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Note: Text has been edited for clarity.

Contents: Transcript Additional Questions

Building a Research Occupational Health Program

Speakers:

- Eileen Morgan, NIH, Office of Laboratory Animal Welfare
- Ted Myatt, Sc.D. University of Rhode Island

Broadcast Date: March 12, 2020

View Recording: https://youtu.be/1glKbn29nV0 (YouTube)

Slide 1: Building a Research Occupational Health Program

>> Neera: Hello. Today is Thursday, March 12, 2020. I am Neera Gopee, Director of the Division of Policy and Education at OLAW.

Before I formally introduce our two panelists, OLAW would like to address concerns regarding the expanding outbreak of a respiratory illness known as COVID-19 which is caused by a novel coronavirus.

Slide 2: OLAW FAQ G.9.

Most cases and person-to-person spread of this novel virus have occurred outside of the US, but clusters of affected persons have been increasing in the US. Although the immediate risk to most people inside the US remains low, the potential global public health threat posed by this virus is high. This is a rapidly evolving situation and the risk assessment for people in the United States may change.

OLAW is deeply concerned about the impact of the COVID-19 outbreak and the inability of affected Assured institutions to maintain an animal care and use program in complete accordance with the <u>PHS Policy</u> [Public Health Service Policy on Humane Care and Use of Laboratory Animals].

OLAW's immediate concern is for the health and safety of people and animals in the programs we oversee. OLAW recognizes that as the novel coronavirus outbreak continues, it increasingly generates questions from our stakeholders. Institutions must adhere to provisions of the PHS Policy, the *Guide for the Care and Use of Laboratory Animals (Guide)*, and the commitments detailed in their Animal Welfare Assurance with OLAW. The *Guide* specifically requires institutions to have a disaster plan that takes into account both personnel and animals. This includes advance planning for conditions that could arise as a result of a human pandemic, potentially with COVID-19. Such an outbreak could jeopardize the health and well-being of animals because of a lack of personnel to care for the animals and to conduct official IACUC business.

As an initial step, to address your concerns and questions, OLAW recently updated its <u>FAQ G.9.</u> to help provide guidance to institutions and IACUCs on how to best prepare for a pandemic. In addition, we released a <u>News Flash</u> on preparing for the coronavirus disease 2019 (COVID-19) outbreak. In implementing a pandemic plan, the institution may wish to consider using options provided in the PHS Policy that it does not choose to use in the normal operation of its animal care and use program. For example, the PHS Policy contains some provisions that can be instituted as social distancing measures to prevent the spread of disease, including:

- the IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing;
- [the number of IACUC meetings may be reduced to as few as once every six months]; and
- the IACUC may choose to expand their use of designated member review.

Please visit our FAQ G.9. on our website and I also encourage you to visit the <u>Centers for Disease</u> <u>Control and Prevention's website</u> for up-to-date information and guidance on how to prepare against COVID-19. We've also put out a PDF of our FAQ G.9. and our recent News Flash on the GoToWebinar control panel under Handouts.

Lastly, OLAW is developing a special webinar to address contingency planning for pandemics. As soon as we have a date for that we'll send out a News Flash and an email blast.

Additional guidance will be developed and posted on the OLAW website if an emergency situation is sufficiently severe and long-lasting, such that OLAW determines that additional measures must be implemented to meet the needs of the research community and funding components. OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

In light of the number of questions we've received from institutions thus far on the topic of building a research occupational health program and regarding preparations for COVID-19, we plan to extend this webinar for about 30 minutes or so to provide clarification and guidance. During this time, we will address questions we've received prior to the webinar and take your questions related to the particular challenges that your institution may be facing.

Slide 3: Building a Research Occupational Health Program

And now to the introductions. Today it is my pleasure to welcome our speakers, Dr. Ted Myatt and Eileen Morgan, to the OLAW Online Seminars to present Building a Research Occupational Health Program.

In his role at the University of Rhode Island (URI), Ted oversees the Office of Sponsored Projects, the Office of Research Integrity, and the Comparative Biology Resources Center. Prior to joining URI, Ted lead the Life Science Practice for the consulting firm, Environmental Health and Engineering, Inc. (EH&E), where he focused on providing guidance on research regulatory and safety issues. Ted also served as the Director of the Partners Healthcare Institutional Biosafety Committee (IBC), which served as the IBC for Massachusetts General Hospital, Brigham and Women's Hospital, and McLean Hospital.

He received a Bachelor of Science in Microbiology at the University of Illinois, a Master of Environmental Management at Duke University, and a Doctorate of Science at the Harvard School of Public Health, where his research focused on the impacts of the built environment on the transmission of respiratory viruses. Eileen Morgan currently serves as the Director, Division of Assurances, in the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health. Ms. Morgan previously served as a Senior Assurance Officer in the Division of Assurances within OLAW. Eileen holds a BS in Technology Management from the University of Maryland and an Associate Degree in Animal Health Technology. She has 37 years of experience in animal models-based biomedical research and compliance oversight in the humane care and use of laboratory animals. Her experience includes service as Chief of the Facility Management Branch in the Division of Veterinary Resources, NIH Intramural Program, and positions at Johns Hopkins University School of Medicine, the American Red Cross Holland Laboratory, Cleveland Research Institute, and Affinity Biotech, Inc. She has served as an IACUC member and an IACUC Chair.

Slide 4: Occupational Health and Safety Programs

It is my pleasure to welcome you both to the OLAW Online Seminar. And now I'll hand the microphone over to Eileen.

>> *Eileen*: Good Afternoon.

Slide 5: Objectives

My objectives today are to identify occupational health and safety program requirements per the PHS Policy and the <u>Guide for the Care and Use of Laboratory Animals</u>, indicate who is responsible for the occupational health and safety program, and identify essential components of an effective program.

Slide 6: Requirements: PHS Policy

From the PHS Policy, the requirements include that institutions with an Animal Welfare Assurance must include a description of "the health program for personnel who work in laboratory animal facilities or have frequent contact with animals."

Slide 7: Requirements: Guide

The *Guide* states that "each institution must establish and maintain an occupational health and safety program (OHSP) as an essential part of the overall Program of animal care and use." The nature of that occupational health and safety program will depend on the facility, the research activity, the hazards, and the animal species involved. An occupational health and safety program is not one size fits all.

Slide 8: Requirements

Additionally, the *Guide* states under the heading "Medical Evaluation and Preventative Medicine for Personnel", that "development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health professionals, such as occupational health physicians and nurses." Also, that "confidentiality and other medical and legal factors must be considered."

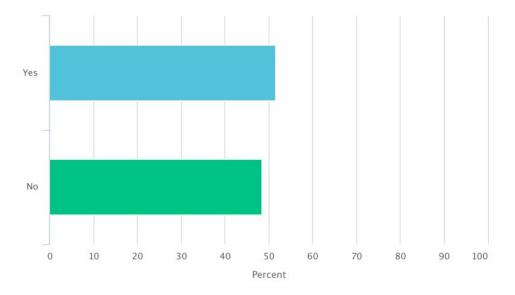
Polling question 1: Is the IACUC responsible for the OHSP?

Now I have a polling question for you. Is the IACUC responsible for the occupational health and safety program? [Yes/No].

What do you think? We'll take about 30 seconds.

We have—just about everybody. 77%. Everybody else vote!

Okay. We've hit 30 seconds.



Is the IACUC responsible for the OHSP?

Okay. That's good! So, we have about a 50/50 percent split. So, the correct answer is, "No". It is not the IACUC that is responsible for the occupational health and safety program. Rather, it is an institutional responsibility to establish and maintain an occupational health and safety program appropriate to your organization. That was a good result.

