

NWX-FDA OC

**Moderator: Helene Clayton-Jeter
November 1, 2016
1:30 pm CT**

Coordinator: Welcome and thank you for standing by. At this time all lines are in a listen only mode until the question and answer session. At that time, if you'd like to ask a question, you may do so by pressing star then 1 and recording your first and last name. Today's call is being recorded. If you have any objections, you may disconnect at this time. I would now like to introduce your host for today's call, Ms. Helene Clayton-Jeter. You may begin.

Dr. Helene Clayton-Jeter: Good afternoon and thank you for participating in today's stakeholder call. My name is Dr. Helene Clayton-Jeter and I'm with the FDA's Office of Health and Constituent Affairs. I will serve as your moderator. The purpose of today's call is to discuss the agency's investigation of infections associated with the use of the Stockert 3T Heater-Cooler System manufactured by Livanova PLC, formerly Sorin Group Deutschland GmbH, and to review our recommendations, to help prevent the spread of infection related to the use of these devices.

Today's conference call is scheduled for one hour and will be recorded with the first portion of the call dedicated to opening remarks and an overview of the agency's safety concerns related to 3T heater-cooler devices. Following

the presentation we will give you an opportunity to ask questions. Joining us today, as our main speaker, is Dr. Suzanne Schwartz, Associate Director for Science and Strategic Partnerships at the FDA's Center for Devices and Radiological Health.

Additionally, we will have representatives from the Centers for Disease Control and Prevention, on the call, who will assist with answering questions you might have related to heater-cooler devices. At this time, all lines are in listen only mode until the question and answer session. During the question and answer session, please limit yourself to one question. I will now turn the call over to Dr. Schwartz.

Dr. Suzanne Schwartz: Thank you Helene. Hello everyone. I appreciate the opportunity to be here with you today, to discuss the agency's safety concerns with heater-cooler devices. As Helene stated, we will have time at the end of the call, to take questions. I would like to first emphasize that one of today's main recommendations is for healthcare facilities to review their infection control procedures along with FDA's safety communication, to determine on a case by case basis, if the benefit of using the 3T heater-cooler device, in a particular situation, outweighs the risk.

I will now begin by providing a brief summary of the issue. Heater-cooler devices are commonly used during cardiothoracic surgeries as well as other medical and surgical procedures, to warm or cool a patient in order to optimize medical care and improve patient outcomes. These devices include water tanks that provide temperature controlled water through closed circuits to external heat exchanges or warming and cooling blankets.

It's very important to note that the water in the circuits does not come into direct contact with the patient. However, because these devices are not

intended to be airtight or water sealed, there is a potential for contaminated water to enter other parts of the device or transmit bacteria through the air, aerosolized, in other words, through the device's exhaust vent, into the environment and into the patient.

Through the FDA's analysis of adverse event reports, medical literature and information from national and international public health agencies, we are aware that the use of heater-cooler devices has been associated with nontuberculous mycobacteria or NTM infections, primarily in patients undergoing cardiothoracic surgical procedures. NTM organisms are widespread in nature and can be found in soil and water, including tap water sources.

They are typically not harmful, but in rare cases, may cause infections in very ill patients and/or in individuals with compromised immune systems. In October of 2015 the FDA issued a safety communication on nontuberculous mycobacteria infections associated with heater-cooler devices, and provided recommendations that healthcare providers and staff at healthcare facilities, could follow to help minimize patients' risks of infections associated with heater-cooler devices.

In April of 2016, a European study was published that suggests a direct epidemiologic link between *Mycobacterium Chimaera* or *M. chimaera*, that infected European patients during open chest cardiac surgery and the *M. chimaera* isolated from the 3T heater-cooler model utilized during these patient surgeries, as well as environmental samples from the device manufacturer's production and servicing facility in Germany.

M. chimaera is a type of NTM and is classified as a slow grower and may cause serious illness or death. Because these bacteria grow slowly, it can take

several months to over a year, for an infection to develop. The FDA believes *M. chimaera* infections associated with the 3T are rare and the infection risk is relatively low. However the actual prevalence of the infections is unknown. And infections are difficult to detect because infected patients may not develop symptoms or signs of infection for months to years after initial exposure.

