Undergraduate Thesis Prospectus

Noninvasive Mask for a Low-Cost, Portable Ventilator

(technical research project in biomedical engineering)

The Struggle over Perceived Bias in Medicine in the United States

(sociotechnical research project)

by

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General Research Problem

How is a patient's access to healthcare resources determined?

Four percent of annual Emergency Medical Service activations, or 1.2 million people, require mechanical ventilation (Stephens et. al, 2019). Supply disruptions during the early COVID-19 pandemic raised ethical questions about medical biases. Because medical supplies were limited, healthcare workers were forced to ration life-saving equipment like ventilators and choose which patients received care. Beyond COVID-19, additional factors that affect access to healthcare resources are race, socioeconomic status, age, and gender along with the way that medical bureaucracy manages and addresses discrimination and bias.

Noninvasive Mask for a Low-Cost, Portable Ventilator

How can a noninvasive mask be designed for a low-cost, portable ventilator?

In 2018, up to 20 million people in Intensive Care Units were dependent on mechanical ventilation in order to breathe (Ambrosino, 2018). This number has increased by 31.5% due to the COVID-19 pandemic (Tsai et. al, 2022). My technical research problem is creating a noninvasive mask for a ventilator called the Ventis 2000. For my biomedical engineering capstone, I am working in a team with my peers: Emma Mitchell, Eamon McElhinney, and Charlie Hepner, for a start-up company called Ventis. Under the advisory of Dr. Lamb and Dr. Allen, our goal is to create cost-effective, accessible, portable, noninvasive ventilators for Emergency Medical Services (EMS) and the medical industry to use. The mask's criteria are that it must comfortably fit over the nose and mouth, remain sealed on the face while providing the patient with a certain amount of respiratory pressure, and be able to recognize when the patient is taking a breath.

There are three key aims for this project. Our first aim is to identify a suitable mask and design a means of attaching it to the existing ventilator. Our second aim is to adjust the current ventilator algorithm to accommodate non- invasive ventilation. Finally, we aim to investigate a solution to maintain an open airway during noninvasive ventilation. Our product must be user-friendly, allowing one without training to operate it. The equipment also needs to be easily disinfectable. Automatic ventilation in emergency transportation will be possible due to successful integration of the mask to the existing VM-2000. This will allow EMS personnel to provide better patient care. The non-invasive component will also lessen the stress on the lungs that come with invasive or manual ventilation. The ultimate goal of this project is to improve emergency ventilation for both the patient and emergency personnel.

The Struggle over Perceived Bias in Medicine in the United States

In the U.S. how are social groups competing to respond to allegations of bias in medical care delivery?

Medical bias is a divisive issue in U.S. healthcare, affecting patients, hospitals, doctors, insurance companies, and medical device companies.

Stepanikova (2012) examined racial and ethnic biases in healthcare for the Institute of Medicine, with particular attention to patient safety, concluding with an appeal for fundamental reform. The Institute recommends data collection for analysis of diagnoses by the patient's race. Stepanikova (2012) found that biases influence physicians' decisions. She recommends that clinics limit environmental factors, such as time pressure, that can impair judgment and thereby contribute to disparities. She reports reluctance to acknowledge biases in healthcare, noting that

"The argument that racial-ethnic biases affect medical decisions has been challenged on various grounds" (Stepanikova, 2012).

Some private services exacerbate inequities by helping wealthy clients get priority access to the healthcare they prefer. Private Health Management (PHM) helps patients get prompter appointments, find physicians, and organize medical records. Leslie Michelson, CEO of PHM, explains that clients "bring in a health advisor much like how they would for tax, legal, or estate planning issues." According to Michaelson, the healthcare system is "becoming more bureaucratic and difficult to access." PHM serves wealthy families seeking prestigious doctors (Milburn, 2015). Some hospitals collaborate with private patient services. PinnacleCare advised a patient to switch to NewYork-Presbyterian hospital, promising it had the "best colon cancer surgeon in the world" (Milburn, 2015). When NewYork-Presbyterian/Weill Cornell hospital was faulted for a V.I.P. amenities floor that served only wealthy patients, it issued a statement asserting that it is "dedicated to providing a single standard of high-quality care to all outpatients" (Bernstein, 2012).

Some doctors draw attention to findings that pulse oximeter devices are ineffective for persons with certain skin hues. They demand FDA testing and more publicity to support corrective action and to protect patients (Harlan, 2022).

Medical technology companies have contested these findings. Masimo CEO Joe Kiani speculated that if "sickle-cell patients were not excluded in the Michigan study, that alone could account for most of the difference between what we have seen and what Michigan reported" (Kiani, 2021). On an FAQ page on its website, Masimo purports to explain "what does Pulse Oximeters are not racist mean." The company claims that it tested the devices on patients with a large range of skin colors (Masimo, 2022).

