# Reducing the Risks of Clinical Laboratory Infectious Diseases

All right. Let’s go ahead and get started. So my name is Chelsea Parsons, and I am a consultant with Guidehouse supporting CDC’s OneLab Initiative. We’re really excited to have everyone here today, and especially excited for our special guests who will be presenting on this very imperative topic.

A couple of notes about the webinar before we dive in. If you’re having any technical issues throughout, feel free to email our OneLab inbox. It’s onelab@cdc.gov. That’s onelab@cdc.gov. If you or any colleagues are having some issues joining the webinar, we’ll be monitoring that just to help mitigate any of those issues.

If you have any questions throughout the session, I want you to insert them in the Q&A function. So you’ll see that on the very bottom of your screen in the banner below. That is where you can address any questions to our OneLab team specifically about OneLab or about the topic at hand as well.

We’ll have a Q&A at the very end of the session where we’ll try and get through as many of those questions as we can, but if any questions do arise after the event or we weren’t able to get to your question, please feel free to shoot an email to our inbox that I just listed, and that’s onelab@cdc.gov.

You’ll also see a link to closed captions popping into the chat here in a second. Those will enable you to access closed captions live throughout the event. The one thing I’ll note is that if you are going to access closed captions, please be sure to have both screens pulled up. So you’ll need the Zoom webinar pulled up as well as the closed captions link.

So let’s just go ahead and walk through our agenda for today’s session. So we’ve got some exciting news. We’re announcing our new OneLab Network Lead. We’ll be presenting– we’ll be introducing our presenter, Dr. Shawn Gibbs. We’ll be going through some OneLab resources, and then we’ll get into the meat of the conversation today. We’ll end with that Q&A session like I said, and we have an upcoming event next month that we’ll share with you.

So first I’d like to take a moment to announce the departure of our OneLab Network Lead, Dr. Triona Henderson-Samuel. We’ve been on these calls before. You’ll definitely recognize Triona. When she was here, she was an incredible network lead, and she has accepted an incredible new position within CDC. We’re very excited for her. We hope she’ll come join us maybe as a special guest coming time, so we want to wish her congratulations.

And now I’d like to introduce our new OneLab Network Lead, Dr. Alicia Branch. Alicia Branch is a health scientist and safety specialist in CDC’s Division of Laboratory Systems, Quality and Safety Systems Branch. Dr. Branch is over 20 years of professional experience as an academic researcher and she served in various roles in the clinical laboratory.

She supported three pandemics at CDC, including serving twice during the current COVID-19 pandemic as a separate subject matter expert for external biosafety, and as a laboratory scientist on CDC’s Infection Prevention and Control Team where she performed point-of-care SARS-CoV-2 testing in three nursing homes facilities in Atlanta, Georgia. So welcome, Dr. Branch, we’re so excited to have you here.

And for our next guest, I’d like to introduce our speaker for today, Dr. Shawn Gibbs. Dr. Shawn Gibbs is the Dean of the School of Public Health at Texas A&M University. He has over 100 articles on industrial hygiene and environmental exposure assessment focusing on disrupting the transmission of highly infectious diseases such as COVID-19 and Ebola virus disease.

He was a member of the United States Environmental Protection Agency Board of Scientific Counselors, Homeland Security Subcommittee, and the Southeastern Conference Medical Task Force on COVID-19. He was a US Faculty Fulbright Scholar to Egypt and has been the principal investigator of three Fulbright Junior Faculty Development Programs, Egypt and Libya.

His research has helped determine national policies, procedures, and best practices for responding to Ebola virus, COVID-19, and other highly infectious diseases. Dr. Gibbs has held roles in organizations such as the National Ebola Training and Education Center, Hispanic Health Disparities Research Center, NIOSH People and Aging, and the Director of Research for the CDC DHHS-funded Nebraska Biocontainment Unit.

Before we give this to Dr. Gibbs for his presentation, I’ll turn it over to Alicia to share some of our new resources. Alicia?

Thank you, Chelsea, for that introduction. I’m excited to be with you for the OneLab Network Lead, and I look forward to continue the great work. But before we get to the main presentation, I would like to take a moment to share some new resources. We are excited to introduce the OneLab Rapid Education and Capacity-Building Hub, or REACH, a customized learning management system for laboratory professionals.

OneLab REACH is the first of its kind. It’s a CDC-developed learning management system created specifically to meet the needs of laboratory learners. Consider this a laboratory professional’s one-stop shop for relevant resources for COVID along with other resources, and they’re found in various formats such as videos, downloadable and printable job aids, as well as full courses, including courses for PACE credit. You can see the link in the chat.

