

Moderator: We're now going to start our Q&A portion of this webinar. As Dr. Schwartz mentioned in her presentation, the FDA would like to hear from you. What are your reprocessing challenges? What are your concerns about reprocessing reusable medical devices? Are you experiencing challenges implementing current recommendations? We would now like to take questions.

In order to ask a question, you must type it in with your organization's name and who your question is directed to. We will not take any audio questions. So if you have questions, please type them in and we'll get those going. Thank you very much.

We see people are typing, so we're going to mute for a minute and wait for those questions to come on in. Thank you.

Cynthia, thank you for your question. She asks, "Will the seminar have any video demonstration?" No. It will not at this time.

Our next question, "Do scopes have to be stored in negative pressure rooms or in just a covered cabinet?" Lisa?

Lisa: Thank you for that question. In regards to where you store an endoscope such as a duodenoscope, the room itself and these are various locations. They are vertically hung in a cabinet or contained fashion that minimizes the risk of contamination. There are various evidenced-based guidelines which you can adhere to, but they all have similar language.

So there are well-ventilated cabinets and rooms that endoscopes are hung and stored. But the bottom line is those rooms aren't necessarily negative pressure versus positive pressure. It's the storage containment that it typically ends up being well-ventilated, vertically hung, and stored in a manner that minimizes cross-contamination.

Moderator: Thank you. Our next question comes from John Wachowiak. "What are your recommendations to ECRI wanting scopes to be cultured?" Dr. Schwartz, can you answer that?

Dr. Schwartz: Yes. Just a moment. What is the question again?

Moderator: The question is, "What are your recommendations to ECRI wanting scopes to be cultured?"

Dr. Schwartz: So with respect to surveillance culturing of duodenoscopes, what we're stating, as I presented in the formal presentation, really an overview of what we heard at the advisory committee meeting, which was that the concept of surveillance culturing of scopes is good. However at this stage, we are seeking validated protocols for

surveillance culturing and those are efforts that really have not taken place as of yet but that are definitely forward-looking.

So at this stage, we're not going to recommend, but we certainly think that that is appropriate for consideration and much of that also depends upon the hospital's capabilities and resources as well.

Lisa: Lisa Waldowski. Thank you. In addition to that comment, I'd like to make sure that the person submitting that question and anyone else interested in that has referred to and looked on the CDC website for their recommendations for surveillance culturing and frequency. There is an algorithm on there that can assist organizations in looking based on how often and how frequently they're using scopes, whether or not to do it once a month or after every 60 procedures, etc.

So I encourage the individual in those organizations that are contemplating this issue in addition to what Dr. Schwartz brought up in her talk and reiterated just now that you do take a look at the interim surveillance recommendations on the CDC website.

Moderator: Great. And I do want to remind everybody these slides will be available to you in the next two or three days on the Joint Commission website. So if anyone has asked that question, that is your answer.

We have another question. What is the recommended amount of days a scope that has been cleaned and processed should be on a shelf before being used?

Lisa: This is Lisa Waldowski. In regards to endoscope hang time after reprocessing, it will depend on the evidence-based guideline that you have chosen within your organization. [audio cuts out 00:05:26] And you also want to double check to see if in the manufacturer's instruction for a specific scope that you have, that they have made any recommendations there within that content.

There are various evidence-based guidelines that still state that this is an unresolved issue. There are evidence-based guidelines such as AORN that do recommend a five-day reprocessing after you have hung the scope and you haven't used it. So on day five or thereafter, you would reprocess a scope that's hung in storage. There are organizations, though, based on a risk assessment that have decided to reprocess their scopes and put it in their organizational policy and procedure to do it on such dates. That is up to you.

At the Joint Commission time of survey, we would expect you to follow your organizational policy and procedure. I will, however, add because this is such a scrutinized topic right now that there may be forthcoming recommendations that will change regarding the recommended reprocessing time. But AORN is the only one at this point that states in the recommendations a five-day reprocessing. The

other entities basically say this is an unresolved issue in the present evidence-based guidelines. Thank you.

