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Overview of PPE Choice, Use, and Recommended Practices

Speakers:

- Kevin Barrett, RN, BSN is a subject matter expert in the provision of safe clinical care to individuals exposed to high-consequence pathogens. He is the NIAID Clinical Research Specialist and clinical interagency coordinator for the Special Clinical Studies Unit, known as the NIH's patient biocontainment unit. His responsibilities include staff preparedness and training for the care of individuals potentially exposed to a high consequence pathogen, while also leading the strategic operational coordination of the occupational exposure response plan between the BSL-4 labs at Fort Detrick and NIH.

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Slide 1: Title Slide

>>Moderator: Hello, welcome to the NIH Office of Laboratory Animal Welfare's January 2026 webinar titled Overview of PPE Choice, Use and Recommended Practices.

Slide 2: Credit

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Slide 3: Speaker: Kevin Barrett, RN, BSN

I'm pleased to welcome our speaker, Mr. Kevin Barrett, today. Kevin Barrett is a subject matter expert in the provision of safe clinical care to individuals exposed to high consequence pathogens. He is the NIAID clinical research specialist and clinical interagency coordinator for the Special Clinical Studies Unit, known as the NIHS Patient Biocontainment Unit. His responsibilities include staff preparedness and training for the care of individuals potentially exposed to a high consequence pathogen, while also leading the strategic operational coordination of the Occupational Exposure Response Plan between the BSL 4 labs at Fort Detrick and NIH.

Slide 4: Overview

>>Kevin Barrett: This is an overview of personal protective equipment, or PPE, intended to provide an expanded understanding of how the PPE ecosystem functions and from there, ensuring that we can understand the context for the PPE choices we make and what we mean by certain terminology. Additionally, it seeks to provide an understanding of how PPE selection varies across health care facilities while still staying in line with existing guidance and appropriate practice.

Slide 5: Disclosures

I have no relevant financial disclosures. The content of this presentation brings together existing public sources of evidence based practice guidelines, and is not intended to serve as a guidance document in and of itself, rather, to provide better understanding of rationale and expectations.

Slide 6: Objectives
So our objectives here. We're going to want to look at understanding PPE within the matrix of safety controls and how linking PPE selection and donning and doffing to the context provided by these controls makes for a safer environment.

We're going to look at common PPE components, understanding the intention and proper use of each one, and how they link to quality SOPs in environments that support high levels of isolation, whether they be research or clinical.
Lastly, implementation-- a better understanding and awareness of administrative controls as the bridge that ensures staff understanding how to utilize safety controls most effectively.

These include considerations for both creating and updating SOPs, including potential downstream impacts.

Slide 7: Transmission Based Precautions
So we're going to start foundationally where we can delineate between standard precautions and transmission based precautions. This presentation explores the nuances of implementing transmission based precautions, because when you get to those you're looking at all that we've discussed so far. The controls, how do you maintain them? How do you decide the PPE that you use? And we're going to go through them in a way that doesn't focus so much on symptomology of the infection, but rather the inherent risk of the pathogen in question.

Slide 8: Dress for Transmission
So dressing for transmission, dress for transmission is the same as dress for success. Different levels of transmission mode from left to right, moving from the least, quote-unquote "risky" to the highest level of risk contact, droplet and airborne. And as you can see, the PPE that is generally recommended for each of these levels increases as we move towards the higher level of risk. The higher level risk would be, for example, H5N1 and the minimum PPE for clinicians. How that [minimum PPE] looks, as we alluded to, will be different depending on the resources available and the facility's own guidelines.

But this gives you a general understanding that just like in BSL-rated labs, as you increase the biosafety level you are adding on, you're not replacing. And the same is true here. You're adding on to what you had before each time the known or potential risk of the pathogen in question in terms of transmission increases. But this can also be looked at in terms of dressing for transmission, but also dressing for severity of illness, availability of medical countermeasures. All of these go into stratifying risk. But for this presentation we're going to focus on the most basic piece of it in terms of, you know, how do you elevate? How do you make it consistent?

Slide 9: What is Personal Protective Equipment?
So what is personal protective equipment? This seems like review, but it's helpful to start from a consensus definition. So it's usually clothing or equipment or both, and it's worn as a barrier protection against hazardous substances or environments. It's important to remember it is a barrier between you and a hazard. It does not remove the hazard and it does not remove the risk, but it does mitigate it, minimize it. And donning and doffing are two of the most important parts of this, because how you put it on is going to impact how you take it off.

So I provided different variations in terms of PPE. The visuals may look different. As you can see, they are designed for different practice environments.

Slide 10: Why Use PPE
So why use PPE? It doesn't remove the hazard that it only minimizes it, but when used correctly it does a very effective job. So "why use PPE" could also be stated as why do we spend so much time making sure we use the correct PPE? Why are we using it properly? Because it does act as the barrier between you and a hazard. And for most of us, this hazard comes in the form of either an animal inoculated with a potentially high consequence pathogen or in the clinical realm, you know, an individual who may have been exposed to a similar pathogen. But it can serve a dual duty of providing protection from exposure as well to certain cleaning solvents, environmental contaminants. So all of this is about proper use. PPE used improperly does not minimize exposure. It does not provide a barrier, and it does not reduce the risk of injury and illness. Luckily for us, it is not difficult to create an objective framework with which we can use to understand what "proper" means. What does "proper" look like. That's what we're going to get into. The first step for this is understanding that training, practice, competence, and observation is key to safe and effective use of PPE. To this, I would also add consistency, ensuring that changes that are made to PPE are communicated swiftly to staff and have a robust rationale.

