**Date of session:** 11/3/2022

**CHELSEA PARSONS:** Good afternoon, everyone. And thank you for joining. We’re going to give participants just one more minute to hop on, and then we’ll go ahead and get started. So thanks for your patience, and we’re going to start right in about one minute. Thanks, again.

All right. Welcome, everybody. And thank you so much for joining our OneLab Network session today. My name is Chelsea Parsons. And I’m a Consultant with Guidehouse, supporting CDC’S OneLab Initiative. I just wanted to bring up a couple of notes and housekeeping items before our webinar today. If you have any technical issues throughout the session, please feel free to email our inbox. It’s onelab@cdc.gov. That’s onelab@cdc.gov. That’s for any technical issues you might be having, any follow-up questions following the session.

If you have questions throughout the session, you’ll notice in your bottom ribbon on Zoom that there is a Q&A function turned on. You can feel free to submit questions in there throughout the entirety of the session. We will save all questions for the end during a Q&A portion.

We’re going to try and get to as many as we can. But if we don’t get to your question, we will do our best to share the answer with you following the session. You can email additional questions to that inbox. You can drop them in the Q&A. We’ll try and do our best to address all of them.

All right, notice that we’ll be posting a link to live captions in the session chat right now. If you need closed captions throughout the session at all, you can feel free to open up that link. The only thing to note is you’ll need to keep that link open as well as this Zoom session open as well. You have them side by side.

All right. So let’s take a look at our agenda for today. So we’re going to start by talking about some new OneLab resources, and some that are relevant to this conversation. We’ll introduce you to our presenters and our moderator for the day. We’ll get into the main meat of the conversation when receiving samples from patients suspected to be infected with Ebola, what’s the plan?

And then we’ll have that Q&A session. We’ll try and do our best to get through as many questions as we can. And then we have one more event coming up in a few weeks that we’d like to share with you. All right. So I’m going to ask our OneLab Network lead, Alicia Branch, to come on join me on camera, and talk us through some of these resources before we get into our conversation for the day.

**ALICIA BRANCH:** Thanks, Chelsea. Before we begin the main presentation, I would like to take a moment to share some of the relevant, helpful OneLab network resources. First, I would like to highlight a LOCS message sent on October the 19th. Even though the risk of travel associated Ebola cases in US is low, CDC recommends that clinical laboratories review information on specimen collection, handling, and transporting infectious substances safely.

Next slide, please. Also, the new Emergency Preparedness Response Guide is a great practical guide to review. This guide covers available laboratory resources during an emergency response, and may help train new laboratory professionals hired to support emergency responses. Another helpful resource is the Ebola Specific Job Aid, which provides guidance for collecting, transporting, and submitting specimens for virus testing in the US.

Next slide, please. Additional and helpful resources can be found by visiting OneLab Rapid Education and Capacity Building Hub, or Reach. The link should be provided for you in the chat.

I want to remind everyone that the slide deck may contain presentation material from panelists not affiliated with CDC. In addition, presentation content from external panelists may not necessarily reflect CDC’S official position. Next slide, please. I want to introduce our moderator for today’s event, Dr. Nancy Cornish. Dr. Cornish is a physician, pathologist, and clinical microbiologists.

She earned a BA in philosophy from the University of Vermont, and a doctor of medicine degree, and completed her pathology residency at the University of Vermont School of Medicine. After completing her fellowship in clinical microbiology at the Cleveland Clinic foundation, Dr. Cornish served as the Director of the Clinical Microbiology Department at Cleveland Clinic, and then as a General Pathologist, and Director of Clinical Microbiology at Nebraska Medical hospital in Omaha, Nebraska. She now serves as a Medical Officer and Senior Advisor for Quality and Safety at CDC in the Division of Laboratory Systems

Dr. Cornish has been active in laboratory safety and biosafety for more than 20 years, and was awarded the 2019 CDC Foundation Gerald R. Cooper Laboratory Safety Award. She instrumentally led subject matter experts in the publication of Clinical Laboratory, Biosafety, Gaps Lessons Learned From Past Outbreaks, Reveals a Path to a Safer Future in the CDC’s town hall meeting on laboratory safety, use of laboratory instruments in June of 2022. Your moderator for today’s event is Dr. Nancy Cornish.

