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

(Technical Paper)

Discriminatory Nature of Quality Adjusted Life Years: Especially during the COVID-19 Pandemic

(STS Paper)

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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

Introduction

Following the outbreak of the COVID-19 pandemic in March 2020, the need for ventilation and general health care equipment skyrocketed. Americans watched as European hospitals were flooded with patients waiting for the same spikes in COVID-19 hospitalization rate to occur here too. Reports indicated that the US would need between 60,000-160,000 additional ventilators (Ranney et al., 2020). In response, Ventis Medical was founded to create a ventilator, called the VM-2000, that was portable, easy to use and low cost. Now that the pandemic is largely over, the VM-2000 is intended to be used by hospitals and first responders in emergency situations.

Annually, there are 1.2 million emergency mechanical service activations that require prehospital mechanical ventilation (*Office of EMS: NEMSIS*). A study done by Weiss et al. (2005) found that automatic transport ventilators (ATV) performed better than bag valve devices (BVD). Despite this, ATVs are rarely found on emergency vehicles since they are clunky, complicated, and expensive. Furthermore, most emergency personnel are not trained to intubate patients, a requirement of ATVs. Intubation is the process where a tube is inserted down a patient's throat and into their trachea to keep the airway open. It is the standard practice for automatic ventilation and requires a trained professional (*Intubation*.). The VM-2000 would be a better option than an ATV since it is smaller and less complicated; however, it is currently only capable of invasive ventilation through intubation.

Technical Discussion

The goal of our capstone project is to integrate a mask attachment to the VM-2000, making it capable of ventilation. With a non-invasive option the VM-2000 will be more

accessible for emergency personnel because it will not require the time or knowledge of intubation. The three aims that will guide us during the design process are outlined below.

This first aim is to identify a suitable mask to attach to the existing ventilator, and design a means of attaching it. The mask we chose must satisfy a variety of criteria to ensure that it will integrate with the existing ventilator and interact well with the patient. If the mask will be marketed with the VM-2000 it must fit Food and Drug Administration (FDA) and International Organization of Standards (ISO) standards. A mask that is approved by both organizations will integrate with the VM-2000. The additional criteria we have set for the mask is that it must be clear, it must only cost around $4.00 and it must pass fit factor and leak tests. These features will ensure the mask interacts well with the patients. We plan to select several commercially available tests, test each mask according to the constraints above, and choose a mask.

The second aim is to adjust the ventilation algorithm to accommodate for non-invasive ventilation. The current algorithm is only for invasive ventilation, which administers a volume based breath. To successfully integrate the mask attachment, the VM-2000 should administer a pressure based breath. We will need to determine the pressure needed to fill the patients' lungs. Using this calculation we will adjust the algorithm logic maps for the respiratory cycle during non-invasive ventilation. The algorithm will be tested in MATLAB and integrated into the VM-2000 operating system with the help of the Ventis Medical software team. The new pressure-controlled ventilation will be tested against the volume controlled-ventilation to ensure the new algorithm produces satisfactory results.

The third aim is to investigate a solution to maintain an open airway during ventilation. Since there will not be an intubation tube to maintain the patients' airway, head position is vital to ensure the airway remains open for ventilation. We plan to conduct a literature review to

explore methods to maintain an airway and design a solution in SolidWorks. The current plan is a neck brace or pillow to keep the patients' head in the proper position.

STS Discussion

During the COVID-19 pandemic, medical resource rationing was a subject of much debate. Because the US was facing shortages in all types of medical and personal protective equipment, protocols were put in place to prioritize who received this equipment (Chen & McNamara, 2020). Many of these protocols came from " Crisis Standards of Care" put in place following the Swine Flu Pandemic in 2009. Unfortunately some of these standards were blatantly discriminatory toward those preexisting mental and physical disabilities (Bagentos, 2020). In theory these new protocols would give the most ill people access to any equipment necessary, however it inadvertently excluded those with physical disabilities. Because many protocols gauged a patient's level of illness compared to their life before contracting COVID-19, those who were physically disabled prior to infection would not see a drastic change in physical ability. As a result, they were passed over for medical equipment (Chen & McNamara, 2020). Learning about these examples of discrimination forced me to wonder if there are other, seemingly good intentioned, treatment standards that actually discriminate. I had previously studied quality adjusted life years (QALY) in class and the medical equipment rationing seemed similar. This prospectus will outline how I will answer the question: **do quality adjusted life years discriminate against those with physical disabilities, and if so, how?**

In order to determine if QALY are discriminatory it is vital to ask *what is a QALY?* A quality adjusted life year is the measurement of how much a patient's life is worth after a medical treatment compared to a year in full health. For example, a cancer treatment may save a patient's life, but how will it affect their quality of life? Figure 1 from Whitehead et al. (2017) is a

graphical representation of QALY. The goal of a QALY analysis is to determine if a given treatment is worth the cost and effect it will have on their life. Will the treatment improve the patient's life enough? Are the side effects not worth the little time a patient might gain? Is the treatment too expensive to justify its results?