Slide 10: Components of an OHSP

Let's talk about the components of an occupational health and safety program. These are some of the components. You could argue that disaster planning emergency preparedness is pertinent because it's concerned with keeping people safe in planning your emergency preparedness, especially in this time of uncertainty. The others include personnel training, risk assessment, medical treatment, facilities, equipment and monitoring, hazard identification, health assessment, and personal protection.

Slide 11: Risk Assessment is an Essential Component

Risk assessment is an essential component of an occupational health and safety program. There really are two parts to risk assessment. That is, identifying the hazards associated with the risks of the job, and identifying the risks of the individual. The National Research Council <u>Occupational Health and Safety in the Care and Use of Research Animals</u> describes that assessing the risks of new employees and rapid evaluation is essential to ensure their protection.

Slide 12: OLAW FAQ G.2. What is Required?

OLAW provides guidance on what is required for an occupational health and safety program in our FAQ G.2.

Minimally, the program must include these: a pre-placement medical evaluation, identification of hazards to personnel and safeguards appropriate to the risks associated with the hazards, appropriate testing and vaccinations, training of personnel regarding their duties, any hazards and necessary safeguards, and personal protective equipment.

Slide 13: OLAW FAQ G.2. What is Required? Continuing the list:

Policies and facilities that promote cleanliness, provisions for treating and documenting job-related injuries and illnesses.

Facilities, equipment and procedures designed, selected, and developed to reduce the possibility of physical injury or health risk to personnel.

Good personal hygiene practices, prohibiting eating and drinking, use of tobacco products, and application of cosmetics and/or contact lenses in animal rooms and laboratories.

Slide 14: Summary

In summary, the institution is responsible for establishing and maintaining an effective occupational health and safety program. The nature of the occupational health and safety program will depend on the facility, research, hazards, and species involved, beginning with an identification of those hazards and assessment of the associated risks. An effective program requires evaluation of program components and coordination of various research, program, administrative, and facility personnel.

Now I'll hand the microphone over to Dr. Myatt.

Slide 15: Building an *Effective* Research Occupational Health Program >> *Ted*: Thank you, Eileen, and thank you Neera for inviting me to talk about occupational health programs related to animal care and use. It's an honor to be here today.

First, I wanted to note that I tweaked the title of this presentation slightly to "Building an *Effective* Research Occupational Health Program." As that title indicates, my focus today is on strategies to build or improve existing programs.

Slide 16: Requirements for an Occupational Health and Safety Program (OHSP) As Eileen mentioned in her presentation there are requirements for occupational health and safety programs both in the PHS Policy and in the *Guide for the Care and Use of Laboratory Animals*, so I won't belabor that point. I think that this point is well understood.

Slide 17: Health Risks of Animal Care Staff

So why is this a requirement? Because there are obviously health risks to animal care staff. In fact, based on data from the US Bureau of Labor Statistics, veterinary services ranks second in incidence rates for non-fatal occupational injuries and illnesses. The veterinary services category encompasses a wide range of activities, but animal care and use staff in a research environment clearly fall under that umbrella. To me, this is really surprisingly high! There are more injuries and illness in veterinary services than working in a foundry—higher than working in the police department!

What types of injuries and illnesses are most common? Clearly allergies and asthma are an issue. Up to 46% of those with allergies to laboratory animals will go on to develop asthma, so that's certainly an important illness that we want to try to minimize. There are other illnesses and injuries to consider as well—needlesticks and sharps injuries, musculoskeletal disorders, compassion fatigue, stress and burnout, a cluster of mental health issues, and zoonotic infectious diseases. These are just some of the more common injuries and illnesses that may occur within an animal care and use program.

Slide 18: Topics for Today

In considering the goal of providing an effective occupational health program, I wanted to talk about a couple of main points. Everyone listening should be aware of the requirement to have an occupational health and safety program, and the major illnesses and injuries that can result from working with animals seem to be a pretty obvious thing. Therefore, everyone should be onboard with having a well-run occupational health and safety program, right?

But what I've seen, and what I'm sure OLAW has seen, are institutions that don't have reasonable programs. And why is that? Because there are challenges and barriers to building an effective program.

So, today I will talk about some of the barriers that I've seen over the years and how we've tried to tackle them—within the institutions I've worked at. Secondly, I will talk about ways to improve a program that you already have. How do you enhance or improve a program already in place at your institution? And lastly, I'd like to present the goal that occupational health and safety programs must be and should be inclusive, going beyond the *Guide* and ensuring that occupational health and safety programs consider the broader research community, and consider staff and students that do not directly work with animals. It's important to remember each institution is different—each occupational health and safety program, but hopefully give you some ideas on strategies to improve your program.

Slide 19: Challenges and Barriers to an Effective OHSP

Let's first talk about some of the challenges and barriers to an effective occupational health and safety program. Some of them are listed here. I am sure there are many others that you've all have encountered, but some of the ones that I've run into over the years include a lack of expertise, such as a lack of an occupational health or medical staff available to run or contribute to an occupational health program, lack of resources and funding, and other institutional barriers. For example, a situation that may be common in academic settings is that there may be on-site or on-campus health services at an institution, but they focus only on student health and there is no on-site employee health program.

I've also seen occupational health programs that are very focused on clinical care. This can occur in an academic medical center or medical school environments, where there is just not a lot of translation of that occupational health program into the research environment. Those are just some of the barriers or challenges that I've seen over the years working at or helping institutions with these sorts of programs.

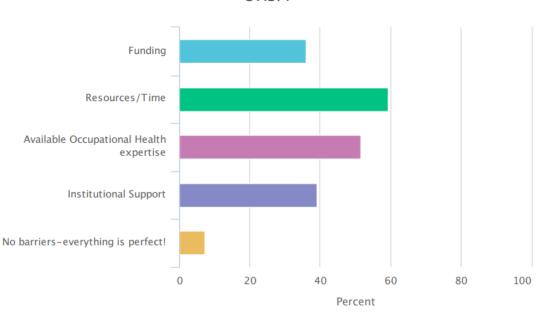
Slide 20: Polling Q2

So, I have a polling question. Let's put this question to everyone: What is your biggest barrier? Do you have issues with funding, resources or time, expertise, institutional support, or do you have no barriers at all, and everything is just perfect?

I'll give you a few seconds to answer those questions and I think you can check off all that apply to you and we'll see what sort of barriers people are confronted with.

If you have specific examples of barriers, please consider asking questions or providing comments about them during the Q&A portion at the end of the webinar.

Let's see what sort of answers we have. That's probably enough time.



What is your institution's biggest barrier to an effective OHSP?

Polling 2: Results

What do the answers look like? "Resources and time" and "available occupational health expertise" lead the pack. Seven percent of you can turn off the webinar right now and go home because you're all done, you've got it all set.

Certainly, resources and time are a big one. Knowing what to do, but not having the time to do it can be very frustrating. And certainly not having readily available occupational health services or staff available can be a challenge that I've seen at many institutions. So those are top of the list for sure. So, we're going to talk about some of those ideas, some ideas on how to tackle some of those barriers and challenges.

Slide 21: What Does Your OHSP Need to be?

If you have barriers, and you are not alone, and if you are concerned your program is not sufficient, the first thing you need to understand is what your occupational health and safety program needs to be. This is an issue that Eileen mentioned earlier. The nature of the occupational health and safety program will depend on the facility, research, hazards, and species involved. So essentially, one size does not fit all.

So, where do you start? How do you determine what your program needs to be or the elements that should be included? I think the first place to start is to understand the risks from the type of research your institution is involved in—you must understand the species utilized, understand the procedures that are involved, and based on that, you will get an understanding of the health and safety risks that may be related to working with those species. You can also refer to injuries and illnesses that have occurred in the past. What sort of potential exposures, illnesses, and injuries do you have at your institution?

