Advancing the Design of the VM-2000 for Improved Efficiency and Ease of Care Administration
(Technical Topic)

Examining the Mental Health Impacts of Utilitarian Ventilator Rationing Protocols on Healthcare Workers in the US During the COVID-19 Pandemic
(STS Topic)

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By
Casey Ma

November 1, 2022

Technical Team Members:
Christian Anton
Cat-Thy Dang

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.

ADVISORS

MC Forelle, Department of Engineering and Society

Timothy Allen, Department of Biomedical Engineering

Introduction

Since the first confirmed case in early January 2020 to social distancing and masking protocols in October 2022, COVID-19 has greatly changed society and medicine as the world grappled to deal with overflowing hospitals and social isolation that seemed to shut down the lives of people around the world (CDC, 2022). With rapid transmission rates and no vaccines developed in 2020, hospitals struggled to meet the demands of inpatient surges in both resources and manpower. In testing Health Pulse, a new form of health care system surveillance that is functional during emergencies and supported by data from 625 hospitals in 29 states that are voluntarily enrolled in this system, 63% and 61% of hospitals reported alerts of emergency department (ED) and intensive care unit (ICU) overcrowding, respectively, from March 7, 2020 to April 30, 2021 (Sandhu et al., 2022). With an estimated 60,000-160,000 ventilators in the US and broad estimates ranging from several hundred thousand to a million ventilators that would be needed to care for COVID-19 patients, by any metric it is evident that there were simply not enough ventilators available for use (Ranney, Griffeth, & Jha, 2020). Further exasperating this shortage was the shortage of trained medical personnel needed to administer ventilator care. Full-featured ventilators can cost anywhere from $30,000 to $60,000 so for many medical facilities, simply buying more ventilators is also not a viable option nor does it solve the issue of inadequate medical staff (Van, 2020).

In the face of such scarcity, many hospitals had to implement rationing protocols to determine which patients would be administered ventilator care. These rationing protocols prioritized “saving the most lives and saving the most life-years” (Kerr & Schmidt, 2021). These protocols would be categorized as utilitarian in its approach where “outcomes determine the means” and is society-centered, which serves as a shift from more ordinary practices of patient-centered care, or a deontological approach (Mandal, Ponnambath, & Parija, 2016). The

deontological approach employed during times of non-emergency are centered around the four pillars of bioethics, namely: autonomy, beneficence, nonmaleficence, and justice (Gillon, 1994). When ventilator care is an essential treatment in determining patient outcomes, the act of choosing certain patients over others can result in harmful moral strife for healthcare workers that exacerbated other mental health challenges due to the pandemic. Studies have shown that healthcare workers "reported symptoms of anxiety, depression, irritability, insomnia, distress, and PTSD" from working during COVID-19 and so addressing these mental issues is of critical importance for protecting medical personnel (Hall, 2020).

My technical project is to advance the design of the VM-2000, specifically the ease of use of the tubing configuration and the fabrication of a remote ventilator access device (RAVD). This will be done by designing two manifolds to encapsulate the tubing and wiring for easier device set-up, designing a tubing sleeve for organizational optimization, and by integrating an external button to both administer and halt care. In doing so, I hope to optimize device usability and efficiency of patient care while also working to ameliorate accessibility issues for both medical responders and patients. My sociotechnical thesis is to apply a framework of applied ethics to examine how utilitarian rationing protocols have impacted the mental health of medical professionals in the wake of the COVID-19 peak. The relationship between utilitarianism often applied in emergency/natural disaster situations and the four pillars of bioethics will also be discussed in how they shape policy making.

Technical Topic

In 2018, up to 20 million people were dependent on admission to Intensive Care Units and mechanical ventilation in order to breathe; this number has since increased due to the COVID-19 pandemic (Ambrosino & Vitacca, 2018; Tsai, Orav, Jha, & Figueroa, 2022). Despite

this high demand, ventilators tend to be costly ($30,000-$50,000), heavy (7-18 lbs), difficult to use without extensive training, and inaccessible ("ALS Noninvasive Ventilation (NIV) – Portable Ventilators" n.d.; Sandy Van, 2020). This became more problematic during the pandemic, in which there were shortages in ventilator supplies and trained staff. Ventis Medical seeks to improve emergency ventilation and patient care by reducing expertise and training barriers that are currently present in ventilation delivery with its low-cost emergency ventilator, the VM-2000.