The Division of Laboratory Systems hosts LOCS calls every third Monday of the month, and the calls are an opportunity for CDC and other participants such as federal partners and professional organizations to provide updates and answer questions from the laboratory and testing community about emergency preparedness and response.

And lately, of course you know in the last three years, it’s been about SARS-CoV-2, and more recently, about the monkeypox updates. The calls are scheduled for one hour, and we are inviting you to join us on our next call which is scheduled for Monday, September the 19th from 3:00 to 4:00 PM Eastern Standard Time. If you haven’t opted in yet, send an email to locs@cdc.gov.

And we’re excited to announce a new emergency preparedness response guide which will cover laboratory resources during biological, chemical, and radiological emergencies. Consider this a helpful tool to train new laboratory professionals hired to support emergency responses. And this is expected to be released in September.

OneLab has many other e-learning training and resource relevant to today, including today’s– relevant to today’s topic. You can access this via the OneLab REACH for free. See the links and for these resources in the chat. I like to remind everyone that the slide decks may contain presentation material from panelists not affiliated with CDC. In addition, the presentation content from external panelists may not necessarily reflect CDC’s position.

Please note that we will not offer PACE credit for today’s session, but stick around to hear about our September PACE credit-eligible network event. And now, I’ll turn it over to Dr. Gibbs for his presentation.

All right. Sorry, that took a second longer than I anticipated. Hopefully now you can all see and hear me. So before we get started, let’s thanks our– give thanks to our host, the CDC, for putting on this presentation this afternoon. I’d also like to thank them for a premier time slots.

I love the East Coast Central Time post-lunch time so that not everyone is wanting to get to lunch. Sorry to those of you on Pacific and Mountain Time who are probably just now sitting down to lunch and watching this while having lunch. So just wanted to let you know, what we’re doing is I’ll spend some time on lab-acquired infections, then the rest of our time will be on highly hazardous communicable diseases in laboratories. And then at the end, we should have some time for a good Q&A.

So the reason why I’m here today, aside from being a Dean of Texas A&M University’s School of Public Health, is I’m here because I’m a certified industrial hygienist. My research focuses on disrupting the transmission of highly infectious diseases. I’ve worked for a number of years as faculty for the National Emerging Special Pathogens Training and Education Center, as well as the NIHS’s Worker Training Program.

And more relatively to years, I spent a number of years as Director of Research for the Nebraska Biocontainment Unit, including when we were treating Ebola patients in 2014 and 2015. I’ve had a– I’ve had a lot of experience in this area, both with treating patients as with– patients with highly hazardous communicable diseases from a laboratory standpoint, as well as dealing with persons under investigation.

I’ve also had the distinction of having to set up a point-of-care laboratory for treatment of an active Ebola patient on very quick, short notice. So there’s a lot of things that we’ve seen in regards to this that I’d like to share my experiences with you today.

Now the one thing I will say is, I don’t think that there’s any one person in the country who can answer any and all of your questions, so particularly when we get to the Q&A portion, I’m happy to answer what I can, and if there’s something I can’t, I can get back to CDC and get that answer back to you.

So need to also thank that this presentation is brought to you by a Texas A&M School of Public Health as an addition to the CDC. And it’s through funding from NIHS as well as CDC ASBrS, and as well as the American Industrial Hygiene’s Distinguished Lecture Program. So I greatly appreciate the CDC and other sponsors.

We’ll be going over a number of items here that are related to the objectives that I’ll go over in a second. At the end of the presentation, if you had the chance to or the ability, I’d appreciate it if you could go into the Qualtrics survey and just let us know what you think of the presentation.

So before I get to the learning objectives, I’d also like to thank Dr. Peter Iwen, a colleague of mine I worked with very heavily at University of Nebraska Medical Center and still do to this day, who provided a number of slides and perspective for this presentation.

As well as Dr. Scott Patlovich who’s an Assistant Vice President of Environmental Health Science Safety at University of Texas Health– University of Texas Health at Houston who provided a number of slides in regards to the laboratory-acquired infections portion.

So the objectives we’re going to be covering today are essentially these four objectives. These objectives are the basis of what we’re going to hopefully be discussing, and then at the end of the day, what I hope you take away is the importance of developing a culture of safety within your organization and empowering employees to provide constructive feedback and to point out potential safety issues become before they become an issue.

When it comes to the cultivation of a safety culture within a laboratory or an organization, I cannot highlight enough the importance of leadership and the supervisors within this, and really working with people so that they understand that their voices are going to be heard.

A couple of examples of this is a number of years ago when I was with Nebraska Biocontainment Unit, one of the things that we did as we went through our processes is even though I was the person who helped develop many of the SOPs, everyone was empowered to point out if I had missed a step or if anyone in the system had missed a step.

