regulatory considerations

The rush to quickly produce new types of ventilators is likely to face regulatory challenges. Non-traditional manufacturers do not have licenses to manufacture medical devices, and it generally takes several months to years for a newly designed ventilator to meet regulatory criteria before they can be used in hospitals. Calling on non-medical device manufacturers to enter the medical device manufacturing arena is not likely to speed up the production of ventilators in time to meet the current and imminent demand.

As existing and new manufacturers of medical devices rush to develop next generation ventilator prototypes, regulatory systems will be overburdened. In Canada, medical devices are classified by risk, whereby Class I represents lowest-risk devices and Class IV represents highest-risk devices. Ventilators are classified as a Class III medical device and are required to meet ISO 13485:2016 standards in design and manufacturing, as well as demonstrate safety and effectiveness through clinical studies.<sup>50</sup> The U.S. Food and Drug Agency (FDA) requires similar criteria<sup>51</sup> be met for the approval of devices such as ventilators.

It is important to note that a change to a device, such as developing a new critical part (e.g. rapid prototyping valves), would normally require regulatory approval. Ventilators produced outside of the standard approval path must be assumed to be a custom-made device, which in

---

<sup>50</sup> Government of Canada. Medical Devices Regulations. Justice Laws Website, 16 December 2019 [accessed 21 March 2020]. <https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-3.html#h-1021513>

<sup>51</sup> A key difference in the FDA requirement is that the manufacturer must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent (see Overview of Device Regulation by the FDA, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation#510k>).

Canada, for example, could be regulated under the Special Access Program. This program allows access to devices that have not been approved for sale in Canada, based on need, and absence of a viable alternative.<sup>52</sup> It is the responsibility of the health care professional to request access for use of special access devices.<sup>53</sup> In the U.S., devices can be used under the Emergency Use provision if there are no viable alternatives.<sup>54</sup> Many other regions and countries have similar regulatory concessions, but this still leaves the medical professional in the position of having to request a medical device, and provide enough information to facilitate its evaluation by regulatory authorities.

In response to COVID-19, regulatory bodies in Canada and the U.S. have made key changes to their regulatory approval pathways. Health Canada recently released a statement stating that it will expedite the review and issuance of Medical Device Establishment Licenses (MDELs) for companies requesting to manufacture, import, or distribute personal protective equipment and other Class I devices.<sup>55</sup> On March 18th, the federal Minister of Health issued an Interim Order for Health Canada to expedite access to COVID-19-related medical devices by healthcare providers, including new diagnostic test kits, via quicker and more flexible approval process.<sup>56</sup> This order eliminates the need for ISO 13485 quality system certification upon application, and makes licensing fees free of charge. In the U.S., the Secretary of the Department of Health and Human Services determined that there is a significant potential for COVID-19 to affect the health and security of U.S. citizens. Based on this, the Secretary declared that circumstances exist justifying authorization of PPE's and diagnostic devices during the COVID-19 outbreak under FDA's Emergency Use Authorization (EUA) program.<sup>57</sup> Since then, the FDA has already issued EUA's for more than 10 point-of-care COVID-19 diagnostic tests and one disposable facepiece respirator.<sup>58</sup>

---

<sup>52</sup> Health Canada. Medical Devices - Special Access Programme. Government of Canada, 10 March 2020 [accessed 25 March 2020].

<https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/medical-devices.html>

<sup>53</sup> Health Canada. Guidance for Health Care Professionals on Special Access and Custom-Made Medical Devices, Medical Devices - Special Access Programme. Government of Canada, 18 February 2016 [accessed 25 March 2020].

<https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/medical-devices/guidance-health-care-professionals-special-access-custom-made.html#a212>

<sup>54</sup> U.S. Food and Drug Administration. Expanded Access for Medical Devices, 21 June 2019 [accessed 25 March 2020].

<https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#emergency>

<sup>55</sup> Health Canada. Expedited access to disinfectants, hand sanitizers and personal protective equipment to help limit the spread of COVID-19, as well as swabs for testing. Government of Canada, 18 March 2020 [accessed 25 March 2020]. <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72623a-eng.php>

<sup>56</sup> Health Canada. Notice: Expedited Review of Health Product Submissions and Applications to address COVID-19. Government of Canada, 18 March 2020 [accessed 20 March 2020].

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-expedited-review-health-products-covid-19.html>

<sup>57</sup> U.S. Food and Drug Administration. Emergency Use Authorizations, 24 March 2020 [accessed 25 March 2020].

