Undergraduate Thesis Prospectus

Improving Upon the User-Friendliness of Emergency-Use Ventilators

(Technical research project in Biomedical Engineering)

Public Health Outreach in Response to the Coronavirus Pandemic in the Rural United States

(Sociotechnical research project)

By

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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

"How have public health authorities sought to optimize responses to the coronavirus pandemic?"

The pandemic has limited the amount of interaction between persons due to the contagiousness of the SARS-CoV-2 virus. In response to lockdown efforts by government officials, many health organizations, nonprofits and local advocacy groups have found creative ways to provide care to communities affected by COVID-19. With the use of government funding, many national health organizations have been able to provide funding to clinics and increase the availability of health centers to ensure care is administered to as many persons as possible. Local advocacy groups and organizations have also been able to create emergency COVID-19 testing clinics and provide educational resources to further prevent the spread of the virus and keep their community safe.

However, this is not the same for rural Americans. Rural areas have a median household income of $52,386 versus $54,296 in urban America between 2011 and 2015. This has repercussions for health as lower-income households are less likely to have health insurance and overall less expenditure to seek care. While approximately 15% of the U.S. population lives in rural America, only 10% of the nation's physicians practice in rural areas. Thus, these demographic challenges in addition to the effects brought by the pandemic, pose an increased concern for healthcare demands in rural areas – coupled with the growing rate of closures among rural healthcare facilities and declining supplies.

Improving Upon the User-Friendliness of Emergency-Use Ventilators

For my BME capstone project, the advisor is Dr. Timothy Allen, a professor of Biomedical Engineering. Myself, Cat-Thy Dang and Casey Ma are working together with Dr.

Glenn Laub, from Ventis Medical based in Princeton, NJ, to simplify the design of a low-cost, emergency use ventilator and its exhalation valve, flow sensor and pressure line. A major unknown with this capstone is its 'innovative ceiling' given its pre-market status and limitations. 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 et al., 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 (UCLA Health, n.d.; Your ALS Guide, n.d.). 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.

The ultimate goal of this project is to improve 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), which will be accomplished through 1) Enhancing the usability of the breathing circuit and 2) Implementing a RAVD in the design of the VM-2000. We aim to accomplish these goals by researching the limitations of current ventilation techniques and use CAD, 3D printing and Arduino microcontrollers in designing the technical parts needed to optimize the ventilator. Test methods include: creating two 3D-printed manifolds and one sleeve using Fusion 360 to encompass the two different breathing and four different sensor tubing components for optimal organization. For the RAVD, we aim to integrate an external button connected to the main

ventilator via Bluetooth with code provided by Ventis Medical and determine an optimal range for Bluetooth connectivity through prototype testing. Finally, we aim to use third-party prototype testing with emergency responders to refine design specifications and iterate each design until a finalized, optimal configuration is reached for all components.

Some constraints important in our capstone project include: the sensor manifold must securely hold the four sensor lines by one connection point, the RAVD must be external from the main ventilator body and must be functional within close proximity of the patient and components (tubing sleeve, manifolds, RAVD) must be waterproof. Currently, mechanical ventilation using invasive techniques are standard for giving external care to a patients' lungs. However, mechanical ventilation can induce or worsen lung injury due to the body relying on external measures, which can lead to muscle atrophy specifically in the diaphragm. More than 50% of patients experience dysfunction related to an excessive level of ventilator assistance. 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.

Our work intends to advance the functionality of portable ventilators and to serve as a foundation for simplifying ventilator usability. Furthermore, 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 ventilator administration methods, reduce the amount of manpower

needed and enhance the usability of the device from the caregiver's perspective by lessening ventilator-expertise needs.

Public Health Outreach in Response to the Coronavirus Pandemic in the Rural United States

In response to the COVID-19 pandemic, how have healthcare responders reached out to rural communities to deliver medical care and spread awareness of health concerns?

