ASPR TRACIE Webinar Transcript
COVID-19: Optimizing Healthcare Personal Protective Equipment and Supplies
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Shayne Brannman: On behalf of the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and the Healthcare Resilience Working Group leadership team, I'd like to welcome you to ASPR's Technical Resources Assistance Center and Information Exchange webinar titled COVID-19, Optimizing Healthcare Personal Protective Equipment and Supplies.

Before we begin, we have a few housekeeping items to note. The webinar is being recorded. To ensure a clear recording, everyone has been muted; however, we encourage you to ask questions through the webinar. If you have a question, please type it into the question section of the go to webinar console during the Q&A portion of the webinar, we will ask the questions we receive through the console. Questions we are unable to answer due to time constraints will be followed up directly via email after the webinar. To help you see the presentation better you can minimize the GoToWebinar console by clicking on the orange arrow.

Today's PowerPoint presentation and speaker bios are provided in the handout section of the go to webinar console and will be posted along with the recording of this webinar within 24 hours on ASPR TRACIE. The opinions expressed in this presentation and on the following slides by nonfederal government employees are solely those of the presenter and not necessarily those of the US government. The accuracy or reliability of the information provided is the opinion of the individual organization or presenter represented.

My name is Shayne Brannman and I'm the Director of ASPR TRACIE and I want to welcome new and old friends to this webinar. I want to thank you for what you do daily to enhance the preparedness, response and recovery activities of your healthcare entities and communities. Your role is so vital to addressing the daily and arduous challenges being presented so your willingness to spend the next 90 minutes with us to further advance your knowledge is noteworthy, thank you. I also want to convey my heartfelt thanks to our awesome lineup of panelists and moderator for this webinar. Your willingness to lend your precious time and share your substantive expertise so others might benefit is commendable and generally appreciated. And lastly, thanks to the TRACIE crew, particularly Audrey Mazurek for coordinating this webinar.

For our new friends to ASPR TRACIE on the webinar today, this slide depicts the three domains of ASPR TRACIE, technical resources, assistance center and information exchange. If you cannot find the resources you are looking for on the ASPR TRACIE website, simply email, call or complete an online form and we will respond to you to your enquiries directly. Next slide depicts meaning of the virtual resources that are currently available, so please check them out

and return often as new resources are being added continually or updated. It is now my pleasure to acknowledge Captain Ignacio, the Deputy for the COVID-19 Healthcare Resilience Working Group who is available for this webinar during the Q&A and Ms. Leslie Hintz, the COVID-19 response deployment team lead of the COVID-19 Healthcare Resilience Working Group who will now provide some brief remarks before we begin the presentations. Leslie?

Leslie: Thank you, good afternoon, I am Leslie Hintz, the supply preservation support team lead for the Healthcare Resilience Working Group within HHS ASPR. On behalf of everyone in the HRWG, we are very excited for this webinar to hear from our esteemed speakers and to continue the much needed discussion on PPE preservation. Before the webinar gets underway, there are a number of people we would like to thank for making this webinar possible; first ASPR Tracie staff under the direction of Ms. Brannman have been instrumental in coordinating and collaborating on this webinar, thank you. To our esteemed speakers and esteemed moderator, Dr. Hick, thank you for sharing with us your knowledge and we look forward to continuing to work together. In addition, thank you to all the healthcare professionals demonstrating fortitude and resilience in helping our country and the world to fight the COVID-19 pandemic, thank you for your service to our country. And thank you to the family and friends of the healthcare professionals for your mental and physical stamina to be the support system for your loved one. Thank you for all that you're doing.

Over the past several months, PPE preservation strategy developed by the Healthcare Resilience Working Group amplifying CDC and FDA's guidance were communicated in a variety of outreached efforts to various healthcare and first responder organization. PPE preservation is still a needed topic in this country and around the globe. As PPE resources may not be at the needed capacity and our country relies on PPE to limit the spread of disease, cross contamination and COVID-19, an objective for the national COVID-19 response has been the mantra of reduce, reuse, repurpose. That's contingency and crisis capacity plan are implemented to ensure the continued availability of protective gear. This includes reducing the rate of PPE usage, reusing PPE through optimization, decontamination and reuse procedures and repurposing alternative types of PPE. PPE availability should be regularly monitored and projected needs should be regularly assessed.

Conventional capacity measures should be implemented as standard practice. Contingency capacity practices used temporarily during periods of expected PPE shortages and crisis capacity practice considered during periods of known PPE shortages. Contingency and crisis capacities should not continue indefinitely. So as PPE availability returns to normal, facilities should promptly resume conventional practices. We encourage everyone to be aware of, prepare for and if applicable implement preservation strategies. You'll hear from our speakers today on hopefully some valuable information for you to consider putting into practice. For additional information, the HHS FEMA fact sheet, coronavirus pandemic, PPE preservation, best practices document along with additional resources developed by HRWG are included at the end of the webinar. You'll hear from a variety of speakers today on the federal government, industry and academia.

As a reminder, the findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Department of Health and Human Services or its

component. We look forward to the discussion today on optimizing PPE and addressing any questions or concerns you all might have in our question and answer portion of the webinar today. Stay safe and thank you for your participation. I'll turn it back over to Ms. Brannman at this time.

Shayne Brannman: Thank you Leslie, I will now turn it over to Dr. John Hick from Hennepin Health and ASPR's TRACIE's senior editor who will serve as the moderator for today's webinar. John, over to you sir.

Dr. John Hick: Thank you Shayne, I'm pleased to be able to moderate this webinar today which offers you a number of private and public system perspectives on PPE issues knowing that based on the breadth of the audience we have out there today, the different circumstances under which you're using PPE and your healthcare role or within your facility or system or program or homecare and also the significant variability in what you have available in the market. And what you're using for personal protective equipment that you know hopefully all of you will gain some answers even though even the speakers today will not have all the answers to all the questions because we continue to learn significant amounts about both coronavirus itself and its transmission as well as a better PPE, its effectiveness, its durability and a number of other aspects. So with that we just hope to provide you a good perspective on current state and current issues in PPE and with that I want to lead it off with Maryann D'Alessandro from NIOSH. Maryann, thank you so much for making the time to be with us.

Maryann D'Alessandro: Thank you John, can you go to the next slide please? So today, I am going to focus my discussion on respirators including federal authorities, NIOSH activities and healthcare applications and standards gaps, supporting supply optimization, next slide. For those of you who are not familiar, I'm with the National Personal Protective Technology Laboratory of NIOSH and NPPTL's mission revolves around personal protective equipment including PPE research, standards development, certification with an emphasis on respirator certification and approval, post market activities and translational science including workplace interventions. Next slide please. There's a lot of confusion regarding the federal authorities in the respiratory protection space and the COVID-19 pandemic has brought to light some of the gaps. NIOSH approves all respirators used in occupational settings in the United States from the self-contained breathing apparatus used by firefighters to particular respirators like N95s that have been so prevalent throughout the COVID response, essentially all of the products shown on the left side of the slide.

