

**FDA Webinar Series –
Respirators and Other Personal Protective Equipment (PPE) f
or Health Care Personnel Use During the COVID-19 Pandemic**

**Moderator: Irene Aihie
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12:00 pm ET**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time, you may press Star 1 on your phone to ask a question. I would like to inform all parties that today's call is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the conference over to Ms. Irene Aihie. Thank you, you may begin.

Irene Aihie: Thank you, hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education.

Welcome to the 10th CDRH webinar in our PPE webinar series. The FDA will share information about protective barrier enclosures and representatives from the FDA and OSHA will be available to answer your questions.

Following a few opening remarks, we will open the lines for your questions related to the information provided during today's discussion. Now I give you

Dr. Suzanne Schwartz, Director of CDRH's Office of Strategic Partnerships and Technology Innovation.

Dr. Suzanne Schwartz: Thank you and welcome everyone. As Irene mentioned this is the 10th session in our biweekly webinar series on personal protective equipment, PPE.

Today I'm pleased to introduce Dr. (George Gibeily) Medical Officer in CDRH's Office of Health Technology or OHT4 Surgical and Infection Control Devices within the Office of Product Evaluation and Quality, who will provide an overview on FDA's approach to protective barrier enclosure devices intended for use in the COVID-19 response. Dr. (Gibeily) will cover the Emergency Use Authorizations or EUAs for these devices.

After (George)'s presentation, we'll return the operator - we will turn to the operator for live Q&A. Our federal partners and colleagues from OSHA are on the line with us and they are available to field questions relevant to their respective mission, roles and responsibilities.

At this time, I'd like to turn the webinar over to (George).

Dr. (George Gibeily): Thank you Suzanne and good afternoon everyone. Thank you for the opportunity to present FDA's current thinking on protective barrier enclosures.

Protective barrier enclosures were created in response to the COVID-19 pandemic as an adjunct to and not to replace personal protective equipment to further protect healthcare workers from particle aerosol, splashes, droplets containing SARS-CoV-2 the agent of COVID-19, because there were no real good alternatives available.

Their proposed benefit is to prevent contagion from SARS-CoV-2, surface contamination through droplets and splashes as well as airborne viral contagion. These devices can be single use or reusable and are of two different types. The first - can I have the first slide - next slide please, Irene.

The first are passive protective barrier enclosures that is without negative pressure. They're defined as a transparent device much like a box (frequently), designed to cover a patient's head and upper body and incorporates one or more ports through which healthcare personnel can pass their arms and hands to perform medical procedures providing an extra layer of barrier protection. These devices are frequently acrylic or plexiglass enclosures that are not airtight and may have sharp edges with limited internal space to perform procedures.

The second main type of enclosure is the protective barrier enclosure with negative pressure, that is airflow, defined as a transparent device with negative pressure that partially or fully covers a patient to prevent healthcare personnel exposure to pathogenic airborne particles. These barrier enclosures include ports for medical care and procedures. They have an air intake source and suction which can be fixed or portable with airflow such that there's a constant air exchange.

The intake and output filters are, HEPA filters are placed in line with intake and output conduits. These enclosure barriers may be tent-like with plastic or metal reusable disposable struts covered with a polyvinyl sheet much like a tent or they can be fixed acrylic enclosures. Can I have the next slide, Irene.

(So) Emergency Use Authorization for protective barrier enclosures with negative pressure have been authorized only for in-hospital use for airway management, respiratory treatments, direct patient transport to different levels

of care in a hospital with a nurse or physician in attendance while monitoring the patient's EKG, vital signs, blood oxygen levels and carbon dioxide levels when available through end-tidal CO₂.

The ultimate purpose of these Emergency Use Authorizations for protective barrier enclosures with negative pressure is to increase the negative pressure treatment areas in hospital for COVID-19 patients. You might remember in China they built two full-service hospitals to house and isolate and treat COVID-19 patients.

Some of the negative pressure barriers that we review may increase negative pressure isolation treatment areas within hospitals that are already existing in the US and globally rather than building completely new enclosed hospitals.

