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ORIGINAL RESEARCH

Infectious Disease

Development and efficacy testing of a portable negative pressure enclosure for airborne infection containment

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Abstract

Objectives: To overcome the shortage of personal protective equipment and airborne infection isolation rooms (AIIRs) in the COVID-19 pandemic, a collaborative team of research engineers and clinical physicians worked to build a novel negative pressure environment in the hopes of improving healthcare worker and patient safety. The team then sought to test the device's efficacy in generating and maintaining negative pressure. The goal proved prescient as the US Food and Drug Administration (FDA) later recommended that all barrier devices use negative pressure.

Methods: Initially, engineers observed simulations of various aerosol- and droplet-generating procedures using hospital beds and stretchers to determine the optimal working dimensions of the containment device. Several prototypes were made based on these dimensions which were combined with filters and various flow-generating devices. Then, the airflow generated and the pressure differential within the device during simulated patient care were measured, specifically assessing its ability to create a negative pressure environment consistent with standards published by the Centers for Disease Control and Prevention (CDC).

Results: The portable fans were unable to generate any airflow and were dropped from further testing. The vacuums tested were all able to generate a negative pressure environment with the magnitude of pressure differential increasing with the vacuum horsepower. Only the 3.5-horsepower Shop-Vac, however, generated a −3.0 pascal (Pa) pressure gradient, exceeding the CDC-recommended minimum of −2.5 Pa for AIIRs.

Conclusion: A collaborative team of physicians and engineers demonstrated the efficacy of a prototype portable negative pressure environment, surpassing the negative pressure differential recommended by the CDC.

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KEYWORDS
clinical engineering, COVID-19, medical device design, negative pressure isolation, negative pressure pods, personal protective equipment, protective devices

1 | INTRODUCTION

As the COVID-19 pandemic outstripped worldwide supplier of personal protective equipment (PPE) and airborne infection isolation rooms (AIIRs), many clinicians and investigators sought to build devices to increase healthcare worker (HCW) safety, especially during aerosol-generating procedures such as intubation. A plethora of devices were developed and published. Many of the initial devices were passive barrier protection devices, including the quintessential example of the acrylic aerosol box.[1] These passive barrier devices were meant to restrict the spread of viral particulates—both aerosols and droplets—away from HCWs by using a physical obstruction to particulate movement such as a plastic sheet or acrylic wall. Later devices incorporated some degree of negative pressure, ranging from connection to wall suction to attachment of small portable suction devices all the way to incorporation of industrial air scrubbers attached to multiple containment devices at once.[2–4] As highlighted by a review by Sorbello et al, many of these devices were published without any testing to prove efficacy, either in protecting the HCWs or in ensuring the safety of patients within the device during use.[5] Moreover, these devices almost universally expected HCWs to remain in full PPE, and unfortunately, many of the devices may increase the risk of HCW PPE integrity breaches.[5]

Testing the devices' efficacy is essential to determine which devices, if any, should be further tested in a clinical environment to possibly improve HCW safety while maintaining patient safety. The passive barrier devices, for example, "may not be effective in decreasing healthcare provider exposure to airborne particles, and in some circumstances, may instead increase HCP exposure," as highlighted by the US Food and Drug Administration (FDA) in August 2020.[6] A proposed mechanism for this increased risk is that the air within the barrier is highly concentrated with viral particulates and that any changes in air pressure within the device—from coughing, for instance—could channel highly infectious air toward HCWs performing patient care at the device ports.[5] Unfortunately, the passive barriers' possible harm to HCWs was stated months after they were initially granted Emergency Use Authorization (EUA), leading the FDA to revoke the EUA for such widely published passive barrier devices. Instead, the FDA recommended only barrier "devices that incorporate negative pressure." Although the FDA has granted EUAs to several such negative pressure devices, the rigor of the device testing is unclear from the product websites.[7]

The Centers for Disease Control and Prevention (CDC) recommends a negative pressure of at least −2.5 pascals (Pa) for AIIRs, which should be a reasonable standard to prevent aerosol and droplet escape from any containment device.[8] None of the myriad devices highlighted by Sorbello et al documents success in generating such a negative pressure gradient.[5] Rather, many of the tests use either smoke clearance from within the device or fluorescent particle spread as their determinants of efficacy. Although these tests provide the visual suggestion of high efficacy, the devices' ability to generate the CDC's recommended negative pressure environment is uncertain.

