FDA Webinar: Duodenoscope Sampling and Culturing

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the question and answer session please press Star 1 and record your name. Today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn today's meeting over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On February 26, 2018 the US Food and Drug Administration, Centers for Disease Control and Prevention and American Society for Microbiology along with other endoscope culturing experts announce the availability of voluntary standardized protocols that were developed for duodenoscope surveillance sampling and culturing. These protocols are an update to the interim duodenoscopes surveillance protocols released by CDC in 2015.

Today's presenters are Dr. Shani Haugen, Microbiologist here at the FDA Centers for Devices and Radiological Health, Dr. Michelle Alfa, an Independent Researcher Professor for the University of Manitoba, Dr. Kevin Alby, representing the American Society for Microbiology and Clinical Microbiologist at the University of Pennsylvania and Dr. Judith Noble-Wang, a Microbiologist at the CDC's Division for Healthcare Quality Promotion. The group will review the voluntary duodenoscope surveillance sampling and culturing protocol. This can be leveraged by facilities to help monitor the

quality of their reprocessing features. Following the presentation, we will open line for your questions related to the information provided during the presentation. Now I give you Dr. Haugen.

Dr. Shani Haugen: Thank you. On this slide I'm showing the outline for today's Webinar on the recently released protocols from the FDA, CDC and ASM on duodenoscope surveillance sampling and culturing. I'll be providing an overview of the document, Dr. Alfa will walk through the sampling method, Dr. Alby will discuss the options for culturing samples and Dr. Noble-Wang will provide a comparison to CDC's 2015 interim recommendations for duodenoscope sampling which have been replaced with the current method. After our presentation we will be taking your questions about duodenoscope surveillance sampling and culturing.

The protocols we'll be talking about today were released on February 26, 2018. On this slide I've included the Web site where you can download the document. These protocols were developed by a working group comprised of staff from the FDA and CDC, representatives from ASM, duodenoscope manufacturers in the US and other experts in endoscope sampling, culturing and reprocessing. The recommendations in the document are largely based on expert opinion and experience with sampling and culturing including benchtop validation of these methods by the duodenoscope manufacturers, but they also draw upon scope sampling and culturing guidelines from Australia and Europe. During the development we received helpful feedback from multiple professional societies which are listed at the beginning of the document. These protocols are meant to be used as a tool for healthcare facilities that voluntarily choose to conduct surveillance sampling and culturing of duodenal scopes. This document was developed to provide validated methods for surveillance sampling and culturing of duodenoscopes

that would address some of the concerns that have been previously raised about duodenoscope sampling and culturing.

You may be wondering why would a healthcare facility conduct surveillance sampling and culturing of duodenoscopes and use these protocols? The answer is this type of surveillance is the only way to monitor with testing the quality of start-to-finish endoscope reprocessing procedures in a clinical environment. While there are methods to assess the quality of cleaning processes such as ATP and other assays, those methods are not intended to be used after high level disinfection of clinically-used devices and they are not a substitute for microbiological testing.

Surveillance sampling and culturing was discussed at FDA's May 2015 Advisory Committee meeting and is included as a supplemental measure to enhance duodenoscope reprocessing as noted in FDA's August 2015 safety communication on this topic. We want to emphasize that the use of this protocol is voluntary and FDA, CDC and ASM are not requiring its use. Healthcare facilities should check their state and local requirements regarding sampling and culturing endoscopes. As you'll see in the document, conducting surveillance sampling and culturing requires specific resources, training and expertise. It also requires cooperation within the healthcare facility to identify resources and designate responsibilities for different staff members and different departments within a facility.

Surveillance sampling and culturing is not a substitute for complete adherence to the endoscope manufacturer's recommendations for reprocessing and maintenance. Results after following these protocols cannot be used to certify that an endoscope is sterile.

On this slide I'm showing an excerpt from the table of contents from the protocols. You can refer to the table of contents to provide a snapshot of the entire document and to get a sense of how the document is organized with multiple subsections and options in each section.

The document is divided into three sections. The first section provides an overview and introduction to surveillance sampling and culturing. This section includes topics such as the goals and limitations of testing, references, definitions, and a discussion of how the document was developed. The second section describes the actual handling and sampling of duodenoscopes which Dr. Alfa will discuss in more detail. And the third section provides the four options for microbiological culturing of samples and include suggestions for microbial limits. Dr. Alby will be discussing this section of the document.

One of our goals for the document was to write the protocols in a way that would allow them to be widely adopted. To that end there are duodenoscope model specific options in the sampling method. And as Dr. Alby will discuss there are four options for culturing. Healthcare facilities should select the appropriate method for sample collection, culture and interpretation that best suits their needs.

Please note that the methods themselves such as a flush brush flush method for sampling the instrument channel were validated in benchtop testing and are not intended to be modified. We recognized that different facilities will have preferences for protocols and standard operating procedures such as organization of the document, placement of illustrations and the level of detail and terminology used. To address this we included many details in a strict organizational structure with the understanding that healthcare facilities could adapt the content to suit their own institutional formatting preferences, simplifying the language and structure of the document based on their

preferences and remove options that are not relevant for the healthcare facility.

Because there are options, healthcare facilities that choose to conduct surveillance sampling and culturing will need to make a number of decisions. Those decisions will be based on the facility's individual needs and resources. Examples of the types of decisions that must be made include the frequency of surveillance sampling and culturing, endoscope handling after sampling, clinical use of duodenoscopes during culturing and before results are available, selection of a microbiological laboratory to conduct culturing, and the microbial limits, results reporting an action plan. I'll now turn the presentation over to Dr. Michelle Alfa.

Dr. Michelle Alfa: Well thank you Shani. As you can see on this slide for the sampling method two staff are required for the sampling. And this is an important aspect because it ensures maintenance of aseptic technique during the sample collection process. The staff who do sampling should be familiar with duodenoscope handling and they should also be trained in aseptic technique and duodenoscope sampling.

And I think it's important to remind people that as in all staff functions an endoscopy reprocessing proficiency assessment of the duodenoscope sampling capabilities is recommended. The easiest way to do this would be to have a visual audit of the individual to make sure they're actually following the appropriate steps and maintaining aseptic technique Sampling should be conducted on patient ready duodenoscope. And I'd like to point out as Shani mentioned that the sampling methods described in this protocol have been validated by the three duodenoscope manufacturers and have been demonstrated to have recovery efficiency between 65% to 100% of inoculated organisms.

