Containment effectiveness of expedient patient isolation units

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Background: It is generally recognized that the health care system does not have adequate isolation capacity to meet the surge in demand during a major outbreak of airborne infectious disease. Alternatives to engineered isolation rooms undoubtedly will be required as surge isolation requirements exceed the available resources. The purpose of this work was to estimate containment efficiency of expedient airborne infectious isolation units with and without anterooms in the absence and presence of care provider traffic.

Methods: Fluorescent 2-μm aerosol particles were released into the interior of expedient-construction isolation modules exhausted with a high-efficiency particulate air (HEPA)-filtered fan unit. Particle concentrations inside and outside the enclosure were measured with and without provider traffic simulated with a mannequin. Measurements were obtained on modules constructed with and without an anteroom, which was not separately ventilated.

Results: Containment estimates were excellent for all isolation configurations evaluated, generally exceeding 99.7%. Particle escape was statistically significantly higher with simulated traffic than without; however, there was no statistically significant difference in particle escape with and without an anteroom.

Conclusion: Our findings demonstrate that effective isolation may be possible using low-technology, low-cost, easily built structures that can be readily constructed within hospital and other environments in emergency response situations.

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In the event of a large-scale airborne infectious disease outbreak, whether naturally occurring or due to a bioterrorism incident, the health care system will be faced with receiving, assessing, and isolating infectious patients in far greater numbers than usual. Under normal conditions, known and potentially infectious patients are isolated in specially engineered airborne infectious isolation (AII) rooms that are designed, constructed, and operated according to American Institute of Architects (AIA) and Centers for Disease Control and Prevention (CDC) guidelines.[1,2] These are dedicated rooms, preferably with an anteroom entrance, in which all seams and joints are sealed and that are maintained under negative pressure (0.01 inches of water or 2.5 Pascals) relative to adjacent areas. Differential pressure is monitored to alert staff when adequate negative pressure is not maintained. Whereas 6 air changes per hour (ACH) were sufficient under previous design standards, current design standards require that rooms be ventilated at a rate of at least 12 ACH of total ventilation, including at least 2 ACH of fresh air. All air is exhausted to the outdoors unless it is appropriately filtered for return to a dedicated heating, ventilating, and air-conditioning (HVAC) system serving only that room.

It is generally recognized that the US health care system as a whole does not have an adequate airborne isolation surge capacity to meet the increased needs associated with a major outbreak. A 2002 US Government Accounting Office report[3] noted that ''many hospitals lack capacity to respond to large scale infectious disease outbreaks,'' and that '' most hospitals lack adequate…isolation facilities.'' In recent years, improved isolation capacity has been facilitated by increased bioterrorism and infectious disease preparedness funding, including funding to states under the Health Resources and Services Administration Bioterrorism Hospital Preparedness Program. Nevertheless, alternatives to engineered AII rooms undoubtedly will be required during a major event as surge isolation requirements exceed available resources.

The New York State Department of Health recently recommend that health care facilities plan for establishment of AII units (AIIUs) during surge events.[4] An

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AIIU is defined as ''a separate, dedicated area to care for patients suspected or confirmed to have an infection capable of being transmitted via airborne droplet nuclei.'' In contrast to AII rooms, AIIUs are areas not normally used for isolation but can be ''quickly converted to cohort patients with the same infectious agent,'' with negative pressure relative to adjacent areas, adequate ventilation, and exhaust to the outdoors without recirculation to other areas. Establishing a properly functioning AIIU requires a detailed understanding of the facility layout, HVAC systems, traffic flow patterns, and patient care requirements under emergency conditions; thus, planning and preparation before an outbreak event are essential.[4]

Mead and Johnson[5] have explored the use of exhaust-ventilated expedient isolation enclosures for use as AIIUs. In the present work, we evaluated single-patient room-sized expedient enclosures that might be constructed in a cafeteria, gymnasium, commercial building, or similar large space to provide isolation surge capacity during an emergency response. An important study of the effect of door configuration and provider traffic on isolation room containment efficiency was recently reported by Hayden et al,[6] in which air volume migration from the room to the surrounding area during door opening and provider movement into and out of the space was demonstrated. With the exception of this work, there are little published data on the containment efficiency of isolation rooms during provider traffic into and out of the space. We could find no data in the peer-reviewed literature on the containment effectiveness of expedient enclosures such as those that would be required under surge conditions during natural disease outbreaks or bioterrorism events involving airborne-transmitted infectious diseases.