Healthcare workers are most familiar with N95 FFRs or filtering facepiece respirators and surgical N95 respirators. FDA clears all medical devices as shown on the right and only the surgical N95 has requirements for protection such as fluid resistance required by the FDA. Since 1972, about 9000 respirator designs have been approved by NIOSH. The Occupational Safety and Health Administration is the agency that oversees worker compliance including respirator selection and use. The OSHA 1910.134 Respiratory Protection Standard establishes permissible practices for using NIOSH approved respirators in the workplace and this standard also requires workplaces using respirators to establish a respiratory protection program, next slide please. FDA has requirements for surgical N95 respirators in healthcare settings. FDA requires fluid penetration testing, flammability and biocompatibility testing. In 2018, a memorandum of

understanding between NIOSH and FDA led to FDA entrusting the responsibility to evaluate these requirements to NIOSH, next slide please.

While all the respirators you see on this slide have been used in healthcare for years throughout the COVID response, we have experienced a significant increase in the NIOSH approved air purifying respirators, the FFRs on the left, elastomeric half mask respirators in the middle and the powered air purifying respirators on the right. FDA issued emergency use authorizations authorizing all NIOSH approved APRs to be used in healthcare throughout the response. The pandemic has increased our awareness of the utility of these respirators and the standards gaps we need to address, next slide please. In addition to increased use of NIOSH approved devices because of the respirator shortages, CDC provided crisis capacity guidance to permit the use of respirators conforming to standards in other countries. Those countries include Australia, Brazil, China, European standards, Japan, Korea and Mexico.

While products conforming to these standards provide protection similar to NIOSH approved devices, we were receiving reports that users did not feel protected by these devices so we initiated a limited evaluation program to evaluate the filtration efficiency of these respirators. These evaluations revealed that approximately 60% of the products we received that claimed to conform to the standards did not meet the minimum NIOSH filtration requirements. So going forward, we do not know how long these products will be sold in the US market and NIOSH, NPPTL will continue to evaluate requests we receive that these requests indicate that we cannot have confidence that these products will protect our workers.

When the guidance was established, we considered the standards and their equivalency to the NIOSH standard to keep our workers protected but we did not include in the equation was the need for products conforming to these standards to meet particular conformity assessment requirements i.e., to have third parties to evaluate them to have quality assurance requirements for example. As these products continue to be sold in the US market we will continue to do our due diligence to provide the evaluations needed to identify substandard and counterfeit products to keep our healthcare workers and critical infrastructure workers safe and to keep those products that do provide the protection on the FDA EUA list, next slide please.

Another issue revealed during the COVID response is the issue of source control. This became even more important as it became clear that individuals who may have the virus could be a symptomatic for days before presenting with the virus, so now respirator users who previously used respirators with exhalation valves to protect themselves now have to consider what is coming out of that exhalation valve and if that respirator is not only protecting the wearer but providing the source control needed to protect others. Because more data is needed to answer these questions, CDC guidance states that these respirators should not be used if source control is needed, unless the exhalation valve is covered.

Some respirators have a diverter exhalation valve cover but we do not know if that is sufficient to provide source control. NIOSH is conducting several studies to quantify what is coming out of the exhalation valve to improve the current guidance and we have some preliminary results that hopefully will lead to improved CDC guidance, next slide please. Elastomeric respirator use has increased throughout the response as well. During routine operations, disinfection is not part

of the respirator approval. OSHA permits employers to use the cleaning recommendations provided by the manufacturer. CDC published guidance for disinfection of elastomerics points to those methods that several facilities have used successfully including the use of EPA authorized disinfectants and the Bessessen protocol and using filter cartridges that enclose the filter media as shown on the picture above rather than the pancake style filter as shown below.

Moving forward, if these devices are to be disinfected in healthcare during routine operations, standards gaps exist regarding the number of times these devices can be disinfected and validation that the filter media and ancillary components are not degrading and validation that there is no off-gassing and a facepiece is needed. By using these during routine operations that will increase the inventory of respirators as well, next slide please. Powered air purifying respirator use has also increased throughout the response and here we also have a situation where disinfection of these devices is not part of the NIOSH approval. OSHA permits employers to use the recommendations provided by the respirator manufacturers similar to the elastomerics and similar to elastomerics, CDC provided crisis capacity guidance for use of PAPRs as well in healthcare settings including recommendations using EPA authorized disinfectants and similar to elastomerics, one study found that PAPRs can be disinfected up to 150 times without degradation.

Again, science based standards are needed to address these gaps to allow this in routine operations, next slide please. In addition to the respiratory protection needs and healthcare identified so far, NIOSH is involved in several initiatives to address gaps in non-occupational respiratory protection in source control. While these efforts go beyond healthcare establishing recommendations for respiratory protection for the general public in the contingent workforce will be extremely beneficial to the nation, also the development of a standard for a barrier face covering will provide a consistent way to benchmark products to inform user selection because of the wide variety that are available today, considerations for the standard four barrier face coverings include filtration efficiency, breathing resistance fit and reuse, next slide please.

In summary, the COVID-19 response has revealed several standards and conformity assessment gaps that if addressed could contribute to optimizing supply as we consider how to address these standards needs, we should be mindful of the NIOSH PPE conformity assessment framework here and consider what the hazards and risks are to the workers as we explore how the hazard could be addressed and what the new standards could be. Once those standards are identified, we need to define the level of conformity assessment that should be applied to address these standards. Together these efforts will continue to contribute to respiratory protection optimization, thank you and I'll go back to John.

Dr. John Hick: Thanks so much Maryann. During COVID-19 how many models of N95s have been newly approved and, and what's involved with that process?

Maryann: So to date in 2020, we have completed about 575 approval decisions that includes about close to 470 granted and about 100 denied and there are 64 new filtering facepiece respirators approved that have been issued to dates and that includes 54 conventional and 10 public health emergency devices. We have 50 new HEE PAPRs that includes 46 conventional and 4 public health emergency and 2 new PAPR 100s and 681 new elastomeric respirator

approvals with a minimum of N95 protection. So what's involved in that process is manufacturers have to submit an application to us and we conduct, have a process that includes testing and quality assurance reviews, reviews of the manufacturing plants and their quality assurance processes and once they become a NIOSH approval holder then we have ongoing monitoring of both the plant and the devices themselves.

Dr. John Hick: Great, thank you so much. And we'll go next to our next speaker from FDA Dr. Aftin Ross. Thanks for taking the time with us today.

Dr. Aftin Ross: Good afternoon, my name is Aftin Ross and I'm a Senior Science Health Advisor in the Office of Strategic Partnership and Technology Innovation and FDA Center for Devices and Radiological Health. I would like to thank everyone for attending the webinar today. We recognize that many of you on the front lines of care and appreciate your commitment and hard work during the pandemic. Please note that as a part of its commitment to protecting and promoting public health, FDA is working diligently to support your efforts. Today, I will be providing an overview of FDA's respirator oversight and actions we have taken during the COVID-19 public health emergency to increase availability of respirators for healthcare personnel in healthcare setting, next slide please.

FDA works collaboratively with federal partners CDC, NIOSH and OSHA to ensure the safe use and availability of respirators. FDA regulates the devices and for respirators intended for use in healthcare settings, our oversight includes premarket review, post market surveillance and compliance. During the COVID-19 public health emergency, FDA has health facility access to critical, quality, medical supplies and regulatory flexibilities afforded by the issuance for emergency use authorizations for certain respirators and decontamination system. We have also issued guidance on enforcement policy.

