Cost-effective protection of healthcare workers and patients from airborne pathogens with SafER Medical Products Portable Negative Pressure Respiratory Shield Kit

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Abstract

The safety of hospital health practitioners, hospital patients and other staff has been severely tested during the SARS-COVID-19 epidemic of 2020-2021. The so-called fugitive emissions of viral particles from infected patients either through coughing, sneezing or through use of aerosol therapies have been identified as likely sources of virus transmission. Precautions ranging from the simple (improved hygienic practices) to a more thorough use of PPE to finally usage of negative pressure rooms have been advocated. Yet usually there are not an abundance of such rooms in typical hospitals, and an alternative method to limit the inter- and intra-room spread of the virus would be a boon. In this study we introduce the SafER Medical Products portable negative pressure system (PNPS) with respiratory kit that can be fitted directly over the patient's face, negating the necessity of negative pressure rooms. Through an extensive series of particle count measurements at diameters of 0.3µm, 0.5µm, 0.7µm, 1µm, 2.5µm, 5µm and 10µm, which encompass the size of most virus particles, bacteria and nebulizer droplet diameters in a hospital room environment, the PNPS was found to reduce particle counts at all measured size fractions. The reduction was significant, by approximately two orders of magnitude, or ~ 100%. Furthermore, the portability of this system also makes it highly applicable to hazardous transportation environments such as ground and air ambulances (planes and helicopters).

Background

The SARS-COVID-19 pandemic that originated in China and spread rapidly across the globe in 2020 tested the resolve of governments and citizens worldwide. School and shop closures, lockdowns, the mandatory wearing of masks in those few stores left open (grocery and pharmacy) all became part of the daily routine. Hospital emergency wards were overflowing, scavenging beds wherever they could at the expense of treatment of other non-COVID related illnesses. It became rapidly apparent that those at incredibly high risk of contracting the virus were hospital workers and emergency medical service front line responders. Specific hazards were identified with aerosol therapies, commonly used to treat pulmonary diseases. Such treatments had potential to emit so called "fugitive emissions" due to their generation of aerosols and droplets, providing a vehicle for the spread of pathogens. Ari[1] provided some early advice for health care practitioners, noting that delivery of aerosolized medications to patients with COVID-19 who have spontaneous breathing or receive non-invasive ventilation or high flow nasal cannula were at particularly high risk. However, if aerosolized medications are absolutely required in patients with COVID-19, the patients should be isolated in an airborne infection isolation room (AIIR) or negative pressure rooms with a minimum of 12 air changes per hour or at least 160 liters/s/patient in facilities with natural ventilation. Of course, these guidelines were in addition to the more obvious which included training on infection prevention and control, proper use of personal protective equipment and good hand hygiene and double gloving practice. In addition, use of surgical respirators such as N95 or FFP2 standard or equivalent, goggles/face shield, gloves, gowns, and aprons (if gowns were not resistant to fluid) during aerosol therapy was advised. Sethi[2] also supported the use of negative-pressure rooms,

disposing or disinfecting PPE after each use, and maintenance of at least 6 ft or greater distance from the patient. Notably, they also recommended that nebulizers be used with a mouthpiece and filter. The narrative review from Wilson et al.[3] provided a somewhat different outlook, as they suggested that several aerosol-generating procedures may in fact result in less pathogen aerosolisation than a dyspnoeic and coughing patient. They recognized a lack of evidence and suggested that measures to mitigate airborne transmission should be employed and while awaiting more robust evidence, a precautionary approach should be considered to assure the safety of healthcare workers. Miller and Englund[4] added that aerosolization of the virus could occur during procedures such as bronchoscopy, endotracheal intubation, administration of nebulized treatments, manual bag ventilation before intubation, pronation of a patient, tracheostomy, and cardiopulmonary resuscitation and as a result healthcare workers should wear N95 masks, eye shields, gowns, and gloves. Jeschke et al.[5] were a little more blunt in their recommendations and suggested that nebulized medication should be avoided. Benge and Barwise[6] were also not keen on the use of nebulized therapies, recommending that nebulized therapies on medical wards and in intensive care units be deprescribed as an infection control measure and also avoided in any outpatient health care setting. They were also against the use of unproven nebulized therapies. These sentiments were largely echoed by Reychler and Vecellio[7], who advocated for the use of pressurized metered dose or dry powder inhalers where possible. If a nebulizer was absolutely required, an expiratory filter or disposable nebulizer was recommended. Throughout 2020, the consensus in the literature seemed to be that use of proper PPE was of utmost importance to prevent spread of the virus to healthcare workers, and the use of nebulized medication should be looked at by the physician on a case-to-case basis. But as 2020 drew to a close, there were still those that believed there was no clear evidence that the virus was spread by nebulization procedures[8,9]. In fact, Wei et al. found no evidence in their sampling study of hospital rooms for fugitive virus particles[10]. But case studies looking at infections acquired by hospital care workers, which may or may not have been acquired via a nebulized treatment, indicated the need for the highest levels of precaution[11,12].