Our goal in the present investigation was to estimate and compare the average containment efficiency of airborne particles generated within expedient AIIUs with and without anterooms and in the absence and presence of personnel movement into and out of the enclosures.

METHODS

Assessment method

The adequacy of any AIIU configuration in meeting both isolation and patient care needs should be evaluated in advance through environmental measurements, as well as drills and exercises. A well-designed AIIU will prevent the escape of all or nearly all pathogenic bioaerosol particles. Consequently, verifying the performance of a well-functioning unit presents a technical challenge, because few, if any, contaminant particles will be present outside the containment. Commonly used particle sampling and analysis techniques and instruments are not designed to work with extremely low particle concentrations. In addition, although such instruments as single-particle optical aerosol spectrometers can count the number of particles of various sizes, they cannot distinguish between particles of the same size in terms of their composition or origin. Time-of-flight aerosol spectrometers with fluorescence capability can distinguish between biological and nonbiological particles but not between different airborne microbes with the same aerodynamic behavior. In both cases, these instruments are expensive ($5000 to $180,000) and are not readily available to emergency preparedness planners. Although certain less-expensive viable bioaerosol sampling methods, such as jet-to-agar impaction or liquid impingement with subsequent plating, incubation, and culture identification, may be considered because of their potential ability to identify organisms, these methods are notoriously error-prone.[7,8] Genetic analyses of captured particles also might be considered, but these require the availability of a highly specific technique targeted to the organism,[9] as well as the absence of problematic environmental interference.[10] Viable bioaerosol and genomic approaches also require relatively expensive equipment and analyses. The overriding consideration, however, is that these approaches cannot be used until the organism of concern is actually being aerosolized inside the containment area. Therefore, these approaches are generally unavailable or excessively hazardous and thus are unsuitable for pre-event evaluation of candidate AIIU configurations.

In this work, containment was evaluated by releasing bacterium-sized fluorescent particles inside the enclosures and conducting air sampling inside and outside the enclosures to estimate the fraction of the particles that escaped containment. The number of particles collected on filters inside and outside the enclosure was determined by counting through fluorescence microscopy, as described by Johnson and Lynch.[11] This technique was chosen because (a) very low concentrations of particles can be quantified, providing excellent sensitivity; (b) the particles released inside the enclosure can be distinguished by their fluorescence from naturally occurring particles of the same size and shape, thereby enhancing specificity; (c) the assessment is not influenced by issues of viability, as would be the case if biological aerosols were used, promoting both accuracy and precision; and (d) rapid analysis is possible through automated counting with a motorized-stage fluorescence microscope system with image analysis capability.

AIIU construction

The structure shown schematically in Fig 1 was constructed in an empty floor of a commercial building. The frame was made from 2-inch diameter PVC

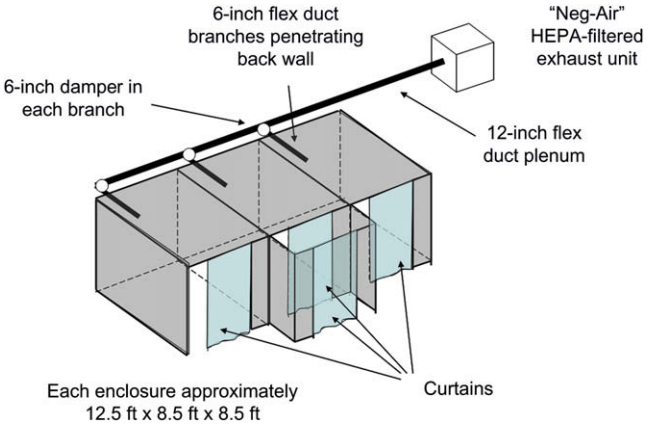

Fig 1. Schematic of a 3-module AIIU.

