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DEVELOPMENT OF A NEGATIVE PRESSURE ISOLATION SYSTEM FOR CONTAINMENT, FILTRATION, AND DISINFECTION OF AIRBORNE DISEASES FOR USE IN HOSPITALS, AMBULANCES, AND ALTERNATE CARE SETTINGS.

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ABSTRACT

COVID-19 has renewed focus on the potential for medical interventions to nosocomially spread airborne infectious diseases to healthcare providers and other patients. Of primary concern is generation of potentially infectious plumes of droplets or aerosols by aerosol generating procedures (AGPs). This project developed a proof-of-concept prototype of a portable device capable of being deployed into hospitals, ambulances, and alternate care settings that is intended to reduce potential nosocomial spread of disease by mitigating aerosols and droplets in those environments.

Keywords: COVID-19, Negative Pressure, Nosocomial infection, Aerosol Generating Procedure, Airborne Infection Isolation Room, EMS, isolation hood

NOMENCLATURE

AIIR	Airborne Infection Isolation Room
AGP	Aerosol Generating Procedure
DMAT	Disaster Medical Assistance Team
EMS	Emergency Medical Services
HEPA	High efficiency particulate air filter
HVAC	Heating, Ventilation, and Air Conditioning
NDMS	National Disaster Medical System
NIPPV	Non-invasive positive pressure ventilation
UVGI	Ultraviolet Germicidal Irradiation

1. INTRODUCTION

The COVID-19 pandemic has created an international crisis in healthcare, especially with regard to our capability to care for patients who are in need of respiratory support. Before COVID-19 many patients with respiratory distress could be managed with Non-Invasive Positive Pressure Ventilation (NIPPV) or delivery of inhaled medications via nebulization. Unfortunately, the emergence of COVID-19 has highlighted the risk of pathogen dispersion and nosocomial spread that may be created through aerosols and droplets generated by these and other aerosol generating procedures (AGPs).[1, 2, 3, 4] These concerns led to the development of recommendations made by many entities to avoid AGPs whenever possible, and to only perform AGPs in Airborne Infection Isolation Rooms (AIIR) if possible.[5,6]

Early in the COVID-19 pandemic limitations on the availability of AIIRs in hospitals led to the development of novel strategies to mitigate the risks of AGPs so they could be performed outside AIIRs. Multiple versions of "intubation boxes" were constructed, though when subjected to critical analysis most were found to be ineffective in reducing the spread of aerosols created by endotracheal intubation and other AGPs.[7, 8, 9]

The design and construction of many of these devices was focused on creating solutions for the in-hospital environment. These devices were often cumbersome, large, rigid, heavy, and/or reliant on existing vacuum or ventilation (HVAC) systems within the hospital, making them impractical for use in healthcare settings such as EMS ambulances or alternate care sites such as National Disaster Medical System (NDMS) Disaster Medical Assistance Team (DMAT) field hospitals. Additionally, many of these designs were limited in their portability even within a hospital.

This project was undertaken to build on the lessons learned during the development of other similar devices and to address gaps in the ability to deploy such devices into non-hospital based clinical environments and to improve portability of the device.

Specifically, this project involved developing a proof-of-concept prototype of a portable device comprised of a bonnet intended to be affixed over the head and torso of a patient laying on a stretcher, bed, or gurney and that is connected via a flexible

duct to a box in which a blower fan unit is interposed. The fan unit is intended to create laminar flow through the system originating from the cranial end of the patient's bed and exiting through the terminal end of the fan box. Biological aerosols originating from the patient, such as viral particles, are intended to be contained from the air flowing through the system by passing through a HEPA filter at the intake port within the bonnet. Any remaining biologic contaminants in the airstream then also pass a UVGI lamp as an additional level of disinfection. The entire system is designed to be collapsible and stored within the fan-box unit allowing for storage and easy transport of the device. Several failsafe features are integrated into the prototype to prevent the system from circulating unfiltered aerosols and to protect the patient and other end users from UV radiation.

2. MATERIALS AND METHODS

In addition to addressing the primary technical requirements of being capable of collecting, isolating, filtering, and mitigating infectious aerosols and droplets in a clinical care setting, several other critical prototype features were prioritized.