During the pandemic, guidance not only for hospital procedures but for all aspects of life was in a constant state of flux, taking advantage of data and lessons that were learned only a few weeks to months prior. As a result, literature published in 2021, summarized in the following paragraphs, had the benefit of more expansive data and healthcare practitioner experiences.

Cazzola et al.[13] recognized that there was still a rather intense debate about the appropriateness of the use of nebulizers during the pandemic. Based on their examination of the issue, they believe that if the patient followed social distancing guidelines, undertook extra precautions such as increased nebulizer hygiene, avoided nebulizer use in the presence of other people and preferably near open windows or areas of increased air circulation, the risks toward others could be minimized. They also advocated for the use of negative-pressure rooms, disposal of used equipment after each use, and maintenance of at least 6 feet (1.8 m) distance from the patient during nebulizer treatments. A second article by Ari et al.[14] elicited basically the same thoughts as their original paper, but this one placed more emphasis on issues and precautions with the use of high flow nasal cannula (HFNC). They concluded that given the unknown risk with the transmission of COVID-19 during HFNC therapy, the benefits of HFNC should be weighed against the risk of infection to healthcare workers and other patients. Also, as a result of the limited availability of ventilators in hospitals and the confirmed effectiveness of HFNC in treating hypoxemic respiratory failure, HFNC may prevent early intubation and prolonged ICU stays in patients with COVID-19. Shah et al.[15] offered several guidelines based on their experiences which included maximizing air exchanges and using negative pressure isolation, minimization of nebulization, and avoidance of routine suctioning were amongst

their 13 recommendations. Kato et al.[16] reported results from their visualizations of droplet spreads from nebulizers indicating that active ventilation should be performed with nebulizer therapy to reduce the risk of nosocomial transmission. Furthermore, once a patient uses a nebulizer in a room without any form of active ventilation, the air in the room would be contaminated for 300 s or more. Liu et al.[17] also provided a cautionary tale from their aerodynamic analysis of virus particles in two Wuhan, China hospitals. They surmised that the COVID virus may have the potential to be transmitted through aerosols but that room ventilation, open space, sanitization of protective apparel, and proper use and disinfection of toilet areas could effectively limit the concentration of the virus in aerosols. The work of Lavorini et al.[18] still continued to preach the lack of evidence that nebulised treatment represents a risk for infection transmission due to the scarcity of information. They however cautioned that although there is no evidence showing that aerosols generated by nebulisers contain pathogens unless the nebuliser is contaminated, healthcare workers should continue to exercise caution with nebulisers and protect themselves from COVID through thorough sanitization protocols and the use of personal protective equipment during aerosol delivery to patients with known or suspected infection. They concluded that if precautions, such as nebuliser hygiene, avoidance of nebuliser use in the presence of other people, and nebuliser usage only in areas with adequate ventilation, were abided, the possible risks for health care personnel could be minimised. Though van der Walk and in 't Veen[19] felt that the evidence for virus transmission via aerosols was at least as strong as the evidence for transmission via deposition of droplets on surfaces, their recommendations for the protection of healthcare workers was similar to those described previously - face protection using masks and good quality ventilation. Hebbink et al.[20] examined the application of nasal high flow therapy (NHFT), continuous positive airway pressure (CPAP), and bi-level positive airway pressure (BiPAP), and determined that caregivers need to be protected with adequate PPE, with no clear preference given to one therapy over the other with regard to risk of transmission.