plumbing pipe and fittings, and the ceiling and walls were formed using 6-mil-thick polypropylene sheeting commonly used for constructing asbestos remediation enclosures. The wall–floor, wall–wall, and wall–ceiling seams were sealed with duct tape. The front of each module was a partially retractable curtain extending from floor to ceiling. The curtain bottom was weighted with lightweight utility chain hemmed into the curtain base with duct tape. The curtain's top and one side were sealed to the frame. The center module was equipped with an anteroom with curtains at both the anteroom entrance and the anteroom module entrance, with one curtain opening to the left and the other opening to the right. This anteroom had no dedicated exhaust or supply ventilation and served primarily as an air flow buffer zone between the module and the surrounding space. Because the outer and inner curtains were not tightly sealed, the patient room exhaust system continually pulled outside air through the anteroom and into the patient care space, providing continuous ventilation of the space. Each module was approximately 8.5 feet × 12.5 feet, with an 8.5-foot ceiling (2.6 m × 3.8 m × 2.6 m). This floor area was consistent with AIA requirements of a minimum of 100 square feet of floor area per bed in multiple-bed rooms.[1] The anteroom was 4.5 feet × 8.5 feet, with an 8.5-foot ceiling (1.37 m × 2.6 m × 2.6 m).

The modules were placed under negative-pressure ventilation using a high-efficiency particulate air (HEPA)-filtered industrial ''neg-air'' exhauster (Mach 2; Critical Systems, Houston, TX) connected by a manifolded and damper-controlled duct system to the individual AIIUs. This HEPA unit is typical of the type already owned by many hospitals for the containment and capture of airborne dust during construction and remediation activities. The HEPA-filtered air was released back into the general space surrounding the AIIU.

Each module was ventilated at 225 cfm (382 m^3/hour), which is equivalent to a ventilation rate of approximately 15 ACH for these spaces. This exceeded the airborne infectious isolation room ventilation rate of 12 ACH recommended by the AIA and CDC.[2] The overall footprint area of the 3-unit configuration was approximately 18 feet × 30 feet (5.5 m × 9.1 m).

Aerosol generation and sampling

We simulated an airborne pathogen using 2-μm-diameter fluorescent plastic microspheres or ''beads'' (Duke Scientific, Palo Alto, CA). The beads were used rather than actual bioaerosols because they are of uniform size, insoluble in water, durable, nonpathogenic, not naturally occurring, and of the same respirable size as many potential airborne pathogens. Because different airborne particles of the same aerodynamic size will have the same transport behavior in air,[12] the potential for these particles to escape the containment would be identical to that of an actual airborne pathogen of the same size. The use of fluorescent particles allowed sensitive and precise particle counting by manual or automated fluorescence microscopy, as described below.

The fluorescent beads were aerosolized from water suspension within the AIIUs using a standard medical air-jet nebulizer (PARI Star nebulizer with ProNeb Ultra compressor model 85B 0000; PARI Innovative Manufacturing, Midlothian, VA), operating at 20 psi pressure. The suspension was prepared as 4 drops (approximately 0.125 mL) of concentrated source suspension in 50 mL of filtered distilled deionized water. The manufacturer's literature indicated a source suspension concentration of approximately 1×10^9 particles/mL, so that the nebulizer suspension was approximately 2.5×10^6 particles/mL. This concentration would be expected to produce > 99% single 2-μm aerosol particles in the air-jet nebulizer's output.[13,14] Approximately 11 mL of this suspension was poured into the nebulizer cup for each test run.

The nebulizer was placed inside the module on a 34-inch-high (86 cm) table located approximately 4 feet from the back wall. Two air samplers also were placed inside the module on similar tables approximately 4 feet apart, midway between the curtain and the back wall. Because the nebulizer's air flow rate was < 4 L/min and the nebulizer was centrally located in the space and well away from the entrance, room air turbulence due to the nebulizer output was not expected to be significant. Seven samplers were placed outside and within approximately 1 foot (30 cm) from the curtain opening. The outside samplers were positioned as follows: 1 at floor level, 1 at a height of 34 inches (86 cm) and 1 at a height of 60 inches (152 cm) on

both the left and right sides of the curtain's opening side, and 1 at 8.5 feet (260 cm), above the curtain door. All samples were collected using 25-mm polycarbonate filter cassettes connected to battery-powered personal air sampling pumps. The cassettes contained 0.8-μm-pore mixed cellulose ester (MCE) filters on backing pads (SKC; Eighty Four, PA). The sampler flows were calibrated at 1.5 L/min before each use (DryCal DC-Lite; BIOS International, Butler, NJ).