If we can go to the next slide please, in terms of the actual sampling method there was a long committee discussion of how to do this. And there's different ways of doing it in different countries but we opted to take an approach that would reduce the workload but ensure that we are targeting the key duodenoscope components. So the protocol describes a sampling method that is one combined sample which is collected from the elevator recess, the instrument channel and also the elevator wire channel if it is an unsealed channel. The idea being that pooling all of these three samples together will reduce the workload in terms of the sample collection and also in terms of the microbiology laboratory that's doing the culture.

Now you can see that the three sites are indicated on the diagram shown on this slide. The elevator recess is at the very end of the duodenoscope and there's a red circle around it. And it includes the elevator lever and the recess itself. The second sample is the instrument channel and it is collected from the biopsy port to the distal end. So that channel has a flush-brush-flush methodology. And finally the elevator guide wire channel opening is shown on the control head. And if it's unsealed a sample would be collected from that as well. Now if there is a need to sample other types of endoscopes or there is other situations the protocol guideline does provide information in Appendix 1 regarding collection of samples from other types of endoscopes based on the approximate channel dimensions. So there's some help if sites want to culture endoscopes other than their duodenoscopes.

If we can go to the next slide, I'm just going to spend a few minutes to go over the sampling method. So where the elevator recess, this seam between the distal end cap when that cap is present and the distal end should be sampled with a swab moistened with sterile water. And that's because we want to make sure that not just the lever recess but also the area around it that

had been shown to have problems is also being sampled. When that swab has completed sampling the swab head should be cut off into the sample collection container. And then the elevator recess should undergo a flush - brush and final flushing sample collection. The appropriate brush to use for this is indicated in the protocol. Essentially the protocol refers to the manufacturer's recommendation for the appropriate brush that would normally be used for cleaning of those tiny areas in the lever. And because of the differences in device design, sampling the elevator recess for Fujifilm and Olympus duodenoscopes will differ from the method used for Pentax duodenoscopes. That's because there are design differences in the elevator recess area.

If we can go to the next slide. In terms of sampling method for the instrument channel, the channel from the biopsy port to the distal end is flushed with sterile water. It is then brushed with a sterile brush using a single pass of the brush down the channel. The brush end is cut off into the sample container. The wire shaft of the brush is removed and the channel is flushed again.

Now the step where the brush is introduced into the channel is the one that's most prone to introducing external contamination. Care is needed to ensure that the sterile brush shaft doesn't accidentally get contaminated during the brushing step. And it's important also to realize that the brush that's used should follow the correct dimensions provided the duodenoscope manufacturer in terms of the dimensions of a brush that will fit properly through that channel.

If we go to the next slide, this is dealing with the sampling method for the elevator wire channel. And it's only sampled of course when it's not a sealed elevator guidewire and there is an accessible port on the control head. So

when it is accessible this channel should be flushed with sterile water following the instructions in the protocol.

Please go to the next slide. In terms of sample handling; the extracts including the swab and the brush heads from the elevator recess, from the instrument channel and from the elevator wire channel are combined in one sample for microbiological culturing. As soon as the sample is collected an appropriate neutralizing media (for example Dey-Engley Broth) should be added to the sample in a one-to-one ratio. The use of neutralizer is very important because published data have shown that addition of neutralizer helps damaged organisms be able to grow on the cultured media. And this is especially important if the organisms present are viable but non-culturable organisms within biofilm or build a biofilm in the duodenoscope.

The sample once it's collected should be kept on ice or refrigerated prior to microbiological culturing. And this refrigeration and ice step during transportation is important to ensure that there isn't replication of low concern organisms because if they replicate and get to the level that's high it may lead to unnecessary action. So in many ways it's very similar to the transport of biological samples such as a urine sample that also require refrigeration to ensure that the organisms in the sample do not replicate and become a false positive.

If we can go to the next slide, one of the issues after the samples are collected is what do you do with that endoscope that's been sampled? Because the device was handled with sterile implements and sterile water only re-conducting the complete manual cleaning is not necessary. Sites can choose to take one of the following three actions. They can, after sampling repeat manual high level disinfection without the complete manual cleaning. They can choose to process the endoscope again in an automated endoscope

reprocessor again without doing the manual cleaning before that. And also they can undertake simple drying and then send the scope for sterilization. I think that covers everything I'm going to talk about so I'd like to pass it on to Dr. Kevin Alby.

Dr. Kevin Alby: Thank you. As was mentioned I will cover in the next few slides which focus on culturing of the sample that was obtained from the duodenoscope. Now the goal of the working group was to create a method that could be conducted by any lab environmental or clinical that had experience with standard microbiological culturing.

Next slide. In order to achieve a protocol that was accessible to a large number of labs the working group actually came up with four different but related culturing protocols that could be implemented. The four methods are membrane filtration with culture on solid media, centrifugation with culture on solid media, membrane filtration with liquid culture and finally centrifugation with liquid culture. It is important to note that membrane filtration with culture on solid media is the protocol that was validated by the duodenoscope manufacturers. For healthcare facilities trying to decide which of the four methods to use key stakeholders such as members of infection control and the microbiology laboratory should evaluate which option best matches their goals with the available equipment and resources in the laboratory.

Next slide. For solid media cultures the entire sample needs to be concentrated for use. The filter or concentrate - the filter of the concentrate should be placed onto a single blood auger plate and incubated for 72 hours at 35 degrees to 37 degrees Celsius. Cultures should be monitored daily for growth. And it is important to note that these are the conditions for routine surveillance to detect a large number of relevant organisms however

incubation media, temperature and/or time may need to be adjusted if the goal of sampling and culturing is to detect a specific organism.

Next slide. For the liquid culture media again the entire sample should be concentrated for use. The protocol recommends utilizing a neutralization culture brought such as Dey-Engley Broth. And that broth is incubated for three days at 35 degrees to 37degrees. Similar to the solid media cultures the liquid culture should be monitored daily for growth and subculture when growth is detected. Again this method should recover a large number of relative organisms but modifications may need to be made for the recovery specific organisms. And we leave it up to the individual healthcare facility to determine those modifications.

Next slide. If growth is detected in either culture method it is important that the laboratory identify the organism or organisms present to an extent to be able to develop an action plan based on the classification of that organism. This workup should be documented as any other culture would within the laboratory or healthcare information system to allow for review at a later date. It is important that the healthcare facility develop a plan of notification that is important with institutional as well as local regulations and policies.

