Improving Equity in Ventilator Access: A Sociotechnical Analysis of the COVID-19 Pandemic and Ventis Medical

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

The United States healthcare system is challenged with providing equitable care for all citizens, a feat which demands innovative technology that is able to overcome disparities among our communities. A major focus of medical technology development is on the improvement of accessibility in order to help ensure safety, effectiveness, and usability for a diverse set of individuals regardless of their background or the application of the technology. These factors are especially considered in particularly diverse places including the United States, where a variety of demographics and cultural perspectives add a unique complexity to the innovation and provision of healthcare.

For example, access everywhere to safe and effective ventilation methods during patients' time of need is critical. The focus of this paper is on the ventilator industry and how the development of mechanical ventilators has changed particularly since the COVID-19 pandemic. In this sociotechnical research paper, an investigation will be launched into how this public health crisis revealed the striking variance in the accessibility of medical technology in order to understand current, reformed efforts being made by medical device engineers to expand the quality and readiness of vital ventilatory care.

COVID-19 Outbreak and Social Determinants of Health

The COVID-19 pandemic has illuminated many disparities within the American healthcare system including disproportionate health risks and limitations to access to quality medical care associated with race and poverty. Many are aware of the shortage of mechanical ventilators and trained ventilator operators that occurred beginning in March of 2020 when the initial COVID-19 outbreak spread throughout the United States. A mechanical ventilator is a life-saving form of medical equipment that helps patients who are unable to breathe on their own

by pushing air into the lungs and allowing it to release in an automated manner. These machines are an advanced form of technology that can oftentimes be difficult to use and require thorough training in order to operate correctly. The 2020 ventilator shortage in the United States impacted some communities more so than others, however. In a retrospective observational study, researchers found that Black race, low socioeconomic status, disability, and non-English speaking status were significant risk factors for the requirement of mechanical ventilation upon COVID-19 infection (Giovanatti et al., 2021).

Amid this outbreak, the Journal of Racial and Ethnic Health Disparities quickly distributed a guidance publication explaining alternative ventilation strategies in response to limited ventilator availability (Sharma et al., 2020). This guidance focused on the heightened impact that ventilator shortages would have on rural and medically underserved areas, which were more vulnerable to poor outcomes from COVID-19 due to "limited healthcare infrastructure, long distances to advanced healthcare, and population characteristics (e.g., tobacco use, hypertension, obesity, older age)" (Sharma et al., 2020, p. 1). The authors emphasize that these distanced communities with limited healthcare infrastructure seem to be most at risk for needing these critical pieces of equipment (Sharma et al., 2020).

Issues like this disproportionate impact of ventilator access on certain communities boil down to a set of factors known as social determinants of health (SDOH). The health, well-being, and quality of life of individuals is determined by a variety of factors beyond their genetic makeup and lifestyle choices. SDOH consist of the conditions in the environment in which individuals are born, live, and work. These conditions include economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context (*Social Determinants of Health*, n.d.) Each of these aspects of an

individual's environment has a direct impact on their health outcomes and risks, and that effect becomes clear when significant challenges develop in our healthcare system.

SDOH has been an area of study in the United States for decades. Researchers have discovered alarming health inequality trends relating to factors including race/ethnicity, education, income, poverty, area deprivation, unemployment, housing, rural-urban residence, and geographic location. For example, studies have indicated these factors result in disparity statistics such as a 10-year difference in life expectancy between Asian/Pacific Islander (87.7 years) and non-Hispanic Black (75.7 years) individuals, and a 55% higher prevalence of heart disease among unemployed adults as compared to those with full-time employment (Singh et al., 2017). In a 2021 meta-analysis, researchers found that statistical adjustment for confounding variables like social determinants of health and socioeconomic factors decreased risks of COVID-19 infection in racial and ethnic minority groups (Magesh et al., 2021).

The overwhelming impact of SDOH in the United States has particularly been observed since the emergence of COVID-19. Straining healthcare systems, the COVID-19 pandemic tested the "tragic imbalance between needs and resources" that exists in our country's healthcare system and resulted in overwhelming shortages of healthcare workers, personal protective equipment, ventilators, and hospital beds (Badalov et al., 2022, p. 1). This situation has been referred to as a "double jeopardy" in which SDOH factors have resulted in groups that disproportionately suffer from health issues generated by disparities while being less likely to have access to scarce life-saving resources (Badalov et al., 2022).

