Transcript of “Recognition and Resolution of Duodenoscope-Associated Multi-Drug Resistant Organism Transmission at Virginia Mason Medical Center” Webinar
Presented March 18, 2015

Note: The Question and Answer section is on pages 11-15 and is highlighted in yellow.

Good day, ladies and gentlemen and thank you for joining us for today's recognition and resolution of duodenoscope associated bacterial transmission. My name is Tyler and I will be in the background exit -- answering WebEx testicle questions. You may contact me in the Q&A panel and I will do my best to assist you. If you have trouble joining the WebEx session called technical support, (866)779-3239. Please note that as an attendee you are part of a larger audience. Due to privacy concerns the attendee list is not displayed. All attendees will remain in listen only mode throughout the duration of the presentation. This webinar is being recorded. We will field questions throughout the duration of the presentation and you may ask an online question at any time throughout the presentation by entering the question into the Q&A panel and clicking send. Please leave the default set to all panelists. There may be a live Q&A session, time permitting. You will need to have a phone icon in your name next to the Q&A panel. If you need help, let me know and I will assist you as best I can. We invite you to sit back and relax and enjoy the presentation.

Thank you, Tyler. It's my pleasure to welcome me to the webinar recognition and resolution of the duodenoscope associated bacterial transmission.

We are Qualis Health, the quality improvement organization for Washington state and Idaho in today's webinar is brought not only by our agency, but by the Washington State Hospital association. We're pleased to partner with our other entities in the state to bring in this very important webinar. My pleasure to introduce our speakers, Dr. Michael Gluck a Virginia Mason Medical Center and Doctor Andrew Ross, the first speaker is Doctor Glock, the chief of medicine at Virginia Mason Medical Center. Prior to this appointment he held the position of section head of gastroenterology department. Especial interest in ER CT, employment toy ball disease, pancreatic disorders, pancreatic necrosis, GI limit -- GI malignancies. Is a fellow of the American Society of Gastro and Roscoe P. Has numerous scientific publications. Also presenting is Doctor Andrew Ross the section head of that andrology and hepatology Department director of therapeutically -- and therapeutic endoscopy Center at Virginia Mason Medical Center. Is my pleasure to welcome Doctor Michael Gluck.

I have passed control of the slides to you. I'm joined by Andy Ross to mighty men the unit left and we will talk about the recognition and
resolution of that duodenoscope associated bacterial transmission visible and multiple publications in the lay public, recently. Today, the first part of the conversation will be on the background of endoscope infection. We will turn to a case example of the associated multi drug does this didn't institution and discussed next steps and recommendations that we have after undergoing this process.

The prospectus on high-level disinfection depends on what it is looked at. If you ask an endoscopy asked how he approaches endoscopy, you will ask for an interest -- instrument that is an efficient tool to get the job done. We presume so she presumes the high-level disinfection is undertaken and is very effective with the transmission of infectious organisms almost zero. When you ask an endoscopy this specific questions about high-level disinfection, they have a limited amount of information.

The manager of endoscopy is usually much more aware of that. The want to know if the instrument can be disinfected. The staff should be trained to do that in an effective manner and it is instrument they purchase, if it's too expensive they may not be able to offer that service. Finally, is that instrument available? Is it durable? For example at our institution we use double balloon scopes and they tend to be fragile instruments, frequently retiring -- requiring return to the manufacturer per manufacturer.

Is this service capable of being performed? Organizational perspective is, is the process save, effective for patients? Can we measure it for quality and can we institute programs to ensure that safety? Will this staff that performs that be safe in doing that? With the current reimbursement, and if it can't be supported with current reimbursement, let's support other fields such as surgery or thoracic surgery. The most important person in this equation is the patient because they presume a procedure is totally effective otherwise it would not have been suggested and they presume it is safe for the patient really understand the difference between a high-level disinfection and sterilization which are two unique processes.

The evolution of endoscope reprocessing is one that is quite old, over 50 years. In the 1960s, there was the first recognition for potential disease transition -- transmission through endoscopes. At that time, scopes were predominantly cleaned by cleaning the outside and channeling and using the channels and flushing it with a disinfectant. In many places in the world that is the only thing that is done so in endoscope, an expensive piece of equipment can be used multiple times during the day.