Examining all these studies, presented in somewhat chronological order, the debate over virus transmission through nebulizer use remains, but regardless of what side the clinician stands on this debate, there is no arguing the need for precautions such as excellent hygiene, proper PPE and good ventilation with several arguing for negative pressure rooms. But it is clear that any improvements in virus transmission mitigation technologies would be most welcome.

In this study, we introduce the SafER Medical Products Portable Negative Pressure Respiratory Shield Kit and demonstrate its high effectiveness at reducing room particle count rates during simulated nebulization treatment.

Experimental

The SafER Medical Products (Branson, MO, USA) portable negative pressure system with respiratory kit is shown in Figure 1. The volume of the respiratory shield is 1000 ml, resulting in 4 air exchanges per second under shield. The vacuum is rated at 260 liters/min and operates with < 60 dB noise and provides an open negative pressure of vacuum of .757 PSI. The vacuum filtration is an ultra-low penetration air filter (ULPA), which can remove from air at least 99.999% of dust, pollen, mould, bacteria and other airborne particles with a minimum particle penetration size of 120 nm. The nebulizer used was an Invacare Select IRC1705 (Elyria, OH, USA). For comparison, tests were also performed in a negative pressure room with dimensions of 10 ft. x 10 ft. x 8 ft. for a room volume of 800 cubic feet. The air handler in this room was rated at 205 CFM, providing 15 air exchanges per hour and equivalent to a typical hospital negative pressure room. This results in 99% of the particles

being removed from the room every 18 minutes. A high efficiency particulate air filter (HEPA) was used in the negative pressure room system. These can theoretically remove at least 99.97% of dust, pollen, mould, bacteria, and any other airborne particles with a size of 300 nm.

Figure 1: SafER Medical Products portable negative pressure system with respiratory kit

Particle count data was acquired using a Temtop PMD 331 particle counter (Milpitas, CA, USA), which uses a 50 mW, 780 nm wavelength laser to determine particle counts using the Mie-scattering principle. It provides counts for 0.3µm/ 0.5µm/ 0.7µm/ 1µm/ 2.5µm/ 5µm/ 10µm particle sizes. To put this in context, a typical human hair has a diameter of roughly 50-75 µm.

The respiratory shield study was conducted in the negative pressure room. The negative pressure may or may not have been turned on depending upon which parameters were to be investigated. A human mannequin was placed sitting in a chair in the center of the room. The particle counter was placed in front and to left side at a 45 degree angle, 3 feet from and level with the patients head. An aerosol mask and acorn nebulizer with compressed air delivered via the nebulizer compressor at an approximate rate of 0.5 ml of 0.083% Albuterol Sulfate solution (2.5 mg/3 ml) as an aerosol particle surrogate (this is a commonly used as test surrogate). A volume of 3 ml of this solution was placed in nebulizer and allowed to run for 5 minutes. The particle meter recorded 5, one-minute recordings per session on 7 simultaneous channels to measure particle count rates at different sizes (0.3, 0.5, 0.7, 1, 2.5, 5, and 10 µm). Following this measurement, the room was allowed to ventilate via the air handler for at least 18 minutes (which was calculated to produce sufficient air exchanges to remove 99% of emitted particles).The procedure is repeated 10 times to get 50 one minute readings. The study was duplicated with and without negative pressure, and with and without the vacuum device. Data was then downloaded from the particle counter and entered into a spreadsheet.

All statistical analysis was performed using JMP V15 software (Cary, NC, USA). The data was first examined to observe if it was normally distributed or not such that the correct statistical comparison tests (parametric versus non-parametric) could be chosen. Enough evidence was observed of fairly strong deviations from a normal distribution that non-parametric tests were chosen for statistical comparisons (Wilcoxan tests).