Through that process, you are beginning to conduct a risk assessment. This is a process I have been through when starting a new position. Whether I understood it at the time or not, I was determining what the real risks to the staff and students were.

Slide 23: Building an Effective Program

Based on a good understanding of the risks, the next step is to understand the resources that your institution will need to establish an effective program.

What sort of resources do you need, what sort of staffing do you need? Especially at smaller institutions, it's okay to start small. I think it can get quite intimidating to look at occupational health and safety programs at larger institutions and try to live up to their standards if you are at a much smaller place. So, it's okay to start small. One suggestion I have is to consider outsourcing some or all of the elements of program. If you are using outsourced expertise, [I recommend trying to] build in training opportunities for your own staff, make sure your own staff are engaged, that they are building on and learning from that outside expertise.

Certainly, the program needs to have champions, those champions are probably on the line right now. Those champions can be both leadership and folks that actually get things done—the doers. It's one thing to know as someone involved in the IACUC or the animal care world what to do and what the needs of a program are, but it's another thing to get that leadership to buy in.

Regardless of size, there needs to be a team approach. As Eileen mentioned, it's not an IACUC responsibility to create an occupational health and safety program. It's an institutional responsibility and as such, it really needs to have more involvement than just a single person, even at a smaller institution. I have been in the situation where it has essentially been a one man shop to develop or improve upon an occupational health and safety program and ultimately that becomes very challenging to sustain and it's ultimately too much to put on any one person.

With that, I wanted to mention that a hallmark of an effective program is to figure out how to implement that program with sound strategies so you are not relying on a single person, and you are developing a program that is realistic for your institution, without unnecessary requirements because maybe you are basing what you need to do on others.

Each time you evaluate your program you should be thinking about whether the resources available match the needs that you have.

Slide 23: Engage Leadership, Gain Support

What do you do if you are in a situation where the resources don't match the needs? You obviously must try to build institutional support. This starts with ensuring senior leadership is involved and aware. Start with proactively discussing regulatory requirements and risks with senior leadership. I know I fall into this trap sometimes when I have the opportunity to speak with senior leadership, it's not necessarily speaking on a proactive basis. Rather than talking about things before they are a problems, I end up talking only about the 10 fires that need to be put out that day, and sometimes that results in programs that are [just] okay, but not a crisis, don't get the attention that they need.

So consciously try to think about speaking proactively when you have that opportunity.

Another approach is to ask senior leadership if a gap assessment can be conducted. Conducting a gap assessment is where you assess the strengths and weaknesses of a program—like your occupational health and safety program. That is a valuable exercise. In conducting that assessment, you can compare your program against the requirements for occupational health and safety program, as Eileen mentioned earlier. You can also compare your program to [programs of] peer institutions. Another idea is to conduct surveys of users such as faculty, staff, students or other active participants. To me this exercise is a little different than a risk assessment where you

are looking at your program needs. A gap assessment is a little different. Here you are looking at needs, but also the effectiveness of a program. What is working? What needs improvement? You are essentially rating the different program areas. An example may be an element is not present, under development, or mature and has a solid foundation. We may be categorizing elements in those areas.

We conducted a gap assessment like this to demonstrate to new leadership that additional funding was necessary for the program, it essentially was effective at raising an alarm bell to those senior leaders.

Keep in mind that with something like this gap assessment, it may be advantageous to have this done by an external group as opposed to someone internal to your institution that may or may not hold more sway. Regardless, the engagement of senior leadership through proactive discussion of strengths and weaknesses, builds strong administrative support for the program.

Slide 24: Challenge, Lack of a Broader OHSP

Let's talk about one challenge that seems fairly prevalent: a lack of a broader true occupational health and safety program. I think this challenge, where there is no on-site occupational health and safety program, is becoming more and more prevalent, both in academic and other institutions. There could be a variety of reasons for this, and I can't say that I am an expert in worker's compensation [programs], but I know these situations exist and I have experienced them, and I have spoken with others that have experienced them as well.

There are situations where the first line of treatment is an urgent care facility or maybe your institution has a list of allowable providers for occupational health services. Thinking about your animal care and use needs for occupational health and safety, how do you integrate into that lack of a broader occupational health and safety program? I have seen this, and it has presented challenges for me over the years. If that is an issue at your institution, I think a good strategy in addressing this is to reach out to someone in your institutional risk management group. These are the folks that deal with workers compensation claims and deal with occupational health issues as they relate to workers compensation. Explaining your situation to them might be helpful, they may be a good resource and could be a good advocate for strengthening your occupational health and safety program.

Slide 25: Example Situation: Growing Research Institution

I wanted to go into a bit more depth on this topic, so here is an example at a growing research institution. The situation is similar to the one I just described, there's no on-site occupational health service and no in-house expertise. The approach we took in this situation was to utilize an outside occupational health consultant to provide remote support for health histories and pre-employment screenings. I don't think this is too uncommon, but I think the thing we learned over time was to use that consultant to not only perform the service of reviewing those health histories and potential exposures, but to also train our own staff, so that we could gradually expand the in-house programs we provided without relying on that consultant.

Eventually we were at the point where we only relied on the consultant as an on-call expert. This process allowed our own staff to gain experience in research-related occupational health, and gain institutional support, time, and resources to run an occupational health and safety program internally. In this example, the in-house staff were student health medical staff that generally served a student population. Over time we were able to expand their role to serve as an occupational health resource for employees as well as students.

Slide 26: Be Efficient

Through the build out of on-site services, we were still dealing with limited resources. Therefore, it is important to consider how to be as efficient as possible. In our case, we made use of some available capabilities and services by piggybacking onto student health service's electronic medical records system for screening questionnaires and health histories. This was a great solution as it was free and it was a secure system to maintain the confidentiality of the information. This was something that didn't happen immediately—it took some time; it took some patience. It took us time to grow from using paper forms into the use of this electronic portal.

Slide 27: Improve Your OHSP-Learn, Grow, Evolve

Growing into using the medical records program is an example of our program learning and evolving. If you are at an organization that has a well-established and strong program, there still should be ways to grow and evolve. It should be ever-changing as research changes and consequently, risks also change. Additionally, I don't think many of us say there is no way to improve. There are seven percent of you that said that, I guess. There are always ways to improve programs, and programs should not be allowed to become static.

I imagine that all of us participate in semiannual animal care and use program reviews. These are good mechanisms for self-evaluation and an opportunity to take a deeper dive into occupational health and safety. It allows you to take a hard look not only at meeting the requirements of the PHS Policy and the *Guide*, but to also determine how to improve in those areas. So instead of asking if your program is in existence, ask the deeper questions.

Additionally, I would like to talk about allocating funding, even for limited amounts, to training opportunities. Offering training for staff allows staff to grow and allows for the growth of the program in general. Building these costs into an annual budget so that you don't have to request the funds every year or every time is a good opportunity or a good way to ensure that it will always be there. Finally, there will always be some turnover of staff, so you're always going to need that training whether or not you use it every time you have that opportunity.

Finally, improve logistics. Make the program as easy as possible for faculty and staff to gain access to and rely on. Is it difficult for a new student or employee to become enrolled and get the resources they need, is that a question? Are there ways to improve communication between occ health, the IACUC, and your facilities, for example?

A couple of things we are working on now is on a better way to interact with human resources here to connect more immediately with new hires involved in animal research. We are an academic institution so we are beginning to work with enrollment services as well to identify students as early as possible who will be in classes involving animal contact, so that we can enroll them in the occupational health program as early as possible. These are things again that take some time, especially in terms of interfacing with existing HR or enrollment electronic systems. But such efforts will not only make it easier for new enrollees, it will make it easier and more efficient for occupational health staff to administer the program in the future.