In the 1970s, the first analyzing liquids were used at high level disinfection and one was 2% [Indiscernible]. They didn't know how long to utilize that and flushed channels with that. Later, it became known in -- in 20 to 30 minutes of flushing was necessary. In the 1980s, the first reports of Pseudomonas bacteremia associated with ERCP and this was thought to be due to moisture in the channel because scopes were
often not dried completely. They weren't hung and this predated the automatic endoscope reprocessing which developed early in the 80s and continued on. In 1983 watertight scopes were established. Ahead of the scope is one that prior to 1983 could not be submerged. Further my, all channels were irrigated. There were continued improvements in automatic endoscope reprocessing and the importance of biofilm was undertaken. These AER is where improved so that biofilm wooden form.

Between 19831986 access to the wire which is in Dr. Ross' presentation was made available for manual flushing so the detergent and disinfection could be passed through that in that area. Between 19931996, the Teflon channels in the endoscopes were exchanged for an impervious, cleanable material that was a very hard, difficult to damage, so that could be improved and the cleaning of it and reduce the likelihood of bacteria forming within those little crevices.

Furthermore, the air water valves were made so durable that they could undertake steam autoclave, a sterilization process, and tolerate high heat. By 2010, they developed duodenoscope SPOC those used in ERCP that had enclosed the wires within them hoping that would reduce the likelihood of infection.

After 2013 and up to 2015, we recognized is a possibility and high likelihood of duodenoscope induced transmission of bacteria and with that, we anticipate changes that will be undertaken.

High-level disinfection is not equivalent to sterilization. The main goal of high-level disinfection is to eliminate about 99.9% of pathogenic organisms from the endoscope. The most important step is manual cleaning. Eliminates the bio burden and starts in the procedure room as soon as it is completed. There a section of normal saline or in our case, we use a disinfectant detergent that is sectioned and immediately after the procedure is completed. If there is a failure to remove the bio burden it increases the likelihood of high-level disinfection failure. That is the most important step in has to be overseen by the managers and organization. Automatic endoscope preprocessors use per acetic acid, hydrogen peroxide or chlorine dioxide. We use one set of well dried -- glutaraldehyde and forced air drying following that the endoscopes were hung vertically to avoid any pooled water and growth of bacteria within that. Some advocates have argued for ethylene oxide, a room temperature sterile and. Many institutions, they have eliminated it because it is a known carcinogen, very difficult to dispose of and if the toxin is not completely cleaned off the endoscope, it can expose the patient to that, then on top of that there are reports of ethylene oxide in which bacteria were grown suggesting it is still not the failsafe Mexican -- medicine.

The chain is key because this is the underlying way that patients are exposed in susceptible to bacteria.

Microorganism of known pathogenicity virulence must be present in high numbers. Only a handful is needed to cause bloody diarrhea where you need log factors greater than that for salmonella. The other thing is,
you need certain virulence in certain environments. Those has to be susceptible. Whether that be because he or she is immunocompromised, has received chemotherapy or has an obstructive system. Of they are not susceptible, the likelihood of an fashion disinfection is very low.

If you swallow strep pneumonia, the likelihood of getting an infection is low however if you inhale it is much higher. The same holds with Clostridium diff is there. Has to be in the right organ system.

The fundamental hallmark of infection prevention is person-to-person transmission and generally that is by hand-delivered or body delivered bacteria. Personal and hand hygiene and personal protective equipment is the hallmark of eliminating infections in the hospital. For everyone endoscope induced infection there are thousands that are transmitted by pour personal hygiene, poor hand hygiene. The environment has to also be controlled. Good ventilation systems, excellent building design, clean water that is not contaminated and adequate and directed air pressure, whether positive or negative and specifically for air transmitted or respiratory type organisms.

After a patient is in the endoscopy unit, the sanitizing work has to be undertaken to ensure the services don't become contaminated and transmitting organisms to the next patient. We have to also disinfectant sterilize medical instruments. The medical instruments are sterilized and they are the ones that are durable and non-flexible endoscopes, as we will discuss later on.