Next slide. This slide offers some insight as to how the working group classifies different organisms. Those organisms that are commonly associated with disease such as Staphylococcus aureus or the enteric gram-negative rod were classified as high concern organisms. Organisms less commonly associated with disease and more likely to be contaminants from the processing and/or sampling and culturing process are considered low concern organisms. Common examples include skin and environmental organisms such as coagulase-negative staphylococci and bacillus species.

The final group is the moderate concern organisms which are similar to the low-concern organisms in that they are less often associated with disease but because of their prevalence in the oral cavity and gastrointestinal tract their detection may more likely represent failure of reprocessing than that of the detection of low concern organisms. Importantly the group does not offer specific recommendations for any other groups of organisms leaving the decisions of what to do for a positive result in the hands of the healthcare facility and its key stakeholders.

Next slide. While the group does not provide any specific feedback and link any specific action to a recovery of a particular organism we do provide a number of suggestions for action. These include things such as removing the duodenoscope from use, notifying patients, reviewing reprocessing as well sampling and culturing methods. Note this is not an exhaustive list and facilities are encouraged to come up with action plans that best meet the needs of their patients. Responses may different organisms recovered and again the decision is entirely up to the discretion of the healthcare facility with input from key stakeholders. With that I will pass a presentation over to Dr. Noble-Wang for a discussion of the differences between this protocol in the interim CDC guidance.

Dr. Judith Noble-Wang: Thank you Dr. Alby. In the next few slides I will compare the new protocol to the 2015 CDC interim protocol. In March 2015 CDC released an interim duodenoscope surveillance protocol that included duodenoscope sampling and culturing methods. A revision to the methods were also published in August 2015. The interim methods were intended to provide facilities considering culturing with a starting point for a protocol that could be adapted for their use to assess the adequacy of their duodenoscope reprocessing. However, the interim protocol had not been validated and was one approach to culturing duodenoscopes. Since then the 2018 methods

produced by the FDA/CDC/ASM workgroup have been validated by the major duodenoscope manufacturers.

This slide shows the major differences between the 2015 CDC interim and the new 2018 protocols. For sampling three locations (the instrument channel, elevator recess and distal cap seam) were identified by the 2018 protocols compared to two locations in the interim method. For the instrument channel location, the 2018 protocol directs a flush-brush-flush method using a 20 milliliter flush of the channel with sterile water, followed by a brushing step and a second 20 milliliter flush with water. The interim method specified flushing the channel with 50 milliliters of sterile water.

For the elevator recess location, the 2018 protocol specifies brushing with sterile water and then flushing with water. The interim method specified brushing with a phosphate buffered saline with a very low concentration of tween-80 to act as a surfactant. For the sample from the distal cap seam, a moistened swab is used to swab the seam between the distal end cap in the distal end. This location was not specified in the interim protocol.

Now let’s move the sample handling. The 2018 protocol directs combining all the samples from the three locations in one container whereas the interim protocol directed submission of four samples for each duodenoscope, the instrument channel flush, elevator recess and three controls. The facility could choose to combine the instrument channel flush and distal end recess samples.

And finally let’s cover the neutralization methods specified in 2018 protocols. The protocol validated the addition of a neutralizer to the sample extract. The Dey-Engley Neutralizing Broth as suggested is added after the samples are combined at an equal volume of the samples to facilitate outgrowth of microorganisms that have been potentially damaged by reprocessing. It was

not known how a disinfected neutralizer would impact cultures when the CDC interim protocol was developed in 2015. A suggested laboratory internal process positive control was included as a proxy.

Next slide please. In this slide we're comparing the culture methods specified by the two protocols. As shown, the culturing options are similar between the two methods for plating after membrane filtration and centrifugation; as well as liquid enrichment culture after membrane filtration and centrifugation. The methods do differ in the volumes that are handled and culture. The 2018 filtration and plating culturing methods have been validated to demonstrate that the new method can extract between 65% to 100% of bacterial cells that were placed on the device.

For agar plating, the 2018 protocol specifies one blood agar plate after the samples are combined and processed by membrane filtration or centrifugation. The interim protocol specified a blood and MacConkey agar for each duodenoscope. Dilutions were also suggested in some cases.

For controls, none are specified in a 2018 protocol other than what are indicated for normal laboratory practices. Three controls were identified in the 2015 interim protocol: an internal process positive control I mentioned earlier and two negative controls which were the water stock solution used for irrigating the channel flush and the Saline/ Tween 80 solution used for sampling the elevator recess.

Moving on to culture incubation conditions: the conditions specified in both protocols are intended to detect the most common highconcern organisms on reprocessed duodenoscopes. The 2018 protocol specify incubation at 35 degrees centigrade for 72 hours compared to 48 hours in the 2015 CDC interim protocol.

Next slide please. In summary, the key components in the new validated 2018 protocol specify: firstly, friction for sampling the instrument channel on the duodenoscope with the use of the flush-brush-flush method and sterile water. Secondly, the addition of a liquid neutralizer to the sample extract to inhibit carryover of disinfectants and allow stressed organisms to grow thereby reducing false negatives. And thirdly, concentration of the sample by membrane filtration for culture. These key components of the new protocol were validated to show optimum growth of high-concern microorganisms from ready-to-use duodenoscopes.

Next slide please. And thank you for your attention. The line is open now to answer your questions about duodenoscope surveillance sampling and culturing methods discussed in our presentation.

Coordinator: Thank you. We will now begin the question and answer session. And we will be taking questions only from the phone. To ask a question or make a comment you may press Star 1, make sure your phone is unmuted and record your name to introduce your question. And to withdraw that request you may press Star 2. Once again for a question or a comment from the phone please press 1 and record your name and it is Star 2 to withdraw that request.

Judith Noble-Wang: While that is going on -- this is Judith Noble-Wang again -- I will answer the first question which is, "Why make changes to the interim protocol?" At the time the interim protocol was released in 2015 there was a pressing need for standardized sampling and culturing protocols. The previous protocol filled that gap, but it was interim, meaning it was always intended to be a placeholder until appropriate testing could be conducted to validate a surveillance sampling and culturing protocol.

Without a validation, the performance of the interim sampling and culturing methods was unknown. Shortly after the release of the interim protocol, the working group was initiated to address the lack of validation. The new 2018 sampling methods and the filtration andplating culturing methods were modified to streamline the sampling and culturing processes and have been validated to demonstrate that these methods can extract between 65% to 100% of the bacterial cells that were placed on the device. We can now move on to other questions.