Slide 28: Be Inclusive—Go Beyond the Guide

I wanted to also talk about going beyond the *Guide*. I'm not talking about new or increased requirements from OLAW here. I am talking about the other requirements and regulations out there that require robust occupational health and safety programs. I'm sure everyone is familiar with a range of OSHA standards related to exposures that can occur in a laboratory or working with laboratory animals. Examples of these include blood-borne pathogens, noise exposure, formaldehyde, and the lab standard. There are also the <u>NIH Guidelines</u> for Research Involving

Recombinant or Synthetic Nucleic Acid Molecules, which requires a medical surveillance program for those working with those materials. So, if you have individuals at your institution working with viral vectors, for example, in both *in vitro* and *in vivo* models, there are requirements that those guidelines put forth in terms of medical surveillance. The other example is the Nuclear Regulatory Commission, they have standards and regulations for occupational safety related to radioactive material usage.

Slide 29: Include Everyone

In addition to meeting other requirements, it is important for programs to consider protections for certain populations—pregnant women, immunocompromised individuals. Do you have a policy that reflects how situations will be handled? We handle these situations generally on a case-by-case basis where the medical staff works with EH&S to evaluate exposures and then make a recommendation to the individuals as to whether to continue the work or hold off for a period of time.

We also consider individuals that do not directly work with animals, both those that have access animal facilities and those that do not. For those that have limited or no animal contact, I believe it is important to educate individuals on any risks they may have.

My point in raising these is to consider whether your institution's occupational health and safety program does enough for individuals that don't have any direct animal contact. I have seen that at other institutions, where institutions strive to meet the requirements of OLAW, the *Guide*, and the PHS Policy, they still have areas they could improve upon.

A program that's inclusive and as broad as possible, that has the largest umbrella possible—helps to build a foundation that senior leadership can really see. Impacting as wide a range of individuals as possible can only help in terms of resources and support for a program.

Slide 30: What Does a Program Look Like?

So, what does a program look like? At a high level, here are the areas our occupational health and safety program covers: medical surveillance, health history questionnaires, and vaccinations. We recommend tetanus vaccines and we have provided rabies vaccines for individuals working on field studies that are exposed to wild animals.

We also capture individuals who work with biological materials, whether they work with animals or not. Those who work with pathogens for which there is an effective vaccine available will be provided vaccinations for those agents.

Slide 31: What Does a Program Look Like?

Other areas we focus on are reproductive concerns. There's a wide range of chemical and biological agents in laboratory environments that can result in potential reproductive and developmental concerns. We've set up a program so that individuals that may be at risk have an opportunity for consultation with an occupational health nurse.

Respiratory protection, especially with respect to animal allergens, is a big concern. Individuals that would benefit from the use of a respirators are identified through a health history and understanding their potential exposures.

And of course, we deal with other occupational injuries as well. With each of these areas it is important to mention that training is a critical element. For example, there must be training on how to handle emergencies, what symptoms might occur based on those exposures, what to do

if incidents or symptoms do occur, and what needs to be done if an individual's health or work situation changes.

Slide 32: Example Situation: Clinical Care Focused Occupational Health Program Here is one more example situation, a clinical care focused occupational health program. This scenario involves a large academic medical center with a robust occupational health and safety program focused on the clinical care environment. The occ health program was focused on clinical staff, nurses, and doctors. While there was a very large research program at the institution, there was a general lack of understanding of other occupational risks that exist in, say, laboratory environments. We engaged the OHSP team to participate in research-related functions in order for them to learn about research health risks. We invited them to attend meetings, to participate, and to become members on the Institutional Biosafety Committee along with the IACUC, so they got some understanding of the biological and chemical materials in the laboratories and their associated risks.

We also reached out to establish lines of communication with local emergency departments to facilitate care in the event of exposures so that they could better understand what potential exposures might walk through their door.

Slide 33: Improve Your OHSP

The best way to improve your program is to coordinate with all those involved, again, not leaving it to one person. Meet regularly with stakeholders, senior leadership occupational health staff, and the research community, so you can understand what they need and can work to provide it. Through that interaction you may better refine your program. For example, those stakeholder meetings may lead to the development of medical SOPs for handling needlestick injuries with viral vectors. As a needlestick injury like this is most likely to involve the use of animals, this is obviously an animal care and use program issue as well.

Are you confident the healthcare providers know what to do or who to call to get information on how to handle the exposure? Perhaps meetings will lead to the development of agent-specific training and hazard-specific training for staff so that they can understand what they should do in the event of an exposure. Or perhaps it might lead to an expansion into new areas. One area where we haven't done a great job yet but that we are working on is the area of ergonomic evaluations.

Slide 34: Build Awareness

While expanding or changing your program, it's important to make sure individuals understand what services are available. In part, we did this by designing a website to describe available services. We are also working on improved signage, magnets, and flyers that are distributed to laboratories. We've also reviewed IACUC and IBC policies to make sure requirements are in there for communicating to staff and students.

Slide 35: Involved the Community, Gain Support

Lastly, it's important to make sure the community understands that an occupational health and safety program is valuable, that it's not just a hurdle to jump over to gain access to an animal facility. Staff and students are the most important resource you have, so how do you ensure the program is there to protect them?

One way to show this is provide data back to the community and senior leadership through an annual progress report. Publish how many employees you interacted with, for example. In addition to pushing out information, request feedback from your research community on how you

can improve through face-to-face conversations or through surveys. This way you can garner both top down and grassroots support for the program. These actions really do go a long way to support a strong and effective program.

Slide 36: Questions

>> Neera: Thank you Ted and Eileen.

We will spend the remaining time responding to questions. Participants, please type your questions into the chat box on your webinar control panel. OLAW will try our best to answer as many questions we can and may edit the questions for clarity, duplication, and fidelity to today's topic.

We'll first start with some questions that we received prior to the webinar.

Slide 37 (Question 1)

>> *Neera*: Our first question: Eileen, can you provide possible approaches or options that Assured institutions may implement regarding completion of a medical evaluation?

>> *Eileen*: Well, there are multiple options to complete the medical evaluation, even if you don't have your own occupational medical services. It seemed to me in the polling questions about 50% indicated that particular item [was a challenge for their institutions].

There are outside occupational health and safety professional services that your institution could contact and use, and I would say a portion of our Assured institutions do exactly that. You might have to reach out to the folks in your area to find out where those are. The other thing that I see in Assurances is that some large universities, who have a very developed occupational health and safety program, offer their occupational health services to smaller institutions or neighboring organizations in their area. Ted had some great examples in his talk and maybe he can expound on that.

>> Neera: Ted?

>> Ted: Sure. So, we certainly used an outside consultant to do remote screenings of individuals and I thought that was an effective method for us, especially when we were a relatively small institution. We also did what Eileen mentioned and reached out to more local providers of occupational health services and assessed whether they could meet our needs as well. I think those are very realistic options for institutions that don't have on-site support.

>> Neera: Thank you, Ted and Eileen.

Slide 38 (Question 2)

So, Ted, would you like to take this second question? My institution involves using animals in teaching. What is the expectation for the oversight of the students in occupational health and safety programs?

>> *Ted*: Sure, I'll take a crack at this.

What we do is we look at the exposure risks for each course that involves live animals. Those exposures could range from hands-on laboratory animal courses, to courses at a farm, to courses that involve handling and catching fish.

For courses with hands-on components with limited oversight, we require those students to be enrolled in our occupational health program.