Those decontaminated respirators in systems are not the focus of today's talk. It is important to know that these require an emergency authorization and are not covered by enforcement policies which have been articulated in guidance. Next slide please. The Emergency Use Authorization or EUA is one of the regulatory tools that FDA has leveraged as part of its COVID-19 response to increase the availability of respirators. The EUA has a specific construct based on statutory authority given to FDA and before the FDA issues an EUA, the HHS secretary declares that circumstances exist justifying authorization. During the COVID-19 response, this declaration has been based on a determination by the secretary that there's a public health emergency. The criteria for issuance are the foundational element of the EUA and are displayed on this slide.

Please note that though the "may be effective" threshold, it's a different threshold than that which is used for an FDA clearance approval when authorized and known and potential benefit of a product outweighs the known and potential risk. To date, FDA has issued 3 respirator EUAs and 11 decontamination system EUAs to help increase respirator availability for healthcare personnel during respirator shortages resulting from COVID-19, next slide please. In addition to the EUA, FDA has also used guidance to provide regulatory flexibility during the COVID-19 public health emergency while assuring that the products are appropriate for their use. The policy provides enforcement discretion for certain FDA requirement and assess for the duration of the public health emergency and implies the respirators not intended for medical purpose.

The guidance indicate that an FDA clearance or EUA authorization is needed for respirators to be marketed in the US for use by healthcare personnel, next slide please. FDA has authorized the emergency use of certain respirators for use in healthcare settings by healthcare personnel in accordance with CDC recommendation to prevent healthcare personnel exposure to pathogenic biological airborne particulates during respirator shortages resulting from the COVID-19 outbreak.

In accordance with the CDC's strategies for optimizing the supply of N95 respirator, this flowchart illustrates which emergency use authorization applies to specific respirator type and provides length to information on performance factors to consider when selecting respirators for use in healthcare and this can be found on our webpage. I'm now going to briefly walk us through the flowchart, starting with the top line. FDA believes that FDA cleared or NIOSH approved respirators should be used when they are available. The NIOSH approved air purifying respirator EUA includes disposable filtering facepiece respirators, FFRs like N95 and reusable respirators such as elastomeric and powered air purifying respirators. To identify a respirator, review the NIOSH Certified Equipment List or CEL to choose a particular manufacture or to do a unique search.

Before selecting a respirator, review the NIOSH counterfeit respirators list to identify if the NIOSH approval has been misrepresented. If we go to the next slide of the flowchart, you can see the next option. If you are unable to obtain NIOSH approved FFRs, consider the use of imported FDA, EUA authorized non-NIOSH approved respirator, not manufactured in China. To identify respirator under this EUA, review the EUA including exhibit one which is a list of the authorized respirators. Before selecting a respirator, please review CDC factors to consider when planning to purchase respirators from another country. And CDCs and NPPTL respirator assessment to support the COVID-19 response that Maryann referenced in her presentation to determine if filtration levels are adequate for use. The final part of the flowchart displays the option if you are unable to purchase an imported NIOSH approved respirator not manufactured in China. Then you can consider the use of FDA EUA authorized non-NIOSH approved respirators manufactured in China including KN-95.

To identify a respirator under this EUA, review the EUA including appendix A which has the list of authorized respirators. Again, before selecting a respirator, review CDC factors consider when planning to purchase respirator from another country and CDC, NPPTL respirator assessment to support the COVID-19 response to determine if filtration levels are adequate for your use, next slide please. Recognizing the critical role of respirators in infection prevention and control, FDA’s actions have been focused on increasing the availability of respirators for healthcare personnel.

Specifically, FDA is first implementing agile regulatory practices such as EUAs in guidance. As the pandemic continues to evolve, a new information has come to light. We have refined and updated our policies accordingly. Second, continuing to engage collaboratively with public health and industry stakeholders to monitor respirator supply and demand and communicate current status of supply and mitigation action undertaken to facilitate access. Specifically, we engage manufacturers, distributors, group purchasing organizations, healthcare organizations,

professional societies and healthcare providers to understand respirator manufacturing capacity, distribution and use practices. Obtaining these insights, helps to further inform our respirator policy.

Third, communicating with our stakeholders. We recognize that there are a lot of nuances to our policies and have tried to be as communicative as possible with our stakeholders. FDA has used a variety of public safety communication vehicle such as webinars, press releases, graphics and web pages to promote our policies and answer questions, in fact our next PPE webinar is scheduled for Tuesday, September 29th. We also continue to answer questions via several FDA inboxes focused on device shortages and EUAs. Next slide, please. The last slide of my presentation provides leveling to some of our respirator and facemask resources. This concludes my presentation and I would like to thank ASPR for the opportunity to speak to you this afternoon. John, take please, back to you.

Dr. John Hick: Thanks so much Aftin, how concerned is FDA about the continued supply of N95s during the winter, any contingencies that you are looking out?

Dr. Aftin Ross: Certainly we recognize I am concerned for and the need for respirator protection. As I mentioned during the presentation, FDA continually engages with public health and industry stakeholders to monitor the supply and demand and to try to communicate as we learn information about different mitigation actions that can be undertaken to health. The good news is that as a result, government and private sector stakeholder efforts it is our understanding that the domestic manufacturing capacity for N95 respirator has and continues to significantly increase and we also heard Maryann speak about the wide range of respiratory protective devices that have been approved by NIOSH this year. We expect to be in a much better place by the end of the year as compared to where we were in March 2020. FDA will continue to evaluate the respirator supply and to implement agile regulatory approaches as needed.

Dr. John Hick: Great, thanks Aftin. Now we're going to turn to our colleagues of 3M, Nikki McCullough and Ms. Jessica Hauge to tell us a little bit about what's going on in the industry side.

Nikki McCullough: Thank you so much, this is Nikki McCullough. I will be starting us off. Next slide, please. I would like to start this by showing a little bit of what 3M has been doing to respond to the COVID pandemic. Certainly, we have been increasing capacity and very much in partnership with NIOSH, CDC and FDA, they've been excellent partners too and I thank them. We have been providing a lot of technical information and helping highlight government guidance to occupational safety and health practitioners. We also have been conducting research both applied and bench research and supporting FEMA as they have imported respirators from around the world.

We also have been doing a lot of media response, responded to questions we received but also helping to try to get information out there to people who need it. Next slide, please. I just want to start a little bit and talk through respiratory protection for those of you who may not be as familiar. Respiratory protection helps reduce the particles that you might breathe in through your nose and mouth and they do this by filtering out the particles in the air. You see a picture of

N95 filter media there, N95 filter media is a random mass of nonwoven fibers and the particles weave their way through there in a torturous path and are collected by different mechanisms.

The way that NIOSH tests respirator filter media is really a worst case scenario, ensuring that if it passes the NIOSH test, to be 95% efficient that it's going to be at least 95% efficient or other particles, both larger and smaller. One of the key factors in using a tight fitting respirator like a filtering facepiece respirator or elastomeric respirator is that it forms the field to the face. When it forms a field to the face that directs all of the air through the filter media giving it the ability to be filtered. If there are gaps around the edge of the device, then the air and particles will take the path of least resistance around the edge and enter the breathing zone. So it's very important that men shave every day and that the nose clip is formed properly and the headbands are placed properly on the head. Next slide, please.