2.1 Primary Design Features

These include:

- being useable in a variety of clinical environments such as ground-based ambulances, skilled nursing facilities, and NDMS/DMAT field hospitals, as well as traditional in-hospital settings including emergency departments, medical wards, operating suites, and ICU settings;
- having minimal or no impact on the delivery of routine, urgent, or emergent clinical interventions to a patient and allowing use of existing therapeutic technology within the applicable clinical setting; and
- being rapidly and easily removed from the patient to facilitate emergency access should the need arise.

2.2 Secondary Design Features

Other important design features were also identified and include:

- portability with regard to the ability to transport the device with a patient when moving a patient across different care settings;
- ease of assembly at the bedside to allow rapid deployment by end-users with minimal training and without tools;
- safety features such as fail-safes to prevent inadvertent distribution of un-mitigated aerosols into the care environment and to prevent end-user exposure from Ultraviolet-C (UVC) light;
- durability for deployment in ground ambulances and temporary or improvised healthcare settings such as DMAT shelters, or other ad hoc clinical environments;
- simple design to allow for rapid manufacturing;
- low-cost of production; and
- low-cost of end-user adoption.

2.3 Technical Requirements

Though there are no technical standards specific to this type of device, several standards exist for devices or rooms that are designed to perform a similar purpose to contain and mitigate infectious aerosols. These include CDC guidelines for AIIRs requiring ≥12 Air Changes per Hour (ACH), and biosafety cabinet standards set forth by the European Standard and NSF/ANSI requiring inward airflow to be maintained at a minimum velocity of 75 cfm (2.1 cmm) (Type A1) or 100ft/min (2.8 cmm) (Type A2).[10, 11, 12] Additionally, the CDC has also set forth standards with regard to Ultraviolet Germicidal Irradiation.[13]

2.4 Prototype Construction

The proof-of-concept prototype device was constructed from various off-the-shelf materials and supplies, either used as-is or following modification. Three distinct prototype components were constructed from various materials: a bonnet, a docking interface, and a fan box. Other off-the shelf components that were used without modification are also described where applicable. Figure 1 is a schematic depiction of the prototype. Figure 2 illustrates various features of the prototype. Figure 3 depicts deployment of the prototype on a typical emergency department bed.

Bonnet

The bonnet was constructed of several articulating ribs connected by a pivot point over which clear PEVA film was affixed, creating a chamber that could be placed over a patient's head and torso upon a hospital bed, ambulance gurney, or military-style disaster stretcher. The opening of the bonnet was constructed to allow variable sizing of the aperture by adjusting a section of PEVA film that draped over the bonnet opening.

The ribs of the bonnet were comprised of HDPE tubular plastic chain-link fence privacy slats (Slat Depot, Lindon, UT). These slats had an original dimension of 28mm x 1.8m and were modified by being cut to length and then heat molded using a heat gun and custom-made jig to bend the slats into an appropriate corner radius.

The film used to create the chamber of the bonnet was custom cut from a sheet of 8GSM PEVA film (Liba USA, Irvine, CA). After being cut to custom size and geometry the film was affixed to the rib frame using aluminum rivets.

In this prototype the film was affixed permanently to the bonnet support struts, though in future iterations the design will be modified to allow for temporary attachment of the film to the support structure, allowing for the film to be disposed of and replaced between patient use. Eye bolts were affixed at the corners of the lower support strut in order to receive elastic cordage (Ball-bungee cord tarp strap, Horusdy, Hangzhou, China) intended to allow the bonnet to be secured to the patient's bed or stretcher.

The construction of the bonnet allows for it to be folded to a nearly flat configuration that can be placed within the fan box for storage and transportation of the device when it is not in clinical use. The final dimensions of the bonnet in folded position is 25cm L x 53cm W x 7.5cm H and in deployed position was 61cm L x 53cm W x 51cm H. The width of the bonnet was determined by the standard width of an ambulance gurney or military litter/stretcher.

Docking Interface

A docking interface was constructed in order to connect the bonnet to the fan box via a flexible duct, allowing the device to generate negative pressure and laminar flow of air originating from the aperture of the bonnet and passing through the filter and past the UVGI lamp into the fan box. The docking interface was built from the following components: a 152mm stainless steel flange kit (Hydrofarm Store, Petaluma, CA), a PP plastic 200mm to 150mm round ducting reduction adaptor (DuctREDUCER-200, Hon&Guan, Shenzhen, China), and a PVC electrical junction box (1 in. Schedule 40 and 80 PVC Type-LR Conduit Body, Carlon, Cleveland, OH).