Slide 11: PPE Selection Review
PPE also does not address the hazard directly, but provides layers of protection from the hazard. So the use of PPE, while not guaranteeing protection, it does mitigate.

Slide 12: Prior to Donning PPE
Prior to donning PPE. So what you want to make sure that you're looking at is that you have these bullet points identified prior to a need to utilize space requiring PPE. Ideally, a safe donning area and a clean part of your practice area has been identified prior to the need to don PPE. Ideally, the area is used consistently for practice of donning and doffing. These may be same location or different locations depending for example- in the Special Clinical Studies unit, which is NIH's patient biocontainment unit. Our doffing process is biphasic. So some of the PPE is removed inside the patient room, the dirtiest part. And then when the individual steps into the anteroom, then that's where the monitor is. And then they're walked through the rest of the process. So other areas of practice, other research facilities, they may have two anterooms, right? It will depend greatly on the architecture of the research area that you work in. That will impact how doffing occurs. But ideally the takeaway from this slide is that make sure that you have delineated a doffing or dining area prior to engaging in research that requires personal protective equipment, and make sure that the area has appropriate supplies, such as waste receptacles for doffing or new PPE for donning. In terms of donning PPE, you're always donning in the context of doffing, if that makes sense. So paying attention to how you put on the PPE, the way in which it layers, these are essential gratifications of the process that will have significant impacts on the doffing process.

Other things to think about: If the components of the PPE are reusable, and make sure that you check with your appropriate subject matter experts, whether it's hospital epidemiology, whoever would be the guiding body in terms of process for whether or not certain equipment can be deconned and reused again.

Slide 13: PPE Selection
So selection of PPE should be based on the following, generally speaking. It should be in line with CDC recommended standards and transmission based guidelines first. Secondarily, then assessed for its ability to mitigate risk of exposure in the context of your specific area of practice so that the procedure and chosen components are fully deployable in the environment where you work. And the environment is going to have a huge impact on the PPE that you choose.

Slide 14: Hierarchy of Controls
No audio

Slide 15:Hierarchy of Controls
Well, NIOSH has provided a really well done chart that helps to show what is in place before PPE and its decision making process.

Slide 16: How to use Hierarchy of Controls
The caveat here is that, in another slid or two, I'm going to show how two of these steps don't really apply to us necessarily. This hierarchy controls assumes that you're working in any environment. So of course, what you're going to want to do is 1: Can you physically remove the hazard? Well, if it's a chemical spill or something like that, maybe. If it can't be eliminated, can we replace it with something safer?

Slide 17: Hierarchy of Controls- Practice
Now, those are the two parts of the system that as clinical or lab researchers, you're not going to be as concerned with. The research that's being done that requires PPE is purposeful in nature, follows a protocol, has been well thought out in terms of both schedule of events, in terms of, you know, pacing of research. And so we don't want to eliminate the threat necessarily, because the "hazard" quote-unquote, is going to be your animal model, or let's say, an individual who is exposed to a high consequence pathogen. In order to do the research that we want to do, we don't want to remove the animal. Can it be replaced with something safer? Well, efforts are underway to see about how we could utilize artificial intelligence to reduce the use of animal models in research, but that's not what this presentation is about. So we're going to be speaking to the now. For us it's going to start out with engineering controls.

Slide 18: Hierarchy of Controls- Practice
So while the previous chart primarily shows how to ensure safety measures are in place and built on each other, here is the same hierarchy except more aligned with what we would expect for research. So whether you're working in a patient biocontainment unit or in a lab with animals, you're wanting to ensure that these controls-- engineering, administrative, and PPE-- are in place and fully functional. Because the elimination/substitution effort that naturally would occur in other environments is not available to us here. We have an expectation and a goal that we need to be able to interact with this quote-unquote "hazard," this risk for exposure to a high consequence infectious disease.

And so while we can't eliminate or substitute, we can certainly start with engineering controls. So these are observation, negative pressure, alarm notifications, cages (animal cages/animal enclosures) that may lock climatically, mag locks that you may find on anterooms entering into the research area.

And then administrative controls: zoning, workflows, how do shifts work, employee placement policies and procedures. These are all the underlying processes that both support and enhance the PPE, but also help guide choosing what PPE to use. Because the PPE that you use will be based on an audit of what's available to you in terms of the engineering controls.

We've looked at the underlying process, the additional controls that support the proper use.

Slide 19: Controls and Risk Mitigation
And so I want to speak to controls and risk mitigation, just with some examples. OK. So here we have engineering controls: environmental, architecture, all the things that we mentioned before. But they can also include autoclaves, portable isolation units, anterooms, sometimes visual aids. These engineering and environmental controls... these are the least flexible generally. They're hard to modify because they are usually, if not often, baked in to the architectural design of the unit. The flexibility of the architecture, placement of the anterooms- you're going to find that administrative controls are how you allow staff to navigate the environment safely. I often say the environment is your second patient. Whether your patient is an animal or a human, you're going to be wanting to make sure the environment is being navigated correctly.