Results

The first test undertaken was with neither the room negative pressure system nor the PNPS respiratory shield system switched on. Only the nebulizer was running. The bar graphs in Figure 2a (particle counts shown on a linear scale) and Figure 2b (particle counts shown on a logarithmic scale) clearly show that just switching on the nebulizer increases the particles counts within the room at all size fractions by approximately two orders of magnitude, or roughly a 10,000% increase. Not surprisingly, this difference was found to be significant ($p < .0001$).

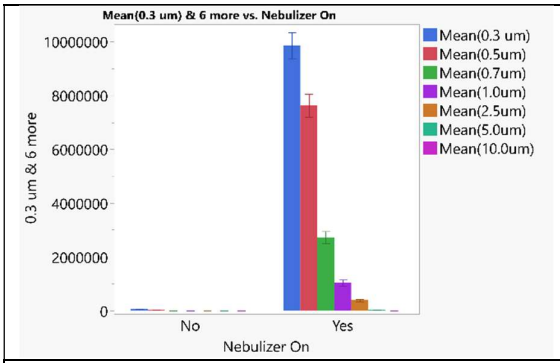

Figure 2a: Particle counts measured in hospital room without negative air pressure or the PNPS. Effect of nebulizer is shown. Linear scale.

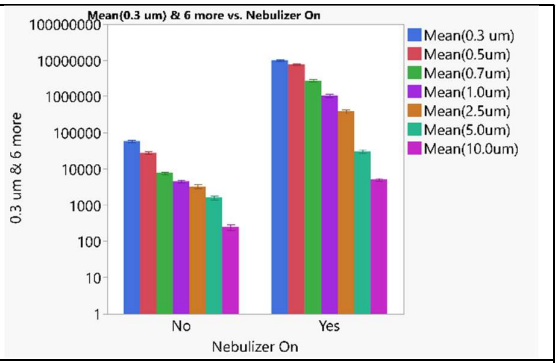

Figure 2b: Particle counts measured in hospital room without negative air pressure or the PNPS. Effect of nebulizer is shown. Logarithmic scale.

With the nebulizer remaining on, the effect of switching on the negative room pressure system was explored. The results are given by the bar graphs in Figures 3a (linear scale) and 3b (logarithmic scale), respectively. In this case, an increase in the particle counts at all size fractions was observed when the room negative pressure system was switched on. This is likely a result of particles being sucked into the room from adjacent hallways that would have been under a relative positive pressure. The Wilcoxan test indicated that the increase was significant at all size fractions ($p < .0001$).

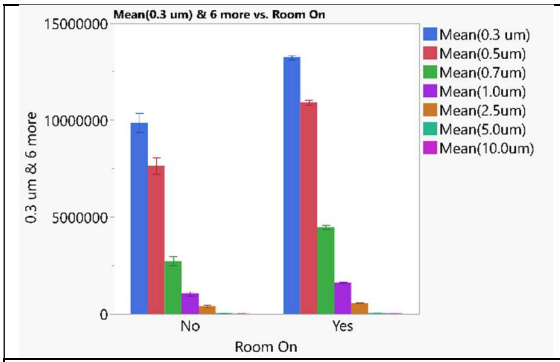

Figure 3a: Particle counts measured in hospital room with nebulizer running. Effect of negative air pressure is shown. Linear scale.

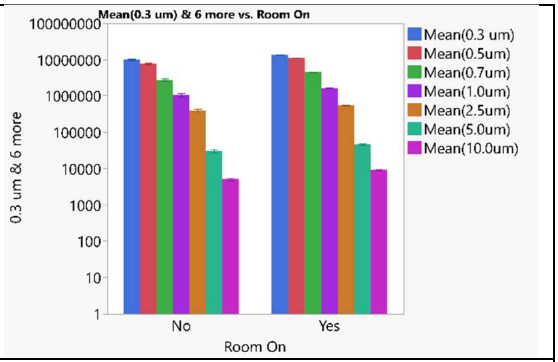

Figure 3b: Particle counts measured in hospital room with nebulizer running. Effect of negative air pressure is shown. Logarithmic scale.