Simulated provider traffic

Provider traffic into and out of the module was simulated using a full-height mannequin. The mannequin was shrouded in a sheet to approximate surgical apparel and was mounted on a rolling base that was guided through the module entrance by a track affixed to the floor. Two fine wires attached to the base allowed the mannequin to be pulled into and out of the module along the track. Wires attached to the curtain (curtains in the case of the anteroom module) allowed the curtain to be drawn open and closed as the mannequin was pulled through.

Experimental conditions

Particle escape was assessed with and without an anteroom in place and with and without simulated personnel traffic into and out of the module. Personnel traffic was evaluated at 3 levels: no movement, 1 mannequin pass into and out of the module, and 3 mannequin passes at uniform intervals. Containment was measured 3 times for each condition, for a total of 2 module configurations $\times$ 3 traffic levels $\times$ 3 replications $=$ 18 trials.

Procedure

In the no-traffic trials, the samplers were turned on and allowed to run for 5 minutes with no one in the space before nebulization was started remotely from outside the space. This allowed the dissipation of air currents generated by the research technician before the particles were released. The nebulizer was operated for 20 minutes, then turned off remotely, but the pumps were allowed to run for another 20 minutes. The total sampling time was 45 minutes at 1.5 L/min, resulting in a sampled volume of 67.5 L.

In the 1-pass trials, the samplers were again turned on and allowed to run for 5 minutes with no one in the space before the nebulizer was started remotely. After 20 minutes of nebulizer operation, the mannequin was drawn into the module, allowed to remain for 5 minutes, and then drawn back out. During each movement, the curtain remained open for approximately 5 seconds. The nebulizer was turned off after the mannequin passed back out of the module, and the samplers were operated for an additional 20 minutes before being turned off. For trials in which an anteroom was used, the mannequin was passed through the anteroom with a pause just long enough to close one curtain before opening the second curtain (approximately 5 seconds). The total nebulization time was 25 minutes. The total sampling time was 50 minutes, resulting in a sampled volume of 75 L.

The 3-pass trials were similar to the 1-pass trials, except that the mannequin was passed into and out of the module 3 times at 5-minute intervals. The nebulizer was turned off remotely after the last exit, and the samplers were operated for an additional 20 minutes. The total nebulization time was 45 minutes, the total sampling time was 70 minutes, and the sampled volume was 105 L. At no time were both curtains open simultaneously.

Sample analysis by fluorescence microscopy

Filters were removed from cassettes, placed on 75 $\times$ 38 mm glass microscope slides, and covered with 35 $\times$ 50 mm coverslips. The coverslip was secured to the slide by placing a few drops of clear fingernail polish around its periphery, taking care to avoid contacting the fingernail polish with the filter, because the solvent in the polish would dissolve both the filter and the spheres. Spheres were enumerated at 40$\times$ power (Plan Fluor objective) using a Nikon Eclipse 80i fluorescence microscope fitted with a motorized stage (Prior Optiscan 29), camera (Nikon DXM1200), and NIS Elements software (AR 2.10, Build 215) (all components from Nikon Instruments, Melville, NY). The software, camera, and motorized stage allowed for the entire filter to be photographed using individual images taken in a serpent fashion and ''stitched'' together into a single image, with a preset 15% overlap of images.

The saved imaged was adjusted to exclude blue and red wavelengths, leaving only green light. Image intensity was adjusted using the software's ''LUT'' (look-up table) function to maximize sphere brightness while minimizing background illumination. The software's ''Threshold'' function was used to establish baseline criteria conditions for sphere enumeration based on light intensity. Size and circularity restrictions were then placed on the image using the ''Restrictions'' function to restrict counting to objects $>$ 12 μm and $<$ 50 μm (the range of the particle's fluorescent image size, which is much larger than the particle's physical size of 2 μm) and $>$ 0.96 circularity. For particle counts greater than approximately 50, the composite images were counted automatically using the software's ''Measurement'' and ''Object Data'' functions. For counts less than approximately 50, the particles were counted manually by direct observation of the slide.

