

# Frugal Innovation: Enabling Mechanical Ventilation During Coronavirus Disease 2019 Pandemic in Resource-Limited Settings

**ABSTRACT:** ICUs worldwide are facing resource shortages including increased need for provision of invasive mechanical ventilation during the current coronavirus disease 2019 pandemic. Fearing shortage of ventilators, many private companies and public institutions have focused on building new inexpensive, open-source ventilators. However, designing and building new ventilators is not sufficient for addressing invasive mechanical ventilation needs in resource-limited settings. In this commentary, we highlight additional interdependent constraints that should be considered and provide a framework for addressing these constraints to ensure that the increasing stockpile of open-source ventilators are easily deployable and sustainable for use in resource-limited settings.

**KEY WORDS:** constraints; coronavirus disease 2019; mechanical ventilation; open-source; resource-limited; ventilator

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## COMMENTARY

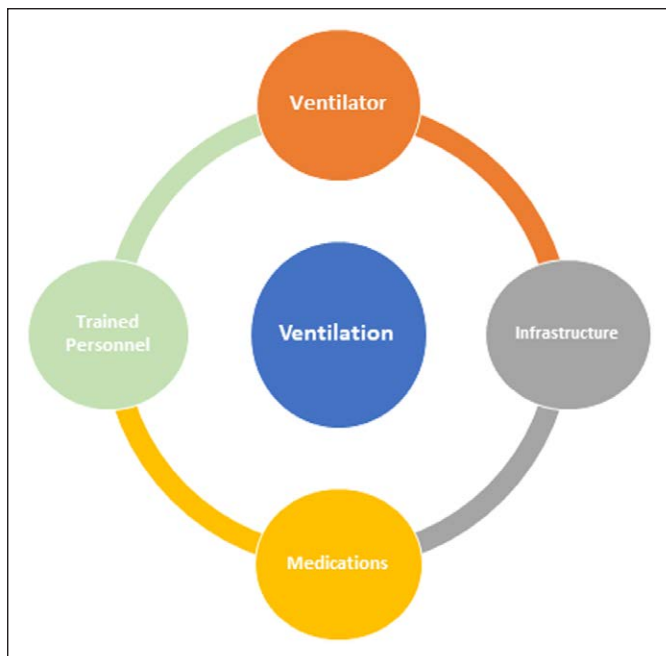
The coronavirus disease 2019 (COVID-19) pandemic has resulted in an unprecedented number of patients requiring ICU admission for mechanical ventilation (1). This surge of ventilated patients, coupled with prolonged duration of ventilation in COVID-19 (1), has precipitated worldwide fear of ventilator shortages (2). This fear has prompted discussions concerning pandemic triage during resource limitations (3) and stimulated public and private initiatives to develop open-source, inexpensive, and rapidly deployable ventilators for use in such settings. Unfortunately, increasing ventilator inventory is insufficient for the provision of safe invasive mechanical ventilation (IMV) in the absence of robust hospital infrastructure, training programs, and medications (**Fig. 1**). In this commentary, we highlight challenges with applying open-source ventilators in resource-limited settings and provide a roadmap for their sustainable deployment and future use.

## BALANCING VENTILATOR COMPLEXITY AND SHORTAGE OF TRAINED PERSONNEL

Modern ventilators are characterized by novel features and automated modes of mechanical ventilation that have not been shown to improve patient-important outcomes over conventional modes of ventilation (4, 5). In addition to increasing capital and operational costs, complexity hinders ventilator usability and increases staff educational burden. Considering the impact of untrained or undertrained providers on the quality of care for critically ill patients

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**Figure 1.** Essential components for safe provision of mechanical ventilation.

in resource-limited settings, developing new complex ventilators or donations of existing ventilators from multiple vendors paradoxically increases system strain in an attempt to address resource needs (6). To improve usability, new ventilator designs should limit unnecessary features, standardize user-friendly interfaces, and incorporate educational aids and clinical decision support systems. In the context of a pandemic, these efforts will also increase usability of ventilators by nonexpert healthcare personnel assisting in ICUs during capacity surges (7).

