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LETTER

Rapid development of a novel portable negative pressure device

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Dear Editor,

The COVID-19 pandemic has put a severe strain on hospital environments and intensive care units (ICUs). Extensive efforts have been undertaken to provide adequate personal protective equipment (PPE) and isolation equipment (including the use of negative pressure rooms) to assure patient and healthcare worker safety. However, many countries continue to have shortages of both,[1] and some therapies for COVID-19 are associated with high rates of aerosolization, which increases the safety threat faced by healthcare workers. Efforts to mitigate these risks are therefore paramount for the safety of patients and healthcare workers.

A portable, negative pressure environment is one means of confronting these challenges, and could offer benefits to patients, healthcare workers, and institutions alike. Potential benefits include increased use of aerosolizing therapies (e.g., heated high-flow nasal cannula [HHFNC], non-invasive ventilation, nebulized treatments), subsequent avoidance or delay of mechanical

ventilation, earlier liberation from mechanical ventilation to HHFNC, prevention of nosocomial infection, decreased exposure to respiratory droplets for healthcare workers, and reduced use of negative pressure rooms. A portable negative pressure environment could also allow more flexible cohorting of patients within the hospital, particularly if used during transport, imaging studies and procedures. Similar safety benefits apply to the pre-hospital environment (e.g., during transport), Emergency Departments (EDs), in-patient settings and field hospitals.

We describe a novel approach to an extension of traditional PPE via a helmet device that creates a portable negative pressure environment for the wearer (Figure 1A). This device is being developed as a collaborative effort across the University of Michigan (Ann Arbor, MI, USA) and third-party manufacturers. Prototypes have been developed from inexpensive materials and have had positive results from early user testing. Further research into standard operating procedures, cleaning protocols, material sourcing and scaling is also underway.

The device utilizes an industrial powered air purifier respirator (PAPR), which we have adapted to reverse airflow through the hood to create a negative pressure environment for the wearer (patient). It supplies room air into the patient's environment by drawing air up through a loosely fitted neck seal into the helmet. Air in the helmet (including air/droplets exhaled by the patient) then passes through a HEPA filter before being released into the room via an exhaust port. When worn by a patient with COVID-19 (or with other conditions spread via respiratory droplets), the device is intended to allow safe use of HHFNC, nebulized treatments, and other potentially aerosol generating therapies, by mitigating the risk of aerosolization.

The helmet device has three fan settings—low, medium, and high, corresponding to flow rates of 130, 210, and 320 L/min, respectively. At the highest setting of 320 L/min, for a patient on 60 L/min of high flow oxygen supplementation with a minute ventilation of 10 L/min, 274 air changes per hour are achieved. This is 22 times more than the >12 air changes per hour recommended for negative pressure rooms by the US Centers for Disease Control and Prevention.[2] The entire apparatus is intended to be disposable and single-patient use with the exception of the motor/battery, which can be cleaned (including replacing the filter) and re-used in a manner similar to traditional health care PAPRs. Clinicians and respiratory therapists who have trialed the device have found it to be comfortable and lightweight, and hearing/communication is not significantly compromised.

Air particle testing of the device was conducted with a healthy volunteer in a number of simulated environments. We used a TSI Condensation Particle Counter Model 3007 (TSI Inc, Shoreview, MN, USA), which detects particles over a size range of 0.01 to >1 μm. For comparison, the diameter of SARS-CoV-2 has been reported to be 0.06–0.14 μm.[3] Particle

counting was performed approximately 15 cm from the subject's mouth, with and without use of the portable negative pressure environment, to simulate aerosolization of respiratory droplets under different conditions. Our volunteer subject was maintained on HHFNC at 60 L/min in each scenario. Throughout testing, the observed particle count in ambient room air ranged from 400 to 1,000 particles/cm^3. We then tested a nebulizer mask with a saline solution at 10 L/min to simulate a nebulized treatment. The mean air particle count rose to 46,000 particles/cm^3. With use of the helmet device, the mean observed air particle count was 518 particles/cm^3. We then removed the nebulizer mask, and instead used a TSI Particle Generator to supplement ambient particle count and simulate additional droplet generation, aerosolization, and viral shedding in our subject while on HHFNC. The mean observed air particle count rose to 27,351 particles/cm^3. With use of the device, the mean observed air particle count was 804 particles/cm^3. We next measured air particle content at the exhaust port of the device (after passing through the contained HEPA filter), and the mean observed air particle count was 43 particles/cm^3.