Eight of these negative pressure enclosures has already been authorized through our EUA program to date. The use of enclosures and procedures such as endoscopy, bronchoscopy, ENT and oral surgical procedures as well as transportation of patients outside hospitals and use in nursing homes at this time are not being considered. They present unknown additional risks to patients with existing respiratory compromise which can further worsen by the need for sedation and inconsistent monitoring.

If additional procedures are necessary, they are likely more safely performed in these COVID-19 patients having placement of a definitive airway prior to the procedure which should virtually eliminate uncontained aerosol generation.

Regarding the passive protective barrier enclosures we initiated an umbrella emergency use authorization because we initially felt these passive devices posed a minimal risk and provided protection to healthcare workers. In order

to expedite their entry into the marketplace we outlined minimal testing requirements in an umbrella EUA and if met the device could go directly to market immediately protecting healthcare workers at greatest risk from aerosols containing SARS-CoV-2.

Subsequently we found that studies performed through simulation testing and published in anesthesia peer reviewed medical literature suggested that these protective barrier enclosures without negative pressure may not reduce healthcare provider risk to aerosol exposure and may in fact increase such risk by concentrating and accelerating aerosol through existing breaks in the barrier.

We found that the enclosure could damage personal protective equipment primarily gown sleeves damaged while inserting arms through the barrier portals exposing the healthcare worker's skin to contamination. These enclosures decrease the probability in some studies of first pass endotracheal intubation and increase the time required and complexity of airway establishment all increasing the risk of hypoxia in the COVID-19 . These patients already have existing respiratory dysfunction due to COVID-19 and can least tolerate an additional cause of hypoxia

So out of an abundance of caution FDA revoked the umbrella Emergency Use Authorization on August 20, 2020. For more details and further information please find the link to our website provided on the resource slide at the end of this presentation.

FDA will continue to review protective barrier enclosure submissions to the pre-Emergency Use Authorization pathway on a case by case basis. We review performance testing of all protective barrier enclosure devices to

ensure that the internal environment of these devices do not become hostile to the patient and yet provide healthcare workers with enhanced protection from COVID-19 generated aerosols.

So the following performance testing may be required for these protective barrier enclosure devices and will be reviewed by FDA as applicable. We ask that you provide aerosol leakage testing using an aerosol generator within the device enclosure for example a saline nebulizer which can be activated periodic timepoints within a predetermined time interval of device use for example every 30 seconds for 5 minutes. This is to simulate a human cough. The same test can be done using human volunteers simulating coughing.

This test should include a study arm with the enclosure ports or slit cuts left wide open thus providing a worst-case scenario for aerosol leakage and pathogen droplet and splash containment.

Then using an industrial particle counter, we ask that you provide aerosol generated particle counts with special consideration for particles that are less than five microns in size to assess the risk of airborne contagion. There is evidence that mucus and water particles containing SARS-CoV-2 virus can remain airborne for a few hours and float for longer distances than droplets and microdroplets.

These particles may be the more concerning vector of contagion because as they remain suspended and their water content evaporates, they can become lighter potentially allowing them to spread even further than anticipated and smaller allowing them to bypass the mucus, ciliary, and lymphatic tissue defenses of our upper airways facilitating travel of the SARS-CoV-2 virus to the deepest regions of the lung where it can inflame and destroy critical tissue for oxygenation causing the patient to present first with fever, dry cough and

in some cases profound shortness of breath ; ultimately, hopefully rarely, respiratory failure.

Particle counts should be gathered within and outside the enclosure device at a level of the healthcare provider's head at different distances from the enclosure device and at different points around a hospital bed, operating table or stretcher where the protective barrier enclosure device may be in use.

The fluorescein dye and smoke testing may be used to demonstrate leaks of larger droplets and splash containment within the enclosure device. Both studies, the particle counts and the fluorescein testing, provide important safety information, particle counts assessing the risk of airborne transmission while the smoke and fluorescein dye also tests the extent of surface contamination.

We ask that particulate clearance times be measured to determine the amount of time required after an aerosolizing respiratory treatment is necessary before the barrier can be removed to avoid unwanted spread of the SARS-CoV-2 virus. This information will inform device labeling.