**NANCY CORNISH:** Good morning, everyone. I’m happy and proud to introduce Sheldon Campbell. He is an MD, MPhD, and a professor of laboratory medicine at Yale School of Medicine, and the Associate Chief for Clinical Laboratories at the VA Connecticut Health Care System. He completed his MD and Ph degrees at Baylor College in Houston, and did his residency and fellowship in laboratory medicine at the Yale School of Medicine. He’s board certified in clinical pathology and medical microbiology by the American Board of Pathology.

He is Director of Microbiology Chemistry and Point of Care Testing for VA Connecticut. He’s had 32 years of practice. And he has served on point of care, microbiology, and checklist committees for the College of American Pathologists, and as Division C Chair on the Professional Practice and Laboratory Practices Committee for the American Society of Microbiology. His research interests include education of pathology residents, and medical students, point of care testing, mycobacterial diagnostics, and laboratory utilization.

Dr. Pentella is also joining us today. He is a clinical professor at the University of Iowa College of Public Health, and Director of the Iowa State Hygienic Laboratory. He is a very experienced clinical microbiologist and infection control and prevention professional. He has served as the Founding Chair for the APHL Biosafety and Biosecurity Committee for six years.

He’s also written several articles and book chapters on biosafety, and given many presentations. He has served on Institutional Biosafety committees in Florida, Iowa, and Massachusetts. And he has also developed multiple successful training courses. And without further ado, let’s start the presentations.

**SHELDON CAMPBELL:** Thanks, Nancy. Dr. Pentella and I our dividing these up. And the title here is, When receiving specimens from patients suspected to be infected with Ebola, what’s the plan? And having a plan is really essential.

So we thought we should start with a situation update. On September 20, the Ministry of Health of Uganda declared an outbreak of Ebola virus disease due to the Sudan variant of the Ebola virus. And as of October 28, there were 109 cases and 30 deaths. There have since been additional cases and deaths since then.

So far, no suspected probable or confirmed cases outside of Uganda. The risk of importation into the US is currently assessed as low. Uganda is screening out departing travelers, and CDC is routing travelers from Uganda to the US through five airports for screening purposes. So there’s at least two layers of screening taking place here. Travelers without high risk exposures who are asymptomatic can travel onward, but the state and local health departments then in a third layer, will follow up with travelers for initial risk assessment and post-arrival symptom monitoring for 21 days after a Uganda departure. Next slide, please.

So our objectives here are for laboratorians and those who send specimens to them, and those who manage them to recognize the factors associated with risk and laboratory handling of specimens from patients under investigation. And we use the abbreviation for PUI for those patients subsequently, for Ebola virus disease. Review the potential test for specimens from PUI for virus disease, recognize the risk assessment approach for testing in persons under investigation, and discuss the steps that laboratories should take to be prepared to receive specimens from persons under investigation. This is a topic that inspires substantial anxiety. next slide, please.

Outbreaks of infectious disease are not new in human history. They’ve had a deep impact on societies on our literature. This painting is from 1887 describing the four horsemen of the apocalypse. And plague is one of the four horsemen in this setting. Next slide, please.

And societies have had various reactions to infectious disease. These include self punishment, persecution, particularly of marginalized and otherwise, powerless persons, or groups of people, and attempts to derive best practices. These have all been observed not only in historical times, but anybody who’s lived through the last few years can recognize these reactions in our own societies. Next slide, please.

So I’m going to start with just giving you some background on Ebola virus and Ebola virus in the context of this particular outbreak in Uganda. Next slide. Ebola virus disease is quite rare in humans, but extremely severe and often fatal. The average case fatality rate in recent outbreaks has been around 50%, but varies depending predominantly on the available resources for caring for patients. Community engagement is key to successfully controlling outbreaks. It’s not enough to just parachute in a bunch of help.

It’s critical to involve the persons in the communities affected. Good outbreak control relies on a whole package of interventions, case management, infection prevention, control, surveillance, and contact tracing, good laboratory services, safe and dignified burials, and social mobilization. And early supportive care markedly improved survival in Ebola virus disease. Next slide, please.

Ebola virus appears to be predominantly a virus carried by bats, though, what the exact ecology of it within the bat populations is a little unclear. Bats then transmit through various exposures to other animals, and typically, humans get it either from exposure to bats, or from exposure to other animals. It’s not entirely clear what route is most common there. But once the virus makes its way into human populations, then it’s not infrequent for there to be human to human transmission, though, that’s not so sustained human to human transmission is not a feature of the disease at this time. Next slide, please.