So to the right, these are just some examples of some controls in place in terms of training. Some signage you can see in the back in the upper right, there's signage as visual aid, [and] engineering, environmental controls to remind individuals the appropriate way to doff as needed. And this is taken from a training set PowerPoint. That would be more of an administrative control where it asks trainees to identify what is wrong in the first picture, and then in the second picture with the red box, that's where the mistakes are outlined. But this sort of visual cue training is helpful regardless of the environment.

And then below you can see that we utilize... for this, when we do exercises, we try to make them as immersive as possible. We utilize glo germ which shows up under UV light mixed with, you know, viscous liquids that allow us to emulate emesis or patient fluids. We can go through an actual practice. This allows staff to see, you know, how far, a spill might splatter, for example.

So engineering, environmental controls, PPE, safety controls, they only work as well as the staff's understanding of how to employ them. Never assume that a process that's been grandfathered in is still the best way to do something, because the industry is constantly improving upon itself.

Slide 20: PPE Components
Now we're going to get into the PPE components. The next three slides are a review of most frequently encountered masks from the lowest level of protection.

Slide 21: Procedure Masks
I'm not saying no protection here. As you can see from the benefits this level does provide [some protection]. Procedure masks would be considered quote-unquote the "lowest" in terms of clinical or research environments, not for just out and about. They may not be understood as "respiratory protection" quote-unquote. That is a very specific delineation. They are an effective source control. They prevent droplets from entering the environment. You don't have to be fit tested to wear it. It still has to be worn correctly.

Slide 22: Filtering Face Piece Respirator
Filtering face piece respirators. They provide reliable respiratory protection. They also require fit testing. So best practice is to wear them in real life the same way that you did during your fit testing. And by that I mean, if you grow a beard between your fit test and your clinical use, or your use in a research lab, you need to get fit tested again. You can't assume that the results you had prior to growing your beard or prior to experiencing weight gain, weight loss, exercising, any physical changes that could change the contouring of the face. Get fit tested again to ensure that the seal is still effective.

Slide 23: Powered Air Purifying Respirators (PAPRS)
Powered air purifying respirators. Now these come in several different forms. 3M has a model that is used by some institutions. We at the SCSU and building 33 on campus in NIH, [and in areas] where they use animal models also use MAXAIR.

We view about 90% of our PPE as single use disposable. So the paper scrubs that the individual is wearing, those are single use disposable for the length of the shift. And then the helmet piece that incorporates both the exhaust fan and a light array that lets you know how much battery power you have left. Those are all built into the helmet, and then the HEPA filter is built into the hood. And so, this makes it easier for us to don and doff. The battery pack goes around the waist at the back. And we use a higher level of PPE as an example here, just because the type of pathogens that we would be expected to work with are high consequence and many of them are considered select agents. And so we wanted to make sure that the PPE that we chose was not, specific to 40 different pathogens, but rather one model of PPE, one connected system of components that could provide adequate protection against, and mitigate the risk of, any of those high consequence pathogens that we might see.

And so for animal research, the same would be true- that you would engage your subject matter experts, you would make sure that you are utilizing PPE that is both being used in line with manufacturer guidelines (down to even cleaning of it, making sure that the cleaning solvents you're using aren't compromising the materials), making sure that the PPE, is not expired. Because, gloves and hoods expire, and so do gowns. I think everything expires. Now they have long expiration dates, but in negative pressure environments, you will find that components like gloves can have a tendency to become brittle over time. And so I would encourage you to keep in mind the expiration date on the different components that you utilize. But also understand that you may find that the gloves don't last as long as the expiration date simply because of your practice area. And so negative pressure, even nitrile gloves, are at higher risk for drying out, tearing. And so it's important that you make sure that every individual who is going to be going into that contaminated environment is doing these checks on their PPE.

In terms of administrative controls, consider an assignment tracking sheet, making sure that the same care provider uses the same helmet, that they have verified functionality, so that if you ever have to do a root cause analysis as to why a battery faulted or why a potential exposure occurred, you can confirm that there has been a single user, you know, for each of those equipment pieces.

Slide 24: Face Shields or Goggles
Face shields and goggles. So you would typically utilize both of these together with an N95 as shown in this slide. It may be hard to see, but the picture in the slide here has, eye protection that is built into the N95 mask and then the face shield below that protects the eyes/face in front of neck against respiratory droplets. And then the goggles as well could be worn with an N95 if there was no face shield that was built in. So as you can see, there are many different ways that we can employ this type of PPE. And it comes in many different forms. For NIH in terms of patient care in biocontainment, we have in the past utilized face shields and N95, when it comes to our doffing monitors. But the issue of the staff coming close to touching their face when doffing led us to decide to use what's called CAPRs- Controlled Air Purifying Respirators. They're sort of like a step down from the PAPR in that they function more as that face shield on the second box there, but still have that negative pressure draw thanks to the exhaust fan that's in the helmet. So it's definitely more protection and less risk of user error than assembling these items individually.