I was at another organization a number of years ago, and this is outside of a laboratory, I was dressed as you see me now, jacket and tie, walking around, and guilty like many of us, I was checking my email on my cell phone, and a young intern came up to me and said, here at this organization, we don’t text and walk.

I just want to highlight those of examples of what we can do when we empower everyone in our organization to think about safety first as they’re going through our various processes.

So basically all of us on this call know that a laboratory-acquired infection is any infection, illness that can be traced back to our laboratories and as a result of our responsibilities. It is of the utmost importance that what we do– what we– that we do what we can so that we can protect those within our laboratories, and that by protecting those within our laboratories, we’re also protecting our communities.

So whether we’re talking about a research laboratory or a clinical lab, the last thing we want is for an infection to impact one of our team members, and then through, that team member impacting our community.

Most of us on this call will be in clinical laboratories where you could see absolutely anything walking through your door. And I would like to talk about the importance of preparing for absolutely anything because the most likely scenario is you are already going to be running a variety of tests even before you know the person has a highly hazardous communicable disease.

So it’s very likely that their samples are in your clinical laboratory before that highly hazardous clinical disease is suspected or even confirmed. And I can’t stress enough the importance of preparing your procedures for that unknown. Your laboratories are environments that you can control. You can control many of the elements within the infectious disease organisms, and you are set up to successfully manage the risk and the perception of risks.

It’s important to understand that we don’t eliminate risk, we only manage and reduce that risk. And we have to understand and educate our people that these risks and these potential exposures are everywhere, but what we can do is work our best as a team to reduce them.

A number of years ago, I was doing a site assessment for a clinical laboratory, and we were preparing them as through the CDC’s Rapid Ebola Preparedness Program. And I remember having a conversation with a technician, and the technician wanted to point out specifically to me that the Ebola virus disease was a pathogen and we had to treat it as such.

And I remember thinking very odd– that comment was very odd. To this day I don’t know if that was– maybe that’s not what they intended to tell me, but my response was, well remember, here in the clinical laboratory, almost everything you’re dealing with is a likely pathogen, so we have to treat it as such.

And I don’t know if that person may be just in the moment just wasn’t able to express themselves properly or if they had become so familiar in their environment that they’d disconnected from the risks that they’re dealing with on a daily basis. I mean, not all of the organisms are going to be Ebola or Lassa or other things like that, but they can be things that would have additional impacts as well.

We are all familiar with the various routes of transmission that these organisms may take. However, when individuals become comfortable in their surroundings, they begin to let their guard down. They begin to maybe think that they’re above some of the SOPs, maybe above some of the practicalities of what’s been put into laboratory.

And that’s where that importance of that safety culture comes in. You need to continually have reminders of the potential danger of the risks of the work environment and of the risks of the work that your teams are doing, and make sure that you have built into your processes the necessary safety check-ins and process improvements.

There’s a variety of different ways that this can go. I want to make sure that we’re talking about not only the various safety outlets that are announcements that we would put out, but also opportunities for group discussion, opportunities for individuals working in that lab to point out something that may have occurred over time or began developing over time that you, as someone who may or may not be involved running those specific tests day in, day out, may not recognize has evolved.

Our risk assessments and our standard operating procedures need to take into consideration each of these potential routes of transmission and also take into consideration how these potential routes of transmission interact not only from the pathogen, but from that pathogen going through the various steps within the clinical laboratory.

Laboratory-acquired infections are not new. As you can see from this graphic that Dr. Patlovich provided, they go back hundreds and hundreds of years. Laboratory-acquired infections have existed as long as there have been laboratories, and the potential for laboratory-acquired infections exist today and will continue to exist in the future.

I want to highlight a couple more recent studies on laboratory-acquired infections. If you’ve not had an opportunity to pull some of these out, and I’ll go over one of the tables in a second, what these studies show us is that the majority of laboratory-acquired infections are caused by a small number of organisms and caused by a smaller number of procedures that we can really focus in on.

And one of the other things that I’d like to highlight with this is, if you take a look at this table, this also shows that we are getting better at controlling laboratory-acquired infections. The most recent data shows the number of laboratory-acquired infections decreasing at a time when reporting and understanding them are getting more– are getting more robust, are getting better. Our ability to recognize a potential or a likely or an actual laboratory-acquired infection is better today than at any other point in history.

It’s very likely that the older data that you’re taking a look here represents an underreporting of that data because of the lack of robust identifications during that time period in which this table is pulled together.

This is really an interesting study that I’d like to highlight that takes place within Wisconsin– it’s Wisconsin Clinical Laboratory-focused.

Although they are important to assess, one of the things that really came out of this study is that risk, data specific to patient occupation, symptoms, travel history, other important pieces of information to various risk assessments are often unavailable or only partially available to laboratory personnel. And therefore, less contributed to a microbiology-focused biosafety risk assessment when you’re looking at specific samples coming through.