The docking interface is integrated into the cranial end of the bonnet and to receive a 15cm circular HEPA filter cartridge (ROTALO LV-H132 Replacement Filter, Anaheim, CA). The filter receiver includes an integrated 2.5A 125V AC dual NC/NO momentary switch, (Refrigerator Light Switch, Module Type: HC-050K.4, Rated Voltage: 125/250V AC, Rated Current: 2.5A 250V/5.0A 125V - 1 NC, 1NO, Connect Pin Size: 4.8x0.5mm/0.19x0.02in, Shenzhen, China) interposed into the electrical supply for the UVGI lamp and the fan unit. This switch is intended to interrupt power supply to the fan and UVGI light in the case that the filter cartridge is not properly seated in the filter receiver.

Audible and visual system status indicators [trouble indicator: panel mount LED/buzzer alarm signal indicator, red lamp 220V AC (Panel Mount LED Buzzer Alarm Signal Indicator Light Lamp AC 220V Red, Shenzhen, China); normal function indicator: panel mount LED signal indicator, green lamp 120V AC NPL-22 22mm 120V AC/DC LED Pilot Indicator Light, Alpinetech, Chino, CA)] are also integrated into the docking interface to provide the end-user both auditory and visual indicators of system operation or trouble status.

Connecting duct

The ducting used to connect the bonnet to the fan box was used without modification and consisted of a 15cm diameter four-layer HVAC ventilation hose (TerraBloom, Walnut, CA). The hose was constructed of an outer layer of PVC, two layers of aluminum, and an inner layer of PET and given support by a steel wire helix. The construction of this hose was chosen due to its flexibility, the reflective inner surface to allow increased distribution of UVC light emitted by the UVGI lamp and because the hose could be collapsed into a small footprint allowing it to be stored with other components within the fan box when the device is not in use. The duct was secured to the docking interface and fan box flanges using stainless steel 6in thumb-screw hose clamps (6-Inch Hose Clamps Stainless Steel Easy Turn Thumb Screw, Glidestore, USA)

Fan box

The prototype fan box is constructed using modified off-the-shelf components, though a final production model would likely be constructed as a custom-molded unit. To construct the fan box a plastic storage tote measuring 76cm L x 41cm W x 39cm H (Remington Weathertight 82q Store-it-all storage box, Iris, USA) was modified by cutting a 15cm diameter hole on one end to attach a duct flange to serve as an attachment point for the connecting duct. On the opposite end of the tote a 30cm x 30cm square was removed to receive the fan unit. The fan unit used for this prototype is a 25cm axial exhaust fan that generates 403cfm (11.4cmm) of air movement (9800512 10" Metal Shutter Exhaust Fan, Home Depot, Atlanta, GA). The interior surface of the fan box and lid were lined with a reflective two-layer polyethylene and metalized aluminum polyester film (reflective foil insulation Class 1/Class A fire rating, US Energy Products, Doral, FL) in order to increase the distribution of UVGI light within the airstream.

A keyless e-26 lamp socket intended to receive a UVGI LED lamp was secured within the duct flange so as to emit UVC light inside the connecting duct and the fan box. A 15A 125V AC SPST push button momentary switch (Heavy Duty Utility AC Push Button Momentary Switch - SPST : 30-1426, Philmore LKG, Rockford, IL) was interposed within the electrical circuit controlling the UVGI lamp and installed near the top edge of the tote such that when the lid is properly applied to the fan box the switch would be depressed allowing current to flow to the lamp. This fail-safe was utilized to prevent exposure of the end-user to the UVGI light if the fan box lid was not properly secured.