The purpose of this investigation was to develop a device that (1) could generate a portable negative pressure environment, (2) isolate the patient and thus preserve PPE, (3) be constructed of readily available non-medical materials, (4) be cost-effective in construction and clinical implementation, and (5) highlight the various stepwise testing methods as performed on this device to guide other investigators who wish to evaluate the efficacy of their potential devices. The construction and testing of the prototype were the result of a collaboration between biomedical research engineers and clinical physicians.

2 | METHODS

2.1 | Device construction

The device uses a rigid, polyvinyl chloride (PVC)–based frame covered in a transparent plastic sheet with a connected sound-isolated vacuum (Figure 1). The device's dimensions were determined during physician-staffed procedural simulation sessions where engineers recorded measurements. The procedures assessed included application of a non-rebreather mask or a nasal cannula, bag-mask ventilation, and intubation using video laryngoscopy. To maximize staff procedural working space around the patient's head, 2 high-efficiency particulate air (HEPA) filters were placed on each side of the patient's head, allowing full access from the head of the patient's bed. Access to the patient can occur from either customizable user-made perforations along guidelines marked on the top and sides of the transparent plastic sheet or from along the sheet's bottom edge (Figure 2). The bottom edge is a large flap that drapes and conforms to the patient's torso and can be lifted to allow access to the patient; two small bags of metal ball bearings are added to give the edge weight.

To generate airflow and create a negative pressure environment, two commercially available 10-inch portable fans or various commercially available vacuums (Dyson 1.6 horsepower, Shop-Vac 2.5 horsepower, and Shop-Vac 3.5 horsepower) were tested. The fans or vacuums were attached to the device's 2 HEPA filter boxes either directly in the case of the fans or using standard 2.75-inch tubing (Figure 1). Because of high vacuum noise while in use, a custom-adapted, sound-isolating box was created using Pelican containers and foam baffles. The enclosure of the vacuums in these boxes allows for rapid

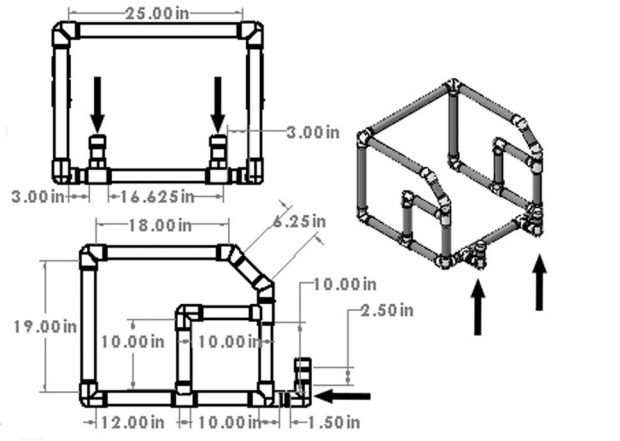


FIGURE 1 Picture of Covering for Operations During Viral Emergency Response (COVER) device on hospital stretcher with vacuum sound isolation box (a) and construction diagram (b). The COVER patient enclosure features a polyvinyl chloride frame with a transparent plastic sheet. The edge of the sheet is highlighted (+) and drapes over a patient's torso. The highlighted filter boxes (#) are cardboard boxes covered in duct tape. Tubing (white arrows) connects the patient enclosure's filter boxes to the sound-isolating box (black arrow). The sound-isolating box has an exhaust on the side opposite the tubing entrance. The construction diagram shows the patient enclosure when looking from the head of the bed (top) and from the side (bottom) along with an angled approach (right). The protrusions from the frame (black arrows) in the construction diagram can be rotated any direction to anchor the device

cleaning between uses and allowed for an additional HEPA filter on the vacuum exhaust. The developed prototype was called the Covering for Operations during Viral Emergency Response (COVER).

The device frame, connecting tubes, sound-isolating box, and vacuum are all reusable after cleaning. Cleaning can be performed with local hospital-approved sanitization procedures, such as those used for cleaning and sanitizing any normal piece of equipment in the hospital room. Because of their proximity to the patient, the HEPA filters and transparent plastic sheet were intended to be replaced between patient encounters.