Using human volunteers, we ask that measurement of CO₂ levels, CO₂ production reported in parts per million, temperature, humidity within the chamber over a maximum of time of enclosure use or until the level of these measured datapoints plateau.

Examples of why this is important, increased CO₂ greater than 5000 parts per million taking note that normal atmospheric CO₂ is about 400 parts per million, can lead to rebreathing hypercarbia which can result in unwanted increases in heart rate and blood pressure in patients who may be at risk for cardiovascular events. High relative humidity inside an enclosure may lead to

condensation and disruption of visualization of the patient's anatomy through the enclosure and may cause HEPA filter malfunction.

Airflow exchange rates inside the enclosure device should be calculated and typically we look for greater than 12 air exchanges per hour. If applicable provide details of the negative pressure source, its ability to maintain negative pressure as well as negative pressure variations over time. This is especially important if portable suction and tanked medical air is used to transport these COVID-19 patients.

Please ensure that there's adequate visualization of the patients in the enclosure; communication with the patient is adequate with measurement of noise decibel levels within and outside the chamber with and without negative pressure airflow; ease of access to accessories inside the enclosure device and assessment of adequate space for medical equipment needed to monitor and treat the patient safely; characterization of the HEPA filters if applicable, their type, are they authorized, are they disposable or reusable frequency of exchange, the method of disposal and if reusable the method of sterilization.

We ask that you give us electrical and EMC testing, viruses and any fire retardation testing if appropriate, cleaning and disinfection reprocessing validation testing if applicable.

We also ask that a human factor study is performed using 15 specialists of different experience levels from different clinical settings. Typical clinical test scenario may be a simulation of establishing a definitive airway with a barrier device in place. It is important to record the time required to establish a definitive airway with and without the barrier device. And after simulation testing with a mannequin, the participants should be asked to respond to a

questionnaire reviewing what they like and what they dislike about the device and this may be accomplished with a five-point Likert scoring system.

Participants should be given the opportunity to enter free text into the questionnaire as well. And the questions should evaluate the ease of access to a simulated airway recording the time required to establish a definitive airway with and without PPE, space restrictions for essential equipment, visualization of the anatomy of the patient's airway, communication with the patient while in the enclosure with and without suction and fans and any other factor that might interfere with critical airway management.

Please take note that sponsors using human volunteers in these tests should abide by the rules of a clinical study whereby all protection of human subjects is insured. An IRB may need to review your protocol for approval or exemption.

Labeling of these devices should include a risk-benefits statement, possible adverse events, indications, contraindications, warnings and precautions. These should be consistent in all the fact sheets, directed at healthcare workers, patients, facilities along with assembly, cleaning, disinfection and safe disposal instructions. A step-by-step emergency procedure for a device removal should also be included in these instructions.

Typical contraindications for use of these enclosure devices which should be in the fact sheets include: use in patients with known difficult airways, patients who are hypoxic and require emergency intubation, patients with anatomic abnormalities restricting neck mobility such as cervical spine injury or arthritis, or the morbidly obese patient with short thick necks occupying much of the space within the enclosure limiting the healthcare provider's ability to maneuver also limiting neck mobility, patients who are less than 45

pounds or in the pediatric age group are among some of the contraindications we would like to see included.

COVID-19 patients using these protective barrier enclosures should receive supplemental oxygen. Please note that manufacturers are required to report deaths, injuries, malfunctions for all EUA devices to FDA within 30 days of becoming aware of these events.

Currently we have not received many MDRs on protective barrier enclosures. Any product issues may be reported voluntarily by any individual to FDA through our MedWatch site listed in our next slide I believe, our next resource slide. Irene, if you can advance the slides to that please, yes.

And with that I'll take any questions and open it up to the audience.

Coordinator: If you would like to ask a question please press Star then 1, unmute your phone and record your name clearly when prompted. If you'd like to withdraw your question press Star 2. One moment while we wait on our first question. The first question is from (Julian Goldman), your line is now open.

(Julian Goldman): Hi thank you for taking my question. I'm curious as to the kind of strong direction to eliminate patients who are - have certain physical characteristics that you outlined and who, you know, are classically - have difficult to manage airways and may be difficult to intubate.

