UNMET NEED

Transmitted via respiratory droplets, the SARS-CoV-2 virus virus is highly contagious, placing healthcare workers at increased risk in the absence of adequate precautions. At the same time, the COVID-19 pandemic is rapidly straining hospital and ICU resources, including ventilator utilization and negative pressure room allocation.

There is a demonstrated need to develop a novel system which is capable of protecting healthcare workers during aerosol generating procedures (AGP) to limit virus transmission as well as provide adequate and safe patient care. While numerous "intubation boxes" have been proposed to reduce risk associated with intubation, none solve the myriad of other issues that emergency and critical care health providers face.

SOLUTION

To address this need, MCIRCC members collaborated with FlexSys, Inc of Ann Arbor, MI to develop a portable negative pressure procedural tent that circulates and removes air—including droplets exhaled by the patient—through an attached vacuum motor and HEPA filter before being released into the room. Unique to this innovation is the additional application of multiple access points in the tent to allow a greater number of procedures than prior proposed solutions.

The structure is completely portable and allows real-time manipulation of the patient. It keeps the providers separated and protected from the virus, but also allows contact and support for procedures, mitigating the need for additional negative pressure rooms. The entire apparatus is disposable and single patient use, with the exception of the manifold base which can be cleaned and re-used.

COMPETITIVE ADVANTAGES

- Comfortable: allows the patient to be supine, semi-recumbent, or seated upright
- Mitigates need for negative pressure rooms
- Improved confidence and comfort among healthcare workers
- Allows for a greater number of patient procedures than other proposed solutions
- Transportable across care environments

SUPPORTED AG PROCEDURES (AGP)

- Heated High-Flow Nasal Cannula (HHFNC)
- Non-Invasive Ventilation (NIV)
- Airway management
- Extubation
- Bronchoscopy
- Tracheostomy
- Chest compressions associated with CPR

Michigan Medicine
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FlexSys, Inc.
Sridhar Kota, PhD, CEO
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“As we move past the surge and into the tail of COVID-19 at Michigan Medicine, it is vital that we discover innovative ways to provide high quality care and the safest way possible.

I strongly believe that the Compact Respiratory Isolation System will be a tremendous asset to both the patients as well as the health system.”

Philip J Choi, MD
Assistant Professor of Internal Medicine, Division of Pulmonary and Critical Care
Medical Director, Assisted Ventilation Clinic, University of Michigan

Left: A patient with COVID-19 undergoing a bedside tracheostomy in the Aerosolve Tent, to assist with ventilator liberation.

PRELIMINARY TESTING

Under supervised, novel protocol, the team performed a mini-trial in Michigan Medicine’s Emergency Department-based critical care unit, obtaining feedback from providers (nurses, respiratory therapists, emergency physicians and anesthesiologists) to make several alterations and modifications.

Air handling and particulate testing was conducted with a healthy volunteer inside the tent wearing a heated high flow nasal cannula (HHFNC) @ 60L/min, CPAP, and nebulizer treatments @ 10L/min. In addition, the team inserted a salt water particulate generator to simulate a particle load similar to what would be seen in a patient with a cough and significant secretions. Despite the significant amount of particle generation inside of the tent, measurements outside (including near the arm ports, with and without arms in the ports) were equal or less than that of ambient air. Additional testing found the tent offers 50 times as many air exchanges per hour as a negative pressure room.

The tent was also tested under much larger aerosolization conditions using fog testing. Click here for video.

The device was then trialed on a patient with COVID-19 with hypoxemic respiratory failure. The patient had been on mechanical ventilation for two weeks and was in need of a tracheostomy to facilitate liberation from ventilator. (see image above).

Clinical, nursing, and respiratory therapy staff found the tent did not interfere with complex patient care, while providing a greater level of comfort and safety while performing the procedure.