Testing conducted by the 3T manufacturer in August of 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility. The 3T devices manufactured at this facility were distributed worldwide. In response to the *M. chimaera* findings in August 2014 the 3T manufacturer added cleaning and disinfection procedures to the production line in September 2014.

Samples taken at the same 3T manufacturing facilities by the German regulatory authorities in July 2015, did not show *M. chimaera*, potentially indicating the contamination at the manufacturing facility had been resolved. In June 2016, the FDA issued a safety communication specific to *M. chimaera* infections associated with the use of 3T devices and encouraged healthcare providers and staff at healthcare facilities, to determine a method for patient follow up, per CDC's recommendation and to continue to follow the recommendations outlined in the FDA's October 2015 safety communication, to help mitigate risk to patients.

This safety communication also stated the FDA received reports of US patients infected with *M. chimaera* after undergoing cardiothoracic surgery that involved use of 3T devices that were manufactured prior to September 2014.

In late August 2016, the agency became aware of new information about *M. chimaera* infections associated with the use of 3T devices in US patients who have undergone cardiothoracic surgeries. Specifically the Centers for Disease Control and Prevention, in conjunction with Natural Jewish Health, performed whole genome sequencing on clinical isolates from infection patients and samples taken from the 3T devices from hospitals representing geographically distinct regions within the US, where clusters of patient infections with *M. chimaera* were identified.

Each of the isolates tested were associated with devices manufactured before September 2014. Samples of the water drained from the 3T devices and air samples collected while the devices were in operation, were also tested. The results obtained strongly suggested that the tested 3T devices had a common source of *M. chimaera* contamination. For this reason, on October 13, 2016, the FDA updated its June 2016 safety communication, to provide healthcare providers and healthcare facilities with this new information.

Our goal of today's call is to discuss the October 13, 2016 safety communication and review the additional recommendations provided to help healthcare providers and staff at healthcare facilities, prevent the spread of infection related to the use of these devices. It's important to note that we issued an updated safety communication, to provide new information. It does not replace our previous communications.

We will now move forward with a discussion considering benefits and risks. Let me restate that the FDA believes that heater-cooler devices are important in patient care. As I mentioned a few moments ago, *M. chimaera* was identified on the production line as well as in the water supply, at the manufacturing facility in Germany, in August 2014. New procedures were

implemented by the manufacturer in September 2014, to remediate the *M. chimaera* contamination.

Although the manufacturer of 3T devices added cleaning and disinfection procedures to the production line in September 2014, the FDA is now aware of some 3T devices manufactured after September 2014, which have tested positive for *M. chimaera*. It has not been confirmed whether these devices were contaminated at the manufacturing facility or became contaminated at the user facility. To date, the FDA is not aware of *M. chimaera* patient infections associated with 3T devices that were manufactured after September 2014.

Given this background, FDA's recommendations are based on the following risk stratification. Number one, devices that have been previously associated with patients infected with *M. chimaera* and/or that have cultured positive for *M. chimaera*. Number two, devices that were manufactured prior to September 2014, and finally, number three, devices manufactured after September 2014.

Healthcare facilities should therefore perform a careful benefit/risk analysis before using these Sorin heater-cooler devices. During this call we will talk about some factors to consider as you conduct that analysis. For example, it's important for you to know the date that your device was manufactured. The need to regulate patient temperatures in certain surgeries is critical for successful clinical outcomes.

In appropriately selected patients, the benefits of temperature control during open chest cardiothoracic procedures, generally outweigh the risk of infection transmission. We strongly recommend that devices that have tested positive for *M. chimaera* or have been associated with known *M. chimaera* patient

infections at your facility, be removed from service because the risk of patient infection may be higher.

If there is no alternative and a patient's life depends on surgery that utilizes a contaminated heater-cooler device, then the benefits may outweigh the risk of infection. The FDA strongly encourages that the use of 3T devices manufactured prior to September 2014, should be limited to emergent and/or life threatening situations if no other heater-cooler devices are available. But as I said, this determination must be made at the healthcare facility on a case by case basis.

Next, I will reemphasize the agency's recommendations to help minimize the risk of infections associated with 3T heater-cooler devices. The FDA strongly encourages that the use of these devices manufactured prior to September 2014, should be limited to emergent and/or life threatening situations. We acknowledge that transitioning to an alternative device may not be an immediate option. Until the manufacturer has implemented strategies for mitigating the risk of patient infection with the heater cooler device, the FDA does recommend steps that facilities can take to reduce this risk.