If you're simply going out and observing animals with no direct contact, what we tend to do is discuss the occupational health program with those students, educate them on the risks, and allow them to enroll if they believe they have some health factors that may suggest that they should enroll in the program.

>> Neera: Eileen, do you have anything to add?

>> *Eileen*: Primarily it's the same—I have the same response, but since one size doesn't fit all in a program, the institutions really need to determine the risks associated with that exposure. Is there a certain amount of time people will be exposed to the animals? What's the species? And at least ensure that the individual should be made aware that live animals would be present, as in a classroom situation for rodents, in case there is a severe allergy from someone taking the class.

>> Neera: Thank you.

Slide 39 (Question 3, Part I)

So, question 3 has four parts. The first part: A PI is considering writing his own IACUC training protocol for rodents. It involves participants who will observe the procedure and others who will have an opportunity to perform hands-on surgical procedures. What are the occupational health requirements for participants observing animal procedures and for the participants manipulating or performing the animal procedures?

Ted, would you like to take a crack at this?

>> Ted: Sure. I think it's pretty straightforward for us. I think for the participant that's performing the procedure, they would have to be enrolled in our occupational health program. For those that are observing and have no other exposures to live animals, similar to what I was describing earlier, we would provide educational materials as to the potential risks of that animal exposure, whether rodent exposure or working within an animal facility, and then request that they enroll in the program if they believe they might have some potential health risk factors like allergies to rodents.

>> Neera: Eileen, anything to add?

>> *Eileen*: No, we [OLAW] would agree with what Ted just said.

>> Neera: Okay.

Slide 40 (Question 3, Part II)

Part 2, what is the most effective composition of the occupational health program that would be amenable for a small university with few resources, such as no adjunct medical school?

>> Neera: Ted!

>> Ted: Well, I'll say this may not be the most effective, but it's the place where we are now. We have a nurse with an occupational health background who works in our student health services center and she provides the medical expertise needed on an as-needed basis. The way we do it is her salary is supported in part by our vice-president of research for essentially a limited number of hours per week. She's a full-time staff member, but she has dedicated hours to occupational health.

Additionally, and I mentioned this earlier as well, we have a group that has deep expertise in research occupational health issues that we have as a consultant that can provide remote support

as needed. So, if there's ever a situation where our on-site—sort of a situation that exceeds our on-site experience or capabilities, we can rely on them.

>> Neera: Thanks, Ted. Eileen, would you like to chime in on this one, too?

>> *Eileen*: Well, the most effective composition of an occupational health and safety program would be one that fulfills the needs of the institution. And the institution simply needs to evaluate the program risks and associated hazards and develop a program by reaching out to the occupational health care professionals.

Slide 41 (Question 3, Part III)

>> Neera: The third part of this question asks, what are the different models that universities use to fulfill the NIH's requirements, such as external contracts, relationship with hospitals? Eileen, what do you think?

>> *Eileen*: Well, it's a similar answer to the one we provided for the first question. So, establishing a relationship with external organizations and external occupational health and safety services group—this describes hospitals, but a lot of times the university settings also have a comprehensive occupational health and safety program. And as I said in some Assured institutions, the smaller organizations use the larger organizations' program because they allowed them to set up contracts to do that. And that's a fairly common relationship that we've seen.

>> Neera: Ted, would you like to add something to that?

>> Ted: Yeah, I would agree with that completely. We've discussed a lot of this already. If you're in a smaller institution, I think one option may be to hire, like we did, a part-time occupational health nurse or physician. The second option is to look at outside companies that provide occupational health services. And that can be done remotely, or they can provide on-site support perhaps. And then third, like Eileen has mentioned, looking at a larger institution in your area that may be able to support you, I think is a great option for many folks out there as well.

Slide 42 (Question 3, Part IV)

>> Neera: Thank you. And the final part of question 3 asks: Who is responsible for ensuring that there is an occupational health program and where does this program fit in the structural organization of the institution? Ted.

>> Ted: Well, obviously the institution is responsible, but for us and for many academic institutions, that would sit with somebody like a vice-president or vice-provost of research who is also likely to be the Institutional Official. I think in many cases the occupational health program, at least specific to research, might sit with that vice-president of research or within sort of a division or group of research, but there may be a larger occupational health program that might sit at a higher level within your institution.

>> Neera: Eileen, is there anything to add?

>> *Eileen*: I don't really have a different answer. Of course, it's the institution that holds the responsibility, but as organizations have wide and varied organizational structures, it depends on each organization where they would sit, but certainly it's at senior leadership and some high level of administration.

>> *Neera*: Thank you. And so now we have a couple of questions on the pandemic, the coronavirus pandemic.

Slide 43 (Question 4)

How can institutions and the IACUCs best prepare for coronavirus pandemic? Eileen?

>> *Eileen*: As Neera mentioned earlier, institutions must adhere to provisions of the PHS Policy, the *Guide*, and the commitments detailed in their Animal Welfare Assurance to OLAW. This includes advanced planning for conditions that could arise from a human pandemic such as the influenza or outbreaks of novel infections such as COVID-19, that could jeopardize the health and well-being of animals because of a lack of personnel to care for the animals and/or to conduct IACUC official business.

Pandemic plans developed by institutions and IACUCs should consider the following:

- that animal facilities must be maintained at a level to ensure animal welfare;
- plans should consider appropriate staffing levels;
- cross-training to cover critical operations; and
- adequate inventories of essential supplies such as feed, bedding, PPE (personal protective equipment), and cagewash supplies.

The IACUC should develop a plan for conducting official business during a pandemic event, taking into account the following:

- the IACUC must continue to be properly constituted;
- a quorum is required to conduct official business at a convened meeting;
- the IACUC must ensure that protocol approvals are not allowed to expire or that if they do expire that no further animal activities or data collection are conducted;
- appointment and training of IACUC members including non-scientific members and alternate members, should be considered as part of the plan.

OLAW encourages that IACUCs use the flexibility mentioned by Neera earlier such as social distancing measures, to prevent the spread of disease, including that the IACUC may institute alternatives to face-to-face meetings. There could be teleconferences or video conferencing.

[The number of IACUC meetings may be reduced to as few as one every six months.]

The IACUC may choose to expand their use of designated member review during this time. Additional guidance will be developed and posted on the OLAW website in dealing with these uncertain times.

Again, OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

>> Neera: Thank you, Eileen.

Slide 44 (Question 5, Part I)

And Question 5 has two parts, which I think would be best answered by Pat [Dr. Patricia Brown, Director, OLAW]. Can OLAW provide guidance to institutions that are unable to conduct semiannual facility inspections at least once every six months as a result of a complete shutdown due to COVID-19 and/or where only essential personnel are allowed into facilities?

>> Pat: Well, as has been mentioned previously, OLAW's immediate concern is for the health and safety of people and animals in the programs that we oversee. It's important to clarify that the PHS Policy affords flexibility in the designation of IACUC inspectors and the conduct of inspections

which may or may not be applicable during the current outbreak. But I'm going to talk a little bit about some of these options.

The timing of facility inspections can include flexibility of within 30 days of the six-month interval from the last review as long as there's no forward drift of the date from year to year.

Also, the IACUC has discretion to determine the best means of conducting the semiannual program review and facilities reviews. This includes the use of ad hoc consultants, although the IACUC does remain responsible for the evaluation and report to the IO based on input that might be received from ad hoc consultants.

For non-USDA discovered species and areas, the IACUC may use as few as one qualified individual to conduct the facility's inspections. And that individual, as long as they're qualified and selected by the IACUC, does not have to be an IACUC member.