Moderator: We have another question from Alison McGrath. "Are folks finding residue on the tip after processing?"

Lisa: The question about residue on the tip, it has not been brought to our attention that that is something that is coming up frequently. So I am not at this point in time able to say that that's a common finding at this point. I do know if there is, on visual inspection, any debris that you would see, the recommendation would be to reprocess the scope. But it has not been a common finding by a surveyor or anything that's brought up in discussion with organizations that have had identified outbreaks or looking at their issues with this scope.

Moderator: Right. Thank you. This question is for the FDA. "If a positive surveillance culture comes back on a scope, are we required to report this positive result to the FDA?"

Dr. Schwartz: [inaudible 00:08:14]. This Ann Schwartz from the FDA. So the FDA would recommend that the hospital refer to the CDC's Interim Surveillance Protocol for recommendations as to next steps with respect to that kind of a finding.

Moderator: Great. Thank you. The next question, "Is ETO the recommendation or standard of practice?"

Lisa: This is Lisa Waldowski. In regards to what is being conducted in organizations that have ERCP procedures and use duodenoscopes, the ETO sterilization is one option based on the manufacturer's instructions for use and if your scope is able to go into a sterilization process or not. That typically has been an indication or a means that organizations have chose to perform when they've had outbreak scenarios with CRE and have gone and chosen to go to ETO. But that would be an organizational decision and is an option.

But again, you would have to refer back to the vendor or manufacturer that you have since there are three different vendors with this scope. I believe that there are still organizations that are still conducting high-level disinfection for their duodenoscope reprocessing. So there is variation as to what organizations have chosen to conduct. For outbreak scenarios, yes, organizations have resorted to that process.

Moderator: Great. Our next question is what precautionary warnings need to be shared with patients?

Lisa: The CDC has an excellent resource on reviewing your consent and the discussion that goes on between the patient and the physician with the procedure before the procedure with the inclusive risk versus benefits and has some language that you as an organization, if you haven't already done so, may want to consider. So yes,

the patient should be aware of the risk versus benefit of the procedure before it is conducted.

Moderator: Terrific. The culturing protocol, does this apply to only the 180 model or all models under the 180?

Lisa: In regards to that level of specificity, I would refer to your manufacturer's instructions for use of the device that you have, if it is an ERCP scope or a duodenoscope as to what the recommendations are for surveillance and for culturing purposes of that scope.

Moderator: Lisa, is there any chance of going to disposable duodenoscopes in the near future?

Lisa: I think it's premature. I don't have any inside scoop as to what's going to happen in the near future. I think there is a lot of discussion as was presented by the FDA with Dr. Schwartz that we have on the table for discussion sterilization of endoscopes. Now, there may be manufacturers that are presently looking at the ability to have disposable endoscopes. I have not heard if a duodenoscope is in the works for a disposable type being produced. But the sterilization piece is definitely being contemplated. I don't know, Dr. Schwartz, if you had anything to add regarding that status.

Dr. Schwartz: Yes. Thank you, Lisa. So the FDA would certainly encourage manufacturers and has been encouraging manufacturers who are working towards that goal to come to us with their designs and with their data, with their validation data so that we can take a look at the possibility of disposable tips or disposable duodenoscopes as a potential solution to this very issue.

Moderator: Next question, "Can scopes be stored in patient exam rooms?"

Lisa: This is Lisa. In regards to where your scope storage is, it's typically a centralized location that has minimal traffic control and has been risk assessed so you're not having random scopes being stored in various locations so you have a good sense of your inventory and control over your scopes. So in regards to storing one here, one there, that is not the intent of the means and resources that you as an organization would look at that you have a central storage location that they're hung, again, vertically hung in a manner that minimizes the risk of contamination.

So we don't specify where that location needs to be, but you do need to risk assess that it's not going to be an interruptive process that someone's conducting a procedure and I need to come in the room to grab a scope. So you do want to look at your process and where that storage of your scope is located.