Healthcare facilities are encouraged to be vigilant in regularly cleaning and disinfecting the device according to the manufacturer's instructions. Regular cleaning and disinfection, according to the manufacturer's instructions, will help minimize the risk of bacterial growth and subsequent patient infection. Healthcare facilities should vent the heater-cooler device away from the sterile field and therefore, away from the patient on the operating room table.

Healthcare facilities should review their infection control procedures along with the FDA safety communications, to determine if the benefit of using the device in a particular situation, outweighs the risk on a case by case basis.

Some healthcare facilities both within and outside of the United States, have moved the device outside of the operating room, to try and reduce patient exposure to aerosolized contaminated water.

Although we know that some individual facilities have taken this approach, we are not aware of data that conclusively demonstrates that this mitigation measure eliminates the risk of patient infection. Also, for facilities that have implemented this approach, be aware that device performance may be affected. I'd like to turn now to talk a bit about cross contamination, monitoring and testing.

As we've stated in the safety communications, if your 3T device is contaminated, it does not mean it came that way. Device contamination also may occur from other sources, such as environmental contamination, such as water and ice, or device contact with contaminated accessories, such as contaminated circuit components. At this time, we do not recommend testing heater-cooler devices to identify units contaminated with *M. chimaera*. This stems from our recognition that such testing presents technical challenges related to sample collection, the long culture time and the potential rate of false negative tests.

Since we understand the reality that many facilities lack the capability for *M. chimaera* speciation, we encourage routine monitoring rather than a broad recommendation supporting testing. Routine water monitoring with a heterotrophic plate count can be used as a marker for good maintenance of the system. However, heterotrophic plate count does not tell you what type of bacteria are present. Rather, it indicates the concentration of bacteria present. And as such, heterotrophic plate count alone cannot indicate the presence or absence of *M. chimaera*.

Healthcare facilities that have *M. chimaera* speciation capability may want to consider testing as an added mitigation measure. Finally, we want to reemphasizes the need to strictly adhere to the cleaning and disinfection instructions provided in the manufacturer's current device labeling. Please ensure you have the most current version of the manufacturer's instructions for use, readily available.

Some healthcare facilities have asked about performing their own enhanced measures, such as establishing their own cleaning protocol, changing cleaning chemicals, volume, frequency, etc. Such enhanced measures may have unintended consequences for the device and its accessories, including material degradation, alteration of device performance and reduction of the device's lifespan. If you have questions about the cleaning and disinfection instructions, we recommend that you contact the device manufacturer.

Thank you.

Dr. Helene Clayton-Jeter: Thank you. At this time, we'll begin the question and answer session. I will now ask the operator to open the phone lines and provide instructions for our callers who may have questions. Please state your name and the name of your organization prior to asking your question.

Coordinator: At this time, we'd like to begin the formal question and answer session of the call. If you'd like to ask a question, please press star then 1 and record your first and last name. To withdraw your question, you may press star then 2. Again, to ask a question, please press star then 1 and record your first and last name. One moment for the first question, please.

Dr. Helene Clayton-Jeter: We're ready. You can go ahead with the questions that are in the queue as presented.

Coordinator: The first question is (Tim Settle). Your line is open.

Dr. Helene Clayton-Jeter: You can go to the next caller.

Coordinator: Next question comes from (Johnson Anthony). Your line is open. Your line is open. Please check your mute button.

Dr. Helene Clayton-Jeter: Okay. Want to go to the next question?

Coordinator: The next question comes from (Russell Olmstead). Your line is open.

(Russell Olmstead): Thank you. I had a question on the disposition of heater-cooler devices that may be removed as part of following FDA recommendations. Is there any notice needed to FDA directly about those devices or recommendations from FDA on disposition of the devices, if they are removed?

Carl Fischer (FDA): No. FDA does not have specific expectations or guidance regarding those devices. I think we would request that you not sell them within the United States.

Dr. Helene Clayton-Jeter: Next question?

Coordinator: The next question comes from (Patricia Montgomery). Your line is open.