If neither of these options are practical options for your Assured institutions, as Neera and Eileen mentioned, OLAW is authorized to make determinations regarding waivers to provisions of the PHS Policy. We may temporarily waive specific IACUC responsibilities and requirements in accordance with PHS Policy section V.D. as we have done in the past in response to institutions adversely affected by natural disasters such as hurricanes.

The IACUC responsibilities that may be waived upon request from an authorized institutional representative include conducting semiannual evaluations of the programs and facilities, submitting reports to the IO, reviewing concerns involving the care and use of animals, making recommendations to the IO, reviewing significant changes to ongoing animal activities, reporting noncompliance with the PHS Policy, serious deviations from the *Guide*, or any suspension of an activity by the IACUC, and maintaining records of the IACUC.

Additional guidelines will be developed and posted on the OLAW website if this emergency situation is sufficiently severe and long-lasting.

And at that time OLAW will determine what additional measures must be implemented to meet the needs of the research community and funding components. As has been mentioned, OLAW is the entity authorized to make determinations regarding waivers to provisions of the PHS Policy and we intend to keep you informed as this current situation progresses.

>> Neera: Thank you, Pat.

Slide 45 (Question 5, Part II)

Subpart 2 of question 5 asks, if OLAW authorizes a waiver regarding the conduct of semiannual facility inspections within the six-month timeframe as a result of COVID-19, will institutions be allowed to pick up where they left off or will they be required to catch up?

>> *Pat*: We would expect IACUCs to complete inspections that were postponed and to schedule the next inspections within six months.

Slide 46 (Question 6)

>> Neera: So, Brent [Dr. Brent Morse, Director, Division of Compliance Oversight, OLAW], this sounds like a good question for you. And Axel [Dr. Axel Wolff, Deputy Director, OLAW], you can chime in if you would like.

If procedures on an IACUC approved activity cannot be performed, such as administration of post-procedural analgesia, as a result of a facility closure due to COVID-19, would that be considered reportable noncompliance to OLAW? Brent?

>> Brent: Thank you, Neera. If veterinary orders aren't carried out or protocols aren't followed, then it does constitute noncompliance. Planning needs to include provisions to prevent noncompliance. This may entail reducing or postponing procedures that require intensive postprocedural care such as post-procedural monitoring, post-procedural analgesia, as referenced in this question, and even monitoring of humane endpoints. Noncompliant activities should be reported to OLAW promptly, but we want you to take into consideration your personnel safety and their animal care responsibilities.

>> Neera: Thank you, Brent. Axel? No? OK.

Slide 47 (Question 7)

Question 7: What should institutions do in the event surgical masks or N95 respirators are not available for purchase due to shortages? Eileen?

>> *Eileen*: It would be prudent that researchers and animal care personnel conserve masks and reuse if possible, following the CDC recommendations. The CDC has published recommendations on the reuse and extended use of N95 masks and there's a couple of references listed here. I would urge you to go to those links and take a look at the recommendations provided:

https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

>> Neera: Thank you, Eileen.

Slide 48 (Question 8)

Question 8: What provisions should be made if an institution is unable to provide the support, resources, or services to maintain a compliant animal care and use program, such as shortage of available animal care personnel? Pat, would you like to address this question?

>> Pat: Well, OLAW will be having a special webinar to address issues related to contingency planning and preparation, in light of the current COVID-19 outbreak. We will be announcing the date and time soon.

>> Neera: So stay tuned for that.

Slide 49 (Question 9)

Question 9: Ted, this one is for you. We have students that take classes on a farm. How should we handle their occupational health needs? Oh, I'm sorry, I went too far ahead.

>> *Ted*: That's okay. That's a good question.

You know, for us, student courses do present some challenges in that we have upwards of 100 students per semester taking courses on our farm. I'm sure larger institutions have many more than that. For most of those students, for us, this is their first contact with animals on campus, this is their freshman and sophomore courses.

To address their needs, we have regular communication with the farm manager and the instructors of the courses to understand the student's exposure risks. So, where possible, we've worked with those folks to limit the students' exposure to the hazardous situations. An example

of that is birthing of sheep. Students are prohibited from being involved in the birthing process of sheep, for example.

For each course we provide educational materials specific to the health hazards on the farm. It's important to note some of these are not directly related to animals, for example, we talk about allergies to hay and bees and how instructors or other folks that are supervising those students at the farm need to be aware of those conditions for those students so that they can be prepared to deal with those issues if they should arise.

As I also mentioned in the webinar, we are working with enrollment services to identify those enrolled in courses involving animals so that students can enroll in the occupational health program as early as possible. That's been very helpful for us so that we've gotten a jumpstart on having students enroll in occupational health programs, given the large number of students involved, this allows time for our occupational health folks to evaluate each of their medical surveillance information. So that way—that helps.

Another thing that we have to take some care to deal with are students that, say, take a course at the farm one semester, but then perhaps later in their time here they take a laboratory animal course. In those cases, we have the students update their exposure profiles on their medical surveillance form so that we have a good assessment of what their actual exposure risks are.

>> Neera: Thank you, Ted.

Slide 50 (Question 10)

Question 10: We are almost finished with our Assurance renewal writing for submission, but our institution is preparing for a shutdown or slow-down due to COVID-19. My fear is that it may not be submitted to OLAW in a timely manner. Is there any accommodation for business that is not as usual?

Eileen?

>> *Eileen*: OLAW is authorized to make determinations regarding waivers to provisions of the PHS Policy. OLAW may temporarily waive specific requirements in accordance with the PHS Policy section V.D., and as noted OLAW will have a special webinar to address contingency planning and preparation.

>> *Neera*: Thank you, Eileen. So now we'll move on to some questions that we received from participants during this webinar.

[Question 11, Part I]

This is a three-part question. Eileen, first one: Does OLAW require the occupational health professional to be involved in the planning and monitoring of the program?

>> *Eileen*: So in the *Guide*, section on occupational health and safety, page 22, there's a statement with the heading, Medical Evaluation and Preventive Medicine for Personnel Development, an implementation of a program of medical evaluation and preventive medicine should involve input from trained health professionals, such as occupational health physicians and nurses.

[Question 11, Part II]

>> Neera: Subpart 2 asks: does OLAW require the occupational health professional to have access to the specific job description of a participant in the program or will a risk assessment of job exposures, such as physical, chemical, or radiological hazards and animal species and personal health history, suffice?

>> *Eileen*: The institution, along with the occupational health professional, should make that decision when planning and developing the program.

[Question 11, Part III]

>> Neera: Finally, the Guide for the Care and Use of Laboratory Animals states that pre-employment health evaluations and/or health history evaluation before work assignment is advisable to assess potential risk for individual employees. Periodical medical evaluation is advisable for personnel in specific risk categories. Would OLAW ever be as prescriptive as to the expectation that an Assurance state that a participant has the option for annual reassessment via health surveillance questionnaire?

>> *Eileen*: OLAW has not had that specific expectation, however for personnel in specific risk categories, they should always have the option to contact the occupational medical services provided at that institution. But the institution should also conduct ongoing assessments of risks as described in the *Guide* and then make their own determination.

>> Neera: Okay, thank you, Eileen.

[Question 12]

So, another question we received: During semiannual program reviews, the IACUC determines that the occupational health and safety program is inadequate and/or does not meet certain requirements outlined in the *Guide*. What is their responsibility other than reporting it, particularly if the institution is not responsive to the IACUC critique?

Brent?

>> Brent: Thank you. This is not an unusual circumstance for OLAW to become involved with and we will consult with both the institution as well as the IACUC regarding issues such as this. But our advice would be to start with trying to educate the Institutional Official, if that indeed is the roadblock to correcting the noncompliances that they have found.