All medical waste has to be -- has to be handled properly and administrative support has to be available for training, oversight and assurance of quality work. That is through the infection control process.

In 1993, David SPOC and colleagues, stimulated by the fear that HIV could be transmitted by either endoscopes or other means undertook the study and looked at all the reports of G.I. endoscopy related infections. At that time those were self-reported. The rate was 1.8 cases per million procedures. We all know that is a vast underestimate because of reporting standards and what we've seen in the last few years with duodenoscope's. In his study published on bronchoscopy and possible transmission of Mycobacterium tuberculosis and atypical mycobacteria. In 1983 there were reports predominantly in France of transmission of HPV through medical instruments and endoscopic instruments and HCV in 1997.

HIV transmission, fortunately, has never been reported, partially because the organism is susceptible to bleach, alcohol and standard disinfection processes that go on in a hospital.

ERCP specific infections were first reported in 1980s through Pseudomonas. When we started having mechanisms that looked specifically at the organism, Klebsiella was reported in 2010 out of France by an author named [Name indiscernible] who showed a clone of a bacteria noted in that group and Klebsiella was reproducible and multidrug resistant.
Once again, and 2410 in Chicago, there was a similar New Delhi E. coli specifically for the Southeast Asia and became traceable in the United States in Chicago and this gives a powerful tool for saying, here is the infection and how we will monitor it.

The most common transmissions up to the most recent reports have been associated with breaches in high-level disinfection protocols and this is not the current case, as we describe.

I would like to turn the podium over to Andy Ross, or the phone over to Andy Ross who will talk about the case study we have at this institution.

Thanks, Mike and good afternoon everybody. Been going to start by talking about what we have done here at Virginia Mason and move through to the end to talk about some of the recommendations that we have, based on some of the work that we and others have performed. In 2012, we participated voluntarily in a statewide surveillance study and this was really looking for the -- to quantify the outbreak or prevalence of CRE in our hospitals here in Washington state. Our participation includes voluntary submission of samples, containing several different multi-drug-resistant organisms to a state reference lab being run through the Department of Health. In 2013 we were notified by the reference lab that they identified an organism that was unique to our medical Center. This was a hyper amp C E. coli. Although the reference lab was looking for CRE, what they actually identified from us was a unique organism. What we subsequently learned was that there were 32 patients in a cluster identified, who had complicated pancreatic disease. When we looked at them a little bit further, all had undergone ERCP or 12 Nazca P using one of the viewing instruments. But they all had in common was the same hyper amp C E. coli. They had the same proven bacteria in each one of them. This let us know that we could have a potential issue related to the ERCP scopes. Our medical center used to patient safety alert process which brings a multidisciplinary team of professionals to look at any patient safety related issue and this is our process for handling the issue we describe. We collaborated with public health of Seattle and the state Department of Health and the Center for Disease Control. Doctor Glock just spent a lot of time talking about infection control in the hospital and what you can’t do in this situation, is jump to conclusions. You have to look at each of those aspects of infection control to try to understand whether or not there's any contribution. Looked at the environment, the endoscopy suites, the room where we do our reprocessing. We looked at the people. The people who perform both the reprocessing and the and Tosca best-performing the procedures and the nurses who assist in those procedures. We actually had an independent validation by outside eyes to look at our technicians performing high-level disinfection and there was no breach found in our high-level disinfection protocol. Going back to Dr. Gluck’s last slide, almost the majority of outbreaks or infection transmission during and I skip he had a breach in high-level disinfection protocol. There, there was no breach. We finally started to -- during this process -- also cultured our duodenoscope's. What we eventually identified on two of the scopes
was the hyper amp C E. coli identical to the patient strains that had been previously identified by the state reference laboratory and we were able to culture these E. coli from the elevator channel. The director says this was the quote-unquote smoking gun. There is a side depicting the descriptive characteristics of the patient cohort. At the present time, the cohort exists with 32 patients, 17 of which have died by this point in time. 15 are currently living. You can see this no difference between the ages within each of these groups. The male to female ratio. There's no difference in the number of the ERCP, but you can see these are patients who had underlying pancreatic or biliary disorders that retired -- required multiple ERCP's. That's one of the issues we need to be aware of. The patient population, going back to the conditions for infection, is a patient population undergoing multiple ERCP is and may have been exposed to multiple antibiotics, I have multiple indwelling stints which may create a set up for infection. They had malignancies at a greater% of patients who died who had advanced malignancy than patients currently alive. Other diseases such as end-stage liver delete -- liver disease or sclerosis, acute pancreatitis are represented in significant numbers. Of the entire cohort, 17 patients have died by this point in time. Seven patients died within 31 days of isolating the bacteria and culture in the majority of those patients had metastatic malignancy with Elyria obstruction that required alterable ERCPs and stents. One patient had multisystem organ failure and prolonged ICU stays in one had walled off necrosis of the pancreas. What you are looking at is a very sick cohort of patients with multiple underlying cohort morbidities. There have been 10 deaths at a median of 180 days following isolation of the culture. The majority had malignancy, cirrhosis and some other conditions.