Now I’m not saying or pretending that you have the ability to do that for every sample coming through your laboratories, particularly those operating large-scale hospital laboratories where you’re putting through tens of thousands or more samples in any given day, it’s just often what this found was there was no ability to flag that information when it was going to be important to the laboratory clinicians.

So this is a very important statement which is essentially, you never know what you’re going to see or be told that you saw after the fact. So you must remain vigilant throughout the entire processes while you’re working in your laboratory environments.

Now one of the other things that came out of this study was task assessment identified deficiencies that trended higher within the general, not microbiology-specific laboratory for core activities such as packaging and shipping, direct microscopic examination, and culture modalities solely involving screening of organisms’ growth. While this was specific to Wisconsin, these are also areas to consider for vulnerabilities in all clinical laboratories.

Another good study, particularly because of the thoroughness of the data involved, this is from the Canadian– this is Canadian data from their Laboratory Incident Notification System, and it showed 42 laboratory incidents that were reported in 2020. And they calculated that out to essentially 4.2 incidents per 100 active licenses within their system.

Most of these were during microbiological activities, which is similar to what the previous study in Wisconsin found. They also indicated that 28 of the 42 incidents involved an inhalation-based exposure, and in particular, that’s one of the things that I think oftentimes can be overlooked in many clinical laboratories, is the potential for aerosolization, and thus, inhalation during the various processings that we may be doing in the various laboratory environments for a variety of tests

I also want to make available to you, this is from the American Biological Safety Association, and they have a searchable laboratory-acquired infection database where you can find US-based exposures that has more of a resource laboratory-based focus.

Now this is a very different type of data set than the Canadian data that we saw, but by reviewing it and looking through it, you can get an understanding of what some of your peers across the country may be running into.

Now, any time we’re talking about biosafety or clinical laboratories, I always want to highlight a number of the various resources that are out there. So there are a number of guidelines available to clinical laboratories and broad research laboratories as well. Of course, we have many of the CLIA items related to biosafety which provide broad guidelines that must be implemented by the operator.

Now these broad guidelines, while sometimes may be frustrating, I think that they’re very appropriate because clinical laboratories are not cookie-cutter. As all of you know, clinical laboratories don’t look like each other. Eventually, even those with similar capabilities are likely to have very different layouts that evolve over time that are based upon the spaces that they’re in as well as the additional spaces that they’re able to grow within.

These clear requirements highlight the need to understand the uniqueness of each facility and the states and/or locality in which they are– which they reside. We have to make sure that we’re working within the various local and state regulations as well as the various accrediting bodies.

It is important to understand that each clinical laboratory facility will evolve over time, and that as they evolve, their safety procedures and SOPs must be updated in face of those changes. And these are going to be changes in space, configurations, new equipment, new personnel, and so on, and this is one of the reasons why I think the constant safety or biosafety check-ins with your team members within the laboratory are so important.

The clinical laboratory is constantly evolving, and even if it’s static for a couple of months in regards to its fit configurations, we all know new techniques, new equipments, space limitations, growth within your facilities are constantly going to be changing what you do.

So often in industrial hygiene, we always come back to the hierarchy of controls. As a certified industrial hygienist, I think I’d have to go back and check, but I may be legally mandated as part of my CIH credentials to, in every presentation, show a representation and a figure of the hierarchy controls.

One of the things that I want to say is, these aren’t magic. These alone do not eliminate risk. And remember, all we’re doing is reducing risk. Too often what I see are people getting into the various areas within the hierarchy of controls and not understanding that they need to be used in conjunction.

That they need to be used across what you do. And in some cases, I feel that representations like this where we talk about PPE being the least effective sometimes may, to team members and to people in safety, inadvertently change how people perceive PPE.

So while PPE are the least effective, when used in conjunction with your administrative controls, with all of the engineering controls that exist within your clinical laboratory, particularly for inhalation prevention during various potentially aerosol-producing procedures within the clinical laboratory, they are still very valuable.

And I just want to make sure that as you’re communicating with your team, as you’re doing trainings with your team and you’re showing an image like this just as I’m doing, you’re really expressing to your team members that these are all meant to be used in conjunction with one another until you get to such a point that you’re able to successfully reduce the risk to the minimum that is either regulated or that makes you feel the most comfortable within the laboratory.

So essentially lessons learned when you’re talking about being in the clinical laboratory is, again, I want to highlight the importance of empowering those team members working in your laboratory. I want to highlight the importance of culture. That just developing that safety culture, just developing that culture where they feel comfortable enough to come back to you and politely and respectfully question an SOP based around a potential safety issue.