Coordinator: Thank you. Our first question or comment comes from (Noreen Johnson). Your line is open. (Noreen) please check your mute feature. Did you have a question or comment?

(Noreen Johnson): No I did not have a question. Thank you.

Coordinator: Thank you. Our next question or comment comes from (Lynn Pasquale). Your line is open.

(Lynn Pasquale) Yes we were wondering do you have a recommendation on the brushes? The current brushes we buy are disposable. They're clean but they’re not packaged sterile.

Dr. Michelle Alfa: In terms of the brush choice that you would use for the channel or the lever recess cavity you are correct the brushes used in clinics are not sterile. You do need to use sterile brushes. One way to do that is to steam sterilize them. And they would be used once for sample collection, the end cut off and then the remainder of the brush should be disposed of. An alternative would be to use sterile brushes available from the manufacturer because some of them do provide that type of brush. These sterile brushes could be used as long as the dimensions match the channel dimensions that you’re putting it through.

(Lynn Pasquale): Thank you.

Irene Aihie: We'll take our next question.

Coordinator: Thank you. Our next question or comment comes from (Chris Bungle). Your line is open.

(Chris Bungle): Yes. I would like to know if unless I missed it -- and I apologize if I did -- once all of the specimens are collected into one container, you know, from the different areas of the scope and we go to culture it what is the recommendation of culture it? Aspirating 1 cc. You centrifuge it first then you take the sediment? I mean how does that go onto the plate?

Dr. Kevin Alby: This is Kevin. I'll take that one. So it depends on which method you choose. So if you are using a membrane filtration method so you will use essentially a membrane filter packet to concentrate the sample so you'll take the 100 or so mils that you'll have after collection, you'll vortex to make sure you get everything off the brushes and you'll put that entire sample on the filter and let the vacuum essentially concentrate it onto that piece of filter paper which is that piece of filter paper would then go on to the blood agar plate or into the liquid broth. If you do a centrifugation concentration then you do like you suggested you would take that sample, you'd put it in conical tubes, you'd centrifuge it and then take the sediment.

(Chris Bungle): Okay so the sentiment will be taken with a sterile pipette 1 cc or does it matter or, you know?

Dr. Kevin Alby: You know, let me pull up sorry, it's in - the specific amount is in the protocol.

(Chris Bungle): Oh it is in the protocol...

Dr. Kevin Alby: Yes.

(Chris Bungle): ...because that will dictate - I guess you're - I guess you'll do a colony count right?

Dr. Kevin Alby: You could do colony count if you are doing solid media or you would do just turbidity if you were doing liquid media.

(Chris Bungle): Okay. So you can use either liquid or so all right.

Irene Aihie: Thank you. We'll take our next question.

Coordinator: Thank you. The next question or comment comes from (Mehran). Your line is open.

(Mehran): Hi, thank you. So what is the recommendation for the cultured scopes while we're waiting for culture results? Is it to take them out of service or…

Dr. Michelle Alfa: It's a very good question and that is one of the decisions that we think the site should actually be making. Ideally the expectation would be that the scope would be quarantined until the culture results are available. But obviously as we're incubating the culture for 72 hours that is a long time for a duodenoscope to be in quarantine. The committee discussed a lot regarding this issue and in the end settled on the approach that if the culture results at 48 hours are negative then it would be fine to take the scope out of quarantine and be able to use it again.

And then when the final result comes at the 72-hour mark, hopefully it would also be negative. If it was positive at 24 or 48 hours obviously there might have to be some action taken depending on the organism and colony count. This type of approach is probably not much different from many other diagnostic samples where you get an interim report and action is taken pending the final report.

If sites choose to sample their scopes and then continue to use them and not quarantine them obviously the risk is if the duodenoscope ends up being contaminated it makes action a lot more complex in terms of how to deal with the patients that might have been exposed to a contaminated duodenoscope. Now we do realize that by quarantining a scope there might be inventory issues in terms of the number of duodenoscopes available because once a duodenoscope is cultured it will be out of circulation until the at least the 48 hour result is available. So again it's a decision that I think the committee that is struck at the site that's doing culture needs to address. They must make a decision about whether they're going to quarantine duodenoscope after being cultured or not. However, the recommended approach is to quarantine because this ensures the least risk of using a contaminated scope on another patient.

(Mehran): Okay thank you so much.

Dr. Michelle Alfa: No problem.

Coordinator: Thank you. Our next question or comment comes from (Elise). Your line is open.

(Elise): Hi. Is there a recommended time frame before the sample gets iced or refrigerated?

Dr. Michelle Alfa: The intent would be that once the sample is collected it would be refridgerated or held on ice. If you're in a healthcare facility and you've got a microbiology lab on site that's going to be doing the culture the sample would be held in refrigeration until such a time as the sample is actually transported to the lab. The lab would then put it in the refrigeration as well.

If you're sending it to an off-site laboratory it may take up to 24 hours to get that sample transported to the off-site microbiology laboratory. And again using ice packs, or temperature-controlled transport containers or refrigeration truly is needed because there are published data to show that if you transport a non-refrigerated sample at room temperature many organisms in the sample will replicate to fairly high levels over the 24 hour time period.

So to recap the expectation is that if you've got an on-site lab you would – it would follow the transport conditions of your facility and you would get to your diagnostic micro lab as quickly as possible, and while it's waiting keep it refrigerated until such a time as it gets to the lab.

If you're sending it to an off-site lab the expectation is that definitely the sample should arrive at the lab within 24 hours. During the 24-hour period it's really important that it is held on ice or refrigerated.

Coordinator: Does that conclude your question or comment?

(Elise): Yes thank you.

Coordinator: Thank you. Our next question or comment comes from (Joline Fedorov). Your line is open.

(Joline Fedorov): Thank you. I have a question about the use of Tween versus the neutralizer. Is Tween a neutralizer?

Dr. Michelle Alfa: Tween is a component that often is in the neutralizers. The problem is that depending on the concentration Tween can have a negative effect on some of the gram-negative organisms that are exposed to this component.

There's a number of different neutralizers. Iff you look at the components of Dey-Engley broth you will see that there are components like Tween and lecithin. Although Tween will give you some level of neutralization it's not one that will cover all of the aspects that need neutralization and that's why the committee recommended the Dey-Engley Broth rather than just Tween by itself.

(Joline Fedorov): So the expectation then is that Tween is now not a part of the culturing as we're used to it?