Moderator: Along those same lines, we have a few questions about the scope processing room. Does it have to have a negative pressure?

Lisa: Again, based on your facility design for your high-level disinfection process, there are organizations based on size of central sterile that they have the ability to have a large enough space to be conducting processes of both natures. The decontamination room, if you look FGI guidelines for this type of process, that room does need to be negative pressure.

So it depends on the organization's facility design on how you have that laid out in your process, but the decontamination portion would be negative pressure. So depending upon, again, where your process ends in that room and what you're conducting, do you have a path through for the next step, etc. will vary as to what your room pressure would be. But decontamination would certainly be negative pressure.

Moderator: Great. Thank you. Any recommendations about the frequency of cleaning the cabinet?

Lisa: Your storage cabinet for your endoscope would certainly be based upon frequency of opening that cabinet and having it standardized that it's cleaned appropriately and it minimizes contaminating the scopes. So you'd have interaction and develop this with possibly your environmental services or whoever is going to be in charge of cleaning that and that you have it standardized so when you risk assess that, you're not noticing visible debris or dirt on the walls or you're not seeing wet stains and marks on your chux or towel or whatever you have at the base of your cabinet.

So you do need to risk assess that and look based on any manufacturer's instructions for use that you're given with your storage cabinet or container what their frequency based on the material that it's made out of, what it is to be cleaned with and how frequently and that you have a process that the staff can state, "We're cleaning in," and how frequently that is occurring. But that's not typically spelled out in an evidence-based guideline.

So you do need to compare what the manufacturer is recommending, risk assess that frequency based on your volume and turnover, how often that cabinet is being opened and then go accordingly for frequency that you will now hold the staff responsible for doing that.

Moderator: Great. A question from Matthew Josey, "Are positive culture results from ERCP scopes that are not MDRO needing to be reported to patients?"

Lisa: In regards to what your organization shares with patients, I would defer to how your entity or your organization when you find out there has been an identified breach or something has come up with a risk to the patient working with the key stakeholders involves a physician, risk management, what your policies and procedures are within your organization--your safety, culture, etc.--on how that is conducted within your organization.

In regards to you disclose everything, you base it on risk assessment, you consult expert consultations on what that breach was, what the organism was would all play into that decision making. So that may vary. The other piece is looking at what your state and local regulations are for any identified organism if that is reportable. So you have a lot of variables in that to make the best decision.

Moderator: We have quite a few more questions. I do want to let everyone know that a replay of this webinar including answers to these questions will be available to everybody who has signed up, registered. I also want to let you know too that some of the questions are repeat questions. So we are lumping them a bit. But if your question is not answered, we will be sure to get back to you with either someone from The Joint Commission or the FDA to answer those questions. So be rest assured that we will answer your questions.

Our next one is from Pam Wallace. "What is the recommendation for sterilization of the reusable buttons and suction ports? Should they be sterilized and stored and used with just one scope rather than be put back in a general area to be used with any scope?"

Lisa: The accessories that accompany or are utilized on an endoscope, you would follow manufacturer's instructions for use on how they are to be reprocessed if they are and they're not single use disposable. So again, based on what the product vendor, manufacturer instructions state on how to clean, disinfect, high level disinfect and/or sterilize, that would be how you would proceed.

Same thing with if you're using biopsy forceps, obviously going back to Spaulding's classification on the intent and where that device or supply is touching or entering a body will determine and typically drive if it needs to be high level disinfected, it's touching a mucous membrane or non-intact skin or it's entering a sterile cavity. So that will drive it. But refer to your manufacturer's instructions for use on how to process those supplies.

Moderator: Here's a terrific question. "Is it better to have a core group trained in the reprocessing or have the entire staff trained?" This particular person has 60 team members.

Lisa: That would be the decision of the organization. I would defer back to what I had mentioned regarding HR and what your job description and what your individual staff are supposed to be doing with high level disinfection and/or sterilization processes. What are their roles and responsibilities?