Power distribution unit

The power distribution unit (PDU) for this prototype was integrated into the fan box. The PDU receives 120V AC power from a standard external supply cord via a sealed 15A 125V AC power plug inlet (15A GCP AC Port Plug, NOCO Inc, Cleveland, OH). Electrical power is routed from the PDU through the docking interface and to the lamp socket and fan unit via a 16/3 3-wire insulated cable that was modified by removing the standard male and female connectors and replacing them with waterproof 3-wire 12AWG connectors (3-wire Weather Pack Connector Kit, Online LED Store, Ontario, CA). Single pole switches (110V-220V 3A Latching Push Button Switch Brass Nickel Plating with Wire Connector Socket Plug for 16mm /0.63" Mounting Hole, Sydien, USA) are integrated into the PDU to allow end-user control of the device. Various failsafe switches described elsewhere are also interposed into the electrical circuit. As an alternative to 120V AC power, Lithium-ion batteries can be integrated into the fan box to provide an independent DC power source. This would allow the device to function without an external power supply for short periods of time such as when

moving a patient from an ambulance into an emergency department or when moving a patient between wards of a hospital.

2.5 Prototype Testing

At present this device prototype has been constructed as a proof-of-concept and has undergone only one of three standard tests used to certify Class A biosafety cabinets. An anemometer (Pyle CFM/CMM Thermo-anemometer model PMA90, Pyle USA, Brooklyn, NY) was used to measure the air velocity at the face of the bonnet using variable aperture sizes. Several other methods of evaluation have been previously described for similar devices and are directly applicable to the evaluation of the functionality of this particular prototype but have not yet been available to our prototype development team.[7,14]

3. RESULTS AND DISCUSSION

The face velocity tests conducted on the prototype revealed expected variable readings that were dependent on the aperture size of the bonnet face. When the bonnet's front drape was fully deployed resulting in the smallest aperture opening face velocity measurements exceeded 100cfm (2.8cmm). When the bonnet drape was fully retracted face velocity measurements exceeded 75cfm (2.1cmm). Face velocity measurements in both conditions met minimum standards for a Class A1 biosafety cabinet, and the prototype achieved measurements that met minimum standards for a Class A2 biosafety cabinet when the drape was fully deployed. Additional testing including visual smoke pattern analysis using neutrally buoyant smoke, and aerosol leak testing using a test aerosol that mimics the size of virus-containing particulates are required to determine if the prototype meets additional Class A biosafety cabinet standards. As the prototype is engineered beyond the proof-of-concept phase the evaluation methods described in Turner et al and Phu et al must be performed. [7, 14] Further assessment should include determination of airflow velocity and volumetric flow rates using the log-Tchebycheff method; spectrophotometric measurements of the UVGI spectral intensity; and fluence calculations determine whether adequate airborne virus log-reduction is achieved via by UVGI.

Early in the pandemic concerns were raised about the worldwide healthcare system's capacity to care for surges in patients requiring mechanical ventilation and other ICU-level care. This situation spurred increased production of mechanical ventilators as well as development of simplified versions of mechanical ventilators for use in low-resource environments.[15] Unfortunately, capacity concerns grew when strategies recommending early use of endotracheal intubation and mechanical ventilation instead of use of NIPPV were made. As an alternative to strategies aimed at early use of mechanical ventilation some hospitals investigated novel methods for delivering NIPPV, such as helmet-NIPPV. Unfortunately, each of these solutions required healthcare institutions to either use scarce resources or to replace existing technology and supplies resulting in increased costs of delivering care.

An alternative to avoiding AGPs includes a strategy to aimed at mitigating the aerosolization risk associated with AGPs by collecting and filtering the air in the patient care environment. Traditionally this has been accomplished by placing the patient in AIIRs. However, most hospitals have a limited number of existing AIIRs, and the surge in patient volumes that has occurred during the COVID-19 pandemic quickly outpaced the supply of such rooms. Some facilities took steps to expand their AIIR capacity by improvising or modifying existing hospital infrastructure, at times at significant expense. Such an improvised modification is illustrated in Figure 4. Unfortunately, such solutions are not currently available in a practical sense in other healthcare settings such as in ambulances or in alternate care sites such as improvised field hospitals.

The prototype described in this paper offers an approach to mitigating potential nosocomial spread of airborne diseases that is compact in size, usable for individual patients, deployable across several different care environments, and that does not require modification of any existing healthcare infrastructure.

This prototype offers several potential benefits. First, it will allow for broader use of AGPs like NIPPV in multiple care environments and may help reduce the need for endotracheal intubation and mechanical ventilation in these settings. In addition, this device will also facilitate safer use of nebulizer-based administration of medication, in turn reducing the need to use scarce and expensive metered-dose inhalers to deliver these inhaled medications. Furthermore, this device enables utilization of technology and supplies that currently exist in most clinical settings, thus helping avoid the unnecessary increased costs associated with adopting alternative technologies or therapies.