Dr. Michelle Alfa: No Tween would not be part of sample collection (Judith may want to comment on this as well). The sample collection for the new protocol that's being recommended is sterile water which is either deionized sterile water or reverse osmosis sterile water. This sample collection fluid doesn't contain any tween in it whereas you're correct in that for the CDC protocol a part of the sample collection protocol related to the lever cavity did have Tween in it.

(Joline Fedorov): Perfect.

Dr. Michelle Alfa: And what we're recommending in the new FDA/CDC/ASM protocol is that you don't need to use Tween because you're going to be adding the Dey-Engley neutralizer in a one to one ratio to the sample. The Dey-Engley

neutralizer covers many more aspects of neutralization compared to just Tween alone.

(Joline Fedorov): Okay thank you.

Dr. Michelle Alfa: Judith did you have anything else you wanted to add to that?

Dr. Judith Noble-Wang: Yes. I would just add that the Tween80 was included as a surfactant just for sampling. It was felt that Tween-80 would help to remove any sticky biofilmsthat would be in the distal recess area. Validation showed – that use of water for sampling performed well. Essentially, we don't need to use the Tween-80 for the sampling.

(Joline Fedorov): Okay. Thank you.

Coordinator: Thank you. And again as a reminder at this time they're taking questions only from the phone. So ask a question or make a comment you will need to press Star 1, make sure your phone is unmuted and record your name to introduce your question. Again for questions there from the audio portion only please press Star 1 and record your name. Our next question or comment comes from (Peter). Your line is open.

(Peter): Hi, just a question on culturing. We missed it or maybe we didn't hear it correctly. We're just wondering what method is validated, the solid plate with centrifusion or the solid plate with membrane filtration or both?

Dr. Kevin Ably: The solid plate with membrane filtration is the validated method. So that was the method that the manufacturers would spike scopes and looked at recovery percentages. The other methods are kind of expert opinion based off of – that they should work because of - based off of expert opinion.

(Peter): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Greg Pennington). Your line is open.

(Greg Pennington): Yes. The question I have is about the brush. You said sterilize the brush but is that brush cleared through the 510(k) for sterile processing?

Dr. Michelle Alfa: I will comment on the brush and then pass it over to Shani for comments regarding the FDA component of it. The expectation is that it would be a sterile brush that's used. The brush can be purchased as a sterile brush if, you know, there is one available for the size that you need for the sites that you're sampling. An alternative would be the steam sterilization of a traditional non-sterile bruh.

The sample collection protocol is basically one that is facilitating the ease of collection of these samples. So obviously the easiest way is to actually buy a sterile brush. And beyond that I'll pass it over to Shani because in terms of 510(k) issues she could address those best.

Dr. Shani Haugen: Yes this is Shani Haugen from FDA. Brushes for cleaning endoscopes are Class 1 510(k) exempt medical devices. And so 510(k)s are not needed for cleaning brushes for endoscopes. For specific questions about models and brushes you can refer to the - you should be able to contact the duodenoscopes manufacturer to address what types of brushes to use.

(Greg Pennington): So, you know, if we're going to - if they're exempt from the 510(k) on the reprocessing what parameter do you use so you don't melt the brush, melt the bristles so you have a functioning brush that you can use?

Dr. Michelle Alfa: In terms of that I think the standard steam sterilization cycles that hospitals have would be appropriate. In my research lab we've steam sterilized the traditional cleaning brushes. But I think the important thing is that for healthcare facilities the ideal solution is actually to buy a sterile brush itself because then you don't have to worry about that aspect.

If you are going to sterilize the brush the key thing it would be for one-time use. It would have to be appropriately packaged and put through a routine health care sterilization cycle. You would have to assess the brush after sterilization to ensure that the brush was not obviously damaged. But in our hands we found that most of the brushes that we used were steam sterilizable. But again I really want to reiterate if there are sterile brushes available commercially that is a better option.

(Greg Pennington): Okay thank you.

Coordinator: Thank you. Our next question or comment comes from (Kathy Mullaney). Your line is open.

(Kathy Mullaney): Yes. Are there any kits available for sampling available at this point?

Dr. Michelle Alfa: In terms of endoscope sample collection kits - yes there are some commercial vendors that have put together sample collection kits. I'm not going to mention any company names because I will maybe mention some and forget others. If you do a Google search you will find that there are some manufacturers that have sample collection kits designed specifically for sampling flexible endoscopes. And they usually have all the types of connectors that are needed, and the sterile water, etc. The may also include the appropriate sterile brush or they may advise what brushes could be used.

(Kathy Mullaney): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Palmer). Your line is open.

(almer): Good afternoon. We have a couple of questions. So we do this on every scope for duodenoscopes?

Dr. Michelle Alfa: Okay I can start this response but the others on the panel may want to chip in as well. If you recall from Shani's presentation the idea of the frequency with which the samples would be taken was one of the decisions that we believe the site committee probably needs to meet and discuss. Ideally you would like the samples to be done on every duodenoscope before it's actually used on a patient. But the reality is that I don't think it is feasible to sample each duodenoscope after each use. So the frequency of duodenoscope culture from published documents indicates that sometimes sites will choose to do duodenoscope culturing at least once a week or they will ensure that within a given period of days that all of their duodenoscopes have actually had culture done on them. And it depends on how you're disinfecting them because if you're sending them for sterilization like ethylene oxide, that scope is going to be out of use for a number of days.

And so the slate of patient procedures has to be correlated with the number of duodenoscopes available and the impact of the quarantine approach after a sample has been collected for culture. So really it is a question the site needs to determine and to be honest I have not seen a lot in the published literature talking about the frequency of sampling. But, generally speaking, the idea of once a week is something that is discussed in the literature. I'll ask if maybe Shani can comment on this as well.

Dr. Shani Haugen: Sure. So when it comes to frequency of sampling Michelle is completely accurate that the group didn't feel that this was a decision that could be made at such a high level and that each healthcare facility would need to evaluate their own needs and resources to determine what frequency of sampling is appropriate for their site. When it comes to using this protocol for other types of endoscopes, this protocol was written for duodenoscopes but as Michelle pointed out earlier there is an appendix that includes the appropriate flush volumes for other types of endoscope channels. So healthcare facilities that wish to conduct surveillance on other types of endoscopes should consider how endoscope designs and the organisms that may be present affect various aspects of the protocols including the extraction flush volume and the culture method.