Obviously, you want to look at if you're cross-training them, if there's any responsibility for frontline, hands on high level disinfection or sterilization, you have to have the supportive documentation and ongoing staff competency and

training to support what they're actually doing. These are high risk processes with a very narrow margin of safety.

So you definitely want to assess who you are training but it does boil back to what are their job descriptions and held responsibility upon hire. What did you actually hire them for?

Moderator: Great. This question is for the FDA. "Is the FDA considering reclassifying duodenoscopes as a critical device?"

Dr. Schwartz: So we did hear discussion as the advisory committee meeting from some of the panelists regarding the consideration for reclassification. At this stage, the FDA is not considering that reclassification from semi-critical to critical. However, as we continue to investigate and there is additional data generated, additional evidence generated, then that's certainly a possibility at some point in the future.

Moderator: Great. Thank you. We have a terrific reminder from Jacqueline Daley that AMI has video and other resources for reprocessing endoscopes. We work with them often and approve a lot of their work. So definitely use them as a resource as well.

The next question is for Lisa, "Has the Joint Commission adopted a universal standard for manual cleaning of the ERCP scopes?"

Lisa: No. Standards and elements of performance that were brought to your attention, as you see, they're broad. So the focus of today's talk was on duodenoscopes. But within our standards, we address that issue under the [inaudible 00:22:16] 20201 as it pertains to medical equipment devices and supplies specific to element of performance too as it pertains a high level disinfection and sterilization.

So under that umbrella would be how we would come across at the time of survey and expect your process to encompass all of those other supportive standards and elements of performance to assure that your staff are conducting this in a safe manner. So all of those supporting standards and elements help drive a safe and effective process.

Moderator: Great. Thank you. And as a reminder, we're still getting questions about the availability of these slides. They will be available on The Joint Commission website in two to three days. We'll also have a recording of this and we will answer all questions that did go unanswered as well.

Here's a question. "Are we to report MDRO to patients following positive results or all bacterial contaminations?"

Lisa: That was actually very similar to another submission. Again, I refer you to what your internal processes are based on the identified organization, based on your practice with the involved stakeholders such as the physician discussing the

procedure and outcomes with the patient. What your organization proceeds with based on your policy and procedure, risk management involvement, leadership involvement regarding identified breaches to work in alignment with your specific state and local department of health, again, specific to the organism identified, that would all be under consideration.

So please pay particular attention to your reporting requirements and what you have policy and procedure wise within your organization regarding such identified breaches as they relate to devices. I think this is what's driving the discussions for today.

Moderator: This question is for the FDA. "At a recent seminar I attended, it was recommended that these complex scopes be sterilizable. Will the FDA consider 10K approvals for semi-critical devices that could be in contact with these superbugs? Be clear, only if sterilizable with the assumption it has been effectively cleaned." Let me know if you need me to repeat that.

Dr. Schwartz: Yes. If you could repeat that so we can digest all the information, please.

Moderator: Yes. Will the FDA consider \$10,000 approvals for semi-critical devices that could be in contact with these superbugs? Be clear, it's only if sterilizable with the assumption it has been effectively cleaned."

Dr. Schwartz: Okay. So it sounds very similar to the previous question that we had regarding whether the FDA was looking to move in the classification of these devices from semi-critical to critical. As stated before, based upon what we have in front of us at present, the evidence that we have at present, these devices from our standpoint remain semi-critical. Whether there's further data generated in the future that we would be open for reconsideration, that's separate. But at this stage, that type of reclassification with a requirement for sterilization is not one that we are planning on making.

Moderator: Great. Thank you.

Dr. Schwartz: This is Ann again. There was just one other question that seems to be repeated quite a bit scrolling down in the question box that we thought maybe needed a little bit further clarification regarding culturing of scopes and whether the culturing of scopes was specific to the 180 or not. So just to clarify, we're talking about the Interim Surveillance Protocol that was produced by CDC and that is not specific to a model of duodenoscope or a manufacturer's specific duodenoscope. It is intended for duodenoscopes in general, just to clarify.