What have we done subsequent to the outbreak? Our response has been what we would consider a multidisciplinary approach. We employed these measures after identification of the endoscope and the likely source of transmission and our goal was for a 0% chance of remission -- of transmission. Deeper dive really indicated that the manufacturer suggested guidelines were followed. But, at the end of the day, less than optimal. Remember, we are the high-level disinfection process that should result in endoscope that is free of 99.999% of potential bacterial pathogens. As we will demonstrate to you in our experience, that is not the case.

What we currently do, is what we call a culture quarantine process. Our endoscopes undergo high-level disinfection according to the manufacturer's guidelines with specific attention paid to the elevator channel. With always paid meticulous attention to the elevator channel. After high-level disinfection, the endoscopes are cultured and held for 48 hours until the culture is return negative for pathogenic bacteria. Scopes which culture positive for pathogenic bacteria undergo repeat high-level disinfection and quarantine. This has required an increase in our duodenoscope inventory from eight to 28 and increased our staff in the micro lab in order to accommodate all of these cultures by a total of 1.0 FTE.
We performed routine patient surveillance with patients undergoing ERCP. We cultured the bile and perform. No cultures and also developed a special informed consent. We've made ergonomic changes to the reprocessing room to minimize the potential human factors which could play a role in any sort of outbreak such as this. We have identified no new cases since full implementation of this protocol. We also have ongoing infection prevention measures such as continued provider staff education and the use of PPE. Skill alignment, we've asked the endoscopy test when they finish a procedure to hand off the instrument and we have a description later in the talk. The instrument is handed off immediately to a skilled technician who actually begins the high level infection process in the endoscopy suite. Finally, we have a routine endoscope maintenance process which we also put into place.

By implementing our culture and quarantine methodology and having the benefit of 1 year worth of data, we've been able to identify a defect rate and high-level disinfection protocol for duodenoscope's, which is around 2%. What you can see from this slide is that when we cultured the endoscopes we not only find hyper amp C E. coli, but other potential bacteria pathogens on the endoscopes. Remember, there is a risk of bacteremia with ERCP in general. Hyper amp C E. coli is unlikely to be special in that it is unlikely to be more resistant to the high-level disinfection process. Rather, these bacteria, these multi-drug-resistant bacteria which we can now fingerprint is a marker of what is likely a larger issue with being able to reprocess the scopes appropriately. This slide shows you in the past two years where the actual reported outbreaks of multi-drug-resistant organisms associated with that what the scope have come from. I suspect this is likely in underreporting. I think this gets to the issue of this being a national and/or international issue wherever the duodenoscope's are used. What is happening here? As you probably know the US FDA put out a warning relative to the duodenoscope. If you read through this document closely, there is an engineering assessment, an FDA engineering assessment of the duo Deana scope that suggests ultimately at the end of the day, this scope may not necessarily be able to be fully reprocessed every time. The FDA suggests meticulous attention be paid to the elevator channel and we are waiting additional it -- additional information around this issue. What's the issue and why is this different and what are we seeing at this point? I don't know how many if you have our look at the bottom of a -- at the actual duodenoscope, the working portion of it. This is a photograph of the head of the duodenoscope. What you can see, this is really a complex -- this device has a very complex design. Unlike our forward viewing endoscope the optics come out the side and unlike our forward viewing endoscope there is the elevator channel. That is here. The mechanism that allows it to move up and down to allow the movement of instruments in an up-and-down access, to access to the site. It's an area where you find tissue. Doctor Glock's boat bio burden from scopes prior to high-level disinfection. The micro crevices where bacteria are microscopic and can be lodged in very, very difficult to clean.