And this could just be around how a cartridge is ejected and the potential for aerosolization while that cartridge is being ejected. And you want your team members to have a mechanism to provide feedback into those SOPs and feedback into those potential risks, particularly as things are evolving month-to-month and year-to-year within your clinical laboratory.

So now as we move away from day-to-day laboratory-acquired infections and into highly hazardous communicable diseases, one of the things I really like to highlight– and these are all pictures of– so the 747 there, that’s an image of an exercise that teams I worked with were involved in a number of years ago, and the pictures of the ambulance and such that are on my right are of actually of Ebola transports that I was part of.

And one of the things that I want to tell you is, unless the patient comes to the hospital in a transport like this, you may not know what you’re dealing with. So you may need to make sure that you have your facilities designed in such a way to process for the unknown.

Highly infectious diseases or highly hazardous communicable diseases, however you want to call them, aren’t always labeled as clearly as these images. Matter of fact, when we were preparing to do one of the Ebola transports and treatments, I was working with one of the paramedics and we had been going over training over and over again. And I was asking him if he had any questions, and I remember what the paramedic said because it’s something that has stuck with me over the years.

And he just said, Shawn, when we’re rolling up to a house on a Friday night, I don’t know what I’m walking into. I don’t know if I’m walking into a case that’s been called as someone having a cardiac event and I’m going to be walking into a domestic violence situation or an overdose or potentially an infectious disease.

But with the situations that we’re in where we’re doing defined highly hazardous communicable disease transports, his understanding was, he felt more confident in what we were doing because he knew exactly what he was getting into, he knew exactly what to expect, and we had choreographed it down for the transport all the way into the facilities. That’s not going to be the case for most people within clinical facilities.

We had established– sorry, I want to highlight the importance of establishing a risk assessment and SOPs that protect your workers regardless of the information that you have on-hand. So these are examples of two commentaries that I helped prepare for the American Industrial Hygiene Association, one in 2018 and one in 2022. And I just really want to highlight the importance of clinical laboratories working with industrial hygienists and vice versa.

The importance of a risk assessment cannot be underestimated, but also knowing the quality of that risk assessment and the person conducting that risk assessment is extremely important. Just as I shouldn’t be the one in the clinical laboratory running the clinical tests, there are other people out there who should not be the ones conducting risk assessments of those tests.

I think the industrial hygiene field needs to actively increase its capabilities and quality of its members to do both these types of assessments in terms of operation and in the development phase prior to manufacturing and marketing of equipment. And as we get in one of the things that I’m going to highlight is, many of the pieces of equipment that we see out there that are operating in your laboratory are designed for a testing function, as they should be.

But I think oftentimes the end user safety or the individual who will be repairing that piece of equipment’s safety is not taken into consideration at the level that I believe it should. I know that an industrial hygienist can be bring a perspective to these challenges, not just to identify potential exposures, but also to work on solutions to reduce those solutions– to produce those solutions.

It’s also important to know that your risk assessment isn’t just something that you do once. Your risk assessment is going to be continual. Your risk assessment is something you’re going to be revisiting as you’re changing your SOPs, as you’re changing your profile within your space, as you’re changing equipment, and just as you get more experience working through various new tests that you may be implementing within your laboratory.

And I also think it’s important that these risk assessments can’t be conducted in a vacuum. So it should not just be an industrial hygienist or a clinical laboratory supervisor.

This is one of those things where you need someone who is familiar with the testing that’s going to be implemented, someone who’s familiar with the equipment, someone who’s familiar with how diseases are transmitted and can be– and how the exposures can occur within an occupational environment, and that those groups can cooperate across the board to make sure that you’re putting forward the safest environment that you can for your team members.

So these are some slides that my colleague Peter Iwen provided. And this is for if you run into essentially– you’ve identified a highly hazardous communicable disease and you find yourself in a situation where you’re having to help to respond them.

The perception of risk is going to be very different if your organization is voluntarily or intentionally takes on the responsibility of treating a patient with a highly hazardous communicable disease versus if such a patient happens to just show up at your ER or so on.

So those facilities that are the regional treatment centers or are being stood up to address state and national needs for special pathogens are going to be held to a higher standard than what are referred to as your frontline or your assessment facilities in which these facility– or these individuals may just walk into. So that perception of risk is going to be much different. The expectations of those facilities are going to be much greater.

Now this may seem a little bit contradictory to what I was saying earlier, but this is not intended to be a contradiction of the first half of this presentation where we discussed the need to be ready for anything.

What this is is it’s essentially– this is an acknowledgment of the reality that when you are opting in to treating a highly hazard– or sorry, a patient with a highly hazardous communicable disease, that there’s going to be greater scrutiny and greater expectations both internally and externally in regards to your safety culture, your process and procedures, and your risk assessments.

