

FDA PPE Webinar

Moderator: Ivory Howard
April 27, 2021
12:00 pm ET

Coordinator: Welcome everyone and thank you for standing by. I would like to advise you that today's call is being recorded. If you have any objections you may disconnect at this time. All participants will be in listen-only mode until the question-and-answer session of today's conference. I would now like to turn the call over to Ivory Aihie (sic). Thank you. You may begin.

Ivory Howard: Hello and welcome to today's FDA Webinar. I am Ivory Howard of CDRH's Office of Communication and Education. Welcome to today's PPE Webinar.

During this Webinar the FDA will share the updated information on respirator decontamination systems during the COVID-19 public health emergency. Representatives from the FDA, NIOSH and OSHA will be available to answer your questions.

Following the presentation we will open the line for your questions related to information provided during today's Webinar. Now I give you Dr. Suzanne Schwartz from CDRH's Office of Strategic Partnership and Technology Innovation.

Dr. Suzanne Schwartz: Thank you Ivory. Good afternoon everyone and welcome. This is the 15th session in our Webinar series on personal protective equipment or PPE. In prior Webinars we've discussed the regulation of a variety of devices during the COVID-19 pandemic including filtering facepiece respirators and decontamination systems for filtering facepiece respirators including N95s.

We're at a very different place in the pandemic today regarding respirator availability than we were in the March or April of last year. As a result of increased NIOSH-approved respirator supply, FDA is recommending that healthcare personnel and facilities transition away from crisis conservation strategies including the use of decontaminated disposable respirators.

In today's Webinar Dr. Aftin Ross from CDRH's Office of Strategic Partnerships and Technology Innovation or OST will present information about FDA's April 9, 2021 letter to healthcare personnel and facilities which recommended this transition. After the presentation we'll turn to the operator for live Q&A.

CDC NIOSH has also updated its strategy for optimizing the supply of N95 respirators to clarify the application of surge capacity strategies such as respirator decontamination. And we are joined by our colleagues from NIOSH and OSHA for the question and answer portion of the session. With that I am pleased to turn the Webinar over and introduce Dr. Aftin Ross. Aftin?

Dr. Aftin Ross: Good afternoon. My name is Aftin Ross. And I am a Senior Science Health Advisor in CDRH. I have been working on PPE supply chain activities as part of the COVID-19 response.

We recognize that many of you are on the front lines of care and appreciate your commitment and hard work during the pandemic. Please know that as a

part of its commitment to protecting and promoting public health FDA is working diligently to support your efforts by ensuring PPE availability. We greatly appreciate you taking time out of your busy schedule to attend today's Webinar.

Today, I am going to provide an overview of the letter to healthcare personnel and facilities FDA released earlier this month recommending that facilities transition from the use of decontaminated disposable respirators. We'll then provide a resource slide for attendees and along with our NIOSH and OSHA colleagues answer any questions you may have regarding this topic.

On April 9, 2021 FDA released a letter to healthcare personnel and facilities recommending that they transition from the use of decontaminated disposable respirators. Respirators decontamination and bioburden reduction were one of the most extreme measures of respirator conservation,

in that there were crisis capacity conservation strategies that were only to be used when new NIOSH-approved or FDA cleared or authorized N95 filtering facepiece respirators are not available. The domestic supply of new NIOSH-approved disposable respirators has significantly increased since the use of respirator decontamination and bioburden systems began last year.

FDA and CDC believe this increase along with the availability of NIOSH-approved reusable respirators such as Powered Air Purifying Respirators or PAPRs, and elastomeric provide adequate respirator supply to facilitate a transition away from the use of decontamination and bioburden reduction systems. From our engagement with various healthcare facilities we know that many have already started phasing out respirator decontamination. And we are recommending that everyone do so as we take a staged approach to getting back to contingency and eventually conventional respirator use.

In support of this transition, FDA will not be reviewing or authorizing any more decontamination systems. During the public health emergency one of the ways FDA used its Emergency Use Authorization authority to expand the availability of respirators for healthcare personnel was by issuing the NIOSH-approved respirator EUA in March 2020.

Under this EUA, NIOSH-approved air purifying respirators including disposable respirators and respirators that are designed to be reusable were authorized for use by healthcare personnel. Once a respirator received NIOSH approval, its automatically authorized under this umbrella EUA until the US Department of Health and Human Services HHS Secretary's declaration that circumstances exist justifying authorization is terminated or the EUA is revoked.

From January 2020 through April 2021 NIOSH has approved over 875 respirator models or configuration with some of these manufactured by approximately 20 new domestic NIOSH approval holders. To give you further insight into the magnitude of respirators available, I would like to highlight that today there are over 6400 total respirator models or configurations on the NIOSH certified equipment list which meet the NIOSH-approved EUA criteria and thus are FDA authorized.