The Bottom Line

To overcome supply and logistical barriers to adequate personal protective equipment and airborne isolation rooms, an interdisciplinary team of engineers and clinical physicians developed a novel, negative pressure patient care enclosure. Using simulations of aerosol-producing and droplet-producing procedures, the team developed and demonstrated the efficacy of a prototype portable negative pressure environment that surpassed the negative pressure differential recommended by the Centers for Disease Control.

2.2 | Temperature and decibel measurements

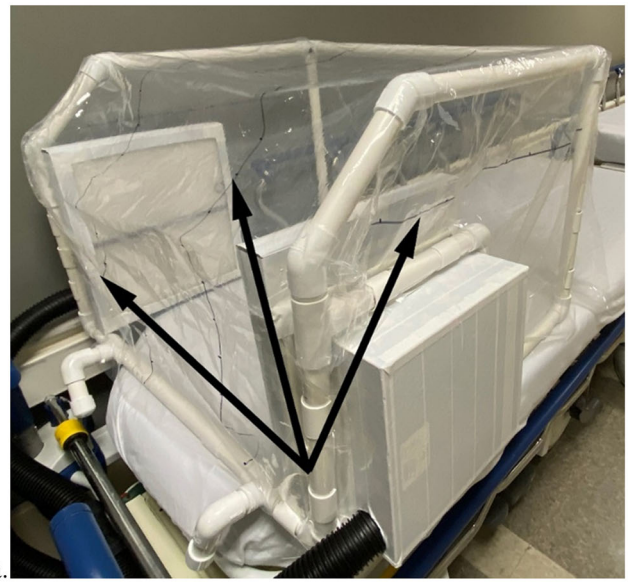
To ensure the fire and sound safety of the vacuum running while enclosed in these custom sound-isolating boxes, a trial of the largest horsepower vacuum set to run continuously for 50 hours was performed in an outdoor setting. The temperature inside the sound-isolating box and the noise level outside the box were continually measured using the commercially available Bluetooth Char-Griller Remote Grill Thermometer (Char-Griller, Atlanta, Georgia) and an Apple Watch Series 5 (Apple, Cupertino, California), respectively.

2.3 | Airflow testing

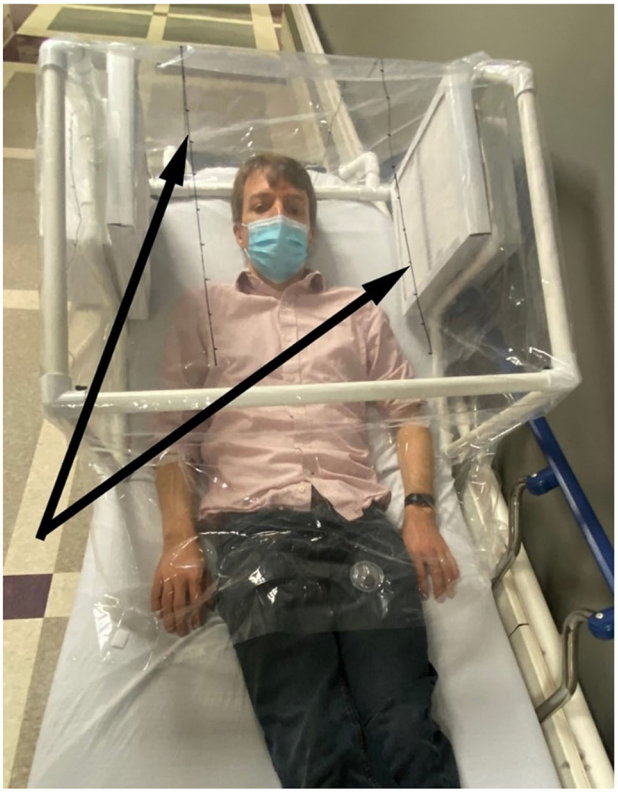
To assess for device efficacy, the airflow generated by the device using either the fans or the various vacuums was tested in an unused hospital room. This airflow testing was performed using a TSI-ALNOR EBT-731 (TSI Incorporated, Shoreview, Minnesota) capture hood and reported in cubic feet per minute.