While your SOPs may have been written to handle anything, once a known, highly hazardous communicable disease is detected, the need for additional containment options will become a paramount– sorry, will become apparent. Staff risk perceptions now change. Individuals that have been working in your laboratory for years may now not want to handle these samples. They may have a different perception of these samples and a different potential– a different perception of their risk to these samples.

This is something that you’re going to have to manage. And one of the reasons why this may be in advance, whether you’re intentionally planning to treat a highly hazardous communicable disease patient or if you’re just preparing for the chance that one may present within your ER, that it may be good policy in advance to identify those within your clinical laboratory who would opt in to advanced training and advanced education and understanding about what it takes to go through the processes for these types of samples.

In order to reduce– sorry, in order to reduce risk further, you may need to conduct testing across multiple locations. There may be tests that there are point-of-care devices available to that can be done in the patient room or adjacent to the patient’s room. Early on when we were treating one of the Ebola patients, I was part of a group who was tasked with setting up a point-of-care laboratory in a vacant patient care room next to where the Ebola patients were being treated.

Testing may also need to be done in the clinical laboratory under a higher level chain of custody and more robust SOPs. Testing also may need to be conducted depending on what you’re looking at within a BSL-3 facility either at your site or across the state or even shipped out to CDC or others.

Depending on the organisms in your facility, you may have to say that you cannot do a test safely as you normally would. And this is something where you’re looking at some of– when you get to the point where you’re looking at some of these more robust, highly hazardous communicable diseases, these are ones that would normally be handled in a BSL-3 or BSL-4 research laboratory, but now you’re dealing with it in a clinical environment because there is a patient who’s been infected.

You’re going to have to work with the care team, you’re going to have to work with the physicians on identifying what tests can be done, what tests can’t be done, and where they can be done? And if they’re tests that can’t be done that the care team believes are going to be instrumental to them, looking at alternatives as to what can be done.

You’ll need to manage expectations of the care team and continually reinforce safety culture with that laboratory team, and I would say even beyond your laboratory team.

You may find yourself, if you’re working with a highly hazardous communicable disease patient, not only needing to manage the expectations and the perception of risk with your employees, you may find yourself in need of having to develop and put together information for their families as well. Or putting together information or listening environments so that their families can ask appropriate questions.

And in these situations one of the major lessons that I’ve seen being very important is just communication, communication, communication. Really making sure that you’re not only– and that communication needs to be bidirectional.

So not only communicating to your team members what’s being done, why it’s being done, what you’re doing to protect them and their safety, but also listening to their concerns and addressing their concerns and making sure that they know, at the end of the day, you’re very aware that in this situation, you’re not only protecting them, you’re protecting their families and you’re protecting the community that you all live within.

So these are some– this paper and the next one will go over are actually some studies that my team have done over the years. This one in particular is looking at our integrated approach to laboratory testing for patients with Ebola virus disease. I think that you can take this and extrapolate this to a number of different illnesses as well to look at how you could expand on how you would treat one of these when they came in.

So whether you’re going down two floors within your own facility, to your own clinical laboratory, or samples are being shipped across the country to the CDC for confirmation testing, handling of these specimens requires following strict procedures to comply with both internal policies, but also various state and federal regulations.

Additionally, just managing the expectations internally and externally of the people you work with as well as the communities so that they understand that you’re working as best you can to manage risk and to protect their safety and to protect their health. All of these components have to be considered an advance and have to come together.

And this is a discussion that doesn’t just take place in the clinical laboratory because there are a number of different stakeholders that are going to be involved in how you move these potential specimens around.

This is a paper that we just completed a few years ago, and this one highlights essentially each of the potential tests needed to be evaluated for risk that we went through and did risk assessments on each of these tests.

This involved evaluating the standard operating procedure, evaluating the equipment, looking at the various “what if” scenarios associated with these tests, and evaluating the actual processes on non-highly hazardous communicable disease samples so that we could see these running in real life.

And when you’re balancing doing highly hazardous communicable disease specimens within an active clinical laboratory that also has the responsibility for hundreds to thousands of other patients within that facility, the importance of maintaining the integrity of that clinical facility, as you know, is paramount.

You need to make sure that while you’re providing the best care possible for the singular or the few highly hazardous communicable disease patients, that you’re not sacrificing the care that you’re providing to the standard patients within the hospital and that you’re protecting them from a clinical laboratory standpoint as well.

So going back to what I said earlier, not everyone is qualified to do these types of assessments, and these types of assessments can’t be done in a vacuum just by a singular individual. This paper we just put out about three years ago, s I particularly want to get into this a little bit with this group.