Key aspects that should be considered include the use of a flush brush flush collection of channel samples where possible, adding neutralizer to the samples collected, whether each sample should be independently cultured or all samples should be pooled prior to culture and concentration of sample to ensure optimal sensitivity of the culture method.

Dr. Michelle Alfa: And I'll just add one other point on to that just for information. In Australia they tend to indicate that culture samples taken once a month for other types of flexible endoscopes is adequate. They usually recommend once a week for duodenoscope cultures - just to give you an idea of what some other countries are doing.

(Palmer): All right. And we currently use Hygiena here to check for the ATP. Will this take the place of it or will that be in conjunction with it?

Dr. Michelle Alfa: The ATP testing is actually designed and there is a lot of published information on it for evaluating the cleaning stage. In addition there are some research laboratories that have actually done testing to assess ATP levels after disinfection. And as Shani mentioned in her presentation the expectation is that if you're trying to test an endoscope post HLD, (i.e. a patient ready endoscope) then really the only way to assess the contamination that's in the duodenoscope is by culture. There is no ATP test at this point that is sensitive enough to detect down to one to ten organisms and therefore it's not appropriate to use ATP as a substitute for culture.

However, ATP testing is appropriate for monitoring the cleaning efficacy so at that stage any rapid ATP test kit could certainly could be used. However, post HLD ATP is not sensitive enough to replace culture as it requires thousands of organisms to generate one relative light unit on ATP. So in answer to your question ATP is not a replacement for culture. Culture would be the test you would do to assess a patient ready scope to determine if it's contaminated or not.

(Palmer): Thank you.

Coordinator: Thank you. And for further questions please limit yourself to one question. If you have a follow-up question you'll need to press Star 1 again. Again please limit yourself to one question. If you have a follow-up question you'll need to press Star 1 again to bring yourself back into the queue. Our next question or comment comes from (Jennifer Lightner). Your line is open.

(Jennifer Lightner): Thank you. I think my question was answered earlier by Michelle but I'm just going to bring it up for clarification. So is it okay to assume that we get preliminary readouts at 48 hours because when we did the 48-hour quarantine

we would get preliminary at 24. So now is it okay to have a 48-hour preliminary readout?

Dr. Michelle Alfa: I'll ask Kevin to comment on this as well but the expectation is that the plates would be read at 24, 48 and 72 hours. The committee felt it would be important that if there's growth after 24 hours incubation of the culture, you would get that positive culture report. If there's no growth at 24 hours and there's no growth at 48 hours, the idea of sending a preliminary no growth report indicating that further results of the final report will follow - was thought to be a practical approach. And so the expectation would be that if the culture shows growth at 24 hours you will get notified of this result. If there's no growth up to 48 hours incubation you would get that information and then you would receive a final report after 72 hours of incubation. Kevin do you have any additional comments?

Dr. Kevin Alby: Yes this is Kevin. A couple of additional comments is that this is something to work out with your facilities between the lab and the key stakeholders, infection control, perioperative processing in terms of when preliminary reports should be issued and what preliminary reports should be issued but that the lab should be looking at these cultures every day.

(Jennifer Lightner): Okay thank you.

Coordinator: Thank you. Our next question or comment comes from (Diane Miller). Your line is open.

(Diane Miller): Yes hi. This is a question regarding culturing. Based on the methods that were presented today it doesn't look like there is any recommendation to do a quantitative by dilution culture over a qualitative. Is that correct?

Dr. Kevin Alby: Yes that's correct. And that's one of those things that if – this is Kevin again and that if there were a specific problem and you were trying to monitor a specific problem is that you would potentially do dilution series to determine exactly how many colonies are present. The filtration method does offer some quantitation for low levels because you know that what your import volume is and how many colonies grow, how many colonies grow if it's a low number of qualities colonies. So there is some level of quantification from that perspective if you do the filtration method onto solid media or the centrifugation method onto solid media.

(Diane Miller): Okay great thank you.

Coordinator: Thank you. Our next question or comment comes from (Dorothy). Your line is open.

(Dorothy): Hi. I think my question's already been answered but I was a little confused when you said patient ready scope in some other dialogue I had with something, you know, we had storage ready and patient ready. So when you were saying patient ready I thought you meant right before we use the scope on the patient but you mean – okay the way we do it now we call for it after we disinfect the scope.

Dr. Michelle Alfa: Yes and that's a good question and it's good to get some clarification on it. The expectation is that the culture would be done after the disinfection phase. But there is some published data to suggest that if you allow the scope to be stored overnight or over a couple of days you sometimes will get better sensitivity in actually detecting organisms because if you sample it right after the high level disinfection process is finished the levels may be so low or so damaged that it's difficult for those organisms to grow and be detected.

(Dorothy): Okay thank you.

Coordinator: Thank you. Our next question or comment comes from (Donald). Your line is open.

(Donald): Yes question on the swabbing of the distal seam, what swab do you recommend and how is the sample collected in the container?

Dr. Michelle Alfa: I would expect that any swab that is currently available for collecting patient samples could be used. It is wetted before it is rubbed across the area that's indicated in the protocol. And I'm sorry the last part of your question if you could repeat it?

(Donald): How do we then include that sample from the swab into the container?

Dr. Michelle Alfa: For swabs there's two ways to do it. One is there's often a snap portion indicated on the shaft of a regular diagnostic swab that allows you to easily break it off into the tube aseptically. And the alternative approach if you want to just cut the head off using sterile scissors. Since sterile scissors are needed for cutting off the channel brush head you could use the sterile scissors for both the brush head and the swab or you could use the snap feature of a diagnostic swab.

(Donald): Okay great. Thank you.

Coordinator: Thank you. Our next question or comment comes from (Deborah). Your line is open. (Deborah) please check your mute feature. All right we'll go to our next question. Our next question or comment comes from (Kate McGuire). Your line is open.

(Kate McGuire): Hi. I think my question has been answered by a previous participant. Thank you so much.

Coordinator: Thank you. Our next question or comment is from (David Michelvitch). Your line is open.

(David Michelvitch): I was wondering what was the thinking of having controls in the 2018 protocol but not in the interim protocol previously?

Dr. Judith Noble-Wang: Hi. This is Judith Noble-Wang. Just to clarify the controls were in the interim protocol. And other than your regular laboratory controls that you do there are no additional controls listed in the 2018 protocol. The new protocol has been validated and shown to be effective to extract most, but not necessarily all, microbes on the device. In contrast, the interim protocol was not validated, and for that reason several controls were included to account for unknown factors that may impact recovery of the microorganisms.