To determine the total airflow capacity of the system, the airflow rates of the isolated filter boxes separated from the fully constructed COVER device were tested. Testing the filter boxes apart from the fully constructed COVER device assessed for the possibility of unintended leaks in the boxes themselves, which would draw in ambient room air rather than the air from within the patient enclosure. The subsequent effect of such a leak would be to reduce airflow through the entire device when fully constructed. The filter boxes were tested both with and without filters and attached to the portable fans or each of the candidate vacuum devices in the sound-isolating box to test the impedance of flow imposed by the filters directly.

Airflow generated by the various fans and vacuums was then measured when they were attached to the fully constructed COVER device, including the rigid frame and transparent sheet with the device placed on a hospital bed within a hospital room as it would be when used clinically. To test the airflow generated inside of the entire constructed device, a central 10-cm circular opening was created within the COVER device's transparent hood to attach the TSI-ALNOR EBT-731 hood, and the edges of the device were sealed to the bed. Although the



a.



b.

FIGURE 2 Picture of Covering for Operations During Viral Emergency Response (COVER) device on a hospital gurney (a) and on a hospital gurney with a simulated patient with head of bed elevated. (b) Linear perforation guides with 5-cm increments are noted by black lines (highlighted by black arrows) along the top, side, and head-of-the-bed device sides to facilitate patient care from a variety of sites depending on the required clinical activity. The device width allows for use on narrow gurneys as well as full hospital beds

edges would normally be unsealed in clinical use and were unsealed for later pressure differential measurement, measuring the device's total airflow capacity required them to be sealed. The airflow was again tested both with and without filters present to measure the degree of increased impedance to flow caused by the filter material.

2.4 | Pressure differential measurements

To determine whether a negative pressure environment was created, the pressure differential between the air within the transparent device hood and the air outside the device was measured continuously within an unused hospital room. A negative pressure differential, meaning the air pressure within the device is lower than the pressure external to the device, should prevent air escape both at intentional functional access ports and at transient barrier gaps generated by patient movement. A PPM3-S Abatement Portable Differential Pressure Monitor (Abatement Technologies, Fort Erie, Canada) was used to record pressure differentials in pascals in real time within the device. The pressure differential was measured with all vacuum strengths and with varying sized linear access cuts made through the clear plastic sheet. These access cuts through the sheet are meant to simulate the same cuts as made by any end user to access the patient during actual clinical use. The aggregate access cut size ranged from a minimum of 10 cm to a maximum of 60 cm. The maximum 60 cm was chosen based on use by clinicians for simulated airway management including endotracheal intubation: four 15-cm cuts would facilitate 2 ample-sized ports for the intubating clinician and 2 for assistant use, for instance. Lastly, the device's pressure differential was measured with both a simulated patient present and with the maximum 60 cm of functional access cuts made into the device. A clinical investigator was used as the simulated patient within the device; the same investigator was used during all the tests for consistency. A sample picture of an investigator in the device is shown in Figure 2b.

3 | RESULTS

3.1 | Device creation and costs

A full device material list with costs as sourced from a local hardware store is shown in Table 1. In addition, the construction diagrams for the PVC frame, pictures of the vacuum isolation box with baffles, and the final device as fully constructed and placed on an emergency department stretcher are shown in Figure 1. The total unit cost is $716.59 US dollars. The replacement costs for the filters and transparent sheets are also included in Table 1.

Although the time required to create the frame, filter boxes, tubing connections, and sound box will vary depending on builder familiarity and tools, a rough estimate of a single complete initial device assembly is 6 hours. Building and exchanging the disposable supplies takes roughly 20 and 10 minutes, respectively. Building multiple devices and additional supplies simultaneously yields a substantially lower per-unit time investment.

