NONINVASIVE VENTILATION AND THE VM-2000: IMPROVING THE VERSATILITY OF AN AFFORDABLE, EASY-TO-USE EMERGENCY VENTILATOR

DIVERSITY AND INCLUSION IN THE DESIGN AND DEVELOPMENT OF VENTILATORS IN THE UNITED STATES

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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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General Research Problem: Accessibility to Mechanical Ventilation Technology

A discussion of current efforts being made to improve mechanical ventilation technology and expand accessibility to safe and effective ventilatory care.

The COVID-19 pandemic revealed a striking inequality in accessibility to ventilatory care. Healthcare professionals have discovered that in some extreme cases, like as a result of a rapidly spreading pandemic, the communities most susceptible to complications relating to infectious disease that result in a need for intensive care also have the hardest time gaining access to the medical resources needed to provide that care. A specific example of this effect is the shortage of ventilators and trained professionals observed in March of 2020 after initial outbreaks of COVID-19 (Grimm, 2020). Marginalized communities of lower socioeconomic status as well as rural and medically underserved areas lacked access to ventilators while simultaneously needing them most due to an increased likelihood of complications relating to COVID-19 (Sharma et al., 2020).

In response to these shortages, a startup called Ventis Medical was founded with a goal to address this gap in healthcare. Ventis Medical is developing the VM-2000, a ventilator specifically designed to expand access to critical emergency ventilatory care. The VM-2000 is portable and affordable while requiring limited training to operate. These factors combine to create a device that is designed for emergency preparedness and expanded ventilator access. In this project, the versatility of the VM-2000 will be further expanded with the creation of a mask attachment for the administration of noninvasive ventilation. Noninvasive ventilation is often more suitable in emergency situations, and adding this feature to the VM-2000 will make it more useful for care providers.

At the same time, the development of ventilator technology in the United States before and after the COVID-19 pandemic will be studied to understand how principles of diversity, inclusion, and human factors engineering are applied in this process. These broader principles are considered in order to expand the accessibility and use of medical devices like ventilators. Factors including cost, efficiency, safety, ease of use, quality of care, and portability are particularly addressed to overcome healthcare inequalities like that observed in the pandemic-related ventilator shortages. Standards, regulations, and best practice guidelines related to ventilators put out by stakeholders including engineers, healthcare providers, the Food and Drug Administration, the International Organization for Standardization, and the Federal Emergency Management Agency will be reviewed to uncover their focus on improving ventilator technology through end-user focused design principles.

These research projects pair to both explore and contribute to current endeavors being made to expand accessibility to safe and effective ventilatory care. Improvement of the VM-2000 serves as a prime example of an effort to refine medical technology through design principles stemming from diversity and inclusion. The novel design of the VM-2000 allows it to be particularly useful in areas that are difficult to reach, medically underserved, or financially underprivileged. Together, these projects serve to document the improving and expanding state of mechanical ventilation technology.

Noninvasive Ventilation and the VM-2000: Improving the Versatility of an Affordable, Easy-To-Use Emergency Ventilator

Expanding use cases of the VM-2000 emergency-use ventilator by designing and implementing a mask attachment for the administration of noninvasive ventilation.

Annually, ventilation is delivered in 1.2 million emergency medical service activations in the United States to provide life support during transport to the hospital (*Office of EMS: NEMSIS*, n.d.; Stephens et al., 2019). In the case of out-of-hospital cardiac arrests, less than 40% of patients that require mechanical ventilation survive hospital discharge, a mortality rate that is often a direct consequence of ventilator-induced lung injury (VILI) (Grieco et al., 2022). In patients that are ventilated, the primary cause of VILI is excess stress on the aerated lung, an unfortunate by-product more preventable with automatic ventilation (Stephens et al., 2019).

In a 2005 study, the usefulness of an automatic transport ventilator (ATV) was compared with manual bag valve device ventilation for intubated patients. The Emergency Medical Technicians-Paramedics agreed the ATV was superior because it allowed them to accomplish more tasks and provide better patient care (Weiss et al., 2005). Automatic ventilation is a safer and more reliable tool, yet current ATVs are not optimized for prehospital emergency use. Because they are often considered to be too bulky, complicated, and expensive, ATVs are rarely seen on emergency response transport vehicles.