We believe that the overall savings this device could achieve for the healthcare system is significant and includes enabling use of existing therapeutic technologies, reducing the need for construction of permanent AIIRs, reducing the use of expensive alternative invasive therapeutic interventions, potentially reducing patient morbidity and mortality, and reducing absenteeism by mitigating the risk of nosocomial spread of airborne diseases among healthcare workers.

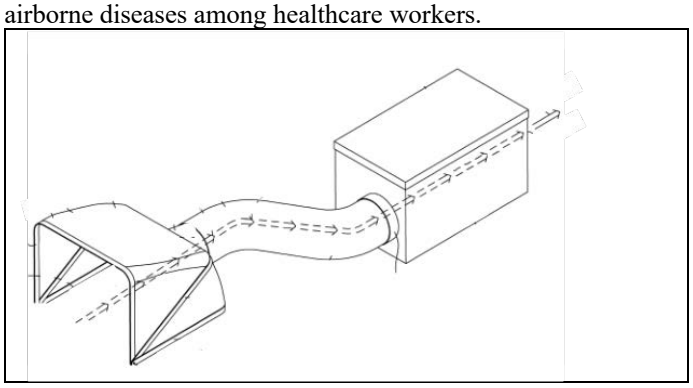

FIGURE 1: SCHEMATIC DRAWING OF DEVICE CONCEPT

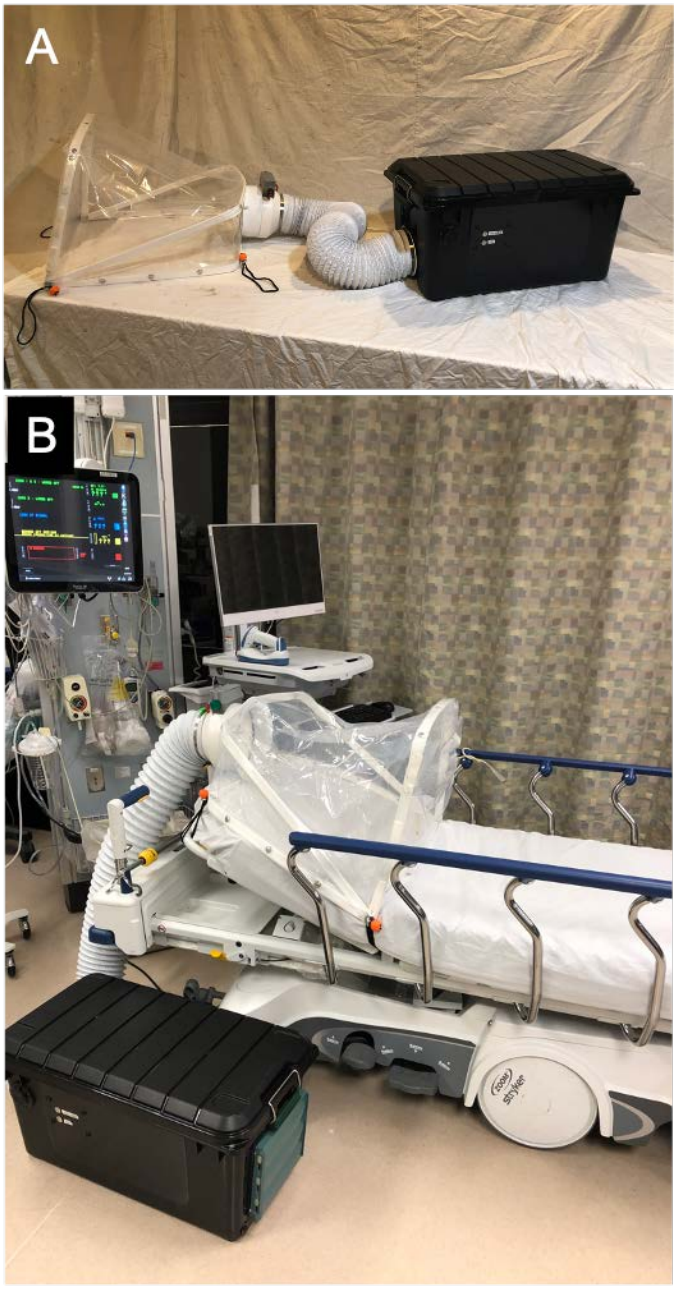

FIGURE 2: A) PROTOTYPE DEVICE B) PROTOTYPE DEPLOYED IN A TRADITIONAL EMERGENCY DEPARTMENT SETTING (*Photo credit: J Lyng, MD)*