TABLE 1 Materials and cost list for Covering for Operations During Viral Emergency Response (COVER) device in US dollars ($)

Part name	Amount	Individual cost	Total cost
COVER device			
10-feet 3/4-inch diameter PCV	3	$2.54	$7.62
3/4-inch TEE PVC fitting	6	$0.59	$3.54
3/4-inch 90° corner fitting	6	$0.61	$3.66
3/4-inch side outlet elbow fitting	4	$1.98	$7.92
3/4-inch 45° fitting	4	$1.14	$4.56
3/4-inch PVC caps	2	$0.72	$1.44
10-inch cardboard gift boxes	2	$6.50	$13.00
String	0.12	$8.36	$1.00
HEPA D filters	2	$45.98	$91.96
Ziploc bags	0.02	$1.44	$0.03
Adhesive velcro	0.03	$11.99	$0.36
Thin weather stripping	1	$3.74	$3.74
Extra large weather stripping	2	$2.88	$5.76
Shower curtain	1	$2.99	$2.99
PVC cement	1	$5.18	$5.18
Duct tape	1	$6.98	$6.98
Packing tape	1	$2.98	$2.98
Thin physical barrier filter	1	$4.98	$4.98
Metal BBs	0.1	$8.46	$0.85
Total			$168.55
Vacuum unit			
Shop-Vac	1	$54.98	$54.98
2-inch Shop-Vac tubing	2	$20.48	$40.96
2-inch Y-split	3	$1.59	$4.77
2-inch caps	2	$2.17	$4.34
Pelican sound box	1	$442.95	$442.95
Total			$548.00
Total for 1-time purchase cost			$716.55
Replacement parts			
HEPA D filters	2	$45.98	$91.96
Thin physical barrier filter	1	$4.98	$4.98
Thin weather stripping	1	$3.74	$3.74
Shower curtain	1	$2.99	$2.99
Velcro	0.03	$11.99	$0.36
Total for replacement parts for repeat use			$104.03

Abbreviations: BBs, ball bearings; HEPA, high-efficiency particulate air; PVC, polyvinyl chloride.

3.2 | Temperature and decibel results

One of the sound-isolating boxes and the largest vacuum ran continuously for 50 hours to measure operating temperatures and noise generation; a thunderstorm disrupted power to the vacuum for 10 seconds during this trial. The temperature within the sound-isolating box ranged between 118°F and 162°F after an initial starting temperature of 82°F. The observed noise range during the test was 63–75 dB, with only 1 measurement exceeding 70 dB. For comparison, Occupational Safety and Health Administration requires hearing protection only if workers are exposed to an average noise level of 85 dB or greater >8 hours.[9] Also, for additional comparison, the Shop-Vac without the sound-isolating box generated 90 dB of noise.

3.3 | Airflow and pressure measurements

The airflow measurements are displayed in Table 2. The fans as part of the fully constructed device did not generate any measurable airflow and were dropped from subsequent testing. The data showed that the HEPA filters produce impedance to airflow but that increased airflow was observed with increasing vacuum horsepower. The pressure measurements generated under the varied test scenarios are shown in Table 3. The data showed that with increased vacuum horsepower there was also an increase in the negative pressure environment generated within the device. The highest measured airflow rates and pressure differentials were observed with the 3.5-horsepower vacuum, and the lowest observed pressure differentials were observed using the 1.6-horsepower vacuum. Importantly, however, all of the vacuums generated an observable negative pressure environment even with a simulated patient and 60 cm of access cuts made into the device (Table 4).

4 | DISCUSSION

The COVER device prototype is designed to overcome the scarcity of negative pressure isolation rooms and provide an increased level of safety for HCWs. Currently designed AIIRs limit the spread of airborne infections outside of the room but provide little protection while inside the room. This device could increase staff safety by reducing the number of viral droplets and aerosols in the ambient air surrounding a patient, whether in an AIIR, a normal patient room, or even an emergency department hallway. The device may help overcome critical N95 supply shortages, for instance, by allowing HCWs proximity to the patient without N95 respirator use, although this would require additional study to prove safety. Moreover, to our knowledge, this is the first novel negative pressure environment made exclusively of non-medical supplies that has been tested for efficacy in generating the CDC's goal pressure of −2.5 Pa. Using the device with the 3.5-horsepower vacuum generated a pressure differential more than this ideal pressure differential even with a simulated patient and 60 cm of access ports. The device could, therefore, increase the availability of negative pressure environments to meet widespread need during this or future pandemics even if traditional medical supplies are depleted.