Slide 25: Gowns/Coveralls
Gowns and coveralls. Again, these are barriers to prevent contamination. And the types used will depend on availability of resources, the hazard in question, environmental control setup, as well as existing facility expectations of practice. So there's different levels of gowns as I mentioned before. Right now you're seeing there's the, what we would call the "bunny suit" that would typically go under the gown. They may look different, but they provide the same essential protection. And the way the gowns are going to be decided is going to be an evolving process. So as I mentioned before, with the yellow gowns that you saw earlier in the presentation, those were fluid resistant. And then we moved to fluid impervious after consulting with colleagues at other biocontainment units as well as with hospital epidemiology. And it was determined that in order to stay in pace with CDC guidelines that we upgrade to the impervious gowns.

So again, this will be similar in terms of animal interaction versus human. The stakes are the same. In fact, probably higher stakes when you're working with animals due to the inherent lack of predictability that you may find with human patients. For areas where, you know, there may be differences in terms of animal environment versus human, I'm making sure to highlight those. But for the most part, when you're looking at PPE and making sure it works, the rationale is the same.

Slide 26: Gowns and Coveralls
For gowns and coveralls. I wanted to bring in a little bit about risk zones. Some of these are pretty obvious, right? And the risk zones are really just what is most likely to come in contact with, you know, the animal in question if they've been inoculated, where you'd be most likely to either experience exposure to fluids, potential bites, you know, all of those things show a higher level of potential to be compromised in the areas that are highlighted here. Always be particularly aware of risk zones, especially when doffing. If you have a contaminated, you know, overgown, that should be removed in the room and a clean one should be available in the room, to replace it with.

So keep in mind that risk zones aren't static. They may change based on where you are in relation to the source of the contamination, which means that you need to be familiar with the room layout equipment placement, as these can all be threats to PPE integrity. So make sure that you have plenty of clear space to work. And I would also recommend that when you do training. Now this may seem obvious, but you do training in a way that reflects the real world. So when we do training for donning and doffing, we utilize, the actual patient room in the actual anteroom because you obviously want the training to reflect real life activities as smoothly as possible.

Slide 27: Gowns as an Example of Potential PPE Compromise
Now, I wanted to add on to this as an example of potential PPE compromise. Situational awareness, deliberate navigation of the contaminated area- all of that ensures that, you know, issues with PPE components or inadequate selection don't occur. You want to ensure that training in PPE also includes understanding of the areas at higher risk for potential compromise, such as securing the gown closed at the back. And this is important whether you are at bedside or at cageside. So the expert tip here from my personal experience, is that ensure you're always facing front first when at cageside. The picture here is of the aftermath of a patient volunteer who simulated projectile emesis, that was infused with, glogerm. And it was done as the care provider had their back to the bed. As you can see, the PPE that they were wearing, the buddy system in place that was designed to make this care provider aware of the fact that her gown had separated in the back, that communication was lost. And so not only was her turning her back to the patient resulting in compromising the first level of PPE, but also the white suit

underneath, and at that point it would be time for an extraction, because you would have to get them out of that contaminated suit without contaminating, you know, the entirety of the anteroom.

So we first instruct the gowns must be tied closed and securely in the back at all times. And we have a donning monitor or a colleague whose job it is to ensure that after an individual is donned, they move around to show that they can have full range of movement without separating the back of the gown. Because even if we are instructing everyone to always face the patient, there will be times of high acuity events where that may be forgotten, or not forgotten but reprioritized because of the patient's presentation.

Slide 28: Gloves

Gloves. Gloves act as a barrier, of course, to prevent contamination to your hands. Gloves are not a substitute for hand hygiene. So prior to every donning experience, we encourage our care providers to sanitize with hospital approved hand sanitizer to ensure that they're working from a clean slate. And gloves you're going to be using pretty much in any clinical area or research area where potential contamination can occur. So working with animals, handling items that are potentially contaminated, you want to change them when they're visibly soiled, as well as changing them between tasks. Here are considerations. So, you know, you can wear three pairs of gloves so the second layer can be considered your skin. I'm aware that in some BSL 3 or 4 labs, three pairs of gloves is, sort of the standard. And I know that some biocontainment units also use three pairs of gloves. The SCSU uses two pairs of gloves because we have found that using two nitrile gloves provides excellent protection but also still allows us the ability to palpate veins successfully to do assessments. And that dexterity decreases obviously with the addition of gloves. So we wear long cuffed gloves to make sure that we cover the wristband of the gown. And then we perform hand hygiene on the gloves during the doffing process. The takeaway, ultimately, is that whether it's two gloves or three gloves, make sure there's a rationale behind it. Make sure that you allow your staff to question SOPs, question the way you do things because you may find that they see something that you hadn't seen because you've been staring at it for so long.

Slide 29: Head Covers

Head covers: less common in my experience. However, in the animal realm they may be more frequently utilized. They can be uncomfortable. They tend to retain heat. It should be flush so that there's no skin showing. And generally, I've seen this most frequently in Africa where you have an N95, face shield, plus the hood because the PAPRs are not available. The issues that we've had with this: potential to come too close to the eyes, you know, wearing safety goggles for comfort. And then consideration should be taken into account regarding increased heat flow due to lack of the PAPR airflow and how that might affect dwell time, and how long, you know, an individual can be with an animal or provide care. Head covers, if there's a lack of PAPR systems available, you see that this increases the potential risk of care providers manipulating several different components right at their face. So this requires significant more dexterity, proper training, and monitoring. And in the absence of other types of PPE, the head covers are a viable option.