These wide-ranging respirator types include more than 600 FFR models of which there are over 530 N95 FFR models, over 360 PAPR configurations and over 5500 elastomeric respirator configurations including new elastomeric respirators without an exhalation valve. Availability of elastomerics without an exhalation valve is significant.

As one of the obstacles limiting the wider use of these reusable respirators in healthcare settings has been the inclusion of exhalation valves as a design feature which means the respirator cannot provide source control and cannot be used in the operating room because exhaled air can transmit respiratory secretions which could transmit infection or contaminate the sterile field.

Our April 9, 2021 letter had several key recommendations that I would like to highlight which are as follows. One, the need to limit decontamination of disposable respirators. We cannot emphasize enough that respirators decontamination and bioburden reduction as crisis capacity strategies were the most extreme respirator conservation strategies that should only be used when there is insufficient supply of new FFRs or if you are unable to obtain any new respirators.

Transition away from crisis capacity strategies such as decontamination of N95s and other FFRs as respirator supply has increased. And third, increase your inventory of available NIOSH-approved disposable respirators including N95s and other FFRs. Reusable respirators including Powered Air Purifying Respirators or PAPRs and elastomerics. including elastomerics without an exhalation valve that can be used in operating rooms.

Currently a surplus of respirators exists in the respirator supply chain. Thus even if you are unable to obtain the respirator model you prefer, FDA recommends that you obtain and use a new respirator before decontaminating or bioburden reducing a preferred disposable respirator.

FDA has been actively monitoring the respirator supply chain throughout the pandemic and will continue to do so as facilities systemically transition away from the use of crisis capacity strategies and work towards a return to contingency and eventually conventional respirator use practices. We will

watch to see how respirator availability is impacted by transitioning away from decontamination to further inform our next steps as it relates to the use of other respirator crisis capacity strategies such as the use of non-NIOSH approved respirators.

FDA is taking this phased and measured approach such that an adequate supply of respirators is maintained for the healthcare personnel that need them. Though we are beginning a phased approach towards the ultimate goal of returning to conventional respirator use practices, respirators specifically surgical respirators, presently remain on the FDA's device shortage list as conservation strategies are still being used.

Please note that the shortage list reflects the categories of devices the FDA has determined to be in shortage at this time and will be maintained and updated as the COVID-19 public health emergency evolves. FDA is committed to being as transparent as possible with our stakeholders. As such, we will continue to keep healthcare personnel and the public informed if new or additional information becomes available.

On this slide you will find several links for resources that are available to you for further information. The first link is for the letter to healthcare personnel and facilities that FDA released April 9, 2021 regarding transitioning away from the reuse of decontaminated respirators.

As I mentioned earlier in the presentation FDA has authorized the emergency use of certain FFRs for use in accordance with CDC recommendations during the public health emergency. The second link can help healthcare facilities identify respirators for use and directly link to NIOSH-approved respirators on the NIOSH certified equipment list. The other links on this slide provide

helpful resources on the CDC and OSHA Web sites with the third link taking you to CDC's recently updated N95 respirator optimization strategy.

Please note that any question you may have after this Webinar may be sent via email to cdrhccovid19surgicalmask@fda.hhs.gov. Also for a copy of the presentation, transcript or the Webinar recording that may be found at www.fda.gov/training/cdrhlearn under the heading Specialty Technical Topics and sub heading Personal Protective Equipment.

We have now come to the conclusion of our presentation and will be answering any questions that you may have. Operator we would like to now open the line for questions. As the operator does so, I will turn the call back over to Suzanne Schwartz.

Dr. Suzanne Schwartz: Thank you so much Aftin for that overview. While we're waiting for questions from the audience I'd like to provide an opportunity for our colleagues who have joined us from NIOSH and OSHA to share their comments as well with perspectives to this topic area. Let me first turn to NIOSH.

So since February 2020 CDC has provided different strategies for optimizing the supply of N95 respirators based on that framework of surge capacity. Can you please provide or describe the recent updates that you've made to crisis capacity strategies for N95 respirators?

(Chad): Thank you Suzanne. This is (Chad) with NIOSH. On April 9 CDC updated the strategies for optimizing the supply of N95 respirators. This update removed some crisis capacity strategies that are less protective to healthcare providers and clarified other conventional, contingency, and crisis capacity strategies.

These updates were done in collaboration with stakeholders from healthcare, respirator manufacturers and distributors and federal partners. These updates were based on new research, a significant increase in the supply and availability of NIOSH-approved respirators over the last several months and because CDC was still hearing that front line healthcare personnel are having difficulties accessing respirators and are still practicing crisis capacity strategies such as reuse of disposable N95 respirators.