As compared to the standard ventilator, the VM-2000 is available at a much lower cost and features improved efficiency, ease of use, and portability, making it better suited for emergency situations. Currently, the VM-2000 requires each of its six cables to be plugged into its own connection port, features a tubing length of 1.8 meters, and has a ventilation function that is enabled by a button on the main body of the device. This may prolong the assembly of the device and delay the delivery of patient care. To address these issues, my team will be adding a tubing sleeve, a manifold, shortening the tubing length, and implementing an external Bluetooth button to administer care. Shortening the tubing would decrease the chances of tubing entanglement to save time and space during ventilation administration. A tubing sleeve would contain the components into one cohesive arrangement, decrease chances of entanglement, prevent wire/tubing damage, and help the caregiver quickly locate all attachable components. The design and creation of manifolds to encompass the breathing and sensor connection ports would shorten the connection process to two quick motions. It would also improve usability by ensuring that all of the wires and tubing are connected securely each time. With the advancement of the VM-2000, this project can reduce the amount of manpower and expertise needed to

provide quality care to patients, and ventilator treatments can be more broadly used across different facilities and situations.

Our work intends to advance the functionality of portable ventilators and to serve as a foundation for simplifying ventilator usability. All in all, this project will improve on existing ventilator designs by: 1) creating a better organizational system of ventilator tubing to save time in device deployment to the patient and 2) considering a “human factors" approach in design specifications to optimize device usability and efficiency of patient care. The accomplishment of these aims would improve and enhance ventilator administration while also considering the usability of the device from the caregiver’s perspective. This is related to the STS topic in working to increase resource accessibility to prevent the need for rationing protocols in the first place. It also works to help healthcare workers and emergency responders, but from a design perspective instead of the mental health perspective as is in the STS portion.

STS Topic

The analysis of ventilator rationing protocols on mental health deeply connects the technical shortcomings of engineers and pre-existing infrastructure with human problems concerning moral conflicts and obstacles. The discussion of the utilitarian ethical framework used to shape the rationing protocols in contrast to the deontological framework normally practiced in the medical field connects these topics by the social problems they are involved with.

Deontology is a moral theory regarding duty and obligation that is applied to guiding and assessing decision-making (Alexander & Moore, 2021). When applied to medicine, the individual patient and their needs are paramount to the physician, regardless of context or situation, as is the prescribed duty of a physician (Vearrier & Henderson, 2021). This is the

predominant framework used to guide medical decision-making in non-emergency situations. Deontology can also be considered to contribute to/be part of/ be applied in tandem with the four main ethical principles in medicine; beneficence, nonmaleficence, autonomy, and justice (Page, 2012). Beneficence outlines the physicians duty to act to benefit the patient, nonmaleficence acts on the flip side to describe the physician's duty to not harm the patient, autonomy refers to the patient's right to make their own decisions concerning their well-being, and justice is the fair and equitable treatment of patients in terms of distribution of care (Varkey, 2021). In emergency situations and as observed during the COVID-19 pandemic, the guiding ethical framework for decision-making is shifted to utilitarianism (Vearrier & Henderson, 2021). In this framework, the greatest good for the greatest number is the guiding principle for making decisions and this is often quantified in numbers such as number of life-years saved or factors such as quality of life improved (Dolan, 2001).

I will be relying on these two frameworks, utilitarianism and deontology, to guide my approach. When shifting from a framework that emphasizes the individual to one that emphasizes the welfare of the group, the moral implications of decoupling mindsets is of interest. Particularly in the context of resource allocation for ventilators during the pandemic that heavily relied on ventilator-based care, the decision to give ventilator care to one patient over another could result in increased suffering and potentially death for the non-prioritized patient. Making this decision that directly affects patient outcome with different guiding principles could result in cognitive dissonance and subsequently, negatively impact a medical professional's mental health. The moral conflict of interest between these two principal frameworks is what I plan to resolve by investigating the moral impacts of utilitarianism-based allocation decisions in

healthcare workers and more generally, the decision by medical governing bodies to turn decision-making principles away from deontological frameworks.