Data analysis

A relative measure of particles escaping, ε, was estimated as the average particle count for the 7 samplers outside the module divided by the average count for the 2 samplers inside the module. This was a relative measure, because the samplers could capture escaping particles only while they were in the region immediately around the module entry (ie, before they were dispersed by room air currents), whereas the samplers inside the enclosure sampled air throughout the nebulization period. Using counts was equivalent to using average concentrations, because all of the samplers were operated for the same duration for a given set of conditions. A relative indicator of mean containment efficiency, η, was calculated as $\eta = 1 - \varepsilon$.

Means of the 3 replicate escape measures for the no-traffic and 1-pass conditions were compared using 2-factor analysis of variance with replication in Microsoft Excel. The no-pass and 1-pass trials involved essentially the same nebulization and sampling times (20 minutes of nebulization and 45 minutes of sampling for no-pass vs 25 and 50 minutes, respectively, for 1-pass). The 3-pass condition was not included in this comparison because of its substantially longer nebulization and sampling times (45 and 70 minutes, respectively). However, a 2-sample *t*-test was performed on the means of the 3-pass with- anteroom and without-anteroom trials to examine the anteroom effect for that condition.

RESULTS

Fluorescence microscopy

The green particles fluoresced brightly as green dots on a black background under fluorescent top illumination and produced sharp pinpoint images at 40× magnification. Even at high particle concentrations, the images were generally distinct from one another, indicating generation of single particles by the nebulizer with little agglomeration of particles while airborne.

Approximately 290 individual images were collected from each filter scan, which took approximately 11 minutes. Considering the large number of spheres present on some slides ($> 10{,}000$), this represented a considerable time savings compared with visual enumeration. But for slides with < 50 beads, enumerating beads visually was faster.

The accuracy and precision of the automatic counting method were assessed through repeated automatic counts of a single sample of known count, automated and hand counts of a set of samples with varying number of spheres, and duplicate counts from a set of samples with varying numbers of spheres. For a single sample with 278 spheres (determined by manual count), the mean automated count was 273 (n = 20; range, 263 to 300; mean accuracy, 98.2%; standard deviation [SD], 12.7%). For a set of samples (n = 25) with varying known counts, based on manual counts (range, 203 to 4347), the accuracy of automated measurements ranged from 69% to 130% (mean, 95%; SD, 16.7%). The precision for automated counts was determined from duplicate samples using relative percent deviation with a mean of 4.9 (n = 21; range, 0.36 to 17.4; SD, 4.5).

Particle containment

Mean percent particle containment efficiency values, η, are given in Table 1. Containment generally exceeded 99.7% for all conditions evaluated. Airborne particles were captured outside the modules with and without an anteroom even in the absence of provider traffic. At least some of these particles entered the space in the exhaust from the HEPA filter, air samples of which contained some previously captured particles.

Analysis of variance found statistically significantly greater escape during 1-pass traffic than in the absence of traffic ($P = .002$), as might be expected to occur due to air volume migration as providers transit the space.[6] The 3-pass particle containment values shown in Table 1 also suggest that particle escape may have been substantially higher during 3-pass traffic than during 1-pass or no-pass traffic; however, these values cannot be statistically compared with the no-pass and 1-pass values because of the different sampling periods used. The presence versus absence of the anteroom demonstrated no significant difference in particle escape for the 1-pass versus no traffic conditions or any significant interaction effect. The 2-sample *t*-test of the 3-pass sample means also failed to show a significant anteroom effect. This is in disagreement with the conclusions of Hayden et al,[6] who inferred that enhanced protection would be provided by an anteroom or buffer zone during provider traffic out of the room. The lack of a demonstrated anteroom effect in our study was likely related to the rather crude construction and small size of the anteroom compared with the engineered and mechanically ventilated anteroom evaluated by Hayden et al. In addition, the lack of a substantial provider pause in the anteroom during the present trial also may have contributed to the drag-out potential. Due to the continuous ventilation of the anteroom as air is drawn through it by the patient space exhaust system, a substantial pause of several minutes would limit particle escape by allowing time for particle-bearing air migrating from the patient room to the anteroom during provider exit to be drawn back into the patient room before the outdoor door is reopened.