This is a little bit of an overview of the different devices we've been discussing today, you'll see procedural masks and surgical masks on the far left hand side, those are really barriers for what you might expel if you cough or sneeze, really large particles. Surgical mask those cleared by the FDA to provide a fluid barrier in case you are working under the high velocity stream of blood, it can provide a barrier. So respirators shown on the right hand side will provide when used properly, a reduction in the particles you might inhale into your nose and mouth, into your respiratory system and that's their primary function. You'll see when filtering facepieces we are showing 2 kinds, both are standard or general use respirator and a surgical respirator.

As Maryann described, both are NIOSH approved but surgical respirators are also tested and cleared for use in surgery. Next slide, please. This chart gives a brief overview of the differences between masks and respirators and a lot of people do use the term mask very loosely, I would encourage you to use the proper terminology. So talking about mask, we are talking about procedure masks and surgical mask and then using the term respirator, when we are talking about N95, reusables or powered air purifying respirators. I will say this chart gives an overview but respiratory protection is a complicated subject and there are a lot of caveat, for example some filtering facepieces and reusable respirators have exhalation valves and as Maryann D'Alessandro explained earlier, it's very important to understand the current guidance around valve and when source control is needed and when force control is not needed. Next slide, please. And I would like to address a little bit about the respirators being imported by FEMA but also we're seeing other imports into the United States, of respirators not approved by NIOSH or holding dual approvals by NIOSH and another agency. As Maryann had mentioned we have seen many counterfeit, fraudulent and substandard products entering the United States. In fact, 3M has opened a COVID fraud hotline to deal with all of the instances of fraud and we have had over 4000 reports globally and have started prosecuting.

For those products that are not fraudulent though, for those products that are actually authentic respirators approved in those countries to those standards, they -- these classifications on the screen are very similar to N95 respirators. So the performance, the filtration testing, the pressure drop is very similar but one of the main difference is that people in the US are experiencing is that they may not see the respirators fit the diverse population of US faces that we have because many of these respirators were designed to fit the population in a country where they were approved and often need to be tested on human subjects during approval. They aren't seeing the

high pass rates that we tend to see with many NIOSH N95 respirators. I'm now going to turn it over to Jessica Hauge to talk about decontamination.

Jessica Hauge: Thank you Dr. McCullough. As many of the speakers have mentioned already the CDC has issued guidance during COVID-19 on which measures, healthcare organizations should consider taking during COVID-19 to optimize the use of available filtering facepiece respirators. Several of these strategies have already been discussed. Shown here are the strategies that are included in the groups called Contingency and Crisis Capacity Strategies. As several speakers have noted, CDC has also provided a list of conventional capacity strategies which are considered standard use practices, those can and in some cases should be undertaken even during times of sufficient respirator supply.

Contingency capacity strategies should be considered when an organization is anticipating a possible shortage in available respirators based on their expected use rate, included in this list are the extended use of respirators, meaning the use of a respirator for multiple patient interactions. Crisis capacity strategies as has been discussed already in this webinar are even more outside the box practices that should be considered only when an organization is experiencing insufficient supply of respirators and these include using respirators that are past their shelf life for respiratory protection and also implementing respirators that are approved to other countries standards as Dr. McCullough was just describing as well as limited reuse of filtering facepiece respirators.

As the manufacturer of respirators being used by healthcare organizations during this pandemic, we here at 3M have frequent conversations with healthcare organizations about these strategies. The next few slides will address some of the most frequently discussed topics. Next slide, please. So limited reuse of filtering facepiece respirator is a practice that's not typically performed in healthcare organizations because of standard infection prevention practices. CDC has provided guidance on specific procedures that should be followed when reuse of filtering facepiece respirators is implemented in healthcare. One of those procedures which can be considered only in the most extreme shortages of FFRs is decontamination of filtering facepiece respirators.

CDC says though that whether or not decontamination is performed before the reuse of a filtering facepiece respirator, the respirator should be handled as if it is potentially contaminated. So these handling practices shown here should be employed by users of respirators that have already been used. Hence should be washed, the wearer should avoid touching the interior surface of the filtering facepiece respirator. It's recommended to use a pair of clean gloves when handling the respirator, both on putting it on and when performing a user seal check, always the respirator should be visually inspected to ensure that the integrity has not been compromised.

There's no magic number for the number of times that a respirator can be reused before it begins to show signs of fatigue or deterioration. It depends on many factors such as the amount that the headbands are stretched during donning or the duration of time that the respirator is used. So wearers need to always every time a respirator is used inspect that respirator to make sure that it is not damaged. If the integrity is compromised or if the wearer can't perform a user seal check, the respirator should always be thrown away and another respirator should be worn and as part of

the inspection procedure and the donning procedure, a user seal check is, is very important in the process of determining the respirator is able to form an adequate seal. Next slide, please.

So as Aftin mentioned, the FDA has issued several emergency use authorizations which temporarily authorize the use of certain sterilization equipment as FFR decontamination methods. The compatibility of a decontamination method can vary by respirator model depending on the material composition and the construction of each respirator model. Nikki just described a couple of minutes ago the way that FFRs function and it's important to confirm that a respirator model is able to continue to function as expected after undergoing a particular decontamination method. There are 4 factors that need to be considered when evaluating whether a method is compatible with the particular respirator model.

So the first one is efficacy, of course the decontamination method must inactivate the target organism and safety, the method must be safe for the person who wears the respirator after it is treated. Filtration is the third. The decontamination method must not damage the respirator's filter material and finally fit. And fit can be impacted by many different components on a respirator, so it's really vitally important to account for all of the components on a respirator and whether the decontamination method has had an impact on each of those components when evaluating the respirators ability to fit as expected after being decontaminated. Next slide, please.

Both OSHA and the FDA have indicated in their guidance that decontamination of filtering facepiece respirators is permissible for healthcare workplaces and only healthcare workplaces during the pandemic, although decontamination of FFRs has attracted a lot of attention during the pandemic, it's important to understand that decontamination should only be undertaken in extreme cases if there are so few respirators that there aren't enough respirators to issue 5 respirators to each wearer and that refers to the recommended practice of wearing a respirator, putting in a breathable storage container such as a, a paper bag and storing it for 5 days before reusing it and the expectation that that practice will reduce the number of viable virions on the respirator surface.

Of course it's important to recognize that FFRs again are not designed to be cleaned and disinfected although other respirator types are designed to be cleaned and disinfected such as elastomeric respirators and powered air purifying respirators. Finally, decontamination does not extend the lifespan of filtering facepiece respirators and this is a misconception that we discussed with healthcare organizations often, in fact decontamination can generally be assumed to likely shorten the lifespan of a filtering facepiece respirator. 3M has published our manufacture guidance on decontamination in this technical bulletin that you see on the slide here and the link to the bulletin is also there. As we stated in the bulletin, we do not recommend the practice of decontaminating filtering facepiece respirators. We recommend exploring many other options to provide adequate respiratory protection to healthcare workers who need it during the pandemic. Next slide, please. So very quickly in summary, N95 respirators are designed to help reduce airborne exposures to particles such as airborne particles that may contain SARS-CoV-2.