Slide 30: Disposable Boots/ Shoe Covers

Disposable boots and shoe covers. So single use boot covers extend at least to midcalf. These are just sort of general expectations. Ideally nonskid soles of course, because cleaning activities that occur both in the animal care space as well as the patient biocontainment space- cleaning solvents can cause slippery conditions. Sometimes the floors are laminate and may not have much grip, so we have found disposable shoe covers ideally have nonskid soles. We in the SCSU have unit dedicated sneakers. Whatever you're wearing into the unit to do your patient care or your animal care, you have shoes that

you use that do not leave the unit and are only on the unit. Again, a wide variety of different types of shoe or boot covers available and how they're utilized will depend on whether or not you're using a coverall. In the SCSU we use two sets of shoe covers, one underneath the coveralls and then one over, again, so that if we are... if we get splashed on, we can take off the outer shoe cover and replace it with a clean one, clean gloves, etc.

Slide 31: Role of Safety Observer or Donning and Doffing Partner
Just a brief about monitors. So, monitors are important. They are accounted for in the CDC recommendations, and they should have PPE worn that's commensurate with the understood risk of their position. So our monitors do not enter the patient room. They do not touch the individual who is doffing. And so therefore they wear a lower level of PPE stationed in the anteroom or simply paper scrubs if they are monitoring donning in a clean area. And this is where I reference the use of CAPRs for our monitors rather than PAPRs. Because they are a slight step down and reflect the accurate level of risk inherent in the anteroom, which is sort of that gray area between the clean area/rest of the unit and the known contaminated area. And so when we look at our anteroom, we look at it as sort of going from most contaminated, being at the point where the patient, you know, room door is and then that contamination gradient begins to fall off the closer you get to the clean side of the anteroom.

So the monitor stands in the anteroom, they observe PPE for contamination, and they direct the care provider in terms of how to take off the PPE. Having a monitor that leads you through each step of the doffing process can be essential in terms of making sure that you get redirected if you are about to do something incorrectly. And so, the way that we do it is we make sure that we have the monitors state what the person should do, and then the person does it. The individual who is doffing does not remove a layer or component of PPE until instructed to do so by the monitor.

Slide 32: Possible Failure Points of PPE
So possible failure points of PPE. Insufficient training. So proper training is definitely required on PPE components. An understanding of the good to know versus the need to know. Improper donning absolutely can reduce PPE's effectiveness. It can complicate the doffing [and] increase risk contamination. And then ill fitting PPE- whether it's too loose or too tight, both of those scenarios can result in increased risk of exposure through either getting caught on a piece of equipment in the room, getting caught on, you know, some of the equipment that you might have in the animal research area and lead to tears, particularly if, as I stated before, you know, the PPE that is being used has been stored in a negative pressure environment for an extended period of time. You need to make sure that the integrity is in check, particularly with the gloves and the gowns, so that nothing rips.

We don't advise reusing PPE. We have a sign out sheet as part of our administrative controls specifically so that we know who to go to. We want to make sure that we have accountability so that someone else won't use the wrong PAPR. That way, every researcher in the lab knows that this is their PAPR, this is their PPE, and they are responsible for it for the length of their shift. Appropriate disposal: we use lidded receptacles that are lined with autoclave bags, fill them 3/4 the way full, and then the staff are trained on how to appropriately prepare those waste packages to be able to be autoclaved.

Hair and Facial Hair. We've talked about the need to make sure that your facial hair is not impeding proper seal for respirators. But also if you have long hair, make sure it's pulled back securely away from your face. And if your hair is styled in a way that that is not possible, it is definitely worth considering the use of a hair bonnet to keep your hair in place so that it 1) doesn't become tangled or caught on any part of the PAPR helmet during the doffing process. That can make it difficult to remove components. But 2)

also that the hair doesn't, move, you know, as you move throughout your, research environment, and potentially block your field of vision or fall in front of your face. You know, all of those things are things to keep in mind.

So we've seen these failure points addressed in previous slides. In terms of SOPs, these would be the ones (for donning and doffing) that we are slowest to update. We want to make sure that the increased safety that results from a suggested change must be great enough to outweigh the potential safety risks of changing a process, which then requires retraining of staff. The safety gains need to weigh the inherent safety challenges in retraining individuals.

Slide 33: Escalating to a Higher Level of PPE
Now, we're gonna talk about escalating to a higher level of PPE. So this slide shows the difference between two levels of protection. And then the next one shows the same thing, but with a different system as utilized by NIH. So here you can see the lower level of PPE would be single or double gloves. Single use gown, face shield, goggles. Elevated or escalated would be and additional layer of gloves, perhaps foot covers, paper scrubs, the addition of a fluid resistant hood. So you can see here this is what would happen if we were working on a PPE model that was signaled to escalate based on, you know, the symptoms and presentation of the animal being studied, the animal being cared for.

Slide 34: Escalating to a Higher Level of PPE (NIH - Special Clinical Studies Unit)
You can see here escalating to a higher level of PPE. This is how we do it in our patient biocontainment unit. Again, I want to reinforce that while we are dealing with humans, this is absolutely applicable to how you would deal with animals. So the CAPR that I was talking about before is on the left. This on the left is what our monitors wear. So this would be sort of like the lowest level: single use, impervious gown, paper scrubs, double gloves, and then one pair of ankle height foot covers because they won't be going into the room. And then you can see with the CAPR it still has the negative pressure flow. It is still an air purifying respirator, but the face shield is more flexible.