If you don't get all of the protein -- remember what we do with the scopes. We pull stents through the bile duct and take out stones. This
is a very different application than other applications you would use a standard endoscope for and so, this issue of being able to get rid of bio burden appropriately and its relationship to high-level disinfection and failure of high-level disinfection in these cases, cannot be underscored enough.

We believe it -- based on our data and experience here -- that the existing high-level disinfection protocol for duodenal scopes is recommended as an adequate. There's a 2% defect and high-level disinfection pic of you consider high-level disinfection should get rid of 99.99% of all bacterial pathogens or potential pathogens on the scope, it 2% rate is significant. Indeed, it's logarithmically higher than what has been proposed by the manufacturers and endorsed by the United States FDA.

The FDA has said this instrument is difficult to clean. Again, we've defined a defect rate in high-level disinfection and existing protocols recommended by the manufacturer may not have been fully validated. If you look in the literature, you don't see studies talking about validation of this protocol for duodenal scopes. No one can rule out operator error as a contributor to the issues related to high-level disinfection. If you have a 20 step process and you miss one half of one step and that ultimately results in failure of the process, that would imply lack of redundancy and existing high-level disinfection protocol. Remember a 747 has four engines for a reason. If three of the engines fail, the airplane can still be landed.

What we likely have is a perfect storm. We have an instrument that is difficult to clean. We have increasing antimicrobial resistance. This is a sign of the times. These bacteria, as opposed to being a generic pseudomonas, are multi-drug-resistant organisms that have a genetic fingerprint and that fingerprint gets left on the scopes and now, we can actually identify these bacteria and identify when they are transmitted between patients. On the other hand, we have a very necessary procedure. It's a procedure none of us want to see go away. None of our patients want to see this go away. This procedure has revolutionized the way we take care of pancreatic biliary disorders and has changed the ability to care for some diseases that may have, in the past, required open surgery and weeks in the hospital. Now, we can do a lot of things on an outpatient basis. The alternatives to ERCP are quite poor. In many cases, what I would consider maximally invasive. It's very easy for a lot of us to sit and call for a design change to the endoscope but the reality is, a design change is a long-term solution. It may take years to achieve. If you think about the way devices that medications have to move through the regulatory process, that -- this takes a long time to build a better scope.

What to do in the interim? The CDC has released guidelines this past week suggesting the following. Number one, informed consent. This goes without saying. I felt what -- I don't think we need the CDC to remind us of this but patients undergoing any procedure should have informed consent. There should be a discussion of the risk benefits and alternatives to any procedure. As it pertains to ERCP, this issue is
widespread in the media and the press. We need to have exhaustive consent in this issue needs to be brought up with patients. We have developed a specific informed consent form around the use of the duodenoscope and all the issues that have surrounded it. And formed is no longer -- it's not any longer good enough to have an informed consent that says I, patient, consent to right in the performed procedure.

The risk associated with the specific procedure you are performing, and it should be at a station by both the patient and the performing physician.