## ENABLING OPERATIONS IN AUSTERE ENVIRONMENTS

Considering the infrastructure capabilities of resource-limited settings during the design of open-source ventilators is critical to ensuring their usability. Common infrastructure threats to safe IMV in resource-limited settings include lack of reliable electrical supply, pressurized oxygen sources, ancillary equipment (e.g., imaging, pulse oximetry, etc.), and ventilator-related disposables (e.g., ventilator tubing, suction catheter, heat and moisture exchanger, etc.) (6). In certain jurisdictions, these shortages were associated with a higher mortality despite adjusting for illness severity (8). Across Africa, Asia, and South America, these problems are

prevalent—only a third of clinicians from 19 countries reported access to uninterrupted oxygen supplies (9). It is therefore prudent that open-source ventilators incorporate ways to mitigate these challenges. Examples include using self-inflating bag-mask designs that circumvent the need for pressurized oxygen sources or incorporating battery or manual operation that enable use in settings with unreliable electricity supply. Such designs may also facilitate intra- and interhospital transfers, improve safety of healthcare personnel, and conserve personal protective equipment by minimizing circuit disconnects during patient transport. These concepts are also applicable in high-income countries, where lack of transport resources or limited capacity at the receiving specialized care centers is a major barrier to safe patient transfer from resource-limited settings (10).

## ACCURATE APPLICATION OF “OPEN-SOURCE” QUALIFIER

Ventilators need to meet the definitions provided by the Open Source Hardware Association in order to qualify as “open-source” (11). Among many requirements, this includes the following: 1) sharing the code to allow reproducibility and 2) providing open hardware licenses. The failure to release computer-aided designs, bills of materials, or software in a timely manner, or issuing permissive licenses thwart sustainable implementation of open-source ventilators in clinical practice, especially in resource-limited settings where the need for ventilators is likely to extend beyond the current pandemic (12).

Given the importance of standardizing the use of term “open-source” (13), an open access website by Public Invention has created an online repository of available resources and the list of 140 ongoing ventilator projects (14). The projects are assessed using Rapidly Manufactured Ventilator System criteria set out by the U.K. Medicines and Healthcare Products Regulatory Agency and color tagged in seven categories to determine their readiness for clinical use and potential barriers to deployment. However, only a few of these ventilators have reached prototype or clinical readiness stages, and none are currently available for use in resource-limited settings (14). To ensure patient safety, it is essential that all open-source

design follow established good design control practices (e.g., set out by Food and Drug Administration [FDA]). This will ensure that open-source ventilators are subjected to the same rigor of testing as commercial ventilators. Finally, all open-source ventilators should undergo the same regulatory scrutiny as their commercial counterparts prior to licensing for use in clinical settings.

## **BASIC DESIGNS OF COMPLEX VENTILATORS VERSUS OPEN-SOURCE APPROACH**

One way to mitigate ventilator shortage is to have established ventilator companies develop, manufacture, and distribute simpler versions of their more complex ventilators. Such process would capitalize on the vast experience of these established vendors and ensure that basic ventilators are developed and manufactured under stringent quality controls. However, given the high costs of associated research, development, and licensing processes, this approach may not be fiscally attractive or sustainable for larger companies. Furthermore, although the capital and maintenance costs of such basic ventilators may be acceptable in high-resourced countries, it may be unaffordable in low- and middle-income countries.

In contrast, the open-source approach would enable ventilator development by both established and new public and private entities. In addition to fostering innovation through competition, this approach may be more sustainable by enabling low- and middle-income countries to retain control over local production and distribution of these ventilators, which may lower capital and operational costs. Furthermore, open-source ventilator blueprints can enable each jurisdiction to produce enough ventilators to meet local needs under normal circumstances, while also enabling rapid scaling of production in case of future pandemics or disasters. Given ubiquitous availability of 3D printing technology and materials, the open-source ventilator blueprints can serve as a virtual strategic ventilator stockpile, while keeping storage and maintenance costs low compared with physical stockpiles. Finally, by enabling updates to existing ventilator blueprints to account for advances in knowledge and technology, the open-source approach will allow democratization of knowledge and equitable access to the latest technologies worldwide.