Updates to the crisis capacity strategies included removing the strategy of using non-NIOSH approved respirators developed by manufacturers who are not NIOSH approval holders, highlighting that the number of reuses should be limited to no more than five uses or five (donnings) per device by the same healthcare provider to ensure adequate respirator performance, removing decontamination of respirators as a strategy with limited reuse, emphasizing that facemasks for caring for a patient with suspected or confirmed SARS-CoV-2 infection should only be used as a last resort if the supply of respirators are severely limited. And lastly removing the table “Suggested well-fitting facemask or respirator use based on distance from patient with suspected or confirmed SARS-CoV-2 infection and use of source control.”

Dr. Suzanne Schwartz: Thank you so much (Chad). I really appreciate that overview. I'd like to now turn to our OSHA colleagues. Could OSHA please provide comment on its stance regarding respirator decontamination at this stage of the pandemic?

Dr. Dionne Williams: Yes certainly. This is Dionne Williams from OSHA. Thank you for the opportunity to comment on OSHA's stance on this.

During the early and peak stages of the pandemic OSHA issued several enforcement memoranda through which the agency provided specific enforcement discretions that were intended for addressing severe respirator shortages. The memos outlined some flexibilities that OSHA compliance staff could consider when evaluating an employer's noncompliance with OSHA standards under crisis capacity scenarios.

And that included circumstances where employers were relying on decontamination to expand their availability of single-use respirators. Keep in mind however that this is a practice that is prohibited under OSHA's respiratory protection standard. So on March 12th of this year OSHA updated its interim response plan for COVID-19 and in this update OSHA informed its compliance staff that shortages were becoming less of a barrier to compliance.

In this document, OSHA also reminded its staff and the public that OSHA had not previously waived any of its requirements and that any enforcement discretions that were granted in the peak of the pandemic were intended to be time limited and applied on a case-by-case basis. So, enforcement discretion under OSHA are not applicable in the absence of crisis capacity conditions.

And that means that where NIOSH-approved respirators or associated supplies and services are readily available OSHA will not exercise enforcement discretion. So the updates that have been described by Aftin and (Chad) from the FDA and CDC NIOSH regarding increased availability of NIOSH-approved respirators and the recommendations that healthcare facilities begin transitioning away from crisis capacity strategies like decontamination of single-use respirators fully align with OSHA's updated guidance to employers and compliance staff.

Dr. Suzanne Schwartz: Thank you very much Dionne. Really appreciate that. Operator, I think we are ready at this time for the first question.

Coordinator: Yes absolutely. Just a quick reminder if you would like to ask a question at this time please press Star 1 on your phone, unmute your line and record your name so you can be introduced. Again to ask a question please press Star 1. Give me just a few moments to see if any come in. Thank you. Speakers I will continue to monitor but I am showing no questions at this time.

Dr. Suzanne Schwartz: Okay thank you. Let's give it about another minute or so.

Coordinator: Absolutely. And just a reminder to press Star 1 and record your name if you'd like to ask a question. And we do have one question from (Leslie). Go ahead please. Your line is open.

(Leslie): Hi. Yes I'm in dentistry and we're unable to eliminate the hazard of SARS-CoV-2 definitively. So if we are performing aerosol generating procedures must employees wear N95 respirators according to OSHA?

Dr. Suzanne Schwartz: I'm going to turn - that question was addressed over to OSHA if OSHA would like to respond.

Dr. Dionne Williams: Yes. This is Dionne Williams from OSHA. We do have guidance on our Web site. The link that Aftin provided should be helpful to get you to some of that guidance. And it basically describes for you that your exposure, your hazard assessment needs to be based on the tasks that people are conducting.

The most recent updated interim response plan is helpful and it is on the OSHA Web site. And for people who are conducting aerosol generating procedures we do expect that you would put those individuals in respirators.

An N95 is the minimum required respirators but as described in (Chad)'s response to his question there are other types of respirators that can also be substituted if N95s are not available.

(Leslie): Thank you.

Dr. Suzanne Schwartz: Operator, are there any additional questions?

Coordinator: I am showing no further questions at this time.

(Chad): Suzanne, this is (Chad), just for that last question I will point out that CDC does have specific guidance for dental settings on their COVID response Web pages.

Dr. Suzanne Schwartz: Okay. Thank you for that. So, I think without any further questions I am going to turn this back to Ivory to close out this particular Webinar. I will say that we are all committed to continuing to provide information to the public as new guidance and new activities are released from the agency. And with that again one last time no questions we'll turn it back to Ivory to close out this Webinar.

Ivory Howard: Thank you. This is Ivory Howard. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be available on CDRH Learn at www.fda.gov/training/cdrhlearn by Thursday, May 6. If you have any 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 the Webinar. Please complete a short survey about your Webinar experience. The survey can be found at www.fda.gov.cdrhwebinar immediately following the

conclusion of this Webinar. Again thank you for participating. This concludes today's Webinar.

Coordinator: That will conclude today's conference and we thank you for participating. You may disconnect at this time. Speakers please stand by for your post conference.

END