Clinically, the incubation period for Ebola virus disease ranges from two to 21 days, but typically, is a little over a week, eight to 12 days. A person with Ebola virus disease is not contagious at least through the usual routes until symptoms develop, and typically, viral loads are low prior to symptoms developing. Initial signs and symptoms are nonspecific, the usual associated inflammatory responses to any infection, fever, headache, myalgia, joint pain, fever, fatigue, abdominal symptoms frequently predominate as the disease progresses, nausea, vomiting, diarrhea, and abdominal pain. Unexplained bleeding occurs later in disease and is not invariably present. So these prodromal symptoms are important to recognize when assessing a patient for possible Ebola virus disease.

Unfortunately, it’s extremely difficult early in illness to distinguish Ebola virus disease from other viral hemorrhagic fevers, or common febrile illnesses, malaria, typhoid fever, influenza, Sars-CoV-2 infection. Finally, and disturbingly, relapses have occurred in persons post-recovery, particularly in immunologically privileged sites, like the eye, and the central nervous system. Next slide, please.

Right now, there is limited vaccine prevention and treatment possibilities against the Sudan strain of virus. There is a vaccine against the Zaire strain of Ebola virus, which was responsible for the largest and most deadly outbreak in 2014-15. However, it’s not tested and probably not effective against the Sudan strain. But a Sudan virus vaccine is expected to go into trials in the near future. There’s two treatments against the Zaire Ebola virus, both of them monoclonal clonal antibodies, but neither has been evaluated for efficacy against other species. Next slide.

Many, many outbreaks have occurred in historical time, the largest, 10,000 or more cases of Zaire Ebola virus in Central Western Africa. The current outbreak is with the Sudan strain in Uganda. Next slide. The large outbreak in 2015 occurred in Liberia, Sierra Leone, and Guinea, and involved more than 10,000 patients. Next slide.

In contrast, the 2022 outbreak in Uganda is confined to a few provinces within Uganda, and only between 100 and 200 cases as of this date. Médecins Sans Frontieres has deploying to address this outbreak. They were heavily engaged and gained a great deal of experience in the 2015 outbreak in West Central Africa, and are experienced both at Ebola treatment and at community engagement, and multi-system management of Ebola. Next slide.

So I want to talk a little more detail about transmission and risk of transmission for Ebola virus. Asymptomatic people who are incubating infection are not infectious through the typical routes. The virus in fully symptomatic persons is found in a large number of body fluids, including stool, vomit, urine, saliva, semen. There have been sexually– most likely, sexually transmitted cases, vaginal fluid, and sweat.

Virus can be detectable influence not always infectious, but some fluids continue to contain virus after recovery. So the hazards associated with virus infection are rather complicated in many. Infectiousness is least early in disease with increased risk as disease progresses, and As patients become sicker, and particularly, as patients develop GI symptoms, where vomiting, diarrhea may be difficult to contain. Not thought to be airborne. Contaminated PPE has been a source of transmission. Other fomites and inanimate surfaces are not documented to play a role in transmission. Next slide.

You can’t get Ebola through the air. You can’t get it through the water. And you can’t get it through food grown or legally purchased in the US. These are important things to recognize and for us in the laboratory community and the clinical community to communicate to the rest of the country. Next slide.

And once careful precautions for protecting health care workers are in place, they do work. This is an outbreak in 1995 in the Democratic Republic of the Congo. . And it graphs the number of infected health care workers against time with the number of cases.

And this arrow marks the point where health staff began using isolation precautions. And within about a week after that, consistent with the incubation period of the infection, cases in health care workers ceased. So we do know how to protect health care workers from Ebola even those engaged in direct patient care of patients who are very sick, and secreting large amounts of virus. Just a matter of doing it. Next slide, please.

Laboratory workers are really critical and essential in diagnosis and management of persons with Ebola, and of persons under investigation. CDC has guidance out on how to collect specimens and how to handle specimens to be tested for virus. Next slide. So here’s guidance on for health care systems in general. This is the header page for the guidance.

It’s continually changing. And so please do check it not just once, but more than once, because this guidance is under continuous revision as we get more experience both with the virus and the disease, and also within our own health care environment. Next slide. So CDC has for this purpose activated its emergency response structure. They’re standing up multidisciplinary CDC Ebola response teams, or CERT. We really don’t seem to be able to do this stuff without a lot of acronyms, do we?