The effect of the portable negative pressure system (PNPS) with respiratory shield by itself (ie. with the negative room pressure system switched off but with the nebulizer remaining on) was then evaluated. These results are presented in Figure 4a (linear scale) and 4b (logarithmic scale). There is

a clear reduction, by about 2 orders of magnitude, or approximately 100%, in the particle counts at all size fractions. This was observed to be significant by the Wilcoxan test ($p < .0001$), and points to the high effectiveness of the system.

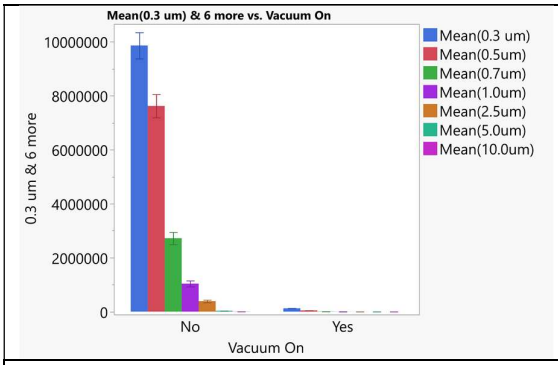

Figure 4a: Particle counts measured in hospital room with nebulizer running. Effect of PNPS is shown. Linear scale.

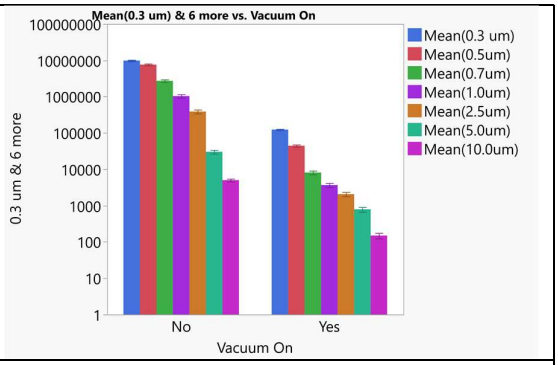

Figure 4b: Particle counts measured in hospital room with nebulizer running. Effect of PNPS is shown. Logarithmic scale.

In fact, if the data from the case where the PNPS is compared (with the nebulizer running and the negative air pressure system is switched off) to the baseline data for the room where neither the nebulizer, room negative air pressure system or the portable negative pressure system are running (ie. the data in Figure 3 for the case where the nebulizer is off), some interesting observations are made (Figure 5a and 5b for linear and logarithmic scales, respectively). First, with the nebulizer on, the particle count rates for the 0.3 μm and 0.5 μm remain higher compared to the baseline room data with no systems running ($p < .0001$ for 0.3 μm and $p = .0081$ for 0.5 μm particle size). At the 1 μm size, there is no significant difference between the baseline room conditions and the case where the nebulizer and PNPS are both in use ($p = .4333$). The situation flips at larger particle sizes. The particle counts are significantly lower compared to the baseline room data (2.5 μm; $p = .0192$, 5.0 μm; $p = .0033$, 10.0 μm; $p = .0362$).

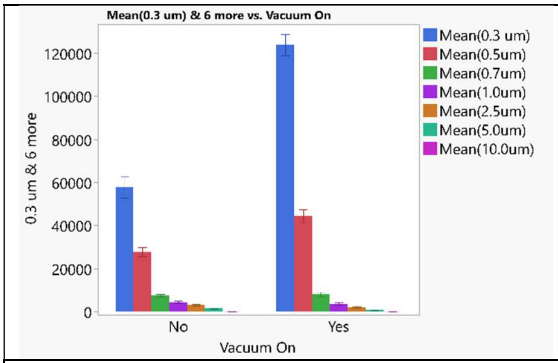

Figure 5a: Comparing particle counts rates under ambient room conditions (no nebulizer or negative air pressure or PNPS) with case where both the nebulizer and PNPS are on. Linear scale.