Moderator: Great clarification. Thank you, Dr. Schwartz. The next question, "Is PPE required in a non-active decontamination room such as to restock?"

Lisa: That question, it can vary based on what that room is quote intended for and labeled as. If you're talking about a sterile storage environment, that is a traffic-controlled environment. If you're talking about a clean utility room on a unit or floor, then there is no expectation of putting on personal protective equipment to go in and grab something or get something. So it depends, again, on the room, what it's intended for in that environment and if it's the perioperative setting, that person very well may be in certain garb that is required in that environment.

So that would be specific to a little bit more detail as to where that's located and what that room includes, what someone would be wearing. But typically, it's not going in with full PPE to go get a piece of equipment. But again, where it's located would drive some of that content and my response.

Moderator: Great. We have another question about the storage cabinets that has not been asked yet. It's from Hanover Hospitals. They have two Olympus scope storage cabinets in their facility that houses their scopes. They've been told that no chux or towels should ever be placed in the base. Is that true?

Lisa: There are no evidence-based guidelines that I'm aware of that specifically say, "No chux, no towels." I think that the intent or what we encounter on survey would show or demonstrate that there may need to be some improvement with the drying process of the scopes as evidenced by water stains, brown, just dirty appearing chux or towels.

So obviously that is a means to see if you need to improve on your drying process. Towels or chux are not required to be at the base of a cabinet that holds your endoscopes, but there's no "do not," but I, again, would caution you when you're opening that and someone's cleaning that, what is the presentation or appearance of something of that nature and is it just being used because the drying is not being done correctly or appropriately?

Moderator: Lisa, does the humidity and temperature of storage cabinets need to be reported daily and does it need to be a positive pressure?

Lisa: The storage cabinets for scopes, again, that varies as to what an organization based on resources. I've seen some very sophisticated types of contained device or means that have ventilation and recording of that information and it's done electronically. But with that said, again, we hold organizations to manufacturer's instructions for use of evidence-based guidelines.

What we want and expect is that they are stored in a manner that minimizes contamination and that they're hung vertically and they're in a location that you don't have multiple people walking through that environment to contaminate them. So depending upon where you locate them, we do not expect to see a temp in humidity and monitoring for that on a routine basis. However, if you purchase

something that has that, then you may already be monitoring that so you are actually practicing above and beyond the intent of what we would be looking for.

Moderator: Great. How often do you recommend facilities conduct ongoing high level disinfection rounds?

Lisa: This is Lisa. High level disinfection and sterilization are so high-risk at this point in time given what we uncover routinely. Year after year, this topic continues to increase. So this should be a continual risk until proven otherwise on a risk assessment for infection prevention and control.

What your frequency of rounding should be is based on what you're seeing and what you assess and get out of those observations. You back off based on your frequency when you see that the practice and processes are meeting evidence-based guidelines. You don't have a new device or new piece of equipment or a new staff member. All these variables alter your risk.

So again, your frequency is determined by you, the organization, but what drives that is your risk assessment. So you want to be down in those locations or off-site decentralized locations frequently enough to assure that the process is being conducted correctly.

Moderator: Great. Just a reminder, all of these questions will be answered either today or at another time. We promise that. This replay will be available to all attendees and on The Joint Commission website as well. We have another question. "Does a regulating org recommend the scopes be covered with a sheet to prevent process scopes from touching each other in the scope cabinet?"

Lisa: I would defer to the manufacturer's instructions for use. I do not see that recommendation in our current evidence-based guidelines specific to use of this. I would risk assess because the concern of using that, I get what the intent is so they don't touch other scopes, but I would be equally concerned as to moisture accumulating in a sheet and what risk that posed. I'm not sure there's enough evidence out there to support such a practice.