(David Michelvitch): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Jan Tibbit). Your line is open.

(Jan Tibbit): Yes I wondered who actually did the sampling of the hospitals or facilities that have already implemented or trialed these protocols? Is it the endoscope processing staff that do them or does microbiology or other people do the sampling?

Dr. Kevin Alby: Hi. This is Kevin. As a facility that has done some of the sampling we leave it to the people who are professionals at handling the scope so the perioperative

processing staff. We recommend - and that's in the recommendations is to have people who are familiar with handling the scopes do the sampling not laboratory staff.

(Jan Tibbit): Okay thank you.

Coordinator: Thank you. Our next question or comment comes from (Lawrence). Your line is open. (Lawrence Muscarelli) your line is open. Please check your mute feature. Our next question or comment comes from (Marlon Williams). Your line is open.

(Marlon Williams): Can you hear me?

Coordinator: Yes.

(Marlon Williams): Can everyone hear me? All right how are you doing? I have a question about the flush brush flush method. I'm wondering in the - of the necessity for it because it seems like it is more movements and it leads us to the position of possibly actually contaminating a scope?

Dr. Michelle Alfa: That's a very good comment. And the reason for the flush…

(Marlon Williams): Can you speak up? I can barely hear you.

Dr. Michelle Alfa: Okay. Sorry I'll put the phone a little closer to my mouth. The reason for using friction is that there is published data that shows that for very low levels of organisms it is important to have a friction component in the sample collection and that fluid flow alone won't be adequate or not as good as fluid combined with friction. You're correct that the brushing step is most prone to introducing external contamination.

But it was felt that it was still important to have that friction because otherwise the sample may not be as sensitive. The use of friction outweighs the risk of contamination. As long as you use aseptic technique you shouldn't be introducing external contaminants and it is important to have the friction component present in the channel. For the lever recess the same reason reasons are relevant for sample collection. Those little brushes can actually get under some components of the lever and the combination of flushing up and down with the fluid and brushing really does facilitate improving the sensitivity of sample collections.

Woman: Thank you.

(Marlon Williams): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Eric Walters). Your line is open.

(Eric Walters): Oh thank you. I think you've already answered my question so thank you.

Coordinator: Thank you. Our next question or comment is from (Linda Lawrence). Your line is open.

(Linda Lawrence): Yes my question is with the brushing do you actually brush down and bring the brush back out before you cut the tip or do you bring it through the scope once and cut the tip before the rest of the brushes fall back through?

Dr. Michelle Alfa: In the FDA/CDC/ASM protocol it actually does clearly spell out the instructions for that. During this webinar presentation we just mentioned that a brushing step is needed. The details are that the brush is inserted through the

biopsy port, and by pushing the brush down the channel it will come out the distal end. When it emerges from the end of the duodenoscope it's then cut off into the sample container. So it's not put down and then pulled up through the channel. It's actually just passed through the channel and once it emerges from the end it's cut off aseptically into the specimen container.

(Linda Lawrence): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Byron Fernandez). Your line is open.

(Byron Fernandez): Thank you. My question is regarding the culturing and subsequent observation and gram staining of any recovered organisms. I understand that there is a requirement to check incubating plates at 24-hour period 24, 48 and 72 hours. Should grant gram stain of those observed isolates be occurring at those time points or after the 72-hour period?

Dr. Kevin Alby: This is Kevin. That's going – so they should have some type of work up at that time that growth is observed. It depends on your facility if you choose liquid or solid culture method and what equipment you have available to you to do your workup. So if you are a laboratory that is a MALDA-TOF spectrometry and you're doing a solid culture technique you would likely be able to go straight to organism identification on day one or as a post if you're doing liquid culture then you would do a gram stain of the liquid culture and then look at the subculture.

(Byron Fernandez): Okay. We are currently taking advantage of the membrane filtration method which is why I ask because at each time period there is a potential points of contamination in terms of recovering a gram stain subculture.

Dr. Kevin Alby: Yes. So the idea would be to provide as much information as you could as quickly as you could.

(Byron Fernandez): Okay thank you.

Coordinator: Thank you. Our next question or comment comes from (Holly). Your line is open.

(Holly Holmig): Hi. This is (Holly Holmig). I guess my question sort of has been answered. It was about sterile brushes. And I think I need to clarify the full guidelines from the FDA so that I can compare them to ARN and AMI guidelines for sterilization a single use items because I don't know that those brushes have an instruction for use to sterilize them. So I'm going to have to do some more research but thank you for answering the questions thus far.

Coordinator: Thank you. Our next question or comment comes from (Nihan). Your line is open. (Nihan) please check your mute feature. Your line is open for your question or comment.

Woman: Oh yes hold on one second. We're here. She stepped out and I believe she's - she asked her question on the line.

Coordinator: Okay.

Man: Thank you.

Coordinator: If she has an audio question she can press Star 1 to get herself back into the queue. Our next question or comment comes from (Jaclyn Daily). Your line is open.

(Jaclyn Daily): Yes I wanted to ask related to not recleaning the scope but going straight to high level disinfection or sterilization. And it ties back to the participant who asked the question about flushing and brushing and flushing again being that it could loosen some organisms from the biofilm. Would it not be prudent then to do a clean and then go towards the high level disinfection? You may not necessarily need to do leak testing but the manual cleaning to me sounds like it would be apropos.

Dr. Michelle Alfa: That's a good question and hello, good to hear from you.

(Jaclyn Daily): Yes Dr. Alfa.

Dr. Michelle Alfa: I think the key thing is that if you are collecting it aseptically properly and you are using sterile water then you do have the choice to re-clean and then disinfect or just to go straight to disinfection. Theoretically you should be able to go right to the disinfection. But we definitely leave it to the site because your point is valid it depends on how the collection is done as to whether anything might be introduced. So, in terms of sites that are worried about that by all means there's no problem, you can reclean it and then send it for the disinfection or sterilization process again. But the expectation would be if the sample is collected aseptically that going directly to the disinfection or sterilization step would be an adequate process.

(Jaclyn Daily): Okay thank you.

Coordinator: Thank you. Our next question or comment comes from (Linda Kane). Your line is open.

(Linda Kane): Hi. Thank you. Can you hear me?

Dr. Michelle Alfa: Yes.

(Linda Kane): Oh good thank you. My question is that this is a voluntary protocol at this time. Are there any states in the United States that it's mandatory, mandated? And are there any ideas when it will become mandatory versus voluntary? Thank you.