The device could potentially be most useful for clinically important aerosol-generating procedures, such as nebulizer treatments and intubation. The device's demonstrated negative pressure environment should facilitate safe nebulized treatments, for instance, even when an entire negative pressure room is unavailable. Although the device's dimensions were chosen specifically to accommodate patient

TABLE 2 Measured airflow rates for the fans and various vacuums both on the isolated filter boxes with and without high-efficiency particulate air (HEPA) filters and for the fully constructed devices with filter boxes both with and without HEPA filters

	Isolated filter boxes		Fully constructed device	
Vacuum model	Without filter	With HEPA filter	Without filter	With HEPA filter
3.5-horsepower Shop-Vac	85	76	46	40
2.5-horsepower Shop-Vac	66	56	30	22
1.6-horsepower Dyson	36	34	21	7
Kitchen fans	65	36	Undetectable	Undetectable

Note: Flow rates are reported in cubic feet per minute.

TABLE 3 Pressure differential inside the Covering for Operations During Viral Emergency Response (COVER) device generated by various flow-generating devices and across various lengths on access cuts as measured in pascal (Pa)

	COVER pressure measurements (Pa)					
Flow-generating device	0 cm	10 cm	20 cm	30 cm	45 cm	60 cm
1.6-horsepower Dyson	−13.5	−13	−9.5	−6	−4.5	−3.5
2.5-horsepower Shop-Vac	−21	−21	−16.5	−10	−8	−7
3.5-horsepower Shop-Vac	−25	−25	−25	−23	−18	−17

Note: These measurements are without a simulated patient present.

TABLE 4 Pressure differential inside Covering for Operations During Viral Emergency Response (COVER) device with a simulated patient across various flow-generating devices and with and without a maximum 60 cm of access cuts and high-efficiency particulate air (HEPA) filters as measured in pascal (Pa)

	COVER pressure measurements (Pa)		
Flow-generating device	Without filter	With HEPA filter	With HEPA + 60 cm access cuts
1.6-horsepower Dyson	−2.2	−1.0	−0.7
2.5-horsepower Shop-Vac	−4.8	−1.8	−1.1
3.5-horsepower Shop-Vac	−8.0	−4.5	−3.0

intubation, any barrier device changes the mechanics of intubation, leading to possible impaired first-pass success. The device's customizable access ports in conjunction with its wide internal working space are designed to limit any impairment during intubation compared with earlier rigid barrier devices with fixed, non-customizable access ports. Overall, safety during intubation and other time-sensitive procedures would require further study and dedicated clinician training to lessen any potential impact on successful completion of these procedures.

Although some of the first published devices were passive barrier acrylic boxes, many subsequently published devices included a combination of a plastic tent or a plastic sheet over a rigid frame, employing wall suction or small vacuums for flow generation. Many of these devices feature a single HEPA filter if they include a filter at all. The COVER device's 2 intake HEPA filters, which provide more surface area to minimize flow impedance, still required a 3.5-horsepower vacuum to generate a pressure differential of −2.5 Pa. Although the efficacy of other published devices was not directly tested, their ability to generate necessary pressure differentials with smaller—and thus higher impedance—HEPA filters and less powerful flow-generation devices seems unlikely. Therefore, although the COVER's device containment structure is similar to other devices with a plastic sheet over a rigid frame, the COVER device is unique among published devices in its ability to generate a negative pressure environment commensurate to CDC specifications.

The testing process for airflow rates and for negative pressure generation is also unique among published devices. Many devices used visual droplet and aerosol testing to highlight the possible safety improvements to HCWs—in other words, fewer particulates were noted to have contaminated HCWs in proximity to or performing care within the enclosures during testing.[5] With regard to airflow testing, one device verified that flow persisted even after the application of an HME filter but did not further test if negative pressure within the enclosure was observed.[10] Both the airflow testing and pressure differential testing process highlighted in this article could serve as a guide for future device design and efficacy testing, especially for prototypes of similar negative pressure barriers.

Unfortunately, the COVER device's success in generating airflow and a negative pressure environment with the vacuum came at the

expense of increased sound generation. While the level of sound generated was mitigated by the sound-isolating box, the increased noise production makes conversation more difficult, although regular volume conversation was still audible. Patients who are hearing impaired or patients with critical illness may struggle to hear HCWs unless workers elevate their voice volumes. Depending on the hospital room configuration, vacuum noise generation could be further reduced by placing the vacuum immediately external to the room.