Professionals in this field strive towards "health equity", described by Singh et al. (2017) as "the absence of disparities or avoidable differences among socioeconomic and demographic groups or geographic areas in health status and health outcomes such as disease, disability, or

mortality.” Certainly, the solution to such a deeply rooted and widening issue in our healthcare system is not entirely technical; a multi-sectoral approach is required in order to improve medical technology, prioritize social justice, and reform allocation policies to tackle the issue at hand (Badalov et al., 2022; Singh et al., 2017).

The challenge at hand consists of a critical demand for highly accessible mechanical ventilation technology due to the geographic and financial diversity of our country, made obvious by the COVID-19 outbreak. Medical device developers have been responding to the challenge of ventilator inaccessibility since March of 2020, and both short-term and long-term efforts to adjust ventilator technology and relieve some of the stress on this face of our healthcare system will be investigated.

In this research paper, one example of more accessible ventilator development will be primarily explored as a case study. Ventis Medical is a startup that was founded with the goal of developing a portable, affordable, easy-to-use emergency mechanical ventilator called the VM-2000. This device has the potential to greatly expand access to critical emergency ventilator care that is safe and effective by minimizing obstacles that currently prevent mechanical ventilation from being used in emergency transport (*Ventis Medical: Pioneering Feature-Rich, Low-Cost, Portable Ventilators*, n.d.). Through an informational interview and further literary review, the unique impact that Ventis Medical and the VM-2000 have on this industry was discovered. The VM-2000 serves as an excellent model for accessible medical technology that is paving the way for future improvements to the challenging field of healthcare innovation.

Methods

Case Study Informational Interview

To investigate the Ventis Medical case study of the VM-2000, an informational interview was conducted with the CEO of the startup, Glenn W. Laub, M.D. In this interview, a variety of questions were asked to better understand how and why Ventis is developing a more accessible mechanical ventilator. Dr. Laub was read an informed consent statement prior to the interview to explain that response to any question is entirely optional and can be held confidential upon request. The interview was conducted and recorded via a Zoom video call, and a transcript was automatically generated through the closed captions feature of the software. Mistakes in the generated transcript were revised before any analysis was completed. Dr. Laub consented to the collection and examination of these materials during the interview.

During the interview a variety of questions were asked about Dr. Laub's educational and career background, the ventilator industry as a whole and how it has been challenged since COVID-19, the March 2020 ventilator shortage and subsequent response by the healthcare industry, the development, design, and production of the VM-2000, and the lasting impacts the VM-2000 will have on the ventilator industry. Following the interview, the generated transcript was analyzed to establish key points and observations from the conversation.

Literature Review

A thorough literature review was conducted to understand how the medical device industry originally created and has now responded to the imbalance between the need for and access to ventilation care. The literature review was informed, refined, and guided by the conversation with Dr. Laub to further investigate certain topics that were discussed. This strategy

allowed for the formation of a firmer understanding of the challenge plaguing the ventilator industry and how Ventis Medical is playing a part in this larger issue.

A variety of reference types were studied in order to observe a wide range of perspectives on the matter. These sources included research studies, review papers, credible blog posts, and guidance publications from industry boards and government agencies. Publications from before and after the initial COVID-19 outbreak were read and analyzed in order to grasp any differing opinions or trends on the matter before and after this pivotal event. In some cases, topics and efforts mentioned by Dr. Laub were further investigated to delve deeper into the matter and better formulate a conclusion. Key terms that were utilized in search of meaningful literature material included: ventilator shortage, COVID-19, accessibility, SDOH, allocation, medical device industry, and ventilator development. This portion of research was focused on observing the manners in which engineers, researchers, and public health officials have taken specific action to respond to the stress COVID-19 placed on the medical device industry and expand ventilator accessibility to previously hard-to-reach populations that are more at risk for requiring critical care.