On the right escalation to a higher level of PPE. This would be the default for care providers until we received, you know, an update in terms of PCR, in terms of infectivity of the individual or, you know, animal. The highest level would be the PAPR. We use a double shroud that goes under the impervious gown and the coveralls. We also use double gloves. The first layer of gloves is taped to the cuffs of the coveralls. Then the gown goes on, and then we layer a second pair of gloves over the outer gown with two disposable foot covers. So very similar, but also very different.

Slide 35: Highlighting Administrative Controls
So I'm going to highlight next administrative controls. Brevity is your friend when you look at administrative controls. And we're speaking about SOPs in this context.

Slide 36: The Importance of Administrative Controls
I won't read this whole slide. But as you can see, administrative controls are sort of the bulwark against chaos. They empower staff to properly utilize and identify the engineering and safety controls through standards of practice that have been tested, tracking performance accountability, using staffing grids, flow charts, visual aids, etc. They provide a consensus understanding of performance expectations as well as defining consensus agreements of what means what. And they map out, really, your processes. They exist for every procedure or action, hopefully. And they are most important when it comes to features that require actions to be done in a certain way in order to reach the required outcome.

So, we focus on SOPs here because they're the cornerstone of safe practice. As we mentioned before, they're sort of like a bridge, right? And because a significant portion of your environmental or engineering controls are often baked into the architecture of your facility, administrative controls like SOPs guide staff on how to maximize the engineering controls available to them and make them actionable in practice.

So what makes an SOP an effective SOP? Well, it's one that staff read and can implement independently after training. So for this, brevity is your friend. Writing in the active voice is your friend. Then clear formatting of each step or action needed to be performed. One thing I added here is a exception that, when used rarely, can be very helpful in training. You know, let's say that an SOP is for shipping out lab specimens. The process for initially preparing the tubes may not be complicated enough to warrant a separate SOP. And if that's the case, then sometimes it's okay to have a nested, you know, sub step collection, as you can see in the bottom of this slide. So used sparingly, you can provide these mini-processes within the context of a larger SOP. And that's great if clarification is not enough to warrant an additional SOP. So if we were to take, let's say, "How do we do that initial handling of those lab specimens?" and make it its own SOP, now you've separated that step from the larger scope of the SOP. Right? So if we want to keep the linear action moving in a logical and consequential way so that we get the desired outcome, it is in my opinion experientially okay to use sub processes (that are also concise) if further detail is needed about a specific element within an SOP. And I hope that makes sense.

You want to use active voice versus passive voice.

Slide 37: Poorly Written SOPs Tend to Result in Poorly Executed Outcomes
Poorly written SOPs tend to result in poorly executed outcomes. Bad procedures can be a recipe for disaster. So this is just a slide that kind of speaks to the key takeaways here in terms of how to make sure that your SOPs are a recipe for success instead. Bad procedures cause errors, frustrations. Often the hallmark is they're written too narrowly or too vaguely to allow staff confidence to navigate issues that may arise if they're not specifically laid out in an SOP. They can also distract from quality goals, or they may not get read or used at all.

So an effective procedure maintains consistency. It's a living document that is modified with discernment as needed based on subject matter expertise that are communicated. They should be developed with a cross-section of subject matter experts that are involved in the topic. And that feedback should be received with the grain of salt because it is possible that you may not feel that what you receive as advisement is going to be compatible with your research environment. The SOPs should be the backbone for training materials developed, and they should be road tested by both individuals familiar and unfamiliar with the process. So for example, what I do is I will have someone who is well seasoned. They will, you know, come on board and I will ask them to run through the SOP, and then I will do the same with a new hire. Why? Because somewhere between those two perspectives is probably the best path forward. New hires may ask questions that have you realizing there's a process that has become part of workplace culture but actually has no SOP to ensure, I mean, that it's consistent, you know, historically. And at the same time, they may question why do we do a thing, and that "why" actually identifies a step that perhaps is no longer necessary or is duplicative. So, that is the benefit of having a set of fresh eyes.

Slide 38: Helpful Considerations on When to Create an SOP
This is a flowchart for helpful considerations on when to create an SOP. This is not meant to be the final word on it, but rather to help you conceptualize sort of a general decision making process. It starts with, well, is there an SOP already in existence for the one that you want to make? And when I say "in existence," I don't necessarily mean just where you work. But have you talked to colleagues at other animal research environments that perhaps they have already created an SOP? And then you could use that as a template, which we'll get to, but I will... [actually] I won't go through all of these, but, you know, feel free to pause this slide if you need to and take a look. Essentially it's helping you to use discernment to try to make sure that you are maintaining you know, the appropriate level of SOPs. Sometimes people fall into a trap where they will create an SOP for something that is common sense. And "common sense" is a dangerous phrase to define because it will change depending on one's experience.