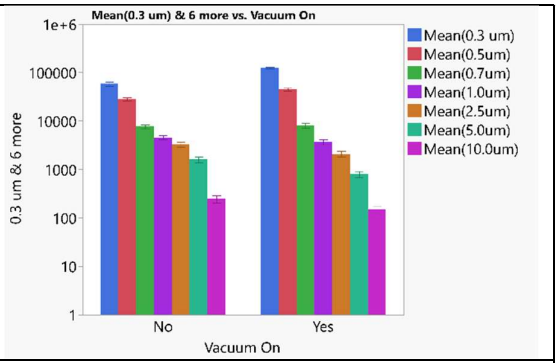

Figure 5b: Comparing particle counts rates under ambient room conditions (no nebulizer or negative air pressure or PNPS) with case where both the nebulizer and PNPS are on. Logarithmic scale.

The next question that was investigated was how well the system functioned in conjunction with the room negative air pressure system. In other words, with the nebulizer and room negative air pressure running, the PNPS was switched on and off. The results of these experiments are given in Figure 6a and 6b on linear and log scales, respectively. There is clearly and added benefit of using the PNPS in a negative pressure room. The increase in particle count rate that was observed in Figure 4 has been negated and an approximate two orders of magnitude decrease, or 100%, is observed for all particle sizes. Not surprisingly this was found to be significant ($p < .0001$).

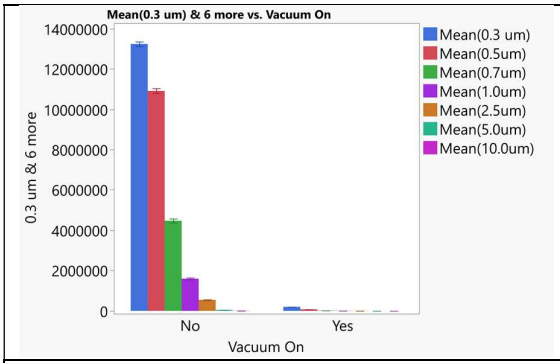

Figure 6a: Particle counts measured in hospital room with nebulizer and negative air pressure system running. Effect of PNPS is shown. Linear scale.

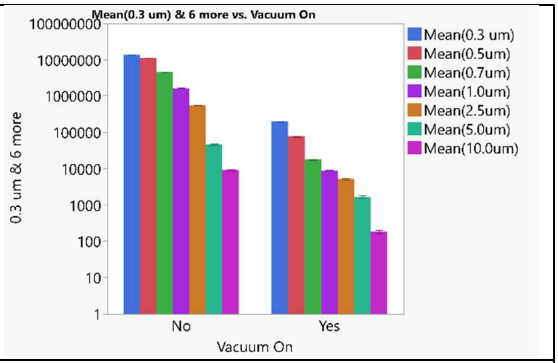

Figure 6b: Particle counts measured in hospital room with nebulizer and negative air pressure system running. Effect of PNPS is shown. Log scale.

This can also be examined in a reverse manner by looking at the effect of switching the room negative air pressure system off and on while the nebulizer and PNPS remain running. In this case, a response similar to that illustrated in Figure 3 is observed. With the negative room pressure system switched on, the particle count rates at all size fractions is significantly greater ($p < .0001$). This data is presented in Figure 7a and 7b. The reason for this may be similar to that proposed earlier, that particles from hallways will be drawn into the room while the negative air pressure system is running, but cannot be removed by the PNPS as it is already snuggly fitted over the patient (mannequin).

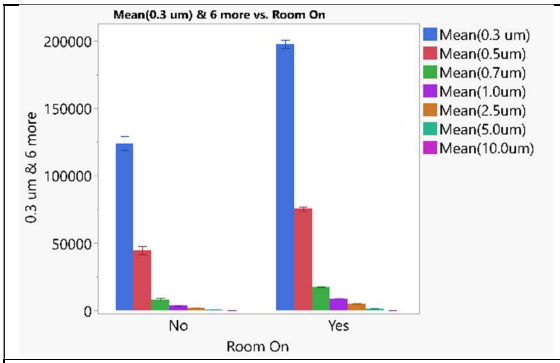

Figure 7a: Particle counts measured in hospital room with nebulizer and PNPS running. Effect of negative room pressure is shown. Linear scale.