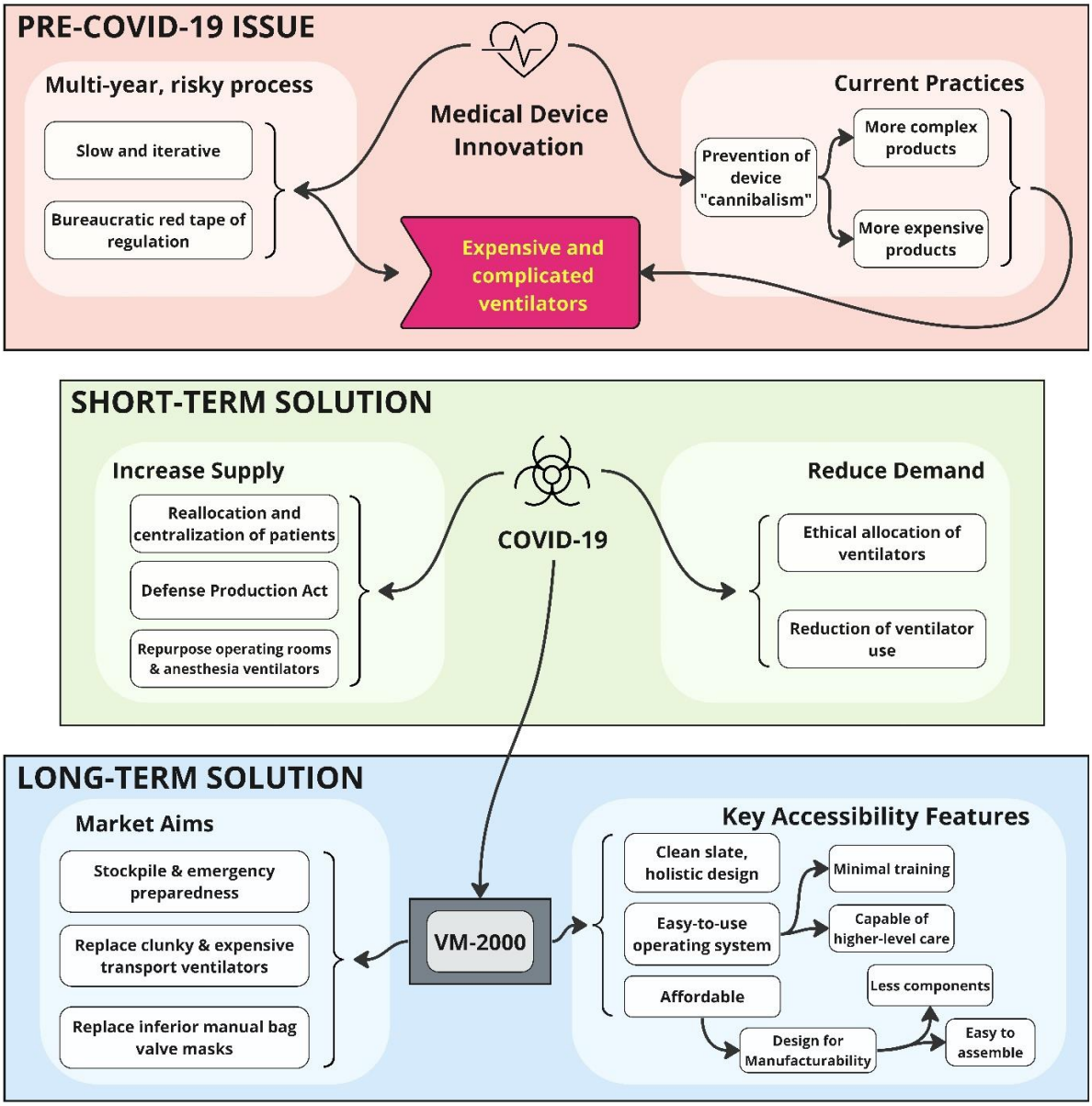
Results

Following the informational interview with Dr. Laub and the literature review, it was discovered that the issue of accessible ventilator development in the United States since COVID-19 can reasonably be split into three components. These components consist of 1) underlying issues in the medical device industry that existed before the advent of COVID-19 and resulted in non-ideal ventilator technology, 2) the short-term ventilation solutions composed in response to the COVID-19 outbreak, and 3) the long-term solutions currently in development to improve ventilator accessibility, including the efforts being made by Ventis Medical. Figure 1 depicts a

map that was created to visually aid in outlining the three parts of these findings, which will be further discussed in the following section.