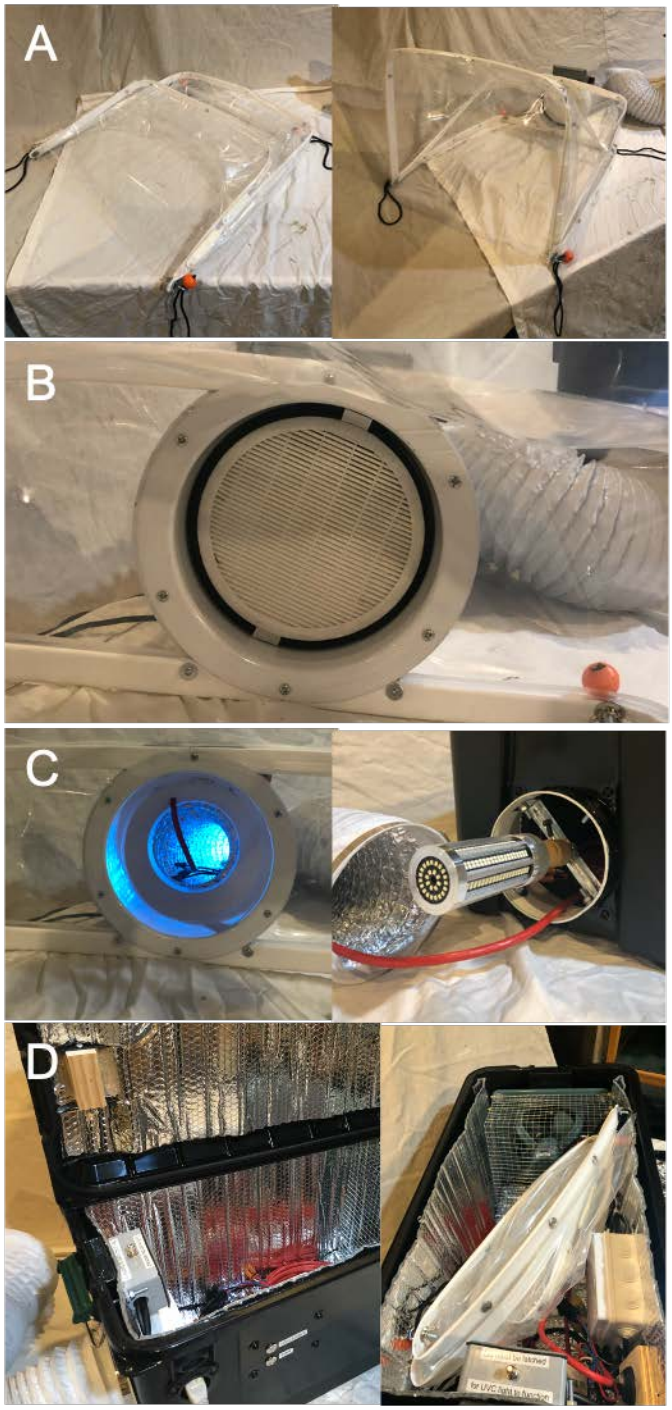

FIGURE 3: PROTOTYPE DESIGN FEATURES: A) TRANSPARENT PATIENT HOOD IN FOLDED AND UNFOLDED STATE, B) HEPA FILTER, C) UVGI LAMP, D) FAN BOX AND FAN BOX WITH SYSTEM COMPONENTS FOLDED AND STORED. (*Photo credits: J Lyng, MD)*

FIGURE 4: IMPROVISED NEGATIVE PRESSURE SYSTEM IN A COVID HOSPITAL (*Photo credit: J Lyng, MD)*

4. CONCLUSION

This protype device has the potential to positively impact patient care by enabling use of AGPs outside of AIIR settings, to reduce the need for invasive respiratory management interventions, to reduce nosocomial spread of infectious diseases in hospitals, ambulances, and alternative care settings, and to reduce the overall cost of caring for patients with airborne diseases.

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