Research Question and Methods

My research question is, how have utilitarian rationing guidelines impacted the mental health of medical professionals in the wake of the COVID-19 peak? Working unforgiving hours in the face of job and health insecurities and dwindling supplies, healthcare workers had to grapple with both physical and mental obstacles throughout the COVID-19 pandemic. In a study of 1,685 healthcare workers, nearly half reported experiencing serious psychiatric symptoms such as mild to clinically meaningful anxiety, mild to severe depressive symptoms, suicidal ideations, and "screened positive for postraumatic stress disorder" during the pandemic (Young et al., 2021). This can be seen to reflect a larger issue of increased risk to mental health issues and psychological distress faced by healthcare workers amidst the pandemic. In order to best support the mental wellbeing of these personnel, it is important to both identify and analyze the sources of distress. This can be further used to guide the implementation of wellness resources, therapy, and other forms of aid. Utilitarianism has been a model framework in times of crises in the past and will likely continue to be relied upon in cases of future medical crises (Ostermayer, 2022). Therefore, the pursuit of this research question will also have benefits in the future for guiding both regulatory bodies in the creation of rationing protocols as well as better preparing medical facilities for dealing with the consequences of such emergencies.

This topic will be analyzed primarily through semi-structured interviews. This will allow for both a comparative analysis to be done across responses to the same question as well as the contribution of unique experiences and input into the discussion. Six interviews will be conducted with participants having worked in the ER or ICU during the pandemic, namely from

January 2020 to December 2021, at the same hospital to allow for the same regulatory guidelines to have applied as well. The hospital will be a facility that implemented utilitarian rationing protocols for resource allocation, with an emphasis on ensuring these also applied to ventilators, that is in Virginia. These experiences will obviously be limited to ERs or ICUs in central Virginia and the number of interviewees will not also not be able to cover people of all backgrounds and walks of life. However, that is why the interviews will be semi-structured, so as to allow for flexibility in conversation to learn as much about each individuals uique experiences and perspectives as possible while also touching upon the same main themes/questions of interest. In addition to an interview, interviewees will also be asked to complete the Kessler Psychological Distress Scale (K10) to quantify psychological distress using 10 questions on a five-level response scale (Kessler et al., 2003). This assessment is originally intended to be used for assessing psychological distress in the past 30 days, so this will serve as a limitation since the time period of interest is about 2-3 years ago. However, this distress scale has been shown to provide a comprehensive measure of psychological distress that has been validated across many studies that prove it is still useful in the spectrum of this analysis (Bougie, Arim, Kohen, & Findlay, 2016).

Conclusion:

In the face of the COVID-19 pandemic, healthcare workers were forced to deal with job and health insecurity, resource shortages, patient overcrowding, and tough physical demands that put their physical and mental health at risk. Shortages in ventilators proved especially challenging as they were a key treatment option but limitations in cost, availability, and trained medical staff led to the need for rationing protocols. These rationing protocols were formulated

using a utilitarian framework, common in medical crises, to do the most good for the most people, which is a shift from typical practices that originate from a deontological framework. In response to the technical challenges highlighted by ventilator shortages, my technical project will be designing manifolds, a tubing sleeve, and a RAVD to optimize care administration for both the patient and the caregiver while reducing costs and lowering training barrieres needed to use the VM-2000. The STS deliverable will be a report detailing findings from four interviews and K10 surveys to examine the impacts of utilitarian rationing protocols on healthcare worker mental health. The results from this research will help guide the allocation of mental health resources for frontline workers and help inform future rationing protocols through an increased understanding of the associated implications. I expect to find moderate levels of psychological distress as a direct result of the implementation of ventilator rationing protocols, which will be in the form of interview question responses and K10 scores above the minimum threshold for mild mental disorder.

Bibliography

Alexander, L., & Moore, M. (2021). Deontological Ethics. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy* (Winter 2021). Metaphysics Research Lab, Stanford University. Retrieved from https://plato.stanford.edu/archives/win2021/entries/ethics-deontological/

ALS Noninvasive Ventilation (NIV) – Portable Ventilators. (n.d.). Retrieved October 27, 2022, from Your ALS Guide website: https://www.youralsguide.com/portable-noninvasive-ventilation-niv.html

Ambrosino, N., & Vitacca, M. (2018). The patient needing prolonged mechanical ventilation: A narrative review. *Multidisciplinary Respiratory Medicine*, *13*(1), 6. https://doi.org/10.1186/s40248-018-0118-7

Bougie, E., Arim, R. G., Kohen, D. E., & Findlay, L. C. (2016). Validation of the 10-item Kessler Psychological Distress Scale (K10) in the 2012 Aboriginal Peoples Survey. *Health Reports*, *27*(1), 3–10.