Figure 1

Three-Part Issue of Ventilator Accessibility



Discussion

Case Study Interview

Pre-COVID-19 Issue

Dr. Laub has a background as an engineer and a cardiothoracic surgeon, and throughout his career as a provider and leader in cardiothoracic surgery he has founded several companies to develop electronic medical devices aimed at solving problems he has experienced and identified. Examples of past devices he has worked on include an ultrasonic flow monitor and an automated external defibrillator. Even before COVID-19 spread to the United States, he insightfully pondered creating an affordable, user-friendly mechanical ventilator that would be helpful should a mass casualty event occur, like a pandemic or an act of bioterrorism. But it was not until the initial outbreak in 2020 that Ventis Medical was founded to turn this idea into a device.

When asked why such technology had not yet been developed if this was a problem already observed by healthcare workers, Dr. Laub emphasized that the evolution of medical device technology is often slow and iterative. This is a challenging process made more difficult by the careful regulation of medical devices by the Food and Drug Administration. He explained that "existing companies have a tremendous installed base of devices" and are hesitant to develop lower-cost products that might "cannibalize" their existing business. They tend to add more complexity and features to their products, which can make them difficult to use, rather than focusing on improving usability.

Dr. Laub continued, "there's a tremendous resentment for a lot of companies to develop better, low-cost devices. And for that reason, you have to basically start with a clean sheet and say, 'how can we re-engineer this?' And that's a multi-year, high-risk proposition." The tricky approach taken by Ventis Medical to start from scratch has allowed them to think intuitively

about how an emergency ventilator should function and be used while maintaining a simple and affordable design.

Short-Term Solution

Dr. Laub explained that the initial response to the COVID-19 outbreak and looming ventilator shortage consisted of stopgap measures rushed to improve the ventilator supply. These efforts were made to get through the potential crisis, but did not aim to develop "a long-term product that could work outside these dire circumstances." He mentioned that outside of these makeshift ventilator solutions, another effort was made to manufacture more of the existing ventilators, which were not very suitable for this situation and made this attempt a poor solution to the problem.

Dr. Laub emphasized that even when vary smart professionals from various industries work together with terrific intentions to solve a problem of this nature, if they do not have much experience developing devices or have a limited understanding of the complexity of respiration, it is "not always the recipe for the best outcome in a product." Dr. Laub has observed that the rush on the ventilator market and current glut of existing ventilators has somewhat decreased people's appetite for developing a new-concept ventilator. This effect has dissuaded others and given Ventis Medical the perfect opportunity to get into the space of developing their novel mechanical ventilator with less competition.

Long-Term Solution

When the COVID-19 outbreak spread to the United States, a ventilator shortage threatened the stability of our healthcare system as a rapid spike in critical care patients arose in our country. Ventis Medical was founded to build the VM-2000, a low-cost emergency ventilator designed for usability. This device is intended to uniquely corner three markets 1) the

replacement of inadequate, manually operated bag valve masks in emergency situations, 2) the replacement of clunky ventilators currently used for emergency transport, and 3) the reinforcement and improvement of the emergency preparedness stockpile. Bag valve masks, while very affordable, have been shown to be clinically inferior to mechanical ventilators as they lack automation, demanding full attention of the user for the administration of ventilation and monitoring of the patient. Existing emergency transport ventilators are large, heavy, and challenging to operate. These factors provide an excellent market niche for the VM-2000 to fill, alongside the existing demand for readily available ventilators in the event of a mass casualty event or widespread healthcare emergency in our country.

The VM-2000 is designed specifically to expand the accessibility of ventilator technology, which is the key underlying factor allowing it to fill this three-pronged market. Engineers at Ventis Medical started with a clean slate and approached the design process holistically. The operating system running on the device is intended to be simple and intuitive to use, allowing the level of education and training period required to operate the device to be substantially reduced. Dr. Laub explained that the operating system remains sophisticated enough, however, that the device is capable of providing higher level care when used by more knowledgeable or experienced operators like respiratory therapists or physicians. Ventis Medical has validated the usability of their device through a human factors study.