The simplest equation for determining QALY is seen in Equation 1. The *T* is time, in years, *Q* is the health state of the patient, and $QALY_G$ is the life gained by potential medical intervention. The total QALY of a patient is the terms of $QALY_G$ summed together (Dolan et al., 2005). A QALY of 1 is one year in full health (Wichmann et al., 2017). This equation, however, does not take any uncertainty in health into account.

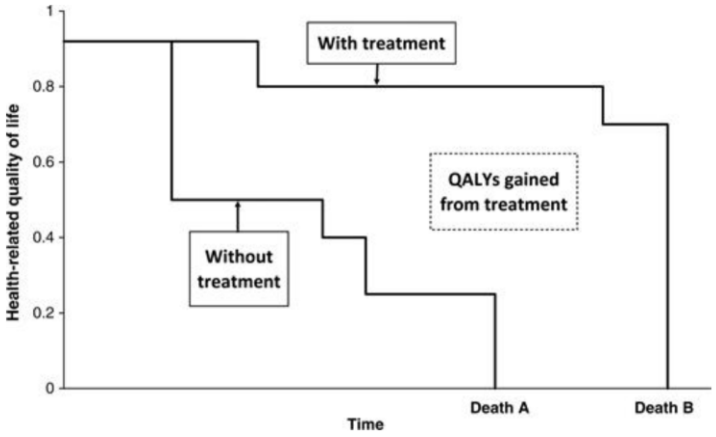

Figure 1: This figure is a graphical representation of QALY. Space between the two lines is the potential life gained with medical intervention.

Equation 1:

$$QALY_G = T_1Q_1 - T_0Q_0$$

The process outlined above may seem straightforward, but *how is the health state of a patient determined*? Health state, defined by Williams, the creator of QALY, is the level of disability and distress a person experiences as a result of a treatment (Hammell, 2006). The effect of a particular treatment is determined by asking a panel of people how they think a side effect or impairment might impact their lives. Analyzing the qu ality of life for a person with disabilities requires the imagination of people who are able bodied. People who are able bodied will likely overestimate the effect of an impairment if it does not already affect them. Since Williams' definition does not take pre-existing physical disabilities or the reason for impairment into account, any person with a

physical disability will have a lower QALY even if they have accommodated accordingly or live longer. (Hammell, 2006).

Now that the process by which QALY are determined, we must ask: *how are QALY used and who uses them?* QALY are generally used to determine one of two things: 1. Whether or not a patient should receive a particular treatment and 2. How to allocate medical resources (Loomes & McKenzie, 1989). Government agencies such as the National Institutes of Health and the Center for Disease Control use QALY to determine recommendations for pediatric drugs (*Cost-Effectiveness, the QALY, and the EvLYG*). The states of Oregon and New York use QALY to determine the cost of Medicaid coverage and it is not ridiculous to wonder if private insurance companies do the same (*Notice of Funding Opportunity*, 2021).

How could QALY discriminate against physically disabled people? Because a large portion of QALY measurements are determined by people who are able bodied, it cannot be assumed they will properly quantify how debilitating a physical disability may be. QALY analysis attempts to put a value on a life and marks people with disabilities as less valuable (Hammell, 2006). This means that Medicaid and insurance companies may not cover the cost of healthcare the same for people with disabilities and people who are able bodied. This was seen in the Crisis Standards of Care and during the COVID-19 pandemic. In my future STS research, I will attempt to find concrete examples of discrimination against people with disabilities as a result of QALY and discuss current alternatives.

Conclusion

As America was forced to ration its personal protective equipment and made plans for rationing larger medical resources, companies such as Ventis Medical jumped at the opportunity to close the gap between supplies available and supplies needed. Had there been more

ventilation options during the pandemic there would not have been the need for medical resource rationing. However, the holes in the current Crisis Standards of Care would not have been exposed. Since the standards of care are based on QALY then they likely discriminate against those with physical disabilities.

The VM-2000 would have been a vital tool that would have allowed for quick, easy, and cost-effective ventilation during the pandemic. However, without a non-invasive option, it would still require the user to have the extensive knowledge and training of intubation. By integrating the mask attachment my group hopes to make the VM-2000 accessible to all potential users while still providing quality automatic ventilation.

Word Count: 1606

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