Elastomeric respirators and powered purifying respirators are also particular respirator options that are designed to be cleaned and disinfected. OSHA, CDC, NIOSH and FDA have offered

robust trends for the selection and use of respirators during the COVID-19 pandemic and as the CDC contingency and crisis strategies are implemented for respiratory protection, it's important to consult all applicable government guidance as well as the manufacturer guidance for model specific information. Thank you so much.

Dr. John Hick: Thanks Jessica. So if people are using a non-3M manufactured filtering facepiece respirator, should they be checking with their specific manufacturer about guidance before they would undertake any decontamination strategies?

Jessica Hauge: I absolutely would recommend always checking with the manufacturer of any particular respirator model and enquiring about what data is available to support the compatibility of a decontamination method with a particular respirator model.

Dr. John Hick: Great, thanks so much. And to talk a little bit more about some of the issues around mask decontamination as well as fit and other issues is Dr. John Lowe from University of Nebraska and thanks for joining us today, John.

Dr. John Lowe: Thank you so much John, pleasure to be here to speak and so just a quick background on myself. So I'm John Lowe, I'm from the University of Nebraska Medical Center and also one of the 3 leads for the National Emerging Special Pathogens Training and Education Center that's funded by CDC and ASPR. Here to talk about our implementation of an N95 facepiece filtering respirator decontamination and reuse protocol that we implemented at our health system early in the pandemic. Next slide. So I always like to start off with our warnings and kind of to answer the inevitable, what led to this decision? It was, it was not a light-lightly reached decision as you've heard overviewed by our colleagues at 3M and FDA and, and NIOSH the complexities of trying to extend a safe supply of personal protective equipment for our healthcare providers.

So we really reached this as a last resort as our N95 respirators supply was dwindling, our particular Flagship Hospital usually see somewhere between 4 and 10 times the number of COVID patients as the other hospitals in our state and region. It's important to note that as our NIOSH colleagues highlighted that facepiece filtering respirator decontamination is not a part of their certification and approval process. So, so this is not covered by that. As we did our reviews and, and deep dive into what our options were to extend our supply, we really focused in on ultraviolet germicidal irradiation UVGI, vaporized hydrogen peroxide and also indicated by evidence and CDC guidances that warm, moist heat method.

Important to highlight that the decontamination should really be undertaken at the organizational level as part of a systematic approach implemented by trained professionals and for us this was a result of multiple tests and evaluations of our process, a review of the literature and then incorporation of institutional practices that happen to be in place at the beginning of the pandemic. Next slide. So this has already been highlighted but this was a key trigger for us was really the approval of non-NIOSH approved masks for use outside of healthcare approved masks and, and this really was a signal to us that we need to take extreme measures to, to prolong our supply chain of N95s. Next slide.

So 3 documents that are really seminal and important for any organization looking to evaluate and implement N95 decontamination for reuse and I really want to point to these linked articles that are available on ASPR Tracie and a number of other resources, first two are 2 studies that were commissioned by the FDA, one evaluating UVGI for decontamination, the other evaluating vaporized hydrogen peroxide for N95 decontamination and then of course our NIOSH colleagues guidance. Next slide.

So getting back to our particular protocol, so we really honed in on having discussions with our healthcare workers knowing that we were going to have to implement a reuse protocol for N95s so make sure that we could keep N95s on any healthcare workers providing direct care to confirmed COVID patients and implementing N95s in all of those care areas that were deemed high priority for respiratory protection. We clearly reached the realization that our healthcare workers wanted as, as much assurance as possible that their N95s were, were safe to handle as safe as possible and we really engaged not only our, our floor level and frontline healthcare workers.

But also our sterile processing and a number of other groups that really have to keep perspectives to how to implement this on a systems level to develop our protocol. We focused a lot on our communication strategy at all of the facets across the continuum of this protocol from the healthcare providers to couriers to the N95 decontamination technicians to make sure that everybody was aware of their part of the expectations of, of the other groups parts and, and to make sure that we could adopt and implement as uniform and a safer process as possible. Next slide. So some key components of that, I'll get into this a little bit more on in 2 subsequent slides but just to kind of show you a couple of the phases or steps across the process and, and one is coming up with a strategy where we can match an N95 respirator with the user.

So it was clear to us based off of a variety of studies and evidence that we did not want to implement a reuse program where an N95 might be used by different wearers upon subsequent use. So we gravitated towards this labeling strategy that's depicted here in that photo on the left, using a soft tip marker and, and not allowing use or marking of the, of the respirators with a sharp tipped writing object that might damage the filters. We've seen a variety of strategies here including adding tape or a label on to the elastomeric bands, lot of different ways to get around having to mark on the face of the mask but this is the approach that, that we took.

We also implemented dating for a first use and then in terms of decontamination for reuse, a system to track how many times a respirator had been disinfected and then we implemented this paper bag strategy so that we could really clearly see an N95 in a bag and, and quickly identify if it had been used and was on its way to our decontamination process or if it had been cleaned and, and returned. Next slide. So why we chose UVGI over VHP or warm, warm moist heat? So a few factors, one was their studies showing the efficacy of ultraviolet light or radiation quickly and efficiently inactivating coronaviruses and enveloped viruses with, with fairly low level exposures.

There are a number of studies that our particular group at the university have conducted so we were very familiar and comfortable with the key parameters related to UV in terms of intensity of light, the duration of the exposure to that light and the distance at which you're, you're

providing those exposures. We also have equipment on hand that was used for whole room disinfection which ended up being quite ideal for kind of mask throughput that was needed to achieve this. Next slide. So this slide overviews our entire process flow for how we implement at the healthcare worker level utilization of N95 all the way to packaging for our courier and then central processing and couriering it back.

So it's difficult to see that the flowchart and what's important that I wanted to note here and we can provide this to ASPR Tracie, it's posted to a number of places on the internet already is that it's broken out really discreetly into healthcare worker steps and responsibilities, courier steps and responsibilities and then what we refer to as our UVGI technician roles and responsibilities, so there's clarity for everyone across the continuum who's doing what and what those steps are and then we use this for training and refresher training as well. Next slide. So this is an overview of, of the particular array that we were able to implement.

We reached this really as a result of multiple trial and errors in terms of how to place respirators, where to place our, our source of UV and then how to measure the UV dose of, of every run. Next slide. Also important to note that when we initiated this we seeded bacteria and viral organisms onto masks so that we could get a benchmark to know if we can achieve this level of exposure in this room to an array of N95 respirators. We know we're getting the kill that's commensurating with this pilot study or the validation study so we evaluated that with 6-log reduction on both chikungunya virus and staph aureus. And then you know next slide, I, I think the important thing that we've determined that we're running a number of follow up studies on this right now is that as earlier speakers have already noted, extended use, reuse and decontamination are all fraught with risk in terms of we are using respirators that were really intended for single use and disposal in an extended and repeat fashion and so it's important to have really clear triggers for if this occurs, this respirator should not be reworn. Here are a number of those.