If the Institutional Official is not responsive at all to the IACUC, we would be glad to mediate any discussion if possible, but as Ted suggested, I think a better course of action is to use a consultant, use an outside consultant. That person may help to identify the specific issues and emphasize the institution's responsibilities.

And I don't know if Ted has any other suggestions, but that's how OLAW would approach this kind of an issue.

>> Ted: I would agree with that. I mean, I think we've and probably many people on the phone, have been in that situation. It sounds like OLAW is aware of many examples of that. I know I've been in that situation in the past, and sometimes it takes some work from the IACUC to make some headway in that area so that having somebody—and it could be—as long as there's agreement with the Institutional Official, say, to have that gap assessment done, I think that proves to be a valuable tool.

>> Neera: Thank you, Ted.

[Question 13]

Another question we have for you, Ted, is: how do you get an institution to include ancillary personnel like contract, housekeeping personnel, that enters BSL-2 labs?

>> Ted: I think that that's a good question. I think what a lot of folks might do is limit the number of people that would access those facilities, whether it's animal facilities in general or BSL-2 laboratories. An example would be—I don't think it's uncommon to prohibit housekeeping staff from entering those facilities. And they may put more responsibility on cleaning to those that work in those facilities.

Other than that, I think talking to senior leadership is another good approach. Those that, in our case it would be, say, the vice-president of administration and finance, that's who housekeeping staff might report to, or facilities people that are changing light bulbs and things like that, report to, and communicating to them the need to have them involved in the occupational health program. And it's probably a great opportunity to educate those folks anyway on what they're seeing in an animal facility, for example, so that they're not intimidated or surprised by what might be there.

>> Neera: Thanks, Ted.

[Question 14]

Eileen, my institution currently has no on-site occupational health program with regard to our animal care and use program. However, we are working diligently to create this mechanism, given that we will soon be negotiating an Assurance with OLAW. What does this mean—what does it mean to enroll your institution's occupational health and safety program? Is there a specific system that must be created in order to complete that enrollment?

And by the way, thank you for this useful webinar.

>> *Eileen*: So the system that you need to create is your own institutional system so that you capture all of those folks working with animals, whether it's on hire or when they perhaps are already working with the institution and they begin to work with animals. Maybe from the protocol, if they're your animal services people, then that would be sort of obvious that you capture them when they were hired for that particular job. If someone moves within the institution from one area of work to an area where they're working with animals, they would also have to be included.

So, it really means that all employees must participate in all aspects of the program that you've developed in your occupational health and safety program as described in your Assurance.

[Question 15]

>> Neera: Thank you, Eileen. Ted, this question is specifically for you. Do universities need to follow OSHA regs?

>> Ted: That's a good question. I think it depends on the state you're in. In some cases, although just sort of stretching my expertise in this area. I don't know if others at OLAW would know. I think the way I would view it is even if you're not strictly required to meet OSHA regulations and maybe you have state regulations, there should be a general intent to try to meet those regulations. You know, they're not exactly the most onerous regulations in the world so I think it's really—you know, there should be an intent to provide a safe work environment and following those OSHA regulations helps in that way.

>> *Eileen*: We'd recommend that the institution contact OSHA and ask about their requirements under those OSHA regulations for their individual institution.

>> Ted: Good answer.

[Question 16]

>> Neera: Okay. So, someone asked if we will be talking about disaster planning as part of the program. As we mentioned earlier, we are planning a special webinar to address contingency plans in preparing for pandemics, so stay tuned for that. It should come out within the next week or so, more information on that.

[Question 17]

Another question: Can someone clarify if an occupational health accredited doctor, MD, is required to provide a medical evaluation of research personnel? Or may a general practitioner—medical practitioner, nurse practitioner or physician's assistant, provide these evaluations?

>> Eileen: So, the Guide for the Care and Use of Laboratory Animals again describes the program should involve input from trained health professionals, and they describe that as occupational health physicians and nurses. However, we do know of some folks that use general practitioner MDs in their programs. If they're a small program, they may use a general practitioner.

If that happens, there needs to be some coordination between your program and that physician so they [the physicians] know what they're evaluating when they look at the collection of the health history to evaluate the individual's assessment to work in an animal program.

So, there would have to be some earlier communication and perhaps a team approach to look at the risks of the program and those associated hazards with those risks. And that would need to be shared with the individual who agrees to take on your occupational health assessments.

>> Neera: Thanks, Eileen. Ted, this one is for you.

[Question 18]

I have seen prescreening occur at hire. How important is this and is it regulated?

>> Ted: From my understanding, OLAW would suggest that prescreening is an important element of the program. We prescreen individuals before they start working with animals. I can't say that we're at a point where we prescreen before hire. We certainly do that for animal care staff, husbandry staff, but we don't necessarily do that right now for, say, research staff because quite honestly, I'm not involved in the hiring of those staff or a post doc. Certainly, in the case of the animal care staff we do some screening and education at the time of hire.

[Question 19]

>> *Neera*: Here's another one for you, Ted. What would you consider appropriate documentation that a person is enrolled in an occupational health program?

>> *Ted*: For us, it's completing the medical surveillance health history and the exposure profile form that we have. Like I mentioned, that used to be a form that was a paper form that is now part of an electronic medical record system. So that's the first step in being enrolled, so that's the form that gets reviewed by our occupational health nurse and she evaluates both the potential exposure risks and their health history to determine if any mitigation should be recommended.

>> Neera: Thanks, Ted.

[Question 20]

Brent, I have one for you. We have a new animal care tech who started husbandry duties on her first day. She's been here for a month, but still hasn't received clearance by our on-base doctor to work with and handle animals. The paperwork has been submitted, but she has not yet been scheduled to be seen by the doctor. Should this be reported when the IACUC conducts a semiannual program review, which will be in two months?

>> Brent: So I'll answer that question and ask Ted to chime in as well, but I think it's important to see this is not meeting the expectations of the *Guide* and potentially putting the employee at risk, as well as putting the program and the institution in jeopardy. Waiting 90 days before meeting with a medical professional is a little excessive. I think it's important to look out for both the employee as well as for the program, potentially moving the employee to a non-animal exposure duties temporarily. And no, you should not wait another 60 days to address this.

Ted?

>> Ted: Yeah, I think that that does—I don't see that as being an uncommon challenge in that getting those assessments done early in their career at your institution or whatever. But I agree, that's over and above. I guess I would say that in many places I don't think it's a requirement to have an in-person evaluation. So these can be done remotely as far as I understand it, and so there is—you know, say it's working with rodents and there's nothing in their health history to indicate that they will or have any allergy situations, for example, then maybe they're cleared to work with animals and it doesn't have to be an in-person evaluation. I don't know what a doctor might learn from an in-person evaluation that they couldn't from that form or a phone call, I guess.

[Question 21]

>> Neera: Thanks. So, another question. And I think both you and Eileen have touched on this and discussed this. What about external contractors that must enter an animal research facility? What kind of occ health responsibilities does the institution have?

>> *Eileen*: Well, the institution has the same responsibility to either enroll individuals or offer enrollment in their program or advise the individuals of the potential risks and hazard of that area and offer personal protective equipment in the cases where that enrollment is not possible or reasonable.

>> Neera: Ted?

>> *Ted*: I would add the only other thing that I've seen in the past is say you have an external contractor that's going to be conducting work in an animal facility. I've seen institutions require that the contractor's employer ensure that that person has been through an occupational health program that is consistent with their own and to attest to that.

You know, some places might say, well, I'm not going to enroll somebody else's employee in my occupational health program, for example, but they will review and attest that that employee's own occupational health program meets their requirements.

>> *Eileen*: And I would just add to that that we have actually heard of institutions doing that, having a contract for facilities personnel to meet the requirements of their occupational health and safety program, but that would be for long-term continuing work in the facilities.

