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Mini Review

Pandemic-Response Mechanical Ventilators: Global Health Considerations

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Abstract

We are witnessing the largest mass production of mechanical ventilators in living memory. Low- and middle-income countries (LMICs) are beginning to record increasing severe and critical 2019 Novel Coronavirus Disease (COVID-19) cases and deaths. Mechanical ventilators manufactured in response to the COVID-19 pandemic will potentially be distributed to LMICs as the pandemic evolves around the world. Challenges to mechanical ventilation in LMICs need to be considered during the different phases of mechanical ventilator design, certification, and distribution. Some LMICs are already manufacturing their own mechanical ventilators locally. This unprecedented expansion in access to mechanical ventilators in LMICs presents unique avenues for future research and collaboration in critical care in low-resource settings.

Keywords: *COVID-19; Pandemic; Mechanical Ventilators; Critical Care; Intensive Care Unit; Low- and Middle-Income Countries; Low-Resource Settings; Global Health*

Abbreviations

AAMI: Association for the Advancement of Medical Instrumentation; COVID-19: 2019 Novel Coronavirus Disease; EUA: Emergency Use Authorization; FDA: Food and Drug Administration; HICs: High-Income Countries; ICU: Intensive Care Unit; LMICs: Low- and Middle-Income Countries; MHRA: Medicines and Healthcare Products Regulatory Agency; 3D: Three-Dimensional

Introduction

As the 2019 Novel Coronavirus Disease (COVID-19) pandemic continues to unfold worldwide, low- and middle- income countries (LMICs) are bracing themselves for what could be the most significant strain on their healthcare systems to-date. Current modeled estimates for Africa are dire [1], with reports of an excess mortality of 250 to 1 million under-five deaths, and 12 to 56 thousand excess maternal deaths over six months [2]. The increased demand for medical equipment, particularly mechanical ventilators, has led to national

health governing bodies relaxing their manufacturing requirements resulting in an influx of mechanical ventilators on the world market hitherto unseen. As LMICs are likely to acquire these ventilators, important considerations need to be made beforehand. Challenges to mechanical ventilation in low-resource settings, such as inadequate training of health and bioengineering staff to effectively deploy and maintain the ventilators, limited access to consumables and spare parts, inconsistent compressed oxygen and electricity, and the need for end-users to master multiple brands of mechanical ventilators in the same Intensive Care Unit (ICU), have been documented [3]. There has been a surge of patients requiring mechanical ventilation during this pandemic in high-income countries (HICs) and increasing numbers of non-traditional manufacturers designing ventilators [4]. A similar phenomenon is likely in the ICUs of LMICs. We believe it is vitally important that the following design considerations be included for any ventilator currently being manufactured.

Considerations

Simple, user-centric design

Thanks to advances in microprocessor technology, user interfaces of conventional ICU ventilators display an array of interactive features and waveforms as impressive as the modes of ventilation they provide. However, ventilators being designed for any ICU must not compromise on the most basic requirement for widespread adaptability: simplicity. The more complex the design, the steeper the learning curve. The interphase, therefore, should be as intuitive as possible, with input sought from the specialists most likely to use them in LMICs as early in the design phase as possible.

Software

Conventional mechanical ventilators are driven by complex algorithms that optimize ventilation across a spectrum of lung disease. However, the underlying principle remains the ability of the ventilator to sense the patient triggering a spontaneous breath and providing the necessary assistance, with minimum lung damage. The ventilators currently in production must, therefore, employ a symbiosis of essential control circuitry with pneumatic functionality to maintain safety and efficiency. Differential pressure sensors readily available on the open market can be used in the design and production of these simple but robust systems. The software used must be able to deliver mandatory breaths to a paralyzed patient while maintaining the operating range to ventilate spontaneously breathing patients until successfully weaned off the ventilator.

Robust resilient hardware

Regardless of the basic design, whether based on the Ambu-bag model or the bellows model, the materials used to manufacture each unit should be medical grade, bio-compatible, durable and available in the settings in which the ventilators will be deployed. Designers should ensure additional shock-protection and robustness above and beyond the stipulated requirements for certification. This will provide a safety margin for the ventilators to withstand the repeated external forces exerted on them during air transportation, road transportation over long stretches of often bumpy and unpaved roads to their destination, possible mishandling during unpackaging and installation, and constant movement while in daily use. As there is inconsistency in the composition of cleaning and disinfection agents that will be used to clean these ventilators, materials used must not be susceptible to rust or corrosion. Electrical circuit boards, compressors and filters should be adequately protected from the high ambient humidity and dust commonly found in many LMICs to ensure longevity. The need for biomedical assistance should be reduced as much as possible by designing ventilators that clinicians can easily troubleshoot. The fewer and simpler the electrical components installed, the easier it will be to fix any issues that may arise in daily use. Wherever electrical components are used, an internal battery must be installed as well. Ventilators that provide a longer duration of battery back-up will be preferable for settings with unstable electricity. An in-built surge protector may be necessary to protect the more sensitive components, like motors and sensors.

Certification

Depending on the country of manufacture, designers must obtain national certification of their products. The US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) [5] and waived specific requirements for good manufacturing practice,

registration, and listing for authorized ventilators, ventilator tubing connectors, and ventilator accessories manufactured in response to the COVID-19 pandemic. The Association for the Advancement of Medical Instrumentation (AAMI) has also produced guidelines for the design, testing, and deployment of emergency use respirators and ventilators for COVID-19 patients [6]. Similarly, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) has provided guidance on the requirements for rapidly manufactured ventilator systems, intended for short term use in COVID-19 patients requiring urgent ventilation [7]. All these guidelines clearly delineate the inputs and outputs needed for each ventilator to be licensed. They also include safety features that all ventilators must possess, including an option to use oxygen concentrators a source of oxygen. This could prove beneficial in many LMICs, where access to compressed oxygen is highly variable. However, they also indemnify ventilator manufacturers from liability due to harm caused from the use of their products. Therefore, manufacturers should clearly and legibly describe potential hazards associated with the use of their products in the literature supplied with each unit, translated into the appropriate languages. It may also be appropriate for national health regulatory bodies in the recipient countries to repeat testing of ventilators designed specifically for the COVID-19 pandemic in their local settings, regardless of certification in the country of manufacture.

Affordability and cost

Conventional ventilators normally cost more than $10,000 without shipping and handling fees. Cheaper ventilators being produced domestically or internationally for COVID-19 may, therefore, be more attractive to LMICs seeking to boost their critical care resources quickly. Lower cost ventilators at source currently carry a $100 to $6,000 price tag. Production and maintenance costs should, therefore, be kept to a minimum by using consumables that can be readily sourced from or easily shipped to recipient sites at low cost to the end-user. With more LMICs beginning to utilize 3D printing to make their own ventilators, companies and organizations in HICs should partner with them and share their design source files, assembly instructions, wiring diagrams, firmware, software, and operation and calibration instructions, as well as assist in making crowd-funded resources available to them.

Conclusion

This being the most unprecedented mass production of mechanical ventilators in our living memory, manufacturers, and stakeholders, including clinicians, biomedical engineers, and administrators, should aim to collect and share the vital data that will emerge through this process. This data may include manufacturer demographics, cost of ventilators across the spectrum, different technologies used in ventilator design, benefits and drawbacks of each design in real time use, maintenance issues that may frequently emerge and patient outcomes associated with the use of these ventilators in low-resource settings.

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