(Patricia Montgomery): Hi. Thank you. I'd like to have some clarification on the recommendation about testing heater-cooler units. The speaker said do not - you do not recommend testing the heater-cooler units but rather use heterotrophic plate counts. And then a little bit later said facilities with the

testing capability may test. But I wasn't sure if that referred to testing the heater-cooler unit or (speciating) the heterotrophic plates.

Dr. Suzanne Schwartz: Thank you. So we were referring to utilizing testing specifically for *M. chimaera* as a determinant, in terms of whether to continue using that device. As most healthcare facilities to our knowledge, do not have that capability of performing what is technically challenging, with regard to testing for NTM and then speciating specifically for *M. chimaera*. We also do not know what the false negative rate is for testing.

Dr. Helene Clayton-Jeter: Okay. You can go to the next question. Or do you have a follow up question?

(Patricia Montgomery): No. Thank you.

Coordinator: The next question comes from (Jaclyn Highland). Your line is open.

(Jaclyn Highland): Yes. Thank you. My question is regarding communications to patients and if there is any recommendation whether or not a hospital should send a generic letter to all possible cardiac patients that may have been exposed. And we're an institution where we've had no infections with the *M. chimaera*. Or should this be provider directed?

Dr. Suzanne Schwartz: So this is Suzanne Schwartz from the FDA and I'm going to defer that question to our CDC colleagues who are on the line.

-Kiran Perkins (CDC): Hi there. Thank you for your question. Yes. We are recommending at this time, to notify patients who have been exposed to these devices and have had cardiac surgery, going back to January 1, 2012. And this will likely capture the most number of patients who have been exposed but not yet

diagnosed with infection. And we actually have updated our CDC Web site dedicated to heater-cooler units, with frequently asked question Q&A for hospitals, which has more specific information and guidance regarding patient notification questions.

(Jaclyn Highland): Okay. Thank you.

Dr. Helene Clayton-Jeter: Next question please.

Coordinator: Next question comes from (Kevin Sheely). Your line is open.

(Kevin Sheely): Hi. My question is regarding any modifications to the machine. I know there's a discussion about potentially moving it out of the operating room may be problematic. I know there is at least one publication out of Europe suggesting kind of a modification of the device within the operating room. I'm wondering if the FDA has any statement about such matters.

Suzanne Schwartz: So with respect to any modifications to the device, you know, FDA is not able to endorse those types of modifications that are done in the healthcare facility and that are not undertaken by the manufacturer with our ability to review what those kinds of modifications are.

(Kevin Sheely): Thank you.

Dr. Helene Clayton-Jeter: Next question please.

Coordinator: The next question comes from (Elijah Kahn). Your line is open.

(Elijah Kahn): Yes, hi. Thank you for the information. One thing I missed is that you never made recommendations on machines manufactured after September 2014.

And also, we have not heard any recommendations from the CDC on what to tell our patients other than that this exists and what the follow up should be and surveillance of patients. So if we could get both of those, that would be great.

Dr. Suzanne Schwartz: So this is Suzanne Schwartz from the FDA. I'll take the FDA question first and then we can move it over to CDC. With regard to what our recommendations are for devices, for these 3T devices that were manufactured after September 2014, first I would direct you to our October 13 safety communication where we have stated what the recommendation is.

Essentially it is to continue to be vigilant in terms of the maintenance of the device per the manufacturer's instructions with regard to cleaning and disinfection. Again, at this time, we are not recommending that there be any kind of specific testing for *M. chimaera*, for the reasons that have been previously outlined. However, if you go back to our very initial October 2015 safety communication, we discussed recommendations that are for routine type of monitoring of the device as to a hospital or healthcare facility's basic capabilities of doing so.

(Elijah Kahn): Right. I appreciate that. But I believe the CDC said the other. I believe the CDC came out and strongly recommended that we don't use even the devices after 2014. So if you guys could maybe clarify from the CDC side, and then again, what the patient surveillance recommendations are, would be great. Thank you.

Dr. Suzanne Schwartz: CDC?

Joe Perz (CDC): Well hi. Suzanne, I guess perhaps we could clarify for the caller. The updated guidance does have - your FDA guidance does begin with a section that

applies it looks like, to all 3T devices. So maybe that's been overlooked by the caller.

(Elijah Kahn): Perhaps. I'll go back. But I am sensing some conflict. But you know what? We'll go check that. But if you could do me a favor and go to the other piece, which is, you know, we're talking about notification but we're not sure what to notify our patients and what the surveillance program is recommended.