They’re updating guidance on the management of patients with suspected Sudan Ebola virus, and outlining a process to access experimental Sudan virus therapeutics. Next slide. The 10 regional Emerging Special Pathogens Treatment Centers and 28 Laboratory Response Network Laboratories, predominantly state public health laboratories are standing up testing capacity. They’re also in the process of preparing specialized isolation units for treating patients with Sudan Ebola virus or other highly hazardous communicable diseases. Next slide, please.

So at this time, hospitals in the US fall into three groups. This is being rethought at the moment. But at the moment, it’s still the way we are organized. Most of us fall into the category of frontline health care facilities. Our role is to identify patients with relevant exposure history and compatible symptoms, isolate those persons, inform the health department, initiate testing if the patient’s risk is judged to be low. High risk persons should be transferred for evaluation and testing.

And us in the laboratories there need to be trained on specimen transport, waste management, standard precautions, and appropriate standard precautions for treating Ebola patients, clinical care of patients– treating might be pushing it– and handling those specimens. Ebola Assessment hospitals are the second level of hospitals in this case. And they’re expected to initiate Ebola testing and transport the patient to a treatment center if it’s lab confirmed. These patients are expected to maintain PPE sufficient for four to five days of care. The frontline hospitals are expected to have access to be sufficient for 12 to 24 hours of care. Again, this guidance is evolving, so check back frequently to see where it stands. Next slide.

And every clinical laboratory has a role to play. In the front line facility, we are expected to package and ship samples for testing and support care for at least 12 to 24 hours in the assessment hospitals to again, package and ship samples for testing and support patient care for up to 96 hours. And then the Ebola treatment centers are expected to provide definitive care for patients with diagnosed virus disease. Next slide.

So we in the laboratory community need to be prepared. In collaboration with other facility leadership, we have to plan what care and testing can safely be provided for persons under investigation, ensure that providers are aware of how to collect and transport specimens, have a plan for routine testing to support the care of patients under investigation for as long as we need to. Have communication and collaborations in place with the public health community so that they can monitor personnel involved in care for patients if a diagnosis should be established, have a plan for sending off the diagnostic testing for the pathogen, and have the resources to package and ship presumed category A specimens.

And this is adapted from the health care facility special pathogen preparedness checklist that’s been evolving over the last few years since the last major outbreak. Next slide, please. So I am happy at this point to turn this over to Dr. Mike Pentella, who will tell you how to do these things that I’ve outlined so blithely for you.

**MICHAEL PENTELLA:** Thank you very much, Sheldon. Welcome, everyone. Well, the first place to start is to perform a risk assessment and mitigate the risks that you identified. That’s the key to handling these specimens from patients under investigation. So by performing that risk assessment and implementing mitigation, the laboratorians in Dallas in 2014 were able to safely handle samples from patients who were infected.

So there is a hierarchy of controls which the slide depicts. The clinical labs can’t use the first two. You can’t eliminate the hazard, or do substitution, replace the hazard. But you do have engineering controls, administrative controls, and PPE that can be used to mitigate risk. So this is an inverted pyramid, because engineering controls are more effective than administrative controls. And that’s more effective than PPE, which is at the bottom of the effectiveness, even though it’s often the first thing we think of. So let’s go to the next slide.

So if you have a person under investigation, you’ll be getting certain specimens. First, it’s going to be a consultation between the clinician, the health department, and the CDC. And they’ll determine what kind of testing is going to be needed and what’s going to happen with those samples. So this is very important so that the consultation will determine the next step and it will be clearly planned out.

Then there’ll be collection of specimens that will be transported into the laboratory area. And will be transported to different lab sections once they arrive in the laboratory, but you’ll also need to be doing packaging and shipping to send to a public health lab, that LRN lab that will test the specimens for Ebola. All of the specimens may be prepared for testing in the receiving lab, and they may need to be centrifuged, tested on specific instruments. And then they’ll be discarded, sent to the medical waste stream.

So let’s look at that all a bit more closely on the next slide. The risk of a lab acquired infection is a combination of factors, which the slide is depicting. There’s an overlapping interaction of three factors. And that’s the agent, which in this case is Ebola, and the host of people, who may be exposed, and the environment.

So you’ll also notice that the words starting with a letter P on the outside of the circle. These five words then depict the pathogen, the people, place, PPE, and procedures. So moving on to the next slide, first, let’s define risk. That’s the likelihood of an undesirable event happening that involves a specific hazard or threat, and has a consequence, so its likelihood and consequence.