Our simulation involved a single healthy volunteer and a simulated model of aerosolization. Our ability to make generalisations about these results to patients with COVID-19, including those undergoing aerosol generating procedures, is therefore limited. Nevertheless, these observations indicated a portable helmet negative pressure environment might mitigate aerosolization of respiratory droplets while filtering particles from the exhaled air of the wearer. Use of the device with HHFNC or a nebulized treatment was associated with no detectable increase in air particle counts above ambient levels observed prior to commencing the therapy.

Following pre-clinical testing, we tested prototype helmets on hypoxemic adult patients with COVID-19 in the ED and ICU who were receiving HHFNC (Figure B and C). The device was well tolerated by patients (including in the prone position) and well accepted by healthcare providers at the bedside across job disciplines (including nursing and respiratory therapy). Use of the device did not alter or interfere with delivery of HHFNC, cardiac monitoring, use of nasogastric tube or internal jugular central venous catheter. The patients were able to easily communicate with the care teams and family members (by phone) while wearing the device.

The application of this novel device has broad-reaching implications for resource allocation and protection of healthcare workers from disease transmission. Challenges during the COVID-19 pandemic are not unique to the United States and are magnified in low- to middle-income countries. Although the volume of COVID-19 cases in Africa is still relatively low to date, the ability to mount an effective response is limited.[4,5] Due to the under-resourced

health systems, the inability to practice effective social distancing, limited PPE supplies, the small number of ventilators and ICU beds, and the almost non-existence of negative pressure rooms, the risk posed to sub Saharan Africa by the COVID-19 pandemic is significant. Based on these factors, there is a pressing need for low-cost mitigation strategies. A policy of mask wearing at the population level may help to slow the spread of the virus,[6] and use of a portable negative pressure helmet may help to reduce transmission while patients undergo treatment.

Additionally, there is potential utility of this device long after the COVID-19 pandemic has ended. Based on the ability to limit aerosolization and potentially reduce contagion transmission, the helmet could be used in the treatment of other diseases with airborne and droplet transmission such as tuberculosis and influenza.[7] This is a relatively simple solution to assist in long-term resource allocation and healthcare worker safety with significant potential to benefit the most resource constrained settings.

Rapid innovation and assessment are needed more than ever during the COVID-19 pandemic. We anticipate that further study of this device will allow us to identify additional benefits to patients, healthcare workers and institutions alike.

Conflicts of interest: SK, KRW and SSK have submitted intellectual property on the device through the University of Michigan, Ann Arbor, MI, USA.

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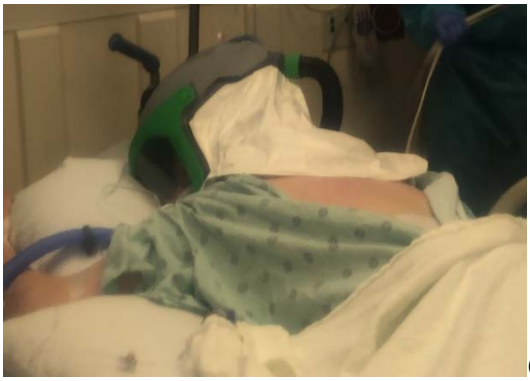
Figure Panel **A)** Healthy volunteer wearing the portable helmet negative pressure device while on heated high-flow nasal cannula. Panel **B)** Patient with COVID-19 wearing the portable helmet negative pressure device while on heated high-flow nasal cannula (photo used with permission after obtaining informed consent from patient and spouse). Panel **C)** Patient with COVID-19 wearing the portable helmet negative pressure device while on heated high-flow nasal cannula in prone position (photo used with permission after obtaining informed consent from patient).

A  **B** 

 **C**