What we are starting to see through our follow up studies is that whether it be from reuse in a controlled group at our facility that's not getting UVGI treatment of their masks or reuse of, of N95s that are going through decontamination, we're seeing a wide array of, of failure. So there's not a real clear definition of a respirator can be used by anyone 5 times safely or can be deconned this number of times. It really comes down to the individual wear and how many times and, and to what length of time they're wearing a mask or respirator. Next slide. So some of the things that are, are really important is seal check. A number of speakers have already highlighted this. So this is a really critical element where we're relying on the user to make sure that they're getting adequate fit with the seal check before they implement the next use of a reused respirator.

Next slide. Some of our other really key triggers are gross contamination use during a known aerosol generating procedure and trying to implement use with a facial or a protective barrier as much as possible so that we're, we're buying down the frontend contamination for the N95 mask. Next slide. I think I've already touched on, on most of these things, again using these paper bags that are breathable as our, our CDC, FDA and 3M colleagues have already covered, so that's it for me John, back to you.

Dr. John Hick: Thanks John, you know talking about the seal check, how sensitive is that for you know adequate fit and we're certainly seeing a little bit of provisional information on the threshold of the number of uses before failure becomes more likely even though there's a lot of individual data there, do you see anything on the horizon as far as data or, or more info coming on likelihood to fail?

Dr. John Lowe: You know I hope to, I know our, our NPPTL colleagues are very interested in this as are we and, and a number of, of other groups. You know we're not done conducting our data analysis and collection but I will say there's, there's just a wide degree of variability between users and, and so we had initially just through following the number of times that a respirator was being reused, coalesced around a number of reuses that appeared to, to, to be the acceptable level before we start seeing failures. When we conducted a systematic assessment where we were, we were retraining and having observed seal checks, our failure rates were kind of all over the place so I think this is going to require a lot more study and data generation.

Dr. John Hick: Great. So in the meantime just be careful with those checks and inspection of the mask and attention to the tension on the bands and all the other things that go into maintaining that seal so that's great, thanks John and over to Mr. Neil Carlson from the University of Minnesota with a few more thoughts about UV decontamination, mask fit and other things. Neil, thanks for being with us.

Neil Carlson: You're welcome, thank you very much John. You can go to the next slide. First off, I want to say that what I am saying here does not necessarily represent the University of Minnesota. It talks about some of the practices that we are doing so in some of the other parts of it are actually for information purposes only or possible generation of future research by other individuals. So the state of Minnesota asked me to do some quantitative fit tests on variety of N95 respirators and also KN-95 respirators that they were looking at for purchase. We have an acute shortage of respirators. They wanted to see if some of these will be available so that we could increase our supply.

So the total number that we have tested, at least that I have on my records are about 39 of them and 20% of those actually passed with a quantitative fit factor using a TSI unit Portacount of 20% and then 80% of them failed and this was only done on one person and that was me, so we wouldn't end up using up too many respirators. The other part is I've worked with some other individuals who are also doing separate tests and my face whether or not seems to be fairly average so that it's, it's when they've done test with 10 or more individuals, I seem to come out kind of in the middle.

So in that respect that's where we are at. Next slide, please. So this is definitely not an approved method of extending the life of a respirator that has been run through a quantitative fit test. I have done it on my own because I'll end up after doing a test on these respirators I will reuse them and I'll do my own UVGI decontamination and I'm doing it on myself so I am taking my own personal risk with it but I get a sense of how quickly some of these masks get breakdown and aluminum foil tape seems to last very long and doesn't do great well and holds up to UVGI decontamination methods and the external part of this can also have a foil put on there.

We would not recommend this necessarily for anybody to try but it is something that I've been exploring. Next. So as Jessica had mentioned before and I think it's been mentioned maybe by some other people as to the standard 5 x 5 rule, we've been using bags with handles on it rather than other ones and that seems to work out fairly well making sure the respirator is suspended in the air and we've also included some desiccants in there because several times when the respirator is in there some moisture in there and one of my areas of expertise is mold growth and I want to make sure that the respirator is at least in this condition have sufficient time to dry.

And I have a (7 days) because in practice most people are, are having a Monday, Tuesday, Wednesday, Thursday, Friday respirator and that's how they're making it through the 5 times and again if they see any conditions where the straps aren't working there's obvious contamination on the respirator and they should be discarded. Next please. So this is definitely going out more on the edge, this is the decontamination device that I developed or using for UVC and this is one that is used for residential decontamination of air systems and it's there's a series of 2 tubes inside here that produce UVGI light and you can place a respirator in there and at least do UVGI decontamination, again this is way beyond what would be standard protocol.

But I was doing basic research on this to see how long I could expose it if we did have to go to this place and we have not had to do that at the university, what are some of the things that we would need to do. Next slide. And this is the device that measures UVGI. I wouldn't recommend doing any UVGI decontamination without having a meter that has been calibrated and some of the tests that I have done have had you know put it into so we're having direct exposure, another one is doing more worst case scenarios so I will place the -- suspend the respirator over the top and then have the sensor pointed exactly the opposite direction in a very difficult location for the exposure to occur. Next.

And these are some of the results on it and the exposure dose that was using was one that was developed by M Health Fairview which is a group at the -- that is using UVGI decontamination and we're, trying to do is at least for their group they chose with the specific respirators that they're working with which is 3M respirators that they felt that 216 mJ/cm2 was an adequate amount and if we're looking at direct exposure at least with the container that I have that took about 1.4 minutes to get to that with the direct exposure and then indirect exposure since the whole interior of it is lined with aluminum, it takes about 5.5 minutes.

So in a worst case scenario if we had to go to where we really needed to do it, this would be something that could be could be done again I wouldn't necessarily recommend it but this is some of the basic research that I wanted to do. Initially I picked up some LED on UVGI light sources and they were not effective at all so if you had gone just based on the advertisement, you would not have been effective in any decontamination. Next. This is another way of repurposing it, this is a commercially available product, it's one for UVGI decontamination of[eye ware

And one of the contingencies we developed if we really had to use it is we would convert this into decontaminating respirators and the beads that are here are ones that are UV light sensitive and they'll change colors upon exposure to light. It's possible to get a semi quantitative /qualitative sense on whether you've got light exposure by increasing the amount of material

around it and then if you can calibrate that based on the UVGI's actual sensor, you can get some type of idea. There are some colors in here that are much more difficult to generate than others and the distance of the bead from the light will modulate the intensity of the color change. Next.

One of the things that the university is able to do is come up with a, we'll call it a mask, it's kind of halfway between N95 and KN-95. We found some material from Cummings that we didn't have a supply chain problem and we also found some, some either rubber bands or other types of strapping material that were also did not have a supply chain problem. We also wanted a material that you could decontaminate by heating, you can do that for 75C for 30 minutes to decontaminate the respirator and so we spent a considerable amount of time optimizing what type of nose clips will work, optimizing the actual staple placement on these origami style masks and we've got it set up.

So that if we have a worst case scenario we need to have these, we have availability and they're very easy to assemble if you follow the directions and we'll get a fit factor that is somewhere between where KN-95 is and where an N95 is. Next. This is the other one that I think healthcare is going to be seeing a lot more. There are several devices that have European style HEPA filter so they aren't as good as an American HEPA filters, at least with the standard at the 0.3 microns, the, the standard has shifted down a little bit. They're actually called PM 2.5 in some of the literature.