CDC. (2022, August 16). CDC Museum COVID-19 Timeline. Retrieved October 27, 2022, from Centers for Disease Control and Prevention website: https://www.cdc.gov/museum/timeline/covid19.html

Dolan, P. (2001). Utilitarianism and the Measurement and Aggregation of Quality – Adjusted Life Years. *Health Care Analysis*, *9*(1), 65–76. https://doi.org/10.1023/A:1011387524579

Gillon, R. (1994). Medical ethics: Four principles plus attention to scope. *BMJ*, *309*(6948), 184. https://doi.org/10.1136/bmj.309.6948.184

Hall, H. (2020). The effect of the COVID-19 pandemic on healthcare workers' mental health. *JAAPA*, *33*(7), 45–48. https://doi.org/10.1097/01.JAA.0000669772.78848.8c

Kerr, W., & Schmidt, H. (2021). COVID-19 ventilator rationing protocols: Why we need to know more about the views of those with most to lose. *Journal of Medical Ethics*, *47*(3), 133–136.

https://doi.org/10.1136/medethics-2020-106948

Kessler, R. C., Barker, P. R., Colpe, L. J., Epstein, J. F., Gfroerer, J. C., Hiripi, E., … Zaslavsky, A. M. (2003). Screening for Serious Mental Illness in the General Population. *Archives of General Psychiatry*, *60*(2), 184–189. https://doi.org/10.1001/archpsyc.60.2.184

Low-cost Ventilator Prototype Could Provide Support in COVID-19 Pandemic. (2020). Retrieved October 27, 2022, from https://www.uclahealth.org/u-magazine/low-cost-ventilator-prototype-could-provide-support-in-covid-19-pandemic

Mandal, J., Ponnambath, D. K., & Parija, S. C. (2016). Utilitarian and deontological ethics in medicine. *Tropical Parasitology*, *6*(1), 5–7. https://doi.org/10.4103/2229-5070.175024

Ostermayer, D. G. (2022). Viewpoint: A Legal History of Medical Mandates and the Utilitarian Principle's Slippery Slope. *Emergency Medicine News*, *44*(1), 2–3. https://doi.org/10.1097/01.EEM.0000815524.69370.94

Page, K. (2012). The four principles: Can they be measured and do they predict ethical decision making? *BMC Medical Ethics*, *13*(1), 10. https://doi.org/10.1186/1472-6939-13-10

Ranney, M. L., Griffeth, V., & Jha, A. K. (2020). Critical Supply Shortages—The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic. *New England Journal of Medicine*, *382*(18), e41. https://doi.org/10.1056/NEJMp2006141

Sandy Van. (2020, Summer). Low-cost Ventilator Prototype Could Provide Support in COVID-19 Pandemic—U Magazine—UCLA Health—Los Angeles, CA. *UCLA Health*. Retrieved from https://www.uclahealth.org/u-magazine/low-cost-ventilator-prototype-could-provide-support-in-covid-19-pandemic

Sandhu, P., Shah, A. B., Ahmad, F. B., Kerr, J., Demeke, H. B., Graeden, E., … Strona, F. V. (2022). Emergency Department and Intensive Care Unit Overcrowding and Ventilator Shortages in US

Hospitals During the COVID-19 Pandemic, 2020-2021. *Public Health Reports*, *137*(4), 796–802. https://doi.org/10.1177/00333549221091781

Tsai, T. C., Orav, E. J., Jha, A. K., & Figueroa, J. F. (2022). National Estimates of Increase in US Mechanical Ventilator Supply During the COVID-19 Pandemic. *JAMA Network Open*, *5*(8), e2224853. https://doi.org/10.1001/jamanetworkopen.2022.24853

Varkey, B. (2021). Principles of Clinical Ethics and Their Application to Practice. *Medical Principles and Practice*, *30*(1), 17–28. https://doi.org/10.1159/000509119

Vearrier, L., & Henderson, C. M. (2021). Utilitarian Principlism as a Framework for Crisis Healthcare Ethics. *HEC Forum*, *33*(1), 45–60. https://doi.org/10.1007/s10730-020-09431-7

Young, K. P., Kolcz, D. L., O'Sullivan, D. M., Ferrand, J., Fried, J., & Robinson, K. (2021). Health Care Workers' Mental Health and Quality of Life During COVID-19: Results From a Mid-Pandemic, National Survey. *Psychiatric Services*, *72*(2), 122–128. https://doi.org/10.1176/appi.ps.202000424