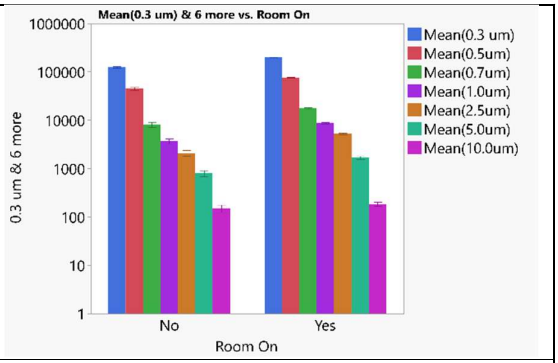

Figure 7b: Particle counts measured in hospital room with nebulizer and PNPS running. Effect of negative room pressure is shown. Logarithmic scale.

Discussion

The results were provided by an extensive data set in a hospital room with negative pressure capabilities and demonstrate the effectiveness of the PNPS with the respiratory shield at reducing particle count rates near the patient. While other solutions to the problem of aerosol and droplet transmission have been proposed with varying degrees of success. Likely by necessity of urgency, some may not be of highly sophisticated designs (eg. mitigation boxes[21,22]), and certain problems with these devices have been noted by other authors[23]. Furthermore, the portability of these other solutions is not very high, and they may not be the most appropriate for use in the more confined areas such as those in ambulances, helicopters and airplanes.

Without any type of mitigation device, the typical scene in a hospital ward may look something similar to that shown in Figure 8 at the top, where particles of all sizes (red) build up in the rooms from the breathing and coughs emitted from the two patients. Virus and bacteria particles (blue) are exhausted more closely to the patient and begin to disperse about the room and the hallway. The results of this study also suggest that if the room is held at negative pressure, the airborne particles emitted by the patient in the hallway can easily be sucked into the negative pressure room. When patients can be equipped with a PNPS with respiratory shield, where a reduction in particle count for all particle size fractions of two orders of magnitude (~100%) was observed, the situation could be much more like that schematically shown at the bottom of Figure 8, where the patients, regardless of their location in the room or hall, can be equipped with a PNPS and respiratory shield system.

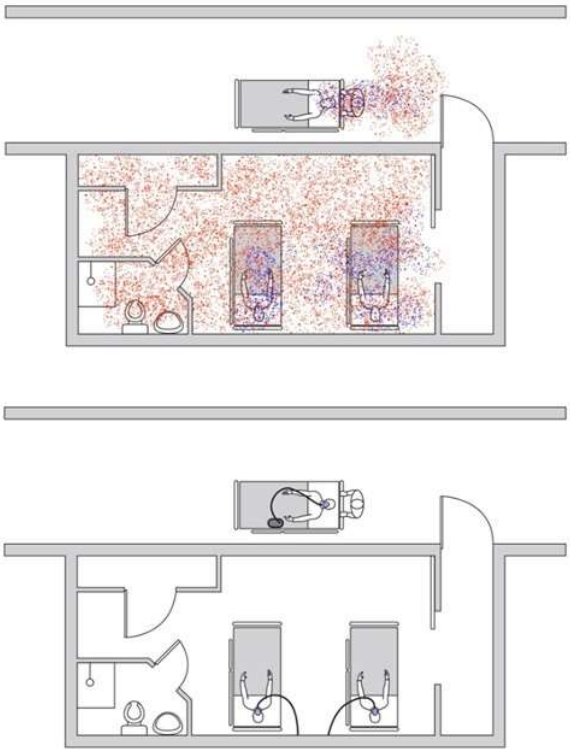

Figure 8: Schematic representation of a plausible hospital scenario with no aerosol transfer mitigation measures (top) where particles and droplets emitted by patients and care workers (red) are mixed with virus or bacterial particles (blue). These are largely eliminated with PNPS and respiratory shields are in place.

Conclusions

1. In a hospital room environment study, the PNPS with a respiratory shield was found to reduce particle counts at all measured size fractions, from 0.3 μm to 10 μm, which covers the range of some viruses, bacteria and droplets emitted from coughs. The reduction was by approximately two orders of magnitude, or ~ 100%.

2. The portability of this system also makes it highly applicable to hazardous transportation environments such as ground and air ambulances (planes and helicopters).

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