Critical Life-Support Air Supply Management in Vital COVID-19

SIGNIFICANCE: This proposal addresses critical life-support air supply management in three vital COVID-19 contexts: (1) advanced Personal Protective Equipment (PPE) for health care workers; (2) advanced patient respiratory support; and (3) rapid deployment of portable isolated COVID clinical habitats and testing facilities. Leveraging the PIs recently awarded U.S. Patent #10155573B2 *Portable Inflatable Habitat with Modular Payload* (Dec. 2018) we will advance the novel integration and field deployment of a lightweight, low-power, self-contained Closed-Circuit Breathing Apparatus (CCBA) architecture with direct implications for successfully responding to the current COVID-19 pandemic (Fig 1). These efforts have strong likelihood for near-term licensing and commercialization—directly responding to multiple federal agencies solicitations.

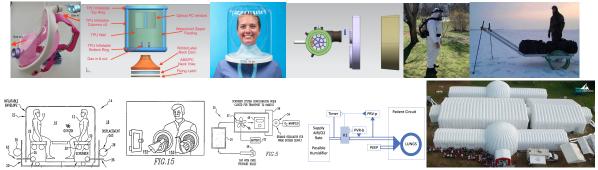


Fig 1. Critical Life-Support Systems: Face Mask, Helmet, Respirator, and Portable (Worn, Cart) CCBA. Bottom: Pls Patent Figs: isolation (habitat / manipulable testing), Ventilator Designs; and Inflatable Clinic. Personal Protective Equipment: COVID-19 is highly contagious and is transmitted through moisture droplets, airborne for up to several hours, and resides on hard surfaces for up to several days. CDC has reported that it can be transmitted through eye exposure, indicating the need for full face protection, not simply respiratory protection for healthcare workers.

Health care workers typically use an N95 mask for respiratory protection. These are in very short supply. Additionally, these are a suboptimal method of protection since the ambient breathing atmosphere must be utilized and any minor imperfections in fit around the oro-nasal area presents risk of viral exposure. Handling the N95 mask in between patients and then re-using the mask presents high risk given potential to contact a contaminated outer surface.

BSL-3 and BSL-4 facilities that commonly work with Ebola, SARS, and other infectious agents utilize supplied air positive pressure systems coupled with hoods. However, these are impractical in a hospital or makeshift 'ground-zero' emergency response setting given the needs for large footprint supplied air infrastructure, and when the ambient air supply must also be appropriately filtered. These systems rely on a consumable paper-like filter similar to the N95.

Until the current pandemic's mix of high patient volume, potential for airborne transmission, and limited effectiveness of N95 protection (physicians are still getting sick), biosafety specific applications for CCBA have not been widely needed.

<u>Solution</u>: Flexible CCBA architectures and active manufacturing supply channels recently developed and patented in the context of underwater habitat life support, now present a compelling solution to affording health care workers with suitable PPE (Fig 1). CCBA will enable extended incursions within infected areas with adequate protection. Similar approaches are used in mining, diving, space exploration, and for emergency egress of confined spaces.

Advanced Patient Respiratory Support: Several million people infected with COVID-19 (approximately 1 in 5) will experience significant respiratory distress. Most of these patients would

benefit from respiratory support technologies, however these are in extremely limited supply and often do not adequately isolate infectious exhalations. Not only have providers been exposed, but they are undertaking extraordinary measures, sharing ventilators and/or having to decide who will receive respiratory life support.

<u>Solution</u>: The PIs CCBA architecture, applicable to PPE as described above, has been readily reconfigured over the past month to prototype a range of advanced patient respiratory support, including CPAP, helmet and noninvasive positive pressure ventilation, and highly robust low-cost ventilators (Fig. 1). CCBA technologies are particularly warranted in the context of isolating infection and low-cost alternatives to (currently unobtainable) expensive ventilators.

Portable Isolated COVID Clinical Habitats and Testing Facilities: Several hundred thousand additional hospital beds are critically needed and municipalities are taking over dormitories, hotels, and convention centers. Outside of hospital environments, and even within, isolating patients and providers and controlling infection, is a challenge.

<u>Solution:</u> Portable isolated clinical habitats and testing facilities that can be rapidly deployed present a compelling option to meet this critical need. The PIs patented *Portable Inflatable Habitat with Modular Payload* addresses key elements of this need, directly, combining the lightweight low-power modular CCBA architecture coupled with a robust readily deployable inflatable structure (Fig. 1, isolated manipulation, cart, and inflatable clinic), provides life support, for providers and patients. The PIs have extensive experience with advanced airlock technologies eminently suitable to COVID-19, in both clinical and field-testing settings. We will demonstrate a portable, modular and readily deployable system that integrates PPE, advanced patient respiratory support, and isolated Habitats in a manner that addresses the provider, patient, clinical, and testing requirements of the COVID-19 pandemic.

WORK TO BE PERFORMED: Prototyping, evaluation, and commercialization activities demonstrating each of the above *solutions* within a comprehensive system, integrated for COVID-19 contexts. We will leverage patented CCBA architectures to achieve project deliverables.

DELIVERABLES: A series of increasingly refined modular systems for critical life-support air supply management that culminate in an adaptive modular integrated system providing advanced Personal Protective Equipment (PPE) for health care workers; (2) advanced patient respiratory support for patients; and (3) rapid deployment capabilities for portable inflatable isolated COVID clinical habitats and testing facilities.

SPECIFIC EXTERNAL GRANT MECHANISMS TARGETED: Include, but are not limited to:

NSF STTR COVID-19 DCL: https://www.nsf.gov/pubs/2020/nsf20065/nsf20065.jsp;

STTR: https://www.nsf.gov/pubs/2020/nsf20528/nsf20528.htm; and NSF RAPID COVID-19 DCL: https://www.nsf.gov/pubs/2020/nsf20055/nsf20055.jsp and NIH NIA 2020 STTR extensions to: https://grants.nih.gov/grants/guide/pa-files/PA-19-270.html

TIMELINE: The investigative team has the capacity for rapid deployment of the full range of these systems. We will work with community partners in AZ, NY, and RI, in the context of the evolving pandemic to maximize the potential of each of these systems, throughout a 6-month period. **INTERDISCIPLINARY PI TEAM:** Consists of Bio5 Faculty, PI Winslow Burleson (Human Factors, Health Sciences, Product Design, Information Science); Co-PI Michael Lombardi (Life Support Technology, Materials and Mechanical Design); Co-PI Kai Staats (Habitat Design, Mobil Logistics, Architectural Design). All PIs have principal investigator eligibility for federal grant submissions, and are or are willing to apply to be Bio5 members.