So in the risk assessment, you start by defining the situation, defining the risks within that situation, and characterizing those risks. But most important is likelihood in consequence, because you can think of all kinds of things that will happen, but most of them are highly unlikely that they would happen. You want to consider the likelihood of what you’re proposing is that risk that you want to mitigate. So let’s move on to the next slide.

And this is looking at the blood and body fluids that are samples, may be infectious. Looking at Ebola specifically, consider the features of transmission of Ebola from these particular body fluids. It’s a bloodborne pathogen, and we have decades of experience. As the page on the right shows you from OSHA, we have Bloodborne Pathogens Standard in effect from several decades. And this has helped us to safely handle other bloodborne pathogens, like HIV, hepatitis B, and hepatitis C. So we can handle Ebola as well by effectively using the standard and mitigation in the risk assessment.

Moving on to the next slide, you want to perform a risk assessment from the collection point, receiving, and handling of the samples. And you start by doing that by looking at the bedside beside the patient, and in the emergency room, for example, and think through the entire testing process from the point of collection, transporting it through the halls, to where it will go to the laboratory. What route will it take? In your specimen assessment area, what will be done with that sample?

Each facility is different. Sometimes, they prepare the sample in a session, and sometimes, they merely transport it on to the next laboratory that will handle it. What instruments will be involved? So you need to identify the mitigation needed at each of the steps and take action to implement the mitigation strategies that you identify.

On the next slide with some of the mitigation controls, like engineering controls include your HVAC system. Most importantly in this though, is your biosafety cabinet and sealed rotors that you might use of your centrifuge unit to prevent an exposure. Then you have your administrative controls, the policies, and standards, and guidelines. Hopefully, you have a biosafety plan in place where you’ve written out these administrative controls. Then the practices and procedures that you follow every day, and the personal protective equipment that your staff are trained to use both donning and doffing of PPE to prevent exposures.

So the next slide lists advantages and disadvantages of each of these. Not every mitigation tool is equal. Engineering tools like the biosafety cabinet, is efficient if it’s properly used, and can reduce the hazard. The disadvantage is that it is costly. It must be maintained, and it takes training to properly use it. Similar statements are true too for the other controls on this list. Each has its advantages and disadvantage. So remember, the PPE is the lowest level of mitigation. So you want to think of engineering controls, administrative controls, practices, and procedures before going straight to PPE.

So on the next slide, it’ll give you some example of how mitigation tools can be used in combination. The biosafety cabinet, for example, is employed in those administrative controls that go along with that biosafety cabinet. And there’s training and competency in the use of PPE, like gloves and gowns, facial, sometimes with a biosafety cabinet as well, a high protection respirator.

On centrifuges, you want them to have a sealed rotor. And you should have a policy in place that you open that rotor inside the biosafety cabinet. You have training and competent documentation on that centrifuges, as well as PPE. Let’s go into the risk assessment matrix on the next slide.

So based on the agent, in this case, Ebola, you perform a hazard analysis for this portion of the assessment, the risk assessment. You have to consider a wide range of factors that impact the risk of a lab acquired infection, including as listed here, the pathogenicity of the organism, the virulence, the infective dose, and the transmission. In looking at Ebola listed in red, I would consider the pathogen to be high, the virulence because it’s a lethal disease, and high infectivity, it’s high. Infective dose is very low, at less than 10 organisms, and transmission to various routes, either direct contact, or indirect contact with contaminated surfaces, direct contact with droplets and tissue, or percutaneous inoculation through a needle stick for example. So those all need to be considered through your risk assessment matrix at the various testing points in your laboratory.

Going on to the next slide, consider what test may be ordered for a person under investigation. The CDC guidance here lists the tests, a complete blood count, a electrolytes panel, liver function tests, coagulation testing, urinalysis, blood cultures, malaria testing, since that area of the world malaria is very common. And it may even be influenza testing, COVID-19, or even at this time, RSV testing. So you have to think through this, the various tests that may be performed on a person under investigation, because most likely, it is another illness rather than Ebola. So for planning purposes, consider any test on this list as a potential test that you need to be prepared to perform.

And going on to the next slide, when you’re looking at the test that you’re going to perform, you have to look at it from that three phases of testing perspective. So the pre-analytic phase, analytic phase, and the post-analytic phase. So think about all of the different tests in these different phases, and consider what’s being performed in performing the risk assessment. What tests are being performed when doing the risk assessment?

