Thesis Project Portfolio

Non-invasive Ventilation and the VM-2000: Improving the Versatility of an Affordable, Easy-to-Use Emergency Ventilator

(Technical Report)

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

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

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Spring, 2023

Department of Biomedical Engineering

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Executive Summary

The COVID-19 pandemic challenged healthcare systems across the United States to provide high-quality intensive care to an unprecedented number of patients. This stress on our nation's hospitals revealed several underlying weaknesses in our healthcare system, perhaps most notably the inaccessibility to safe and effective ventilator technology in certain areas and situations. A mechanical ventilator is a critical care medical device that supports a patient's breathing when they are unable to do so on their own. In March of 2020 these machines were in incredibly high demand, which resulted in shortages in some health systems. In a country as geographically and demographically diverse as the United States, innovative medical technology that is able to overcome disparities among our communities is necessary in order to provide equitable care for all. In this undergraduate thesis project, accessibility to safe and effective ventilator technology is studied through a technical design project as well as a sociotechnical research study. The circumstances resulting in a ventilator industry built for failure is investigated, short-term and long-term responses to the ventilator shortage are observed, and tangible steps are made toward building more accessible ventilator technology.

Ventis Medical is a startup developing an affordable, easy-to-use emergency ventilator called the VM-2000 aimed at expanding accessibility of ventilator technology. The VM-2000 is intended to replace rudimentary bag valve masks and existing transport ventilators, which are expensive, cumbersome, and complex. In the technical research project, a mask attachment system and non-invasive ventilation feature were developed for the VM-2000, expanding the versatility of the device by allowing it to be used without intubating the patient, a procedure that can be difficult to perform in an emergency situation. The technical project consisted of three specific aims. First, a variety of existing respiratory masks were tested for their suitability for the creation of a mask attachment for this application. Second, a non-invasive ventilation mode

developed by Ventis Medical was evaluated for its performance and used to test these masks. Third, an initial 3D model was built for a neck brace that could be used to help easily maintain an open airway in the patient during non-invasive ventilation. The VM-2000 is currently in the process of receiving FDA clearance, and in the future this non-invasive ventilation feature will be incorporated into the software of the device as well as the equipment used to operate it. This improvement will greatly expand the versatility of this life-saving device, and help bring more accessible ventilator technology to the market.

In the sociotechnical research project, an investigation was launched into how the COVID-19 pandemic 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. Social determinants of health and how they impacted health outcomes during the COVID-19 pandemic were studied in addition to limitations within the medical device industry in order to understand the root issue that resulted in a lack of more accessible ventilator technology. An informational interview with Glenn W. Laub, M.D., the CEO of Ventis Medical, was conducted in addition to a literature review to study the initial short-term responses to the ventilator shortage during the COVID-19 outbreak as well as current long-term solutions being developed to remedy this issue. The VM-2000 serves as an excellent example of current efforts being made to address issues within the medical device industry and improve ventilator technology for expanded accessibility to high-quality critical care.

Throughout the completion of this undergraduate thesis project, a variety of limitations were faced and challenges were overcome. Unexpected delays and limited resources resulted in changes to the course of action in some situations. But in the end, a nuanced analysis of the

sociotechnical issue of ventilator accessibility was completed and meaningful progress was made in the development of a non-invasive ventilation feature for the VM-2000. Advancements to technology in the medical device industry is time consuming and methodical, but through careful research of the problem being addressed and iterative prototyping, impactful solutions are possible. In future work, researchers should continue to study both successful and unsuccessful solutions that have been proposed to improve ventilator technology and further advance the VM-2000 as it enters the market to be as feature-rich and user-friendly as possible.