The VM-2000 designed by Ventis Medical is a cutting-edge product that is more successful in its portability, usability, and affordability than all other current designs (*Ventis Medical: Pioneering Feature-Rich, Low-Cost, Portable Ventilators*, n.d.). Currently, the VM-2000 is only capable of administering invasive ventilation, which requires intubation of the patient. Intubation is a difficult procedure that must be performed by a skilled professional.

Noninvasive ventilation incorporates a facial mask to allow for rapid and easy administration of ventilation to the patient. **Through the accomplishment of three specific aims, the goal of this project is to iterate upon the existing ventilator design to create a noninvasive mask for the VM-2000, allowing it to be used in emergency situations.**

Aim 1: Identify a suitable mask and design a means of attaching it to the existing ventilator.

To create a non-invasive mask attachment for the ventilator, we first need to research FDA approved masks currently on the market and identify one that suits our needs best. A variety of criteria will be used to assess each mask. These criteria can be broken up into two categories: interactions with the patients and interactions with the VM-2000. The mask must comfortably seal to the patient's face, which can be quantified using a leak test. In order to monitor patient breathing the mask must attach to an exhalation valve and integrate with flow and pressure sensors. By performing fit and comfort surveys we will iteratively test and adjust the masks until an optimal assembly has been achieved for the attachment to the ventilatory breathing circuit. These tests include fit factor tests, seal tests, and maximum pressure tests.

Aim 2: Adjust the current ventilator algorithm to accommodate non-invasive ventilation.

The current software of the VM-2000 is designed for invasive ventilation. It administers a breath based on the volume needed to expand the lungs and measures each breath with a flow sensor. Administering volume-based breaths with a mask is impossible because of the potential for leaks. Consequently, noninvasive ventilation will require pressure-based breath administration. We need to develop a method for measuring patient breaths and calculating the pressure needed to fill the lungs. With the Ventis Medical software development team, we will develop an algorithm for the respiratory cycle during noninvasive ventilation and integrate it into

the current software. We will test the pressure-controlled ventilation against the current volume-controlled ventilation to confirm that they produce similar results.

Aim 3: Investigate a solution to maintain an open airway during non-invasive ventilation.

One of the major risks of noninvasive ventilation is clogging of the airway which may result in choking or air entering the stomach. An open airway allows for airflow from the nose and mouth into the lungs and protects the lungs from gastric contents. After conducting a thorough literature review to explore methods of addressing this issue, we will design a solution to maintain an airway during noninvasive ventilation using 3D modelling software. We must consider patient comfort and the fact that complicated fittings can be time consuming for EMS personnel. Our intended solution is a neck brace to keep the head tilted back. We plan to test all potential solutions using the VM-2000, which has a sensor to alert the user of any block in the airway.

Successful integration of a mask and a noninvasive ventilation algorithm with the existing VM-2000 will make it possible to implement automatic ventilation in emergency transportation. This will allow EMS personnel to provide better patient care as well as accomplish the multitude of other tasks required of them. The ultimate goal of this project is to improve emergency ventilation for both the patient and emergency personnel.

Diversity and Inclusion in the Design and Development of Ventilators in the Unites States

How are principles of diversity and inclusion within and in addition to human factors engineering considered when designing and developing medical technology like ventilators in the United States?

The United States healthcare system is challenged with providing equitable care for all citizens, which demands innovative technology that can overcome disparities among our

communities. Principles of diversity, inclusion, and human factors engineering are usually incorporated during the development of medical technology because they 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 provision of healthcare. A variety of examples of this struggle exist, but in this project I will focus on the development of more accessible ventilatory care.