The device is also much more affordable than a standard ICU ventilator. Ventis engineers have diligently worked to design for manufacturability by minimizing the number of components in the device and ensuring that it is easy to assemble, which reduces the materials and labor costs associated with the device. The usability and affordability of the VM-2000 makes it an excellent alternative to difficult to use and prohibitively expensive ventilators currently on the market, and

allows for expanded access to ventilatory care in hard to reach, medically underserved areas to be possible.

Literature Review

Pre-COVID-19 Issue

Before the advent of COVID-19 in the United States, healthcare professionals, including Dr. Laub, were already concerned about the accessibility of medical technology like ventilators. One 2014 publication from the Journal of Global Health discussed arguments for and against the provision of mechanical ventilation in the developing world (Krishnamoorthy et al., 2014). The authors explain that critical care is hard to come by in resource-poor communities where basic medical technology is less accessible. Unfortunately, the lack of resources, education, and training relating to mechanical ventilation in these areas can result in patient death that would otherwise be avoidable (Krishnamoorthy et al., 2014). The authors discuss the implementation of a program to improve access to mechanical ventilators in these communities, but also describe the challenges of expanding that access due to large costs and a lack of training among the population (Krishnamoorthy et al., 2014). As mentioned by Dr. Laub, the demand for an affordable and simple mechanical ventilator certainly existed before COVID-19.

Modern ventilators are now equipped with novel features that increase capital and operational costs as well as their complexity, which hinders usability and worsens staff educational burden (Dave et al., 2021). As Dr. Laub mentioned, a major reason for this occurrence is the complex world of medical device regulation, which favors the recycling of existing, approved device technology rather than the creation of new concepts from scratch.

The balance between regulation and innovation within the medical device industry has been a hotly-debated topic for years. Consumer-protection agencies concerned for patient safety

demand more careful regulatory oversight while many businesses and physicians fear that strict bureaucratic regulation currently stifles innovation and prevents patients from gaining access to novel treatments (Lauer et al., 2017).

The U.S. Food and Drug Administration mainly utilizes two pathways to regulate medical devices. High-risk devices must obtain Pre-Market Approval (PMA), a process that requires clinical research evaluating the safety and effectiveness of the device. Medium-risk devices must obtain 510(k) clearance, a process in which the developer must prove the device is substantially equivalent in function as an existing device. Many criticize the 510(k) clearance pathway for being overused and dangerous, as it is by far the most common regulatory pathway used by device developers and does not require clinical testing on humans. To bring a PMA device to market it costs roughly $94 million while 510(k) devices usually cost around $31 million (Lauer et al., 2017).

Despite potential safety concerns from some, the process of navigating these pathways remains highly complicated, time-consuming, and expensive, especially for smaller companies with more limited employment and funding. Obtaining approval and clearance for novel medical devices is of course very necessary, but in many cases, it serves as an obstacle that prevents potentially highly beneficial technology from coming to fruition. It is clear that this is a complicated problem that does not have an obvious solution, and stressors like COVID-19 on our healthcare system reveal the importance of tackling this problem.

Short-Term Solution

The issue at hand is that the current standard-of-care ventilator technology is too expensive and difficult to use for it to be useful during scenarios demanding widespread access to mechanical ventilation. During the COVID-19 outbreak, we immediately observed the impact

this issue had in many hospital systems. To account for this problem, hospitals were immediately forced to both increase the supply of ventilators and decrease the demand for them.

Hospitals reallocated and centralized patients in order to free up ICU rooms containing ventilators. Hospital systems also repurposed operating rooms and anesthesia ventilators in order to create a stopgap solution for ventilation and make more beds available. Because elective surgeries were mostly canceled during this time, operating rooms were more available for patients in need of critical care. Clinicians figured out ways to create make-shift mechanical ventilators out of existing equipment (like anesthesia, non-invasive, or home-use ventilators) and in some cases even connected two patients to the same ventilator (Santini et al., 2022; Sharma et al., 2020). The displacement of non-COVID-19 patients out of ICU beds and improvised methods of ventilation means these solutions were certainly less than ideal but nevertheless developed out of need because the optimal technological solution did not exist at the time.