And the next slide, you’ll see a protocol driven risk assessment. So you consider every step in the process in a protocol driven risk assessment. What procedures are going to be performed? What hazards are involved in these processes and procedures? What’s the competency level of the personnel who perform those procedures, and the laboratory equipment in the facility that’s involved?

So for example, if you’re looking at doing the test, and preparing for doing the test with the sample, what are you going to do in this assessing area? Are you going to be preparing slides, for example, and how will that be handled, all the way through the post analytical step of discarding of it. So let’s go a little further and deeper into this on the next slide with the example of a risk assessment matrix for a protocol hazard.

You’re looking at the suspension volume. How much of the sample are you going to use? You’re going to ask, is there a potential to generate droplets or droplet nuclei for example, during pipetting? And how complex is the protocol? Is it mostly a standard repetitive procedure, or are there changes in the procedure that make it more complex? And is there any use of sharps in this at all?

So on that left hand column, you identify protocol hazards as I’ve listed there as examples. And then the assessor determines the degree of risk, given the procedure in the laboratory, whether it be a low risk, a moderate risk, or a high risk. And I’ve tried to give you some examples there to help guide you through those questions.

And this will lead then to the next step of selection of the mitigation tool to reduce the risk. While the risk can never really be reduced to zero, reducing it to a low level of risk whenever possible is the goal. So let’s go on to the next slide and look at the pre-analytical phase a little closer.

So what can go wrong during specimen receiving is what you need to ask yourself. How likely is it to happen? What factors do you need to consider in assessing that likelihood? And what’s the consequences if a tube breaks, for example? What factors do you need to consider in assessing that consequence? And what mitigation measures should you put in place to make the risk of the specimen receiving acceptable for you?

So you need to also consider risks like a leaking sample, and examining each specimen that comes in before you open that plastic bag to make sure that the sample is not leaking. And educate the submitters to make sure the container is tight and sealed. Maybe placing the bag sample into a secondary container before you transport to another part of the lab needs to be considered at this stage.

So going on to the next slide, I’ve listed for you some potential hazards. I’ve mentioned the leaking package, the breakage of the specimen container, some aerosolization, splash, or splatter. So if you’re taking sample out to transfer to another tube for example, there might be some splash and splatter. You might get some contamination on surfaces, and maybe some external contamination on waste containers.

So looking at these potential hazards then, going on to the next slide, I’ve listed some mitigation that you could consider. So a leaking package, maybe you want to consider transport from the patient bedside to the assessing in your laboratory with a secondary container to prevent any leaky dropping, et cetera. And then breakage of the specimen container would also be using a secondary container.

And use a biological safety cabinet to transfer some of the sample, or behind a splash guard, because everybody has a biological safety cabinet in their assessing area. But you could use splash guards, or additional personal protective equipment, like a face shield, to protect the individual. Contamination of surfaces, regularly disinfecting the surfaces after handling specimens from a PUI. And also disinfect those containers immediately after use, so that you can reuse them.

So going on to the next slide, I wanted to show you again the hierarchy of controls, but this time, talk about your filling in the safety gaps before you work on samples from the first PUI. So you want to look at all your equipment and your instrument safety, the laboratory waste management, disinfecting, practices, also, hand-washing reminders for staff, PPE selection use, and enforcement. Want to really emphasize enforcement, because I know it’s difficult. Some people find wearing PPE in the workplace not easy, but it’s so important for their safety. We have to enforce it. And as the time before the PUI comes to your facility, that you enforce this and make sure it’s part of your routine.

So going on to the next slide, this talks more about PPE. And you can may add or delete PPE based on the protocol driven risk assessment that you identify. And the point is to select the PPE according to the hazards that you identify, and train the staff to use the PPE, most importantly, monitoring the use, as I just said on the prior slide, and [INAUDIBLE] that PPE use waiting until there’s an exposure or other emergency that might happen. Supervisors are very important at this phase to monitor the use and enforce the practices on your administrative controls.

Let’s go on to the next slide, talk a little bit more about the analytical phase. So I previously showed you a list of tests that could be ordered on by PUI. And the list included the CBC, electrolytes liver function test, co-ag, malaria, viral respiratory pathogens. So when performing the risk assessment for this analytical phase, you must consider all of these different tests and instruments that could be used. Each instrument is different. Each laboratory is different, so you have to look at the hazards and determine what mitigation tools work best for your circumstances, and put those into place.

On the next slide, talk a little bit about malaria. And you’ll find that this CDC link, the use of Triton X-100 to inactivate the virus. Malaria signs and symptoms may be mistaken for Ebola, so being able to perform a test for malaria will remove the need to test for Ebola for some low risk patients.