Dr. Shani Haugen: This is Shani Haugen from FDA. So your question was whether there are any states that require use of this protocol? We're not aware of any states that do require the use of this protocol but again this is something that each healthcare facility should check with both their state and local requirements. It is not required by FDA, CDC, or ASM.

(Linda Kane): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Katy Godsey). Your line is open.

(Katy Godsey): Thank you. My question was just answered.

Coordinator: Thank you. Our next question or comment comes from (Atosha Richards). Your line is open.

(Atosha Richards): Is there any plan to make a video to ensure accuracy for the staff to perform this procedure?

Dr. Shani Haugen: This is Shani Haugen from FDA. At this time know there are no plans from the FDA, CDC ASM Working Group to develop a video for this protocol. Thank you.

Coordinator: Thank you. Our next question comes from (Fran Hixson). Your line is open.

(Fran Hixson): My question happens to be very similar to the previous question about training. And videos with the little caveats that you're sharing would be very beneficial for us as we're trying to implement the protocol. In regards to training can you tell me for those who perform the task the time it takes to really perform the procedure and sampling accurately?

Dr. Michelle Alfa: I actually agree with you that having some tools and a video is actually an excellent way of doing it. And we were hoping that maybe some of the sites may actually choose themselves to create a video because it facilitates the training process and also facilitates the ensuring that the individuals know exactly what's supposed to be done.

I think it's really important that there's a committee that involves, infection control specialists because they can review specific aseptic handling of devices and clinical microbiologists who can help review the aseptic handling of samples to avoid accidental introduction of environmental contaminants. In addition the site committee makeup would also endoscopy reprocessing, endoscopy nursing staff and facility educators to determine the best way to provide appropriate training for the duodenoscope sample collection. So your point is very well taken and I think it might be worthwhile for some of the sites or maybe some of the other organizations or educational groups to create a video that would go through all the duodenoscope sample collection steps so that people can actually see it being done in the appropriate way.

Corey Ofstead's publication does mention some of these things but I think the key thing is that this is a new protocol and I think the concept of having a video made to show exactly how that brush is put through the channel and

underneath the lever mechanism in the recess as a training tool a video would be quite helpful.

Dr. Shani Haugen: And just to add to that this is Shani Haugen from FDA. There has been literature indicating that when initially incorporating this type of procedure within the healthcare facility it does take quite a bit of time those first few times for sample collection. But then once sufficient practice has been gained then the time for sample collection can be reduced substantially.

Coordinator: Thank you. Does that conclude the question or comment?

(Fran Hixson): Well I just wanted - the degree of training how long does it take for one to become competent when you were implementing your process?

Dr. Michelle Alfa: So maybe I'll start that one off. I think the first decision that has to be made is related to one of the previous questions that were asked as to who is going to do the sample collection? Ideally it makes sense that individuals who are competent at handling duodenoscopes be trained in the aseptic technique part of sample collection. So in terms of how long it takes it really depends on who you select be the person to collect the sample. If that person doesn't have experience with handling duodenoscopes it's going to take you longer to get them up to speed than somebody who does. And even the person who has expertise in handling duodenoscopes you then need to get them up to speed in terms of this particular protocol and the use of the aseptic technique. So sorry I'm being vague on this but it really does depend on who you actually select to collect those samples.

(Fran Hixson): Thank you.

Coordinator: Thank you. Our next question or comment comes from (Jaclyn Daly). Your line is open.

(Jaclyn Daly): Yes thank you. I had a second question related to the culturing. Being that in the document under regulatory requirements it says sampling the endoscope for microbial culturing is the quality indicator. So if we're using it as a quality indicator and we get some of the high concern organisms there was mention of notifying the patient. But if the patient is healthy and fine and depending on how long between the use on the patient and when the culturing was done how do you go about notifying the patient and offering some constructive feedback as to what to do? How would you do that?

Dr. Kevin Alby: This is Kevin. So we don't offer specific guidance as to what exactly a healthcare facility should do in terms of when they should contact a patient and the type of information they should provide. That is the sort of decision to have with that kind of core team that is hopefully developed. That includes infection control, maybe someone from risk management, you know, to kind of assess what happens in each of those situations. So the idea is that it's an example of something that our facility can do but it's really up to the facility to determine what to do in each representative situation.

(Jaclyn Daly): And I just was – it's the same question but just to follow up why not all organisms because depending on your immune state any of these organisms could become problematic? And I realize it's a GI thing but it seems that we're kind of establishing two levels here. If you've got these organisms that are considered high concern and you've got ones that are moderate to low how do you decide which patients get notified other than what you had stated?

Dr. Kevin Alby: Again that comes down to what your patient population is, the kind of opinion of the experts at your facility as to who they think is at risk for infection with

coagulase-negative staphylococcus because as you said it really depends on your patient population. And your patient population may be susceptible to infection with those organisms whereas other facilities may not have a patient population that would be susceptible to infection with those organisms. And so it's really again going to be a facility by facility decision.

(Jaclyn Daly): Okay. Thank you.

Coordinator: Thank you. Our next question or comment comes from (Kevin). Your line is open.

(Kevin): Hi. You said that the proper technique for sampling the working channel is to advance the brush all the way through and when it comes out the end to cut off the end of the brush. Did you investigate whether there was any possibility for microscopic damage from cutting that and then pulling it back to the channel with maybe a bore scope of something of that type?

Dr. Michelle Alfa: Well in answer to your question I can't speak for the manufacturers when they did the validation. But in terms of putting the brush through and cutting it off from a research lab perspective we've actually done that for years and we've not encountered any instance of failure of leak testing where there was scrapes inside the channel the perforated it. In terms of using a borescope we ourselves did not use borescope examination. I can't speak for the manufacturers when they did their assessment but for the years that we've done sample collection from endoscopes and we've passed sterile brushes down and cut the end off we haven't experienced anything that we could recognize as major damage from the shaft being pulled back up.

(Kevin): Okay. Thank you very much.

Coordinator: Thank you. I would not like to turn it back over to Irene Aihie for any closing remarks.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Friday, March 30. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation.

As always we appreciate your feedback. Following the conclusion of the Webinar please complete a short 13 question survey about your FDA CDRH Webinar experience. This survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live Webinar. Again thank you for participating. This concludes today's Webinar.

Coordinator: Thank you. That concludes today's conference call. Thank you for your participation. You may disconnect at this time.

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