And what I want to focus on for the rest of my time here, the next few minutes is simply the ambiguity around manufacturer policies for usage of clinical laboratory equipment in the treatment of highly hazardous communicable disease patients. Usage of this equipment is a must for the treatment of these patients and it can be done safely, but it can’t it can’t sacrifice the need to protect and to provide treatments for all the other patients within the hospital as well.

However, not all pieces of equipment are designed with user safety in mind, either for running the test or for repairing that piece of equipment later on. And I’d like to see more focus on this in the future from a development standpoint. And one of the conversations that I know the CDC has been having with various manufacturers is the importance of understanding the safety and the exposure risks, bringing that to the forefront from both a repair, a service, and a usage standpoint.

So these processes have to be worked out in advance, and once they are worked out, they need to be clearly and easily accessible. And just right now, those processes are not readily available from many of the manufacturers of clinical laboratory equipment.

And I think one of the biggest headaches that we saw in the US Ebola response and several subsequent response over the past few years was the ambiguity around the decontamination of equipment used for care of these patients with highly hazardous communicable diseases.

And as previously I stated, in some cases, a manufacturer told facilities that they would have to destroy valuable pieces of equipment or that the warranties would be completely voided if the equipment was used for clinical specimens from these patients.

And what we know is that’s just not what should be done. That there are ways to safely decontaminate these. More forethought needs to be done– put into that during the development processes of these pieces of equipment. And we need to get all the parties together so that when it comes to wanting to do the right thing around safety and health, that we’re not sacrificing the ability to still run these tests on these types of pieces of equipment.

There remains a lot of unknowns still that I believe has to be addressed in advance or have to be addressed when you’re actively treating a patient with one of these highly hazardous communicable diseases.

So this is a table from that paper that I just mentioned. And as you can see, one of the things that we went about trying to do was contacting a number of major clinical laboratory manufacturers. And you’ll notice in the table, all of the companies are labeled A through I. Those are all individual manufacturers. We deliberately decided and chose not to identify them. But I will tell you, communication is a big issue.

So we were conducting this study multiple years after the Ebola outbreak here in the United States we were dealing with, and we still could not get clarity of answers not just for Ebola virus disease, but for a whole host of others. So communication is still one of the biggest issues, and this is easily corrected with minimal cost.

In this study, we can conclude– that we conducted, in our own personal experiences, there was not a clear route to ask or to obtain written documentation. As you can see from the responses in this table, often questions were routed through multiple individuals and not in a timely manner.

Oftentimes we would put calls in or send emails in and there were days before we would get responses back. And when you’re dealing with a patient under investigation or a patient with a confirmed highly hazardous communicable disease, we all know you do not have days to wait, you don’t have hours to wait. The decision has to be made whether or not this can be used and you can move forward. So the communication from the manufacturers has to improve.

Just really imagine the consequences if your facility was in a similar situation and you were having to determine whether or not you could use one of the pieces of equipment within your clinical laboratory and what the implications would be. One of the things that surprised me the most but may actually not surprise those of you who live and breathe in the clinical laboratory on a daily basis is very often my questions to the manufacturer were directed to a salesperson.

And that salesperson may or may not have the technical expertise to answer our questions around decontamination for re-use or if it’s even needed for some of these various organisms.

There was also a reliance on oral communications. And this was oral communications, again, oftentimes from various sales teams which did not always match written documentation which we would find through the manufacturers’ warranties or through evaluation of some of their basic operating instructions.

As we all know, oral communication increases the chances for miscommunication. We all know how the telephone game works, s and there’s a reason why all of our SOPs are generally written SOPs.

So when it comes to highly hazardous chemical diseases, there’s opportunities to address a number of these potential issues. Number one is really what we were talking about in the first part of this presentation, which is, those of you working in clinical laboratories, most of you are not going to see a highly hazardous communicable disease patient come in, but you need to be prepared for it just in case.

So you need to have that advanced planning on your SOPs to address most anything that comes through the door, as well as the ability to ramp up if something is identified, s or if you’re one of those facilities that is volunteering or opting in to actively participate in highly hazardous communicable disease patients’ treatments.

Advanced planning and clarity of information and communication is absolutely key. There’s huge ambiguities within this area that further underscores the need for this improved clarity, and the need for manufacturers and various groups around the country to expand dissemination of manufactured and approved decontamination methods that are easily accessible for current customers as well as those who may be researching purchasing.

If you are standing up a laboratory in a building or in a facility where you know there is a high potential now that you could receive and treat a highly hazardous communicable disease patient, knowing and understanding the ease or the difficulty of decontamination of a piece of equipment or even the need to do it may impact whether you go with manufacturer A or manufacturer B. So having access to that prior to purchase is very important.