The design and development process of medical devices typically involves the end user in order improve safety and usability. This involvement usually consists of human factors engineering to consider the conditions of the environment in which a device is to be used as well as the needs of the intended user of the device (Money et al., 2011). 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). The COVID-19 pandemic illuminated many disparities within the American healthcare system including the disproportionate health risks associated with race and poverty, namely the contraction of and complications associated with infectious diseases including COVID-19. Naturally, findings of studies like this motivate providers to optimize treatment for patients at risk and develop a strategized plan for providing care to marginalized communities. These areas with a higher incidence of mechanical ventilation as a result of COVID-19 infection demand widespread access to ventilators and trained personnel to operate them. In order to create ventilators that are most useful, these trends are acknowledged by engineers and device developers to create low-cost, easy-to-use products that are inclusive of patients most at risk for requiring ventilation.

Amid the first major COVID-19 outbreak, the Journal of Racial and Ethnic Health Disparities distributed a guidance publication providing 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)". This study also demonstrates how a wide range of user populations is considered when developing medical devices. The authors emphasize that these distanced communities with limited healthcare infrastructure seem to be the most at risk for needing these critical pieces of equipment (Sharma et al., 2020). That is why we see the efforts being made to design ventilators that are easy and affordable to manufacture and suitable for transport of critical patients as they seek further medical attention at more prominent areas of care.

The health, well-being, and quality of life of individuals is determined by a variety of factors beyond their genetic makeup and lifestyle choices. One set of such factors known as social determinants of health (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.

RAND blog authors have outlined four stages of the medical technology innovation pathway and discussed how technologies can be improved to address healthcare disparities perpetuated by SDOH such as education, living conditions, income, health care system access,

and infrastructure (Romanelli & Marjanovic, 2022). These stages include 1. the prioritization of problems to address and investment in innovations, 2. the design of innovations, 3. the evaluation and testing of innovations, and 4. the access, accessibility, and use of innovations. As medical technology development is broken down into these stages, the intended user must be considered throughout. The arguments and explanations made in this article can be applied to this research topic to help outline 1. why ventilators should be improved in the first place, 2. how ventilator designs can be optimized to benefit the most people in the most impactful ways, 3. how ventilators should be tested to ensure they are safe and effective in a variety of applications for a variety of patients, and 4. the importance of ventilator innovation that is actually useful and expands accessibility. These four topics will be explored through various forms of evidence relating to ventilator device development.

In this research project, I intend to analyze the discussion of these design principles in ventilators specifically, and focus on the various perspectives and stakeholders that are active in this conversation. I plan to read publications regarding medical device development from before, during, and after the initial COVID-19 outbreak to get a better understanding of how the consideration of diversity and inclusion in this field has changed over time. Standards, regulations, and guidelines related to ventilator technology development published by a variety of stakeholders will be studied. These actants include engineers, healthcare providers, the FDA, ISO, and FEMA as they oversee aspects of this issue ranging from the design specifications for ventilator technology to the organization of healthcare responses during emergencies like the COVID-19 pandemic. Through an online investigation into the FDA's Emergency Use Authorizations and other ventilator approvals over time, I plan to study the criteria that are viewed as being most important in ventilator development and observe any apparent efforts

made to expand accessibility to ventilator technology with specific examples. These collections of evidence will be analyzed for considerations of the end user and mapped across the four stages of the medical technology innovation pathway outlined by Romanelli and Marjanovic. From these observations in the end an assessment of current efforts to improve ventilation technology based on principles of diversity and inclusion will be made

Conclusion

The STS portion of this research project aims to investigate current implementations of principles of diversity and inclusion in the design and development of ventilators in the United States to better understand both the need and route for expanding accessibility to ventilatory care. The technical portion of this research project aims to develop versatile features for a specific ventilator designed for accessibility in order to expand its use-cases in emergency situations. It is critical that patients everywhere have access to safe and effective ventilation methods in their time of need, and through this research I will not only describe this challenge in detail but also output a tangible effort to improve accessibility of an existing ventilation device. Beyond the completion of this research, further efforts can be made to continue developing ventilators and other medical technologies that make lifesaving care affordable and easy to deliver to a variety of patients in a variety of situations and environments.

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