## **RELEVANCE BEYOND CURRENT PANDEMIC**

The type of frugal innovation we advocate for has relevance beyond the current pandemic. First, although respiratory failure is the hallmark of the COVID-19 pandemic, it is conceivable that future pandemics may compromise other organ systems. We contend that the proposed open-source innovation would still be applicable in these situations and can be used to develop nonventilator ICU technology such as infusion pumps for delivery of IV medications, cardiorespiratory monitors (15), or perhaps renal replacement therapy machines. Second, even if the primary insult is nonrespiratory, most critically ill patients will still require ventilatory support for airway protection in patients with decreased level of consciousness, management of resuscitation-induced hypoxic respiratory failure, or supportive care in multiple organ failure due to sepsis. Given disproportionate burden of sepsis and high associated mortality in low-resource settings (16), open-source ventilators will remain relevant for management of critically ill patients irrespective of their primary illness. Third, given that scalability and effective contingency plans are vital aspects of disaster preparedness in the ICU (17), open-source ventilator blueprints would serve as a strategic virtual stockpile in high-, middle-, and low-income countries and can be rapidly deployed in future pandemic or disasters should the ICU systems reach capacity thresholds specified in disaster preparedness plans.

## **ROADMAP FOR MOVING FORWARD**

According to the Lancet Commission, low-quality care has become a greater determinant of mortality than lack of access (17). To address this, we suggest a systems-wide approach to improving the quality of mechanical ventilation in resource-limited settings, which includes consideration of the interdependent ventilator design constraints such as cost and complexity, hospital infrastructure, availability of medications, and trained personnel. This can be achieved by designing new open-source ventilators that minimize complexity, facilitating personnel training, and identifying infrastructure limitations. It is also critical that patient safety remains at the forefront of open-source ventilator designs and that good design control practices (e.g., FDA standards for ventilator development) (18)

are used to document development and testing of ventilator features and its safety. To this end, future work should focus on the following:

- 1) Developing minimalist ventilator designs that strictly adhere to evidence-based best practices for provision of mechanical ventilation. Although some aspects of IMV cannot be tested in randomized trials, the best available evidence should be considered.
- 2) Streamlining ventilator usability by facilitating personnel training through development of educational aids, training seminars, clinical decision support systems, user-friendly ventilator interfaces, and guidelines for management of hypoxemic respiratory failure in resource-limited settings.
- 3) Identifying health system deficiencies and infrastructure barriers to provision of mechanical ventilation to raise awareness among regional governments, international organizations, private companies, and the general public, and
- 4) Implementing design controls using U.S. FDA and European Union standards as a starting point given their wide use for medical device regulations in most countries (18). The transition from ventilator design to manufacturing necessitates quality assurance by the manufacturer, and therefore, the posting of an open-source ventilator must include the consideration of regulatory best practices to be credible.

Although addressing the need for mechanical ventilation in resource-limited settings may seem daunting, the timely consideration of the above constraints during ventilator design stage will facilitate usability and clinical applicability of final products. Given that provision of safe mechanical ventilation is the cornerstone of modern critical care, the frugal innovation of open-source ventilators will not only meet the demands of the current and future pandemics in resource-limited settings but also facilitate effective contingency planning and disaster preparedness in high-income countries (19). However, given that ventilators are life support devices, their failure can result in severe morbidity or in the worst case cause patient death. It is therefore critical that the strive for frugal innovation does not compromise patient safety and that open-source ventilator designs are subjected to the same testing and safety standards as commercially developed ventilators prior to their regulatory approval and licensing for use in clinical settings.

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