So again, back to that risk assessment and looking at the manufacturer's instructions for use and intent. We by no means are prescriptive to say you must do something of that nature, but I would definitely look at the pros and cons of what you're introducing into that environment, particularly if the scope is not completely dry and your frequency of use of those scopes. So I would be cautious and definitely review that and risk assess that.

Moderator: Thanks, Lisa. This question is for the FDA. "Standardized ways of swabbing ERCP scopes, we came across several different ways to do it. Shouldn't it be the same for everybody?"

Dr. Schwartz: So this is the FDA. With regard to standardizing ways of swabbing the ERCP scopes or surveillance culturing, this gets exactly to the point that we've mentioned earlier with regard to developing a protocol that's standardized and has been validated for adoption of surveillance culturing.

So at this stage, what we can do, again, is point to the CDC Interim Surveillance Protocol recommendations that are presently out there, but with a caveat, again, that what we heard at the advisory committee meetings and as we understand, the protocol is one that will undergo ongoing evolution as further evidence and further validation testing takes place.

Moderator: Great. Here's another question from Matthew Josey from the FDA. "How do we deal with vague manufacturer guidelines?"

Dr. Schwartz: So great question. So one of the areas that we've talked about both today as well as at the advisory committee meeting was that we are working continuously now in a collaborative way with the manufacturers in terms of getting validated reprocessing protocols in place.

Once those protocols are in place, those will have further robust, refined instructions for use. With respect to when to expect that, again, we're working continuously on this and we're looking forward to being able to communicate that out to the hospital healthcare community within the next bunch of months.

What you can do in the interim with regard to vague instructions that leave the hospital with questions or concerns is certainly to submit a form to the FDA called the MedWatch form so that we can be, first of all, aware of the specific concern and address it.

Moderator: Thank you, Dr. Schwartz. This question comes from Lisa Verheyen. "We were told we have an hour to clean a scope and process it after a procedure. Is this true?"

Lisa: I would defer to the evidence-based guidelines on your process and look at a lot of the terminology is very similar to what the question was about vague manufacturer instructions for use. The same thing can happen with the evidence-based guidelines. A lot of times you see they state "as soon as possible." That is ultimately left open to interpretation.

So in regards to this hour, you could see that in organization policy and procedure of which we would then hold you to. But the more important piece is that most of the evidence-based guidelines that I've reviewed specific to reprocessing is that you don't want the scope to dry with any blood, body fluid, bio-burden after the point of use. So you're immediately pre-cleaning that, you're transporting it to decontamination and the staff in decontamination . . . I know scopes pile up.

You're not the one and only scope ending up in decontamination. But you're getting the process moving as quickly as possible.

So that is what the intent of "as soon as possible" means. If your organization or your endoscopy clinic or program defines as soon as possible as one hour, then that's what we would expect to see. But again, the stressing of the point is as soon as possible means you're moving that process to minimize hardening on any external or internal channels or the outside of the scope.

Moderator: Terrific. Thank you. We are going to take one last question. That is, "What is the position on the use of tip protectors on endoscopes?"

Lisa: This is very similar to what I commented on the sheath. The tip piece on an endoscope, again, risk assess and look at the manufacturer's instructions for use.

If you don't have a process that assures with your scope hanging in that cabinet that they're completely dried, I think from an infection prevention and control risk assessment standpoint, what is going to happen to any moisture that remains in those internal lumens or channels if you have a tip protector, which obviously needs to be assessed because you're probably also using that tip protector to minimize the risk to any of the camera or delicate lenses on that tip from getting damaged.

So obviously there's a resource issue not just infection control-related. But I'd like to know more data as to what happens if there's moisture involved and you're not turning those scopes around very frequently, if that just culminates at that tip and sets up a nice medium for growth, bacterial growth or mold, etc. to grow.

So again, you want to risk assess that with key stakeholders to make sure that your purchasing of something like that really is meeting a true intent and not introducing now something secondary into that environment.

Moderator: Terrific. I want to thank Dr. Schwartz and Lisa for their participation in today's webinar. We also want to thank everyone for attending today's presentation.