Kiran Perkins (CDC): As far as patient notification, the most important piece of that is just making sure that patients are aware of what signs and symptoms to look out for, that could be concerning for infection. Patient education from that standpoint, will help patients identify symptoms that might be concerning. And make sure that they present for medical evaluation and be tested and treated if necessary.

As far as, you know, monitoring, you know, we don't have any specific guidance on monitoring. We are looking to, you know, our clinical colleagues in terms of giving us and giving patients more advice on how long to monitor. And we are continuing to learn more about these cases and - in terms of symptom onset and time from exposure to symptom onset. So this is an area of ongoing research in the clinical community.

(Elijah Kahn): Okay. Thank you.

Dr. Helene Clayton-Jeter: Next question please.

Coordinator: Next question comes from (Chris Lombardozi). Your line is open.

(Chris Lombardozi): Hi. A couple of questions and some follow up on what's already been discussed. First, what are the risks for other devices? So if we have a 3T now,

we were considering moving to a different device. Should we do that? And then second in relation to the patients who have potentially been exposed, and we're also an institution that has not had any known infections or contaminants that we're aware of.

But the letter and I think what the previous caller was getting at, is that the signs and symptoms are so non-specific that we are concerned we're going to get an influx of people who just - we don't know what to do with them. And you're not offering a whole lot of specific advice.

Dr. Suzanne Schwartz: So this is Suzanne Schwartz, FDA, with the first part of the question, which was oh my...

(Chris Lombardozzi): Risks of other devices.

Dr. Suzanne Schwartz: ...risks of other devices. Correct. That is a decision that your own healthcare facility is going to need to make based upon its own analysis. We're not in a position to be able to tell you whether - or to make a recommendation in terms of switching to another device. As far as a patient who has potentially been exposed to devices that were prior to - manufactured prior to September 2014, again the recommendation would be to follow CDC's guidance in terms of provider and patient notification.

(Chris Lombardozzi): Well again, and maybe our frustration is showing here. But these are the signs and symptoms that you've included in that letter - fatigue, fever, pain, redness, heat, muscle pain, joint pain, night sweats, weight loss, abdominal pain, nausea, vomiting. Those are all extraordinarily non-specific. Now I understand that that's the kind of bug we're talking about here.

But when a letter goes out to patients who may have had a procedure done up to four years ago, what are we really supposed to tell these folks? Do we tell them to go to their primary care physician who has no knowledge of this sort of procedure? Do we tell them to go back to the CT surgeon? Do we tell them to go to our infectious disease specialist? And to be very clear, who is going to be involved when the patients have even more questions that we can't answer?

Dr. Suzanne Schwartz: It's a very, very challenging area. There's no question about that. And the fact that the signs and the symptomatology is so vague, has presented, you know, a significant conundrum here. But I'm going to again, defer to - your questions to the CDC.

Kiran Perkins (CDC): So we absolutely understand the frustration. Unfortunately, again echoing what Suzanne mentioned, these infections are presenting with very vague symptomatology. And I think that it's very important to get the right providers involved in the care of these patients. You did mention an infectious disease specialist and these are a provider group that we've outlined in our health alert notification that should be involved in the care of these patients, for further diagnosis and management.

But, you know, unfortunately, the way these infections present where we are left with having to assess each individual patient based on their symptoms and their exposures.

(Chris Lombardozzi): Okay. I hear what you're saying but I'm...

((Crosstalk))

Dr. Helene Clayton-Jeter: We have so many people waiting to get a call...

((Crosstalk))

(Chris Lombardozzi): ...but I have a funny feeling that most of us are wondering the same thing.

Dr. Helene Clayton-Jeter: Oh, okay. Well we thank you for your question. Thank you so much.

(Chris Lombardozzi): Okay.

Dr. Helene Clayton-Jeter: All right. Next call please.

Coordinator: The next question comes from (Marcy Dreese). Your line is open.

(Marcy Dreese): Thank you. I actually first have a comment. We have had cases and we are trying to replace our Sorin units. And I don't know if anyone has tried to buy a new unit on the market now, but we can't get any. We've ordered them. It's going to be eight to 12 weeks. So we really can't cancel all cardiac surgeries for that period of time. We have made some engineering modifications and we think we've mitigated the risks. But it sounds like you can't endorse any of those such modifications either.