UnitedHealth Group is the nation's largest healthcare insurer. An algorithm from Optum, owned by the UnitedHealth Group, determines which patients require the most intensive medical needs. The algorithm underestimates the needs of black patients because the data informs the program that $1800 less is spent on black patients' care a year than that white patients. Consequently, the algorithm calculates black patients as less sick because they require less care. In response to this research, UnitedHealth Group said that it " appreciates the 'researchers' work" and validation that the cost model was highly predictive of cost." However, the algorithm is "just one of many data elements intended to be used to select patients for clinical engagement programs, including most importantly, the doctor's expertise and knowledge of his or her patient's individual needs." UnitedHealth Group has continued to use the algorithm (King, 2019).

The American Society of Nephrology (ASN) is a nonprofit and the world's largest medical organization dedicated to researching kidney disease. The physicians and scientists who compose ASN educate health professionals and promote research. To calculate the glomerular filtration rate, ASN used a model derived from white patients. The calculations consequently supported misdiagnoses of black patients. In 2022, two years after the misdiagnoses were publicized, ASN updated its model (Chakraborty & Ye, 2021).

The National Patient Advocate Foundation (NPAF) is a nonprofit that promotes healthcare equity, patients' rights, rural health, and trust in providers. NPAF vice president Christine Wilson teaches patients to turn anecdotes into evidence to amplify their voices; guest speakers such as Olga Torres guide health professionals in avoiding healthcare bias. Torres cautions doctors that "when the patient and doctor do not speak the same language there is less opportunity to use small talk to develop a comprehensive patient history" (NPAF, 2021).

Biases affect the allocation of scarce medical resources. As utilitarians, most medical ethicists favor resource allocation that maximizes benefit for the greatest number of patients. During the coronavirus pandemic, Bazerman et al. (2020) proposed prioritizing healthcare workers' lives, "not because they are somehow more worthy, but because of their instrumental value: they are essential to the pandemic response." Utilitarians favor the lives of the young over the lives of the old because more years of life are at stake for the young (Bazerman et. al, 2020). Some health professionals favor a first-come, first-served care model. There are biases within this model too. Boom et al. (2021), however, argue that this model "lacks transparency and, in practice, may favor the wealthy and otherwise advantaged."

References

Ambrosino, N., & Vitacca, M. (2018, February 26). The patient needing prolonged mechanical ventilation: A narrative review. Multidisciplinary respiratory medicine. www.ncbi.nlm.nih.gov/pmc/articles/PMC5831532/

Bazerman, M., Bernhard, R., Greene, J., Huang, K., & Barak-Corren, N. (2020, April 9) How Should We Allocate Scarce Medical Resources? | *Harvard Business Review.* hbr.org/2020/04/how-should-we-allocate-scarce-medical-resources

Bernstein, N. (2012, January 22). Chefs, Butlers, Marble Baths: Hospitals Vie for the Affluent. *The New York Times.* www.nytimes.com/2012/01/22/nyregion/chefs-butlers-and-marble-baths-not-your-average-hospital-room.html

Bloom, D., Cadarette, D., Ferranna, M., & Seligman, B. (2020, April). COVID-19: How Best to Allocate Scarce Medical Resources - *IMF F&D.* www.imf.org/external/pubs/ft/fandd/2020/04/allocating-scarce-medical-resources-during-the-COVID19-pandemic-bloom.htm

Chakraborty, R., & Ye, J. (2021, November 18). Bioethics in the Age of COVID-19: Laundering bias and saving lives through AI – *Yale Scientific Magazine.* www.yalescientific.org/2021/11/bioethics-in-the-age-of-covid-19-laundering-bias-and-saving-lives-through-ai

Harlan, E. (2022, August 4). Addressing racial bias in pulse oximetry | *CHEST Physician.* www.mdedge.com/chestphysician/article/256831/diversity-medicine/addressing-racial-bias-pulse-oximetry

Kiani, J. (2021, February 15). Pulse Oximeters Are Not Racist. *Orange County Business Journal.* www.ocbj.com/healthcare/pulse-oximeters-not-racist

King, R. (2019, October 28). New York insurance regulator to probe Optum algorithm for racial bias | *Fierce Healthcare.* www.fiercehealthcare.com/payer/new-york-to-probe-algorithm-used-by-optum-for-racial-bias

Masimo—A Message from our Founder/CEO on Racial Bias and Pulse Oximetry. (n.d.). www.masimo.com/company/news/pulse-oximetry-racial-bias

Milburn, R. (2015, June 12). Wealthy Increasingly Hire Pricey Health-Care Consultants. *Barrons*. blogs.barrons.com/penta/2015/06/12/wealthy-increasingly-hire-pricey-health-care-consultants

NPAF. National Patient Advocate Foundation. *Initiatives Archive*. www.npaf.org/initiatives

Stepanikova, I. (2012). Racial-Ethnic Biases, Time Pressure, and Medical Decisions. *Journal of Health and Social Behavior*, *53*(3), 329–343. JSTOR

Stephens, R. , Siegler, J., & Fuller, B. (2019, May). Mechanical Ventilation in the Prehospital and Emergency Department Environment | *Respiratory Care*. rc.rcjournal.com/content/64/5/595

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. doi.org/10.1001/jamanetworkopen.2022.24853