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>

<sup>58</sup> U.S. Food and Drug Administration. Emergency Use Authorization, 23 March 2020 [accessed 25 March 2020].

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>

## G. Health economics considerations

Not only do modern ventilators take time to assemble and distribute and are subject to regulatory scrutiny, they are costly, placing many of these devices out of reach for middle-income settings and even high-income settings given the numbers required to meet the need. In low-income countries, the situation is even more dire, with some areas reporting a complete absence of mechanical ventilatory capabilities and a scarcity of trained staff.<sup>35,59</sup>

Even in well-resourced environments, many critical care units function at or near capacity.<sup>60,61</sup> As a result, there is a decreased ability to respond to mass casualty disasters, particularly pandemic scenarios such as COVID-19 with high ventilator requirements. Supply chains may also be disrupted in disaster settings, and the number of trained staff is also likely to be a limiting factor, particularly in an infectious disease outbreak that may impact the number of staff well enough to work.<sup>57</sup> Planning for these mass PHEs requiring ventilatory support has been hindered by a lack of knowledge on how many ventilators are available in a country, and whether or not sufficient surge capacity is available.<sup>62</sup> A 2010 study estimated 62,000 full-feature ventilators in the U.S. with an additional 99,000 other mechanical ventilation devices estimated at U.S. hospitals.<sup>58</sup>

The costs and maintenance of mechanical ventilators creates challenging dilemmas with regard to distribution for mass casualty planning. With typical costs in the range of US\$20,000 to US\$50,000 per unit,<sup>63</sup> (most hospitals and regional health authorities cannot afford to stockpile ventilators, even in high-income countries.<sup>18</sup> To address this and plan for pandemic or mass casualty scenarios, governments in high-income countries have created stockpiles of ventilators and associated supplies, such as Strategic National Stockpile (SNS) in the United States.<sup>19,20</sup> However, the central stockpiling also incurs costs to house, transport, and maintain ventilators. Concerningly, it is estimated that many of the stored ventilators are in fact unusable, having fallen into mechanical disarray.<sup>23</sup> However, challenging decisions must be made to estimate the number of ventilators that may be required in this stockpile and plans for managing the maintenance and distribution must be made.<sup>20</sup> Costs of a central stockpile of ventilators must

---

<sup>59</sup> Epiu I, Tindimwebwa JVB, Mijumbi C, Chokwe TM, Lugazia E, Ndarugirire F, et al. Challenges of Anesthesia in Low- and Middle-Income Countries: A Cross-Sectional Survey of Access to Safe Obstetric Anesthesia in East Africa. *Anesth Analg*. 2017 Jan;124(1):290–9.

<sup>60</sup> Hick JL, Rubinson L, O’Laughlin DT, Farmer JC. Clinical review: allocating ventilators during large-scale disasters--problems, planning, and process. *Crit Care*. 2007;11(3):217.

<sup>61</sup> Wunsch H, Wagner J, Herlim M, Chong DH, Kramer AA, Halpern SD. ICU occupancy and mechanical ventilator use in the United States. *Crit Care Med*. 2013 Dec;41(12):2712–9.

<sup>62</sup> Rubinson L, Vaughn F, Nelson S, Giordano S, Kallstrom T, Buckley T, et al. Mechanical ventilators in US acute care hospitals. *Disaster Med Public Health Prep*. 2010 Oct;4(3):199–206.

<sup>63</sup> Lee J. Soaring demand for ventilators creates political tension, promises to ramp up manufacturing. *Market Watch* [Internet], 25 March 2020 [accessed 26 March 2020]. <https://www.marketwatch.com/story/soaring-demand-for-ventilators-creates-political-tension-promises-to-ramp-up-manufacturing-2020-03-25>

also account for costs of maintenance, the physical space required to store them, and the transportation to sites in need.<sup>20</sup> The estimated cost to double the number of ventilators in the United States using inexpensive but functional equipment was estimated at US\$1 billion.<sup>64</sup>

When determining deployment of stockpiled ventilators or new purchases, health regions or countries must first determine the pre-existing ventilator resources in that region, and then develop a process for decision-making and funding for ventilators, training, maintenance, and supply parts.<sup>59</sup> Staff, supplies, and space must all be accounted for in a structured response plan,<sup>18</sup> including whether or not single or multiple brands or models of ventilators will be purchased or deployed, the required features of ventilators, gas sources, dependability of power sources and backup power sources, available ventilation modes, maintenance required, ancillary supplies needed (including tubing and circuits, suction catheters, humidification devices), and cost and performance comparisons of ventilators.<sup>59</sup>

Hospitals, then could purchase the remaining existing stocks of manufactured but warehoused ventilators from manufacturers. It is likely that only small numbers of ventilators were at the stage of being produced, but unsold in manufacturer warehouses. That aside, many hospitals are barely financially able to come up with the extra millions of dollars in their budget during a pandemic response to purchase ventilators. Subsequently, as the pandemic begins to subside, hospitals would be left with an expensive stockpile of aging ventilators, all requiring increasing maintenance as time goes on, with no guarantee they would be needed again within their usable lifetime.