Meticulous attention to high-level disinfection and in particular, the elevator channel of the duodenoscope and also going back to Dr. Gluck's slides, it is far more likely we will transmit CRE and other multi-drug-resistant organisms to patients by poor hand hygiene and other lack of attention to other infection prevention practices than it is by transmission using the duodenoscope. The CDC recommends consideration of routine surveillance cultures of duodenoscope's. They do not provide an interval in that interval remains unclear. However, if you do identify an outbreak, there is a recommendation to perform surveillance culture during an outbreak in quarantine any identified -- any endoscopes identified with the pathogen in question until they are documented to be pathogen free. The CDC has released these guidelines. They are available. We have several resources that are available to you, both on our own external facing website -- we actually have a full description on how we undertake our high-level disinfection protocol. Specifically, around culturing and the quarantine process. Of course, the CDC has their recommendations listed on their website. We will soon be posting our informed consent forms to our own website, as well, as examples of what we are doing here. Mike, I'm going to ask you to come back in. I wanted to run through some of the pictures that we have describing our high-level disinfection protocol.

What we do is have a brief run through of our technique as soon as the procedure is completed, one of the technicians takes the scope from the container and immediately aspirates a detergent-based substance through that, to get rid of about 90% of the bio burden. As you see, they will brush afterwards. The outside is also washed very quickly afterwards and scrubbed on the outside so there is nothing on the exterior portion.

The important piece -- two really important pieces -- number one, this is immediate. Number two, this happens in the endoscopy room. Number three, this is not the physician. If you leave this to the physicians, they will skip steps multiple times and it's important to tell the doctors you are not the expert in this area.

We developed standard work. The technician knows specifically what to do as soon as they're called to come in there. They have a voice monitor and they come in and take the scope away from all the other people who are not really skilled for that.
As it goes to the back, the cleaning process begins. There is a flush pump they are in constant suction of material through that and good cleaning before it goes in the sterile room. This is our dirty room and you can see great attention is used to clean the elevator channel. There is a small scrub being used behind the elevator channel, along the elevator channel and through the elevator channel. As you see in the white looped area, it is already gone through the elevator channel, is all the other channels.

This is a submit several scope. It's prepared to go into high-level disinfection and the reprocessing areas. It is handed off to the clean room by one of the tax and you can see -- one of the technicians and you can see a bank of EER is in the middle.

Understanding that the technician -- even working in the dirty side of the room, PPE, plus mask. And here is covered, as well.

What you can't see is the shoe coverings, and they are on there, as well. This is one of the AER's. It holds two scopes. It has. Acetic acid, little bit more environmentally friendly than glutaraldehyde. There is a water cycle of a minimum of 20 minutes. They are not just holding each other because they are trying to use excellent sterile techniques.

We have a large number of technicians who work in gastroenterology. That is to reduce the chances of any kind of unnecessary variability. Exactly.

It ensures a better level of fidelity of quality within the natural culturing process. The technician is removing a brush from the sterile container. You can see the culture media, which is ready and also some sterile water which is used for flushing. We have [Indiscernible], indicators that are placed on to the endoscope. In our unit, when a scope comes into the procedure room, it should have been cleaned. It has a green tag on it. Of a scope does not have the green Ted, it is like an unlabeled medication. It goes back to reprocessing.

You can see how they are running it through. This is the biopsy channel, they are running the culture device. We use a first in first out, so each scope has the exact amount of time for cleaning and hanging. These are all specially constructed hanging cabinets for these endoscopes.

This is a yellow and Don -- yellow andon, which means it's in process. This is an example of the technician swabbing the elevator tip, to do both sides of the elevator, getting into the sanctuary site which resides behind the elevator. It goes up and down.

The one thing you notice, you already had a culture probe that went through the entire channel and now, this is especially handled into
that, specifically into that region so we get two cultures from the elevator channel.

If there's any questions, would be happy to answer them. We thank everybody for their attention. Let's see if we can answer any questions that might be residing.

Great. Thanks, guys. If you have a question for anyone on the panel, look to the participant panel on the right side of the screen. If you have a telephone icon next to your name you may ask alive question. There is a hand icon in the participant panel. You may click that and raise your hand. If you have a question, you will be called upon. Why don't we go to the Q&A panel while we wait to see if anybody has any live questions?

We have a question that says, where the patient to the cluster identified by clinical isolate blood abdominal recovery only, or were any detected by stool surveillance culture?