This has been used a lot by healthcare workers not at least in clinics that I am at to make the using of the surgical masks much more comfortable. These are people that are not in direct patient care but everybody in the area is required to wear these respirators and it's much more comfortable. We're not comfortable with them doing it if you see on the left side is having them put in with like a N95 respirator because the quality of the filters in these units is really variable sometime and I was very excited by it. The initial one is that the fit factor is around 2500 and I thought well this is really good and then I came to the next one, it was down around 30.

So I think if some additional research can be made to make sure that we get better quality, I think this is some area that has some real potential for future healthcare work because they're very comfortable, it's much nicer than wearing a N95 the whole day being very humid and very uncomfortable. Next. And these are some hole punch that you can use to attach the N95, I found this available at a local healthcare, local arts and crafts supplier. Next. And then we have some face covering, some individuals needed some cloth face covering and that's also included and I was doing that test for the state of Minnesota so I was injecting very clean air into these pieces and I was seeing how long it could retain it.

And I found most of them could not retain it all but there were some cloth face coverings that I could achieve almost N95 status by at least by the amount of air that was put in there. Next. So the CDC has really good guidance saying they're not sure if Gaiters or face shields do any work and I can say pretty much in line with the testing I've done that the face shields alone are really not helpful at all. The Gaiters would tend to be more variable and this is again put in the line of are we protecting other people, not so much are you protecting yourself and here's a simple test that we came up with.

Let's look at the next slide. So in this case, we have both a cloth face covering and a cloth Gaiter, the Gaiter in this particular one is one that set up to minimize exposure to dust as opposed to a standard one and I'm going very hard in the tissue paper at arm's length is not moving at all. Next. And in this case, we both have cloth face coverings but we can blow right through and it's not providing any protection to the other individuals.

So we were able to take off some Gaiters that we were selling at the university based on some of these test results and I think if individuals are wearing cloth face coverings, this is a very simple test that you can do to say well, at least am I doing my part when I am wearing cloth face covering, am I doing my part to protect another individual. Next. Thank you John.

Dr. John Hick: Thanks Neil, you know I think that one of the things that I've been consistently impressed with is you work through you know lots of permutations and experiments in the lab is just the diversity of quality of the products and the fact that you've got to be extraordinarily careful that, that you can't assume that the thing that you've purchased is going to do the thing that the manufacturer says that it would unless you've got a very good quality standards underlying that is as we do with the NIOSH approvals process. And other things but even having a NIOSH approved you know filter media doesn't necessarily guarantee that the fit is going to be good and that was another issue that, that you've mentioned. Can you comment a little bit on where you see the fit failures most commonly on the masks that have been tested?

Neil: Sure. The nose piece is really a particular problem and, and there's 2 parts of it, one is the foam that's underneath there and sometimes there is no foam at all. The other one, some of them are folded up and it's -- the fold is designed so that there is -- it's almost impossible to flatten it out and get a nice fit around the top of the nose so if it's a, it's one a respirator can be folded in half. Some of them, I'm trying it bend it out and I have to use a hammer to flatten it out enough so they can get a good fit on the top of the nose otherwise I'm going to get a gap and I'll fog up the glasses. The edges of respirator may not follow the contour of the face so you may have like a cup shaped respirator that's really stiff and rigid.

So when I'm doing the portion of the test where we're doing the rainbow passage it fails miserably, I'll get a fit factor may be around 10 where the other parts of it will be somewhat better. The other part that seems to work out better is some more respirators are actually putting in a flange on the inside and that seemed to allow face to conform a lot better and I'll get a lot better tests on those. The other one in the more respirators that I'm seeing now are newer designs are having some flexibility with respect to the tension that can be placed on the straps on the respirator.

The other part with the KN-95 and also the surgical masks is that most of them have earlobes and I have been strongly, strongly recommending that if you want to get a modicum of a better fit factor on that that you use ear savers on them, it can be silicone based, it can be whatever, there's a large number of ones that can be used but pulling that close to the face will get a -- usually double the fit factor of where it's normally at and there's a high degree of variability in the surgical masks, some of them only have fit factor like 2 or 3, other ones when I put the ear, the ear savers on, I can get a fit factor almost to 20 which is actually very good.

Dr. John Hicks: Great, thanks, thanks so much Neil, I really appreciate all your work and last but certainly not least from a systems perspective at the healthcare level, we want to touch a little bit on some of the issues that the systems have been dealing with and so from Kaiser Permanente, Dr. Philip Madvig and Dr. Mary Beth Lang to round this out, thanks so much for being with us.

Dr. Philip Madvig: No, thank you John and thanks to the ASPR Tracie staff for inviting Kaiser Permanente to participate today. Can we go to the next slide please? So here's what we're going to cover, we're, we're going to go through a brief overview of Kaiser Permanente for those of you that may not be familiar with it. I'm going to talk about how we organized ourselves to be ready and to respond to the COVID-19 outbreaks and pandemic and Mary Beth is going to speak to the issue of how we managed the supply chain acquisition, distribution and, and so forth.

So if we can turn to the next slide. Just briefly, Kaiser Permanente is an integrated healthcare system and by that I mean that we combine insurance coverage with healthcare delivery. So we insure just over 12 million people in 8 different markets in the United States and we provide their care through a delivery system that has 39 hospitals, more than 700 medical offices and relies on 20 some thousand physicians, 60,000 nurses and additional employees to take care of the needs of those 12 million members.

I might also mention that we have an integrated research operation in our program so one of the things that we've been doing in this, in this pandemic is to be studying what is effective in the current treatment of our patients and we're also involved in some of the clinical trials for COVID vaccine, next please. So what we -- here's how we, we got ready to and then responded to COVID-19, actually the first thing that occurred for us is that our, our infectious disease physicians who meet, their leaders at least meet as a group routinely in January began anticipating that we would be dealing with COVID-19.

And as they anticipated that we recognized that we needed to organize ourselves into this national incident command structure which we did. And in the course of that, we have a national command center and then each of our regions have corresponding command centers and then we have a leadership group that oversees the operation of that command structure. That command structure has created tracking systems that allow us to monitor the magnitude of COVID-19 cases across our system, how you know bed use between intensive care and routine uses, routine med surg wards, supplies and various regulatory issues.

And if we can turn to the next slide. So what we did with that command structure first of all was to start anticipating the future conducting scenario planning for a range of potential attack rates of COVID-19 that we called low, medium and high and then for each of those scenarios, planning out what our needs would be for space, we are talking about bed space, staff and stuff. And by stuff, I mean things like ventilators, pharmaceuticals and notably for this discussion PPE. One of the additional things that we did was to try to address the demand for PPE and other supplies by reducing non-COVID use and this took really 2 major forms.

Number one was we converted the overwhelming majority of our ambulatory care processes from face to face care to virtual care. We, we converted about 85% of our care to virtual. The

second thing we did to reduce demand was to reduce elective procedures, particularly surgical procedures and other hospital based activities that consume space, staff and stuff. And I'm going to turn it over to Mary Beth at this point to talk about how the supply chain was managed.