So that's just a frustrating situation that many of us are in. My question is about the patient notification. We have notified about 2500 patients that we know were on bypass and have started to evaluate them. My question though, is about - we have other procedures such as transaortic valve replacements that are not open heart procedures. And our heater-cooler units were not running during those procedures but they were running before the patient was in the room, maybe for half an hour at most and then they were turned off.

They were used to prime the heart/lung machine in case it was needed. The instruments were potentially exposed during that time but they were at least 15 or 20 feet away from the heater-cooler unit. So we don't really know if those patients are at risk and if we have to expand our notification even further.

Dr. Suzanne Schwartz: That's a tough question. (Kiran), do you have any thoughts or (Joe), do you have any thoughts about that?

(Joe Perz): Yes. This is (Joe Perz) at CDC. If the fan on the machine is running and the exhaust is being generated, you know, even before the patient arrives or if the - in the example given, you know, the patient does not have - is not having an open chest procedure, if there is a sense that contamination of material that is implanted could be contaminated, it seems that that should be communicated.

(Marcy Dreese): Well I think my question is I don't think the implanted material was necessarily exposed but perhaps the instruments were. But again, you know, short duration of running the heater-cooler unit, multiple air exchanges in the room and, you know, a significant distance from the instruments from the heater-cooler unit. It's just really hard to know how much risk there really is.

(Joe Perz): Yes. And, you know, part of what you're illustrating is that, you know, every OR, you know, has some unique qualities and aspects. And so I'm afraid at this point it would be, you know, best left to the institutions to deal with that on a case by case basis. You know, if the decision is made to contact patients and alert them of the risk, they could perhaps be counseled to the effect that the risk might very well be lower than it would be for an open chest procedure.

(Marcy Dreese): All right. Thank you.

Dr. Helene Clayton-Jeter: Next caller please.

Coordinator: Next question is from (William Nate). Your line is open.

(William Nate): Hi. Thank you. My question really relates to prospective patient as it relates to the heater-coolers and whether there is any recommendation to consent those patients as to the potential risk. And is there any stratification between obviously the heater-coolers pre-2014 than those post-2014 as it relates to that consent.

Dr. Suzanne Schwartz: CDC?

Kiran Perkins (CDC): Yes. So in our health advisory and also in our updated FAQ on our Web site, we do recommend (forward) as far as prospective patient notification, to go ahead and do an informed consent with a patient, prior to surgery, to make those patients aware of the potential risk of infection and again, putting it in perspective with that institution specific experience, with these infections. As far as pre and post September 2014, I don't think at this time we would necessarily make any recommendation to stratify the risk of infection.

(William Nate): Thank you.

Dr. Helene Clayton-Jeter: Next question please.

Coordinator: Next question comes from (Jose Corrina). Your line is open.

(Jose Corrina): Yes. I was wondering how many infections have been reported in the US, and - to see exactly what the risk is. Because we're talking about almost a quarter of a million surgeries a year.

Kemba Ford (FDA): Please hold while we look that information up.

Joe Perz (CDC): I'm sorry. Well CDC can offer some information there. As you may have seen in, you know, news reports, media coverage, CDC is aware of 28 cases being reported from US hospitals. A subset of those, 24 cases, were described in more detail at the recent ID Week conference. And I would add that, you know, we're looking forward to more information from, you know, the clinical partners who have actually diagnosed and treated patients, to help provide additional guidance to answer some of the questions that have been raised on this call.

Dr. Helene Clayton-Jeter: FDA?

(Kelly Bauer): Yes. We are aware of 55 patient infections in the US, based on medical device reports, or MDRs, that were submitted to the FDA. However, based on the information or sometimes the lack of information in the MDR, it's difficult to have an exact count when some reports may say that there are multiple patients. So what we have is 55 in the US. My name is (Kelly Bauer).

Dr. Helene Clayton-Jeter: Next question please.

Coordinator: Next question comes from (Tim Settle). Your line is open.

Dr. Issa Ephtimios: It's actually Dr. Ephtimios. I'm the hospital epidemiologist at Sacred Heart Hospital in Pensacola, Florida. I have actually two questions. One, whether the CDC is going to set up a hotline for patients to call. And the second question is what's the rationale behind decommissioning devices in facilities where there has been no infection reported.