In the patient cluster that we identified, they were identified not by stool surveillance but by blood or bile. Or, other bodily fluid aspirated. The stool cultures have been predominantly for surveillance and we have a list of those. It turns out there are probably two to three times people who have stool positivity that have any other organ system weave either aspirated or brought through the bile. We are getting suggestions that these people, the AJC E. coli may be more prevalent than we thought in the past.

The cultures are designed more to identify the prevalence not only of [Indiscernible] but MDRO, in general, with patients undergoing these procedures. This is a sign of the times. These bacteria are going to colonize patients who may not have had any exposure to hospitals. We have a number of patients who have not necessarily HAC, but multidrug resistance, negative bacteria that they have in them and they have never even been exposed to a duodenoscope or a hospital.

There is another question here about how many patients died of uncontrolled infection. We don't know the answer to that. Most people, of the seven who died within one month, those individuals were very, very sick and had obstructions. I'm not sure we know how to answer that question other than they were quite sick and the likelihood of dying, from their underlying disease, was quite high when they entered the institution.

Next question, please elaborate on the kinds of issues encountered in your endoscopy unit that need to be fixed to enhance efficacy of the high-level disinfection process. It's important to stress there was no breach of high-level disinfection based on two independent investigations -- outside eyes investigation into our process. We had recently opened a new endoscopy unit at the time that I had identified -- around the same time we started sending samples to the reference laboratory. We changed when we opened up -- when we reopen the room. So,
when we initially went through the investigation, we actually closed down that new reprocessing room.

We went to our old one.

We were a bit concerned that perhaps being new, it could've raised an issue relative to this outbreak. When of the issues that came up when we close down that room, one of the issues ongoing, where ergonomic issues for the technicians. There was not any part of the process that required the answer.

With a particular scopes requiring servicing responsible for persistent bacterial growth? Or, can they be randomly? At first we thought there may have been a couple of scopes responsible. After we did a thorough investigation we were not able to distinguish them from any of the other ones that were there and we presumed as part of the investigation -- we return the scope and sequence through the manufacturer. They had no functional defects so we sent the scopes in. Several of the duodenoscope's -- by having zero functional defect -- returned with critical repairs. What we can't understand fully, is what more routine endoscope maintenance -- there is no recommendation for routine endoscope maintenance. It's not like the oil in your car that needs to be changed at a certain interval. Could there be any defect that you can't necessarily see because the scope is more confined and could be contributed?

We have a certain number of procedures done before we send the endoscope in for reprocessing and although the jury is out on that, we have now sent scopes in for repairs probably more substantially frequently than we have in the past.

We send them and regularly, at this point.

How many manufacturers make the scopes? The answers are three manufacturers and each one has had out rakes associated with them. It doesn't seem to be a difference, in terms of manufacturer.

What culture medium to do you was? I have to defer that to the website.

If you go on to our external facing website, it will tell you exactly what we are using. We are using a protocol patterned after the CDC recommendations.

Next question, Brock a scopes with elevators -- to that culture positive for CME? As we are looking at those?

We culture every one of our scopes in the pulmonary colleagues who do their own reprocessing have come down to the endoscopy suite to ensure what they are doing is in concordance with what we are doing in the endoscopy suite.
Have you done retrospective surveillance to identify other clusters of disease and how did you perform those? What was found? This is the idea of surveillance, surveillance culture. Any patient who comes in with an ERC -- having an ERCP and has access to the bile duct obtained, they get a perianal culture as well as culture of biopic we've been culturing bilin patients with cholangitis for really talk -- for really long time. 20 years -- they tell us it's like culturing stool. The bile in patients with multiple stents is going to grow stuff in the question is. We may be able to treat it to the patient's ongoing infection problem if they have one. They haven't identified other clusters.

We want to thank our colleagues at the Department of Health and the state labs who been able to use -- been able to use sophisticated techniques of PCR to identify clones that will help us understand. As soon as we did that and started culturing the scopes we recognized there were other possible pathogens that may be two years ago would have been introduced that are no longer being introduced because we are reprocessing. There's a question, to see a movement toward sterilization for the ERCP scopes?

Remember, they can't go through an autoclave. If you put the ERCP scope into an autoclave, it essentially destroys the instrument. There is the issue that Dr. Gluck spoke of earlier about ETO or gas sterilization.