>> *Ted*: Yeah. You're right, I'm talking, you know, not short-term situations.

[Question 22]

>> *Neera*: So, to add on to that question, what about people that only enter the animal facility once, say for setting up hardware and [have] no animal contact?

>> *Eileen*: Well, I would go back to my original answer, in that individuals should be made aware of the risks of that area and the associated hazards and then [be] provided with appropriate personal protective equipment.

[Question 23]

>> *Neera*: Okay. Ted, can an individual who will conduct animal research decline vaccinations? If so, how would it be handled? Or Eileen.

>> *Eileen*: There are certainly personnel who decline vaccinations. The institution has to make the determination of how they're going to assess that and what their determination is going to be regarding access to the facility. So, it's completely an institutional decision on how they're going to handle those individuals—whether they're going to allow them into an area or whether they're going to decline their participation in the animal program.

>> Neera: Ted, would you like to add to that?

>> *Ted*: I would just add that a lot of institutions have a declination form so that you're documenting that they've declined a vaccine. I think that's a good practice.

[Question 24]

>> Neera: Okay. So here's a question: Vaccination requirements seem to be institution and context specific. Are there vaccines that are an absolute must for access to animal facilities and how do we deal with the growing and far-reaching anti-vax sentiments amongst the public? Ted?

>> Ted: I guess I'm not aware—it depends on what's in your animal facility, I guess is one answer, on to what vaccines would be required, but I guess the broader question or broader point I would guess is that I don't know if there are any vaccines that are absolute, that I'm aware of, unless I'm not thinking of them. At least not at our institution.

>> *Eileen*: Well, the *Guide* recommends tetanus as one [vaccination] that should be provided, and an individual should take, but there are also individuals that refuse [to do] that. So, then it's an institutional decision.

[Question 25]

>> Neera: Can you provide more information about the pre-employment evaluation? Are they performed as part of the candidate's interviews? Sometimes I feel that there is a fine line among the procedures and ADA [Americans with Disabilities Act] policies.

>> Ted: One of the things we do, and I think many others do, is write that into the job description, you know, so that that's a requirement of the job description. And that way it should preclude those that are unable to work with animals.

>> *Eileen*: I mean, we would agree with that. We don't really have anything else to add on that.

[Question 26]

>> *Neera*: So, I have one final question. What are some things other institutions do when they have limited nursing care on-site? Ted, would you like to [answer]?

>> *Ted*: You know, I think the things that I've seen are the things that we've described today, so sort of limited use of on-site or consulting services. You know, if your program is small, you

know, a handful of hours a week may suffice to provide the occupational health care that you need for a small program so that can be on-site or not. And we've also seen the use of remote services that can review those medical questionnaires and talk with individuals on the phone as opposed to being on site. So those are some of the bigger things, you know, the more common things that I've seen.

>> *Neera*: Thanks, Ted. So unfortunately, we've come to the end of our discussion on such an important topic during these uncertain times.

Slide 52: Animal Research and Public Support: A 2020 Vision for Strategic Communications and Micro-Messaging

Listeners, if you think of additional questions within the next week as you reflect on this webinar, please send them in to us and we will impose on Ted, Eileen, and OLAW staff to answer them. All additional questions will be amended to the end of the transcript, which we expect to post on the OLAW website as soon as possible.

Please feel free to contact OLAW should you have any questions or concerns with adhering to the provisions of the PHS Policy, *Guide*, and commitments detailed in your Animal Welfare Assurance as a result of the COVID-19 outbreak.

Depending on how the COVID-19 situation progresses, a special webinar will be developed to address contingency planning for pandemics. Please stay tuned again for that, for the date of that.

Many thanks to everyone, Ted, Eileen, Pat, Axel, and Brent, and especially our participants and those who participated in the polls.

You have all been incredibly generous with your time. We look forward to meeting with you again at our next OLAW Online Seminar on June 11. Paul McKellips, who is currently affiliated with the US Army, will discuss the three new micro techniques that are now driving message marketing on a global scale in his talk titled, "Animal Research and Public Support: A 2020 Vision for Strategic Communications and Micro-Messaging."

I wish everyone a safe and wonderful spring.

Good-bye!

Additional Submitted Questions Not Addressed During the Webinar

Question A. What if your institution does not allow pre-medical evaluations?

>> OLAW: The NRC Occupational Health and Safety of in the Care of Research Animals states that "Identification of new employees at risk and rapid evaluation for inclusion in the occupational health component of the occupational health and safety program is essential to ensure their protection." We suggest consulting the legal department or OSHA officials to determine why a pre-exam cannot be done. The risk of liability from a work exposure is greater than any privacy risk of a pre-exam. **Question B.** How does HIPAA affect the operation of an occupational health program? For example, would in-house staff review of medical surveillance information or communication of results with others at the institution violate this act?

>> *OLAW*: Only authorized medical professionals are to have access to employee health records. No other individuals, including the IACUC, are to have access to personal health information.

Question C. Who should be typically doing the risk assessments for institutions?

>> OLAW: Risk assessments are only to be conducted by authorized medical professionals. The *Guide* (p. 22) describes that "Medical evaluation and preventive medicine for personnel development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health professional, such as occupational health physician and nurses." The *Guide* (p. 18) further states that "Health and safety specialists with knowledge in relevant disciplines should be involved in the risk assessment and the development of procedures to manage such risks."

Question D. How do you identify the students taking classes with animal exposure?

>> OLAW: Identification of students with actual animal exposure should be obtained from the teacher/PI responsible for the class with input from the occupational health and safety personnel at your institution to determine the level of exposure acceptable to the organization, and to develop some mechanism to advise the attendees of the potential risks regarding the activity or animal exposure.

Question E. How often should researchers fill out the OHSP questionnaire?

>> OLAW: The health questionnaire is usually completed upon initial identification of animal exposure and updated when circumstances change. Individuals with special requirements such as TB tests may need annual or more frequent interaction with the health care providers. The *Guide* recommends ongoing hazard identification and ongoing risk assessment. "Once potential hazards have been identified, a critical ongoing assessment of the associated risks should be conducted to determine appropriate strategies to minimize or manage the risks."

Question F. Our Attending Veterinarian told us a few days ago that the N95 masks will not protect us from COVID-19. Is this true?

>> OLAW: Please consult the CDC website <u>https://www.cdc.gov/coronavirus/2019-ncov/index.html</u> regarding any specific questions on COVID-19 protections.

Question G. How do you ensure that staff provide health status changes in a timely manner?

>> OLAW: Conduct updates of staff periodically to remind them of health reporting. Have relevant information on the IACUC website.

Question H. Who is responsible for paying for aspects of the OHSP? Can the charges (e.g., evaluation of health history questionnaire) be passed along to the PI who is responsible for the individuals in his lab?

>> OLAW: The institution is responsible for the occupational health and safety program and for determining how costs are allocated.

Question I. Does a certified occupational health nurse (RN) at an animal care facility, require oversight from a physician?

>> OLAW: The roles of nurses and physicians would be addressed in the state medical practice acts.

Question J. If an IACUC member will not enroll in the occupational health and safety program (will not complete medical surveillance forms and will not go to clinic annually), can he stay on IACUC? I realize he can't perform semiannual facilities inspections, but can he remain on the IACUC?

>> OLAW: An individual who refuses to enroll in the OHSP may remain on the committee but cannot have actual animal contact such as during semiannual inspections. If an individual is not willing to conduct all the responsibilities of an IACUC member, perhaps another individual would better serve in this role. It is important that prospective IACUC members be informed of all expectations for completion of IACUC duties, including enrollment in the institution's OHSP or its equivalent.

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