Table 1. Containment efficiencies for modules with and without an anteroom for various levels of simulated provider traffic

	Percent containment efficiency, η (mean ± standard error; n = 3 for each)	
Provider traffic level	**Without anteroom**	**With anteroom**
No passes	99.79 ± 0.139	99.95 + 0.029
One pass	99.83 + 0.017	99.89 + 0.003
Three passes	99.53 + 0.069	99.73 + 0.084

Construction considerations

The strategy of directing the filtered HEPA unit exhaust back into the space surrounding the isolation enclosure would have advantages in many situations. Primary benefits are that it has no adverse effect on the overall HVAC system balance and places no undue burden on the system for heating/cooling large volumes of make-up air. Another benefit is the reduction in dust, allergens (including dust that might contain allergenic latex proteins), and possibly airborne pathogens in the air entering the isolation enclosure from the room space, with resulting improved air quality. Some particle escape may occur through the HEPA unit, however, as found in the present work. Alternatively, the filtered air could have been released to the outdoors to maintain a negative pressure gradient and consequent air flow into the room from adjacent spaces, as was done by Rosenbaum et al,[16] although the effect of this approach on adjacent space pressure requirements or smoke control zones must be considered. Another option would be to release the filtered exhaust into the anteroom serving the isolation enclosure, thereby providing an improved environment for donning protective clothing before entering the isolation area. Certainly, proper operation of the HEPA unit should be verified regardless of where the exhaust is directed, but particularly if it is redirected to the indoor space.

Single-patient ventilated isolation enclosures also could be used in situations when a cohort of potentially infected individuals are housed in a large common space and it is desirable to further isolate those individuals with the greatest potential of generating infectious aerosols, such as those with severe cough. This would minimize the airborne concentration of pathogens in the main space and thereby reduce the overall exposure risk to care providers and other persons in the patient cohort.

Study limitations

A limitation of this and similar studies of containment effectiveness is the difficulty in accounting for all of the contaminant that escapes the space. Air samples collected immediately outside the containment entrance measure the average contaminant concentration in the immediate vicinity of the samplers during the sampling period; however, as noted in the ''Data analysis'' section, this may underestimate escape due to dispersion of some contaminant by the room air currents. Another limitation is the use of a mannequin rather than an actual person during provider traffic trials. The degree to which this may have affected the results is unknown. Finally, although our findings demonstrate excellent containment by the expedient enclosures under the study conditions, more work is needed to better characterize containment under actual work use conditions. Of particular interest may be the effect of thermal conditions inside and outside the containment.

CONCLUSION

Particle escape from expedient isolation enclosures with and without an anteroom was evaluated for various levels of simulated provider traffic into and out of the space. The enclosures were constructed from PVC tubing and fittings and plastic sheeting and were ventilated using an industrial HEPA exhaust unit. The anteroom was not separately ventilated, but served as an air flow buffer zone between the module interior and the surrounding space.

Particle escape was statistically significantly greater with simulated single-pass provider traffic than with no traffic. No statistically significant difference in particle escape with and without an anteroom was shown for any traffic condition, likely because of the small size and crude construction of the anteroom and the lack of a substantial provider pause in the anteroom during transit. A larger anteroom with well-mixed ventilation and/or the requirement for a pause in the space, such as to wash hands and change gloves, would be expected to further improve particle containment.

Our findings support the results of previous investigations indicating that airborne particle entrainment (also referred to as ''drag-out'' or air volume migration), caused by providers moving into and out of the space is likely a primary cause of decreased containment efficiency. Although the data appear to suggest that particle escape may increase with increasing traffic, as might be expected, this could not be statistically tested for the experimental design used here.

Perhaps of greatest importance is that these results demonstrate that effective isolation may be possible in nonhospital environments using low-technology, low-cost structures that can be easily constructed from materials and equipment that are readily available in emergency response situations. This is consistent with

the previous findings of Mead and Johnson[5] for expedient enclosures constructed within hospital rooms to serve as AIIUs.

It should be noted that although evidence is accumulating to support the utility of expedient isolation enclosures in emergency response situations, including surge response to infectious disease outbreaks, other factors also must be considered by preparedness planners. Key among these is the question of possible building code violations from the use of construction materials such as plastic pipe and sheeting that may be combustible or potentially decrease fire sprinkler effectiveness. If the legal foundation has not been laid to allow such codes to be waived in emergency response situations, including the response to a public health emergency such as epidemic infectious disease, then possible liability questions might impede the response.

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