At room temperature.

In our area, GTO is not available. It's a carcinogen to those who use it. It is not currently recommended by the Center for Disease Control.

It fails.

It has a defined rate with that.

There's a question, are you routinely disinfecting your scopes twice? The answer is, because we have a culture in quarantine process in place, that is implied. If we have a scope that cultures polity of -- positive. Just cleaning the endoscope twice may not get rid of bacterial pathogens. Initially, this is one of the things we thought of. We will run it through again and use it. We have identified uncultured at least two scopes which have failed -- grown pathogens even after a second disinfection. We want to advise against routine double disinfection of the scopes.

Do we use ultrasonic cleaning of the elevator area? The answer is, though, we don't.

Are you going to live questions? [Laughter]

If we knew how to work this thing we would be happy to.
Thank you. This is Jamie Moran with Qualis Health. We will go to live questions if we have time. I would like to see if we can open the line to the doctor who asked the question. She has questions for the team.

Doctor, go ahead.

Thank you very much. Is Jamie mentioned, I'm one of the medical epidemiologist at the Washington State Department of Health and I would like to thank you so much for that excellent and detailed presentation. Would also like to commend both public health and Virginia Mason on your efforts to fully investigate and contain this outbreak. My question has to do with the difference between unusual organisms. What is unique about many of the ERCP associated outbreaks reported, is they are producers. Whenever you identify one of these organisms, everyone perks up and pays attention. Their situation was identified because there was some unique testing occurring that was able to identify that there were similarities in these hyper amp C. coli's. Without that testing, my question is, what type of surveillance do you do among your ERCP patients to identify infection. Second of all, what number is unusual? If it is just cephalosporin resistant E. coli, how many of those would identify an outbreak?

Those are important questions that are now coming to light. As I said before, while this is about hyper amp C. coli and scary bacteria, it's likely a marker of a larger problem. A marker of a larger issue in that the recommended high-level disinfection protocol does not get rid of -- does not reliably read the endoscope of potential pathogens. You are absolutely right. Had we not been tooled to be looking for these bacteria and had we not been sending samples off, we wouldn't have found it. Infection control docs will tell you, let's say you have six doctors doing ERCP and they have infectious disease doctors seeing these patients in the hospital. It's not until we have this cluster -- this cluster that you know you have an issue. If you are not looking for this, you won't find it. It remains a big problem.

If we hadn't had this partnership with the Department of Health and the state labs, we would not have recognized it for quite some time.

The value of using the very sophisticated tools in bringing attention to our cluster, everyone who gets an ERCP, the endoscopy list is aware to culture bile and bring the fluids so we can see. This is helping us understand the pathogens there and how we can take care of that. Other than that, all we have to do is wait for symptoms to occur before we change stents or enter the pancreatic or biliary system.

We wouldn't be talking about this.

We are coming to the end. Both Dr. Ross and myself would be happy to answer the questions off-line. We appreciate having this audience to hear our story.

Thank you. This is Jamie Moran. Dr. Glock and Dr. Ross, thank you so much. I said this before when we talked about putting this webinar on.
Allowed to say the audience. Your dedication to patient safety is the story of this situation you find yourself in and I want to commend you for all of the information you provide because I think it will make us all safer. Thank you again.

Thank you for having us and inviting us to speak.

We will try to follow up with you if there are any other questions. We are out of time and I apologize for that. This webinar could not have happened without our partners at the Washington State Hospital association, I'd like to thank Dr. D'Angeli, the Seattle County, Catherine Cole, an infection prevention is to -- and infection prevention us to. Thank you to all the partners including [Name indiscernible] and Virginia Mason. Thank you again. We do have contacts for you. If you have questions, feel free to contact Dr. Gluck and Dr. Ross, directly. We put a link to the Virginia Mason protocol, the CDC protocol. If you have not checked out the association for professionals and infection control they have an entire toolkit available with everything about CRE and scope processing and you can always ask at Qualis Health. Thank you again for staying with us. We hope this was valuable to you and we are interested in your feedback. [Event concluded]