Because the sound and the temperature tests were conducted in an outdoor setting, the temperature fluctuated more than would be expected in a climate-controlled indoor setting, and some sound measurements may have been affected by loud external noises. The maximum observed temperatures, in particular, occurred when the ambient environmental temperature exceeded 90°F and when the device may have been in direct sunlight. Temperatures within the sound-isolating box were roughly 120–130°F overnight when the ambient air temperature was around 70°F. Of note, when used clinically, the patient would not have exposure to even these elevated temperatures as the sound-isolating box is physically separate from the patient enclosure. One foreseeable device limitation, though, would be that the vacuum's expelled air could slowly warm an entire patient room when in prolonged use. Ventilated and spacious patient rooms or hallways might not be affected by this heat generation as it was not experienced during this study's prolonged device testing within hospital patient rooms. As the device was only tested continuously for 50 hours, further testing in a clinical environment would be limited to 48 hours with a plan to exchange the vacuum, sound box, and enclosure at that time.

Similar to all barrier devices or even PPE, the COVER device limits the movement of the patient, affects interactions with staff, and could lead to increased patient discomfort. Anecdotally, the simulated patient during research did not find the enclosure uncomfortable or overly loud. The transparent plastic sheet is easily shifted, such that a patient can adjust an oxygen mask if needed, for instance. The constant flow of air seemed to prevent condensation on the sheet and the perception of stale, humid air within the enclosure. Similarly, the sound within the enclosure was described by various investigators as white noise with a constant yet non-irritating sound of air movement. As a final note, the device can easily be removed both by patients and staff—the frame, filter, and sheet are easily lifted or pushed aside if needed in an emergency. Although outside the scope of this study, the device's constant airflow likely reduces the magnitude of viral particulate concentration within the enclosure, making emergency COVER device removal less harmful to HCWs than removal of a passive barrier device, which abruptly exposes HCWs to a high concentration of viral particulates.[11]

5 | LIMITATIONS

The device was tested within the hospital setting on both emergency department gurneys and hospital beds in unused hospital rooms to approximate real-world application. Device assembly and use during testing, though, was solely by the team of engineers and physicians who worked to develop the device. Therefore, the measured airflows and pressure differentials represent the idealized system implementation; widespread implementation by hospital staff less well versed in the device may result in reduced airflow and lower overall pressure differentials. The simulated patient for testing was roughly 6 feet tall and of average build; further testing for comfort and efficacy for a wider variety of patient body types would be required before wider clinical implementation. In addition, although the simulated patient did move spontaneously during testing, real-world patient movements add a level of uncertainty that is difficult to fully predict, adding unintended leaks to the system. Depending on the magnitude and frequency of these movements, the device may have difficulty maintaining its negative pressure environment. Finally, whether a continuous negative pressure environment is maintained after hours of use and during a procedure such as intubation has not yet been directly studied. To overcome some of these limitations, a future iteration of the device would hopefully incorporate a visual indicator on the device to show HCWs appropriate negative pressure was being maintained during use; this indicator could serve as a warning that too many perforations were created, the vacuum was not performing as expected, or the HEPA filters required replacement.

6 | CONCLUSIONS

The COVER device uses off-the-shelf, non-medical components to generate a negative pressure environment in excess of −2.5 Pa as tested using a simulated patient and 60 cm of patient care access cuts. Further research will be needed to assess the device's patient and clinician usability along with the device's effectiveness in true droplet and aerosol containment.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

Phillip Moschella and John D. DesJardins conceived of the study. Phillip Moschella and Benjamin S. Roth drafted the manuscript. John D. DesJardins, Amanda LeMatty, Robert Falconer, and Noah Ashley designed and created the devices. Phillip Moschella, Benjamin S. Roth, and Chris Gaafary contributed to the design of devices. John D. DesJardins, Benjamin S. Roth, Phillip Moschella, Amanda LeMatty, Robert Falconer, Ehsan Mousavi, and Noah Ashley performed the initial experiments. Ehsan Mousavi and Ali Mohammadi Nafchi are responsible for the airflow and pressure measurements and data analysis. All authors reviewed and contributed to the final manuscript.

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