Mary Beth: Thank you Dr. Madvig. In March, we saw global supply chains quickly become fragile and no longer capable of responding to increasing numbers of unplanned disruptions and so we quickly put all of the PPE into 3 categories. We looked at the, the products that were in conventional capacity, these products are readily available and no supply interruptions were noted and examples at the time were surgical masks and gowns. We looked at contingency, capacity and these were categories where we could source equivalent or comparable products that required clinical acceptability from our clinicians and examples in this category were procedural masks but the area we spent the most time in work, the crisis capacity products where we saw demand spiked. We, we saw raw material shortages or import issues, examples here were the N95 respirators and isolation gowns but we also put gloves in this category in March because of our concern of raw material concerns.

We then looked at product use and so we went to develop a regulatory crosswalk about PPE standards that captured the CDC and OSHA standards in EUA guidance derived from the FDA regulations and we metered our KP usage of the same product so that we could quickly look at regulatory changes or supply changes and availability and then uptake the chart. We collaborated with labor at each stage of PPE response and through this collaboration, we were able to create many different communication tools to ensure that front line staff understood product use. Next slide. Under the command center, we established 25 teams to focus on specific PPE products. We also created a quality oversight team to confirm product authenticity and certification referencing the FDA good ID registry, NIOSH and FDA approval websites, we found that we needed to go back to these websites routinely as approvals changed as more information became available and we wanted to make sure the products that we sourced remained safe to use.

After the validation of authenticity of the product, we sought clinical acceptance of the product and during this time, our office of transformation led an effort to design and manufacture stop gap PPE. KPE provided and created a playbook for businesses looking to create and procure products through COVID-19 pandemic when products weren't readily available through normal sources. In this effort, we called on the Los Angeles garment industry to help us create PPE. And what we found was great innovation from this industry, they were able to quickly mobilize despite several barriers of raw materials were dispersed workers caused by the unprecedented public health crisis and they were able to within a matter of days, create thousands of face masks and gowns to be able to put those into production. We also partnered with, with companies such as 3M on N95 masks, Thermo Fisher and Roach on testing and retailers like the gap on face masks and Apple on face shields but also on the transportation advice to import logistics from China. Next slide.

In pre-COVID, supply chains really would focus on minimizing cost in just in time delivery of goods. We found that manufacturers were hit hard during COVID, many had capacity issues and others were relying on raw materials from China or final products from China that weren't able to be imported quickly. The, the diagram here shows how we had to rely on new channel

partners, we had to learn on importing and exporting requirements as well as considering prepayment options. And that you'll see the complexity that was added into the process. To address this complexity, we implemented a deal review committee comprised of a cross-functional leadership team that included clinical staff, sourcing, supply chain, logistics, demand planning, accounts payable, vendor risk, legal, controllership, finance for procurement and the goal was to leverage everyone's expertise to be able to make quick but very safe decisions around critical products we needed to bring in to help with the pandemic response.

In addition to seeking new supplies, we were blessed with an outpouring of support and donations and through an innovative partnership with the American Hospital Association, Kaiser Permanente, Kearney, Merit Solutions, Microsoft and UPS established protecting people everywhere the PPE program. That created an app powered by Health Equip. This program matched PPE donors and their donations with potential recipients. And this delivered critical PPE and in short it reached the places where they were needed the most. Next slide. Dr. Madvig mentioned the models that were created to look at the different attack rates and we align supply chain needs to all of these models and we created a series of analytics and job tools to help in the, the management of the PPE. We created a 13-week model that tracked current usage, anticipated resupply bi-week and forecast supply of on hand projections. We created many trackers to help with tracking ventilators and other related disposables, the reentry activities for the OR and non-OR areas and then we also created a daily supply rate that went out through our national command center. Next slide.

Today, we are in a much healthier state when we consider the PPE capacity categories, we're out of crisis capacity, we're down to fewer PPE items and contingency capacity. But returning fully to conventional capacity gives us pause, it has taken months to source and warehouse supplies, we are balancing when to move away from EUA and conservation strategies of extended use and reuse and we are evaluating the factors guiding resumption of standard product use, in light of anticipated many COVID surges, wild- wildfires, tropical storms and many other social activities that impact supply chain. Key questions to consider, if all health systems moved to single use will we further constrain supply? Can we support dramatic surge with a large infection rate? When can we stop producing miracles of securing large volumes of PPE? And when will supply catch up fully to demand? So let's pause here and celebrate what we have collectively accomplished and get ready as an industry for the long road ahead, back to you John.

Dr. John Hicks: Thanks Mary Beth. With such a large system, how did you all ensure that your team members were selecting the right PPE for their job duties and using it correctly? Can you talk a little bit about the educational efforts?

Mary Beth: Sure, this is our partnership with labor. We've really worked with our infectious disease chiefs to create the right science behind our decisions and then communicate that with our labor partners on the front line and we used our supply chain operations leaders to put up info graphs and other content information and used our daily briefs to, to make sure we were continually getting that message to those that needed it the most.

Dr. John Hicks: Great, thank you and unfortunately due to the quality and length of the presentations today, we are running out of time for questions. I'm just going to take one of the

questions we received and direct that to Maryann D'Alessandro and then don't worry the ones that you all have submitted we will make sure get answered in text format over the course of the next few days and, and we'll have a little more information on that coming but the question is how much protection against COVID-19 does a surgical mask offer or procedure mask? And Maryann, initial comments on that and we'll let Aftin from FDA weigh in on that as well and then we'll wrap up.

Maryann: Yeah, I think I'd like to direct that to Aftin but the recommendations for protection against COVID-19 are to use a respirator so NIOSH approved respirator with a minimum level of protection of an N95, so we do not recommend that a surgical mask would provide that protection.

Dr. John-Hicks: Aftin, any comments on that? Dr. Ross if you're speaking I think you're muted. Well, unfortunately Dr. Ross may be dropped off, we are at the top of the hour and, and there may have been other commitments that she had Shayne or Audrey to you to wrap things.

Aftin: Sorry, John.

Dr. John Hicks: Oh, go ahead.

Aftin: Yes, no I apologize, I didn't realize I was muted, I was talking away so thank you for telling me that. Yes, so I would concur with Maryann, surgical masks really are intended to be fluid barrier protection and then they do not provide full protection from inhalation of airborne pathogen and viruses such as some of the concerns associated with COVID-19. They are really used more for like source control. As was mentioned you know in the presentation there's a lot of ongoing research to better understand these technologies and what if any filtration efficiency they actually provide.

Dr. John Hicks: Great, thank you. Shayne, Audrey I just want to thank all of our presenters for taking the time today, sharing their expertise, sharing information, what can we expect from a logistics standpoint moving forward, Shayne and Audrey and we'll wrap things up.

Shayne Brannman: Great, thank you so much. First off, thanks for moderating and we'll have the webinar recording posted on ASPR TRACIE by tomorrow and we'll address any unmet questions that we received and get those distributed probably by the end of next week or the first part of the week thereafter depending on how many questions we have and we want to thank everyone and specially the speakers today, our co-sponsors at the Healthcare Resilience Working Group. And most of all to all the participants on the line, we had over 1000 participants on the line today and we appreciate that and we have at least 400-500 who are waiting for the webinar recording that couldn't get in, so thank you all very much, have a great day and we look forward to serving you in the days ahead.

[Audio Ends] [01:32:08]