Another strategy used to increase the supply of mechanical ventilators was the application of the Defense Production Act (DPA). The DPA allows the president to direct private companies to prioritize federal orders and take action to prevent hoarding of essential supplies during times of need in the United States (Siripurapu, 2021). President Trump used this act to order General Motors to manufacture additional ventilators, an action that contributed to an estimated 31.5% increase in the nation's ventilator supply (Siripurapu, 2021; Tsai et al., 2022). While this was certainly a critical step in improving hospital systems' supply of ventilators, the existing technology was expensive and required extensive training to operate. Since staffing hospitals with these trained personnel was also a challenge during this time, this expanded supply was not as helpful as it could have been. Authors of a 2021 publication on frugal innovation in resource-limited settings explain, "considering the impact of untrained or

undertrained providers on the quality of care for critically ill patients 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" (Dave et al., 2021, p. 2).

Healthcare systems were also forced to decrease mechanical ventilator demand by ethically allocating invasive ventilation treatment to the patients who could benefit most (Santini et al., 2022). In a public health crisis like COVID-19, physicians were asked to switch from a patient-centric to a society-centric practice where doing what is best for society is prioritized over what is best for a single patient (Chu et al., 2020). Seemingly unsettling guidelines including the rationing of ventilators reallocation of ventilator treatment from one patient to another were uncomfortable for many practitioners, but this utilitarian approach was advisable by bioethicists and public health officials at the time (Chu et al., 2020). These are actions that would not have been necessary in a perfect world, but the technology required to appropriately manage this situation was unavailable within the ventilator industry at the time.

Long-Term Solution

The proposed long-term solution to this challenge is to carefully design new ventilator technology with the specific purpose of improving accessibility, as demonstrated by Ventis Medical. A variety of methods exist to incorporate equitable design and expand accessibility into biomedical research and product development. In a 2022 Nature Human Behavior publication, the authors suggest businesses apply principles of diversity, equity, and inclusion by recruiting diverse teams, engaging with diverse populations, and preventing marginalization in data to avoid devastating consequences for marginalized communities (Ruzycki & Ahmed, 2022).

Ventis Medical is not alone in this effort. A 2022 publication out of Ecuador outlines fundamental design requirements for the development of new low-cost mechanical ventilators as a reference for future engineers to use when designing ventilator technology in response to the COVID-19 pandemic (Flor et al., 2022). Throughout the paper, the authors suggest a variety of methods to help lower the cost of this complex device, like using affordable and readily available structural materials, graphical computer systems, and programming languages (Flor et al., 2022). Affordability is just one of many characteristics of medical technology that can be leveraged to improve a device's accessibility.

To improve usability, Dave et al. (2021) suggest "new ventilator designs should limit unnecessary features, standardize user-friendly interfaces, and incorporate educational aids and clinical decision support systems" (p. 2). These improvements will in turn allow for ventilator operation by nonexpert healthcare personnel during surges (Dave et al., 2021). These authors propose that established companies could develop simpler versions of their more complex ventilators, capitalizing on their vast experience in complying with regulatory standards and marketing their devices (Dave et al., 2021). This process would be expensive for them, however, and as Dr. Laub mentioned it is not financially attractive or sustainable for a business to develop lower-cost versions of one of its existing products.

Dave et al. (2021) additionally propose an alternative open-source approach, where ventilator development can be made more public through the transparent sharing of software and hardware details for the device design. This concept would enable affordable ventilator designs that have been developed to be accessed and reproduced in more resource-limited settings, without the oversight of a large corporation. In the event of future public health crises, having the blueprints for more affordable and usable forms of this technology readily available, especially

in medically underserved areas, will hopefully improve outcomes and prevent the stress on hospital systems we observed during the initial COVID-19 outbreak.

Conclusion

The research findings presented in this paper describe how the COVID-19 pandemic has exposed disparities in healthcare access and highlighted the urgent need for accessible mechanical ventilation technology, especially in resource-limited settings. Medical device engineers and public health officials must work together to develop technologies that combat negative health outcomes due to SDOH, address underlying issues in the medical device industry, and provide long-term solutions for improved ventilator accessibility. The efforts being made by companies like Ventis Medical demonstrate the potential for innovative solutions to address the challenges facing the ventilator industry. The importance of developing more simple ventilators, streamlining their usability, and combatting deficiencies in our health system that prevent the provision of mechanical ventilation is clear. Prioritization of these aims would certainly positively improve ventilator accessibility, and has far-reaching implications beyond the COVID-19 pandemic.

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