So this helps to provide kind of a general understanding of when is enough, enough. And it tries to show that you will see nuances that are not represented here, but that the core decision making process focuses on. Do you have the right people's opinions? Is there already an SOP in place, or does writing this SOP run the risk of explaining a process that in and of itself is inherently obvious and may constrain rather than improve practice? You want your SOPs to be flexible enough that they allow care providers in animal settings with, you know, how to get to the appropriate outcome. But you also want to make sure that they are not smothered in SOPs, which can have the opposite effect of decreasing their ability to be free thinking should something unexpected happen. And so we try not to write our SOPs into the minutia. We try to allow for some flexibility only where steps don't necessarily have to happen exactly the same. And that's going to be on a case by case basis.

But for here, you know, how do you keep track of the amount of space you have? How do you field feedback from individuals that say they want an SOP? You know, for that you need to look at is it a single staff member? Maybe they need some remedial training. Maybe they don't even realize that there's an SOP available for the question they have. So that goes also to storing your SOPs, making sure they're accessible. You know, if you have 100 SOPs, it can be tiring to have to go through even with proper naming conventions to make sure that, you know, your staff are finding the right ones. I tend to, as a habit, keep all the previous versions of SOPs. I think probably for every SOP that we have in the SCSU, there's about 4 or 5 previous versions. I keep them as reference because inevitably someone will come up with a suggestion, and inevitably that suggestion will be reflective of an SOP that we no longer use. But at least it allows me to provide them historical context for why it didn't work. And just because something didn't work in 2013 doesn't mean it couldn't work now. So I would encourage everyone who is looking at how to better strategize their SOPs to, you know, be open to feedback. You know, have an open door policy in terms of people asking, why do we do this? Why do we do that? But the discernment comes in actually implementing the suggested changes. Make sure that the suggestions aren't coming from a knowledge deficit from the source as well.

Slide 39: Templates Are Your Friend
So for this slide, templates are your friend. There is no reason to reinvent the wheel. And I've included some resources here for SOP templates. You can see the links below. And understanding how different facilities approach SOP creation can also be an ignition for your own SOP construction. You may be able to use a general SOP that colleagues at another facility have created with only minimal changes. And that is far more desirable, you know. Seeing how others do it, keeping in mind, again, the environmental controls in place and how they might differ from the ones that your facility, can save you from recreating something because you're already using what you know works in one environment and may just need a couple tweaks, for the other environment.

When I say "you don't need extra wheels," well I'm speaking to what we mentioned before in the previous slide. Too many SOPs can cause search fatigue for staff that are trying to find a certain one. Even with standardizing naming conventions, keep an eye out for times when the SOP you are considering writing doesn't have a similar version already available, right? Either within your own practice area, within, you know, the larger institute or facility or research center that you work in. But also keep track of the SOPs that maybe nobody has. If nobody has the SOP that you have just thought of, it can mean one of two things. 1) No one has it because it's not necessary, right? Because it is outlining a process that is obvious. You know, there are very few times where you would need an SOP for how to use a fork, for example. But that is, you know, open to your discernment as a researcher. So it could be that, 2) you know, there is no SOP, no one has one, and it could benefit, you know, more than just your practice area. Or [it could just be] the fact that no other facility has found a need for that at SOP. It could be a good indicator that it's too simple of a process; it aligns too closely with common sense or with training that was received as part of the programs that brought people to your animal research area. Right. So I don't think there's a scenario where someone just stumbles in and says, "OK, I'm ready to take care of, you know, an animal. I'm ready to inoculate this animal."

These SOPs are also, keep in mind, written for a specific audience and depending on the audience, will depend on the assumptions that are in an SOP, if that makes sense. So for, you know, negative pressure environments for animal model engagement, you know, for technicians that are taking care of animals, you know, there's pre-training that occurs, there's onboarding that occurs. And so it is okay for SOPs to take some things as expected, that there can be a baseline knowledge level that is needed, right, to employ a specific SOP. And those are SOPs that would be specific to your practice area, specific to a certain demographic. And, it's up to you to decide how in the weeds that gets.

Slide 40: Strategies to Ensure Active Engagement with SOPs
But I wanted to provide a couple strategies to ensure active engagement with that SOPs over the long term. SOPs are a great way to provide onboarding for new staff. You would be well served by turning each of your SOPs into a skills checklist that can also serve as a sign off sheet to confirm successful documentation or to highlight a need for remediation. And that can be part of training and orientation.

It's always important to make sure that if you're working in, let's say, an animal lab and that animal lab is part of a larger research, institute or larger research facility that your specific area SOPs do not conflict with the higher level SOPs of that greater institution, if that makes sense. And so make sure that you are familiar with what SOPs already exist as a baseline and then look at, okay, where are the gaps to fill in for my specific practice and how I engage with animals?

SOP tracking. Great idea to get a simple Excel spreadsheet together. On the spreadsheet you can have, you know, date last reviewed. You can identify the review cycle time, however long that is. And if they're, for instance, if you've decided to review your SOPs annually (or whatever the expectation is for your working environment), then make sure that it's reflected on the tracker. So the rule of thumb here is that you don't want to set yourself up for failure simply by implementing requirements that may not be feasible to maintain in terms of tracking.

So, you know, things to consider. Not all SOPs may require the same review cycle time unless there is a definitive requirement provided by your organization. Consider SOPs that outline high acuity procedures as well as cross department expectations. They may need a more frequent review cycle, particularly if

these SOPs are related to, you know, certain equipment that gets updated regularly or you know, certain notification pathways where staff turnover may be more frequent.