It may seem attractive, then to rapidly create a new High-Acuity, Limited Operability (HALO) class of ventilator devices and deploy them into hospitals and health facilities. Many of the designs currently being created have, by necessity, very cheap, readily sourced parts. These units have a simplified and standardized design with widely sourceable and familiar producible components to ensure that the greatest therapeutic benefit will be realized in the shortest possible time and in the most sustainable manner. It is imperative that HALO ventilators are designed with early and continuous clinical insight and thoughtful post-production monitoring in an effort to optimize utility and limit harm.

The cheapest HALO class designs are estimated to range from US\$100 to \$400. While the economics of such a device seem obvious, there are many hidden costs and risks with pursuing this strategy. The first is that these devices are unlikely to be durable, long-term ventilators, given the nature of their frugal design and parts lists, resulting in the need to purchase many more than current predicted surge numbers. The second is that these devices are likely to only be minimally capable to treat patients with anything but healthy lungs. Many of these devices will lack any sophisticated control systems and provide only simple ventilation modes. They will require additional manual steps to minimize ventilator dyssynchrony and circuit disconnect or obstruction. Patients would need to be chemically sedated and possibly paralyzed to achieve

---

<sup>64</sup> Wilgis J. Strategies for providing mechanical ventilation in a mass casualty incident: distribution versus stockpiling. *Respir Care*. 2008 Jan;53(1):96–100; discussion 100-103.



adequate results, a process that requires significant medication stockpiles, monitoring and staffing. Finally, as multiple, peri-prototype devices are introduced into hospitals, an extensive education program would need to be concurrently introduced, and in-hospital testing required to validate device claims would add costs and time to actual use.

Alternatively, more expensive and more capable ventilators could be created by specialist teams of engineers and clinicians with the funding and support of regulators, funders, and manufacturers. A limiting trade-off is the time needed to create such a device. Likely, small- to medium- sized medical device companies already working on ventilators would be closest to being to provide these devices. Highly capable, specialized teams with the right partnerships could foreseeably meet the demand should this crisis extend into the upper range of estimated duration. The costs of these devices could certainly be an order of magnitude lower than existing ventilators, with some estimates coming in the US\$500 to \$1,500 range. These more complex devices would likely meet all of the published requirements for providing safe ventilation in COVID-19 patients, including ventilatory assist modes for conscious and semi-conscious patients, which would reduce the amount of staff and medications needed. These devices would come with more intuitive control interfaces, decreasing the operating education for simple modes of ventilation, and would allow clinically sophisticated strategies of lung protective ventilation, and prone positioning for secretion clearance.

Economic modelling can be used to answer crucial questions such as the following: how many ventilators will be required to fulfill the needs of all patients? What will be the impact of a shortage of ventilators, economically and on patient health? And what is the optimum strategy for the supply and delivery of new ventilators, including considerations of appropriateness and the clinical and economic consequences of different classes of ventilators (e.g., high vs. low capacity ventilators, with differing production, delivery, and storage costs)?

In order to inform the future need for ventilators as the disease progresses, an infectious disease model describing the contact between population groups that leads to infection must be used to accurately predict the future course of the COVID-19 epidemic. This model should be updated daily as the epidemic progresses and new data becomes available, as this approach can provide the best contemporary estimates of the future course of the disease. These future estimates should be combined with information about the current availability of ventilators, stratified by the types of ventilators available, and the types of patients that require ventilators, since the ventilator needs of non-COVID 19 patients will need to be factored into the analysis. These modelling approaches can then provide insights into the number of ventilators (by type) required over time, and the impact of a shortage of ventilators on patient health (morbidity and mortality).

The economic impact of the shortage of ventilators should also be assessed. In addition to the health-related costs associated with providing patients with sub-optimal treatment, societal costs due to the disease should also be considered, since it is likely that the costs of any intervention to supply ventilators will be incurred beyond the health care system.