So In Iowa, we recognize that not every lab can do malaria testing. And I’m sure there’s many other labs throughout the country who don’t do malaria testing. So contact your public health laboratory to see if they can do that testing for you. We have a plan in place that we would quickly get the slides to our state hygienic laboratory. We use a courier system. And then we could get the results very quickly back to the facility so that they would know the situation for the patient or person under investigation. We’ve done this for years with other tests as well, like measles. So we know we can do this.

So the next slide, the risk assessment for the post-analytical phase, so don’t forget the end of the testing process where you’re going to be discarding the sample and putting it into your medical waste stream, and how many laboratories don’t have autoclaves anymore. If you don’t, how is your site going to handle the medical waste? You may need to discuss this with your facility management staff and consider what needs to be done. So the next slide shows you a very important part of that, and this is communication.

You need to communicate with your staff, hear their concerns, answer their questions, talk to them about what they’re going to be doing. And you need to work this out now. Right now, we’ve sent emails to all of our labs in Iowa asking if they have a category, a shipping container, because they need to have that to be able to send us the sample. Even if you’re going to send it by a private vehicle, you need to put it and package it appropriately in a category A shipping container.

So staff have concerns how they’re going to do this, how they’re going to handle it. Cover all of the shifts, because the need is there to respond 24/7, 365. So speak with your administration. They need to know what you’re doing and what you’re being called upon to be able to do. So this is where you need to speak up to administration so they can support the laboratory and what you need to do for patient care.

Contact your State Public Health Laboratory, your health departments. The State Public Health Laboratory is the Laboratory Response Network Lab that will either perform the test for Ebola, or send it off to another LRN laboratory who will do the test. As Sheldon indicated, there are 28 laboratories that are able to do this testing. So some states will have to be shipping their samples to another State Public Health Laboratory.

Talk to them about how that process is going to be, how is it going to be handled, so that you’re prepared for this. Going on to the next slide, remember, planning is important, but it’s the culture of safety in the laboratory that is going to help you respond to this if you’re called upon to handle specimens from a PUI. Training is really helpful in this, but a good way to get ready is to perform a drill or exercise to make sure everybody is confident in their skills, and ready to respond.

On the next slide, I go into the biosafety roadmap, which I’m not going to go through each of the steps, but this roadmap would establish a strong biosafety program in your facility, build the competency of your staff, and make sure that they are ready to respond to Ebola, or any emerging pathogen that they may be called upon. On the next slide, I’m going to end with a painting that Sheldon– first, I have the checklist. It’s a final checklist for going through these nine items to make sure you are ready. And the next slide will show you a final painting from an Italian play in Naples. in the 1600’s, where 150,000 individuals died.

So this just goes to say that many through the centuries have faced the challenges of spreading infectious agents. And we can face this hazard and challenge as they have in the past in our clinical labs, and come to accept the hazards. We have come to accept many hazards, like HIV in the 1980’s. And we know how to protect ourselves and our colleagues while still meeting the needs of the patients.

We can safely handle specimens from a PUI. We have the knowledge. We can perform our risk assessments. We can mitigate the risk to reduce the risk. So that’s the end of my slides. And we can go on to the questions at this point. Nancy?

**NANCY CORNISH:** Hi. So we are going to take the rest of the time to answer questions. And any other questions that we don’t get to, please send them to our OneLab email, which is onelab@cdc.gov. We really want to hear from you, because we want to be able to help. And unless we know what the problems are, we will not be able to address them.

So I wanted to start with the first question. Have the varying equipment manufacturers been prompted to assemble BSL 3 decontamination best practices and provide them to their customers upon request? And I’m going to add to that the second question, how are you dealing with testing of PUIs, or even ill people who’ve traveled to Uganda, but don’t meet the epi criteria when manufacturers are telling labs that running PUIs through instrumentation will void their warranties and service contracts?

We had a meeting in June with the FDA, the CDC, CMS, and we clinical laboratories, and public health laboratories, as well as AdvaMed who represents manufacturers. And so what we did was bring up these concerns at that meeting. And we are actively working with AvadMed to address these concerns. I think it would be a good idea if you start getting these responses from your manufacturers and instrumentation contacts, that you send a message to OneLab and let us know about it, and which manufacturers they are, and we can work with AvadMed. Sheldon or Michael, do you have any additional advice?