I'm puzzled by that since if anything there's greater value in providing additional protection for personnel with additional and a more extensive and lengthier airway manipulation including the potential need to rescue the airway during intubation and with the rescue of say bag mask ventilation.

So I read that initially online when you posted that information. I was puzzled at that time and since I heard it repeated now, I think it's worth digging into that a little bit, thank you.

Dr. (George Gibeily): Yes (George Gibeily), thank you for that question. You know, that's a very important question and I think you're right in some cases these patients may be more likely to spread aerosol without the enclosure especially if they are combative and put the healthcare providers at risk.

I just feel that what we're seeing is that with these added barrier protections it may be difficult to actually maneuver your arms and hands within the enclosure to effect expeditiously establish a definitive airway. And many of the anesthesiologists that I have personally talked to because I still practice surgery and frequently counter anesthesiologist who feel that with PAPR devices to protect them and full personal protective equipment they can establish an airway expeditiously without the hinderance of these additional protective barrier enclosures.

And so it really comes down to judgement of the healthcare provider, of the anesthesiologist for example. But to struggle to establish an airway because of the protective barrier enclosure resulting in harm to the COVID patient, i.e. hypoxia, failed intubation resulting in the need for an emergency tracheostomy for example. I think that is really a clinical issue that needs to be determined by the clinician but FDA's position is to maximize both health care worker and patient safety and we believe that the contraindications I mentioned should be considered prior to using these protective barrier enclosures.

You know, I hope that answered your question. I know it can be controversial.

(Julian Goldman): Not, well not necessarily. I think the point your bringing out is a different point about what is the best approach to the patient. But if you're talking about a device, a barrier if it's been sized appropriately for the correct patient population and if in the judgment of the clinical team it's appropriate for that patient, I'm still having difficulty understanding why there should be a blanket prohibition that it be used with large or obese patients and folks with, you know, all the other characteristics you mentioned.

That's what I was reacting to that there should be an exclusion upfront, a priori, without really considering the conditions.

Dr. (George Gibeily): You know, I think we're learning as time goes on, as I think all of us are and that's the purpose of the human factors testing. If in fact, you know, through human factors and like I said 15 specialists of different experience levels from different healthcare settings will be asked to perform these procedures with full PPE and is there enough room in the enclosure to establish an airway without a struggle I we may be able to eliminate some of these contraindications.

(Julian Goldman): Okay...

Dr. (George Gibeily): But again, in an abundance of caution I think these should be included in the labeling. They're not slated in stone necessarily, they can be challenged, but we ask that appropriate testing be accomplished and data presented to show that it is safe to remove a contraindication that's all.

(Julian Goldman): Yes and I propose that the ability to rapidly remove it to gain access for unanticipated procedures is, you know, vitally important. Anyway, thank you very much for taking the time to dig into this a bit.

Dr. (George Gibeily): Thank you.

Coordinator: The next question is from (Stephanie Herbert), your line is open. Ms. (Herbert) please check your mute button. I'm showing no further questions. At this time, I would like to (turn the) conference back over to Ms. Irene Aihie.

Irene Aihie: Thank you. Before I close Suzanne do you have any closing remarks for the group?

Dr. Suzanne Schwartz: Thanks, Irene. Yes, I would like to thank (George) for his presentation and recognize everyone who has participated today whether from FDA and we've also had from OSHA some subject matter experts available on standby.

Thank you to everybody who had tuned in. The next session is slated to take place in two weeks which would be Tuesday, October 27 at noon Eastern. Announcement of topics will be forthcoming and please don't hesitate to share with us any topics of interest that you'd like to hear more about.

I'll turn this back now to Irene who will close out this session.

Irene Aihie: Thank you this is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn webpage at www.FDA.gov/training/CDRHlearn by Wednesday October 21. If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback, following the conclusion of today's webinar please complete a short 13-question survey about your FDA CDRH

webinar experience. The survey can be found at www.FDA.gov/CDRHwebinar immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

Coordinator: This concludes today's conference. All participants may disconnect at this time. Speakers please standby for a post conference thank you.

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