The investigation of potential interventions to supply new ventilators should use a model that includes the manufacturing process, delivery of ventilators to patients, and resulting impact on patient health. This model should consider several aspects: the time to initiate and then undertake production, regulatory approval, and delivery of the devices, as well as the clinical capacity available to deliver ventilators to patients, and then the impact of the new ventilators on patient health and costs over time. Furthermore, this modelling of different types of ventilators suitable for COVID and non-COVID patients will enable interventions that incorporate simple low-cost production and the long-term storage maintenance of alternative ventilators to be considered. The analysis should be comparative, with alternative scenarios being compared to the current circumstances. From this analysis, informed decision making can be made about the optimum approach to the production, supply, and storage of ventilators.

Once a decision has been reached regarding the production of new ventilators, model outputs should continue to be updated as new data becomes available to ensure that any decision remains optimal in the face of new information regarding the ongoing need for ventilators. Furthermore, the ongoing results from this model can be used to assess the current value of other concurrent interventions, including social distancing, since as the number of available ventilators increases, the need to flatten the epidemic curve would be reduced.

## 4. Conclusion

We now are entering a new time when there is a democratization of medical device creation, coupled with advances in rapid prototyping, sharing of digital schematics, and the ability to almost instantly mobilize a massive, crowd-sourced effort. The traditional models of responding to these types of pandemics need to be changed to allow for this increasingly important way of mobilizing just-in-time production that also allows our responses to adapt to new and unexpected circumstances.

In the future, instead of warehouses full of dusty ventilators, a simple download from a curated library of disaster response devices and printing and assembly of a ventilator in the biomedical department of a hospital could be easily imagined to overcome the logistical and economic burden of maintaining physical stockpiles of ventilators and other devices. As the needs change, rapidly modified and validated upgrades, or even other devices from the digital catalogue, could be printed or produced to allow a fluid, scalable, and adaptive response to actual needs where the needs exist.

However, we are in a crisis now during this transition from old models of oligarchical medical device creation and directive government disaster response capabilities. Calls for stockpiling surge capacity ventilators were met with half-efforts. Incentivizing device manufacturers to release subsidized stock is unlikely to add many new units to desperate health facilities. Manufacturing using existing designs within usual may be constrained by supply chain limitations and retooled other industry manufacturing sites may incur significant time and cost.

Finally, there is a very real risk of supply chain disruption or massive parts acquisitions with political motivations, exacerbating the chronic global medical device disparity across the globe.

In response to these shortfalls, a concerned, organized, creative, and energetic crowd-sourced voice has risen, determined not to leave the fate of the population in the hands of governments and industries that have been too slow to adopt effective measures. **Care must be exercised as the solutions needed are very complex and have dire consequences if poorly designed or implemented.** Traditional patient safety standards and compliance processes are too slow and cumbersome for the rapidity of the solutions needed to save lives when facing a pandemic. However, with the correct application of a system of ethics and collaboration, adaptive and easily applied safety validation and standards can be developed; this will allow for innovative, safe, cheap, and effective, life-saving equipment to be created to bolster the response in an equitable manner. The holistic response discussed here could easily be applied to other types of medical technology and other types of mass disasters, beyond this specific respiratory disease pandemic.

To answer the question of whether we can respond to the current COVID-19 crisis with hundreds of thousands of new ventilators? The simplest answer is that with a massive coordinated response, led by governments, engaging industry, manufacturing, and design engineering teams, is a certain “yes.” However, perhaps a more important question should be, “Can we effectively utilize this many new capable ventilators to save lives during this pandemic?” The answer is much more nuanced and ultimately more important. The authors hope that this document will provide a basis of discussion for those that are endeavouring to respond.

As a final thought, if we had heeded the warnings from analyses done after the 2003 Severe Acute Respiratory Syndrome (SARS) and 2009 influenza outbreaks, this discussion would be very different. Imagine a world with an equitable distribution of and access to affordable, capable ventilators throughout all countries, with trained staff who use them on a routine basis for surgery and critical care. To this add robust supply chains, appropriate stockpiles, logistics, and clear regulatory guidance for distributed manufacturing and creation of new devices on a very short timeline. In that world, which would already be enjoying a global average standard of care much higher than ours, there would be fewer deaths and less healthcare expenditure and impact on global economies. In that world, the ravages of this COVID-19 pandemic would be more easily contained. It is not too late to create this imagined world to respond to this pandemic now and to prepare for future crises to come.