So this speaks to the concept of, okay, so how do you decide? Well, you want to update your SOPs at the interval or intervals that your institution requires if there isn't a set requirement. These are some examples. And for reference below, I've included at least for NIAID in terms of, you know, proper procedure requirements for managing our SOPs. NIH SOP review varies, but generally the expectation seems to be every year to three years, depending on the context and setting in which the SPP is utilized. So again, this is not intended to say you must do it every three years or every one year. But you can use that example to consider, how can we keep our review cycle frequency at pace with the rate at which potential changes may impact the procedure? You never want to be playing catch up. For example, an SOP on how to open a door may not even need to be an SOP, right? Unless it's a special door. If that door is special but never changes, then, you know, you might want to consider a longer review cycle because that procedure is static. However, if it an SOP on how to open a door, and that door receives modifications every three weeks, or breaks down and has to be replaced with a different part, what you're going to want to think, you know, [is to] make sure that your SOP is updated, that it reflects an accurate procedure based on the modifications that have occurred.

Slide 41: How Many is Too Many?
All right. So lastly, how many is too many? Well, it is really a bit of a trick question. So the answer is found through assessing your practice area and asking a few questions. Do I have the core practice expectations written down in a way that staff are able to demonstrate successful outcomes as intended? Are there SOPs that are available for outlining, quote-unquote "common sense" actions that are not specific to your environment research and maybe they could be included as a one liner in all of your SOPs? For example, adding quote-unquote "select appropriate PPE" as the first step to all of your SOPs that deal with environments with infectious potential, rather than trying to create an SOP on how to select PPE. This is a good example of what not to leave up to the discretion of a lab worker as the appropriate PPE should already have been decided. It can be open for discussion, but you can consider, you know, putting a link in the SOP on how to utilize the PPE that's been decided upon because that supports consistency over subjective decision making. You know, you don't want someone wearing three gloves and everyone else is wearing two.

So consider also organizing your SOPs in a way that staff can immediately discern the importance of them in terms of frequency of referencing. So, for example, for my practice area, I have critical event SOPs like Code Blues, that kind of stuff in one folder, extractions. You know, these are SOPs that outline higher acuity processes but are more rare. And while SOPs that would be used on a daily basis like cleaning, donning and doffing, training, process expectations- they are in a folder that communicates that they are part of sort of the core everyday collection.

So, this is just sort of to give you an idea that as you go along and make SOPs, the first step in deciding how many is too many is to see how many you have. Now, having too few SOPs could run the risk of leaving out institutional knowledge that cross-trained employees would be at a disadvantage without, and so it's important when you do exercises and trainings that you listen to the staff, you watch what they do and you make sure you're tracking- is this in the SOP? Because oftentimes an SOP will be guiding staff for a couple years, and then the workplace culture begins to insert, you know, extra steps or consolidate steps. And these consolidations may lead to a stronger SOP, but if they're not communicated to the custodian of the SOP, then they're not going to be written down. And so new hires are going to be trained in a way that does not reflect the SOP.

So this is about version control essentially as well. The correct amount of SOPs is really having an SOP that is related to any procedure or process where the way in which it is done is necessary in order to achieve the specific outcome at the end of it. Whereas having too many SOPs is more likely that you are trying to standardize interventions in a way that is almost too deep in the weeds. The way to reach that kind of sense of understanding that you have enough is multiple eyes. Look at your collection and ascertaining, you know, is there anything missing? And if there is something missing, why? And if there's a reason why, then there's no reason to include it. But perhaps maybe what's missing could be, you know, put into an existing SOP.

So for the last example of this I'll give you from personal experience, which is regardless of patient versus animal view, is that the SCSU has about 50 SOPs and I was realizing that there was no one central SOP that kind of ties it all together. And so what we're working on now is creating an SOP for the unit that brings together several different SOPs in a narrative format. So individuals who are less experienced don't have to know which SOPs they have to select from, you know, from multiple folders, whereas they can just take one SOP that consolidates similar SOPs that are all part of the same larger process, if that makes sense.

Slide 42: Summary
Always remember that PPE is the final stage supported by layers of safety controls that comprise the design of your clinical space or your lab space. The SOPs are important. They're one of the most important administrative safety controls because they become more relevant to the level of potential instabilities in the environment needing standardization. And they link concept to implementation. They link support consistency and reproducibility. So a strong library of SOPs focused on PPE focused on navigating the environment, on cleaning procedures, donning and doffing. Utilize these both as training assessments in the form of checklists to ensure that we're all on the same page. And you also are removing the ability for creative decisions regarding PPE choice unless it's a consensus decision.

Remember not to over complicate it. Complicating environments.... Complicated environments can be simplified by creating accessible and concise SOPs. You can make a simple environment complicated by making an SOP that is overbearing. And breaking down into steps, you know, something, an action that doesn't necessarily need to be performed the same way each time to reach the desired goal [can be helpful].

So procedures should only include what's necessary written in a way that does not constrain, but to support consistency. Consider adding flexibility to your SOPs for steps that could be done multiple ways without prohibiting movement to the next step. And always advocate for the protections that you, as a subject matter expert in your own field, know you need in order to ensure high quality data outcomes from your work, as well as your own safety.

Thank you very much.

End