**MICHAEL PENTELLA:** No, I agree with you, Nancy. That’s the best step to take. We need to speak with the manufacturers and help them figure this out.

**SHELDON CAMPBELL:** But also, don’t assume that 2022 is 2015, and that the answer you got in 2015 is the same answer you’ll get in 2022. I know that some of the manufacturers have developed decontamination processes for their instruments. So ask your manufacturer before you just assume that they’re going to say that you voided their warranty. Also, I’m pretty sure that running samples from PUIs through instrumentation doesn’t void the warranty. It might be that running samples from a patient who eventually confirms.

Remember that most PUIs are not going to confirm. There are 20.4 million cases of malaria a year in Uganda. And so far, there are less than 200 cases of Ebola virus disease. So don’t assume that PUI equals Ebola infected. That’s the worst case scenario, but it’s not the most likely scenario.

**NANCY CORNISH:** Agreed. Thank you, Michael and Sheldon. So we have another question. Please specify a front line hospital labs can perform non Ebola testing such as CBCs, chemistries, malaria testing on patients at low risk for Ebola. And I think we have discussed that in the presentation. Michael or Sheldon, do you want to reiterate the information?

**MICHAEL PENTELLA:** Yes, performing the risk assessment is where you should start, think through the entire process, and think what your risks and how to mitigate that risk. By doing so, you can safely handle those tests.

**SHELDON CAMPBELL:** And it has been done. The hospital, Dallas Presbyterian, had cared for their patients with Ebola for several days, and nobody in the laboratory was affected. The one thing that I would point out, though, that Michael didn’t emphasize enough is that laboratories actually can have some impact on the levels of that hierarchy.

In particular, the Dallas laboratory was very explicit about limiting the specimens and controlling when they came. So typically, specimens were collected from those patients once a day, brought to the laboratory. A dedicated small trained group of people in the laboratory did the testing. And then the laboratory reopened for doing other things. So they exerted control both over the number of tests that were run, when they were run, and kept the samples sequestered from the usual processes in the laboratory.

**NANCY CORNISH:** Yes, and there’s an additional question to this original question. It says, if routine instrumentation and procedures in the lab can be used for such, if not, please specify additional precautions. And I think that really depends on the instrumentation you’re using and your risk assessment. So each instrument that you need to use, you need to do your risk assessment and do your mitigation to be able to use it safely.

And Sheldon and Michael have both brought up Texas. Texas Health had a patient with Ebola through their doors and to their ED, and they successfully cared for that patient, as well as two health care workers who became infected. So they had three Ebola patients. They’re a community hospital, and they handled them very well and effectively, and none of the laboratory professionals running those tests for those patients became ill with Ebola. I think we really have to point that out.

**MICHAEL PENTELLA:** And I’d like to add one more thought, Nancy. When you’re looking at new equipment, remember this experience with Ebola now, and make sure that the equipment can be used safely, that it’s a closed system that would be used to test specimens from a patient who possibly could have Ebola before you purchase it.

**NANCY CORNISH:** That’s a very good point, Michael. Alicia, I think we have one more minute left, so you’d like to do your reminders. And we can answer the other questions via email. So please send in your questions to onelab@cdc.gov and let us know your concerns. Alicia?

**ALICIA BRANCH:** Yes. Thanks, Nancy. Thanks again, Dr. Campbell and Dr. Pentella, as well as Dr. Cornish for today’s presentation. Here are some important reminders from today’s presentation. There are no documented Ebola laboratory acquired infection cases in the US, and partly, because you want to continue to follow the OSHA bloodborne pathogen standard as well as your special standard precautions.

You all, again, Dr. Campbell said, check CDC’s guidance regularly, because guidance is constantly being updated, and things are changing as we get to know more and more about what’s going on in Uganda, as well as performing a site specific and activity specific risk assessment. Next slide, please. And speaking of activities specific and risk assessment, you will want to join us on November 17 at 12:00 PM to 1:00 PM– this is Eastern Standard Time– for a webinar specifically on risk assessments related to specimens being received, and that may have Ebola.

I think the link should have been provided for you to register in the chat. If not, it will be sent to you as well for all who have registered for today. And one of the things we wanted to do is really say, we apologize for the delay.

And we hope that this webinar was actually helpful for you, and we look forward to you joining us on November the 17th for our risk assessment, because I noticed that there were quite a few questions for our Q&A about risk assessment. So join us on November 17 for an in-depth walkthrough of