The COVID-19 pandemic emerged in Wuhan, China in December 2019. Within the coming months, SARS-CoV-2 spread to nearby countries and the US; COVID-19 was declared a pandemic after more than 118,000 cases in 114 countries and 4,291 deaths. (CDC, n.d.) The pandemic caused reduced healthcare access and fear of exposure. Thus, telemedicine to reach the majority was needed (Mann et al., 2020). With limited communication and access, how did responders achieve the growth of telemedicine to rural communities?

Participants include one national organization that serves to increase accessibility of cost-effective healthcare to rural communities. The Health Resource and Services Administration (HRSA) has contributed $234.3 million to rural health clinics across the US for COVID-19 testing in May 2020 (HRSA, n.d.). The HRSA also provides grants to community health centers supporting the workforce of health centers and reimbursements through public insurance. Early in the pandemic however, the majority of vaccination efforts were focused on healthcare workers in densely-populated, urban areas while healthcare workers in rural areas were secondary. This led to "the impetus for the administration to set up this program to have a direct supply of vaccines to health centers who have long standing relationships with their communities" (Federal News Network, 2022) Suma Nair, director of the Office of Quality Improvement at the HRSA,

states. By doing this, it encourages community outreach and brings individuals to these health centers to get the medical attention needed.

Federal agencies are also combating COVID by increasing funding through the COVID-19 Telehealth Program, allowing health-care providers to purchase equipment for telehealth care. The Federal Communications Commission (FCC, n.d.) made it easier for broadband providers to support telehealth through improved Wi-Fi capabilities. An additional $42.19 million funded by the FCC ensured more resources to improve telehealth needs (FCC, 2022). The FCC also oversees funding of rural telehealth through the Universal Service Fund (USF, n.d.), a mechanism where long distance carriers are assessed to subsidize telephone service to low-income households. This is not to be confused with "a deployment "grant" program… because it does not provide the upfront capital necessary to construct networks," Michael Romano, Vice President of the National Telephone Cooperative Association (NTCA, n.d.) states. The USF merely provides support over a period of time to help recover costs and enable deployment, but does not finance it.

The NTCA, a trade association representing nearly 850 independent, community-based telecommunications companies, works with the FCC in funding the digital development of rural communities. While funding and grant programs are in effect to help rural communities, "we cannot forget that it is equally important to sustain those networks once they are deployed and keep services affordable" (NTCA, 2022) – Shirley Bloomfield, CEO of the NTCA, claims in a press release regarding the FCC's report to Congress about the future of the USF. In response, the "NTCA further encouraged the Commission at a minimum to set the stage in the report for thoughtful consideration of how to update the eroding USF contribution mechanism," Romano states. Thus, expressing the NTCA's desire for the FCC to clarify the USF's purpose and garner

further support from Congress in the future. Relevant to the FCC's demand for clarification, during the first few months of the pandemic, many were "troubled by the lack of transparency regarding the health care providers who have applied but have not yet received an award" (House Committee on Energy & Commerce, 2020), Frank Pallone and Mike Doyle express, whom are chairmen of the Energy and Commerce Committee and the Communications and Technology Subcommittee respectively.

Nonprofit organizations are also driven to help provide education and advocacy to rural communities. In Florida, many Latinx communities, specifically farmers, "were afraid… many of them were working while everybody else was buying groceries to quarantine at home" (Xiuhtecutli & Shattuck, 2021), María Carmona, an organizer from the Farmworker Association of Florida (FWAF, n.d.), explains. To counter this, the FWAF served as a distribution center by receiving and giving donations to help alleviate food inaccessibility driven by the pandemic for Latinx farming communities. In addition, the FWAF provides educational videos in multiple languages to help rural Latinx communities understand COVID-19 risks and provide testing (Silvert et al., 2021).

Researchers have investigated socioeconomic conflicts of rural communities in response to COVID-19. For example, Quandt et al. (2021) revealed that in a study of 105 Latinx farmworkers and non-farmworker families, financial and family concerns were high due to COVID-19 affecting their jobs. Zhu et al. (2022) shows COVID-19 hospitalization trends in rural areas being generally higher, hinting at how policymakers can solve this disparity. Malone et al. (2021) highlights efforts to develop a novel outpatient therapy center for COVID-19 treatment in Midwestern rural communities.

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