This equipment, again, as I highlighted before, needs to be used for the benefits of all of our patients, and we need to be very aware that we can’t put our teams at risk– sorry, at greater risk. What we need to make sure that if we’re doing something in the clinical laboratory or your team is working with point-of-care on-site laboratory near the patient care room or in the patient care room, that you’re able to address the additional potential risks in a way that’s manageable within your institution.

We also want to make sure that we don’t run into situations like we did in 2014 and 2015 where manufacturers were threatening to void warranties or service contracts, and therefore, were really confusing end users, clinical laboratories on what they could and couldn’t do, particularly with patients under investigation who, most time, turn out not to have the highly hazardous chemicals they were suspected of, but this may negatively impact our ability to provide timely testing.

So with that, I’ll move to the next phase, which is, if you’ve got a chance, please go through and complete your evaluation of this presentation. NIHS, CDC, and I would greatly appreciate your feedback. And with that, I’ll turn it over to the team there at CDC because I believe we’ve got about five minutes for questions.

Thank you so much, Dr. Gibbs, for your presentation. Yeah, we’re going to go ahead and jump into the Q&A. Hi, everyone, my name is Johanzynn Gatewood, and I’m also on the OneLab team, and I’ll be facilitating today’s Q&A. We’ve already had a couple of questions come in the chat, but we encourage you to continue dropping your questions there in the chat. And if we don’t get them to them today, please give us an email at onelab@cdc.gov.

All right, so I’m going to jump into the questions starting with our first one for you, Dr. Gibbs. So if the hierarchy of control says that PPE is the least effective, then why is it an option?

SHAWN GIBBS: Well, it’s an option because sometimes we’ve got no other option. And remember, when PPE is being used, it’s being used in conjunction with all of our other controls. So for example, for all of you in clinical laboratories, you have a great deal of engineering controls. Your SOPs, your safety protocols, everything else, you’ve got a large number of administrative controls as well.

PPE is what we put in when those first two just are still not robust enough to protect us against that exposure that we’re trying to reduce or potentially eliminate. And going back to one of the things that I said within the presentation that I think you may have hopefully remembered, when we were looking at some of the exposures from the Canadian data, I believe it was about 28 out of 42 of those exposures were result of inhalation.

Now inhalation you can reduce the likelihood by use of biosafety cabinets, but depending upon– or some other engineering controls within your centrifuges and so on. But just simply as a backup as additional controls or other controls, the use of N95 filtering facepiece respirator or other respirator as part of a respiratory protection program adds just that additional layer of safety.

Got it, thank you. And I made a mistake earlier. I meant drop your questions in the Q&A, not the chat. All right, next question for you, Dr. Gibbs. What are your thoughts on inactivation of a specimen prior to it even being put on an instrument? This has been an issue with SARS-CoV-2, monkeypox, et cetera.

My thoughts are, when possible, I’m a fan Any time that you can deactivate– or essentially eliminate the risk by deactivation of the microorganism and still have the ability to conduct the test that you need, I would be in favor of. Particularly I know for a number of things, that’s S always possible.

So I think that if it is possible and it does not negatively impact your ability to run the test, does not negatively impact your ability to get proper answers out of that test, by all means, do it. If it does, then you need– or if it does negatively impact it, then you need to work with your team to look at what you can do to reduce the risks from moving that potentially live organism.

Great. Thank you, Dr. Gibbs. So we’re about two minutes out, so I’m going to end the Q&A right now and pass it back over to Alicia for closing. Thank you, Dr. Gibbs.

Happy to help. Everyone, thanks for having me. If we didn’t get a chance to answer your question, feel free to send that along and I’ll try to adjust it after the fact, and if I can’t, I’ll bring in people who do.

Thanks again, Dr. Gibbs, for your presentation. I hope everyone learned more about how to prevent laboratory-acquired infections because I surely did. I have a different perspective when making recommendations for a risk assessment.

As stated earlier, we would like to invite you to an upcoming PACE-accredited network event on September the 9th at 1:00 PM. It’s the Public Health Laboratories 101, A Discussion on the Role of Public Health Laboratories as Part of a Large Interrelated System of Organizations, Including Clinical Laboratories and How it Influences Populations Health. The registration for this event should be in the chat right now.

I also want to remind everyone not to forget to go to the OneLab REACH for the useful laboratory training resources, and that link should also be in the chat. As well for as for information on OneLab events and the content from this today’s presentation, and the CDC OneLab Network. That link should also be in your chat at this time.

As a reminder, I want to let everyone know that the slides from today’s presentation will possibly post within the next two weeks. And again, thank you for attending today’s event. We’ll see you on September the 9th at 1:00 PM for the networking event. Have a great rest of your day.