Suzanne Schwartz: This is FDA. We did not hear the last part of that question. Can you repeat it please?

Dr. Issa Ephtimios: The first part of the question is, is the CDC going to set up a hotline for the public to call? And the second part of the question is what's the rationale behind decommissioning devices in facilities where there has been no infection reported?

Joe Perz (CDC): So this is CDC. I'm going ask you to just clarify the second part - something about a facility with no patients or no infections?

Dr. Issa Ephtimios: Facilities with no infections - why do they have to remove the devices from service?

Joe Perz (CDC): Oh, okay. So I guess, you know, the first question had to do with resources for patients. So CDC does have some basic Q&A available on its Web site. But our recommended approach is the facilities that actually perform the surgeries, the sort of main support for these patients and to connect those patients then to clinicians that are part of your hospital or system. You know, something that we've I think glossed over a little bit, is that the health alert from CDC did recommend patient notification.

But it also stressed provider notification and education, which we believe the hospitals that were using the 3T units, should strongly consider. Your other question was, you know, well, you know, what if my facility hasn't detected any such infections or hasn't identified contamination in its units, you know, why would we also perform a notification?

And I think one simple reason is that because case detection is really quite haphazard, we don't really want to leave it to chance, you know, which

institution identifies infections from reviewing records and so on. And so that's why the blanket approach is recommended.

Dr. Issa Ephtimios: Thank you.

Joe Perz: You're welcome.

Suzanne Schwartz: With respect also to your question in terms of decommissioning devices, what we stated in our safety communication a few weeks ago, is that with regard to those devices that either have been directly associated with patients infected with *M. chimaera* or that the device has been cultured positive for *M. chimaera*, those are the devices that we talk about immediately removing from service, along with their accessories, tubing and connectors.

So I just want to make sure that that is clear. That's stated very specifically in terms of again, already an association that has been made that use of that device with a patient that's been infected with *M. chimaera*. Or, you know, to answer your direct question, even if the patient infection may not have been identified. If the device has cultured positive for *M. chimaera* is known to be contaminated with *M. chimaera*, our recommendation is that those devices not be utilized because again, as it comes back to this concept that development of signs and symptoms if a patient that was exposed becomes infected, may not occur for months to years.

And therefore, we do not want to, you know, continue the possibility of exposure and ongoing risk associated with those devices.

(Carl Fischer): And this is (Carl Fischer). We do want to repeat that if there is no alternative and a patient needs surgery that we would recommend that the benefits could outweigh the risk of infection even for those devices.

Suzanne Schwartz: Correct.

Dr. Helene Clayton-Jeter: Okay. It's 3:25. One more question please.

Coordinator: The next question comes from (Brenda Runner). Your line is open.

(Brenda Runner): My question has already been answered. Thank you.

Dr. Helene Clayton-Jeter: Next question, please?

Coordinator: Next question comes from (Jennifer Hertic). Your line is open.

(Jennifer Hertic): Yes. I was curious as to when perhaps we would see the import ban lifted, so that those of us with pre-2014 devices could replace those, if that was necessary. And/or when will the FDA approve some kind of retrofitting of existing devices?

Suzanne Schwartz: One moment please.

(Jennifer Hertic): Hello?

Suzanne Schwartz: Hello?

(Jennifer Hertic): Hello?

Suzanne Schwartz: Yes. We are going to provide a response - oh, actually I think we can respond right now.

(Carl Fischer): So the import alert which is available on our FDA import alert Web page, I'll refer you to that. And so the devices - the 3T devices manufactured at the Sorin German facility are subject to the import alert. And this restricts the availability of 3T devices to only those facilities that determine the use of the device is medically necessary. So do note that there is the ability for facilities to determine use of the device is medically necessary, to have access to medically necessary devices. This is (Carl Fischer).

Dr. Helene Clayton-Jeter: Thank you (Carl). And at this time, this concludes the question and answer period. Operator?

Dr. Suzanne Schwartz: So I - this is Dr. Schwartz. I'd like to thank everyone who was able to join us on today's call. We hope that you found it helpful and informative. In particular, we hope that we clarified that healthcare facilities should review their infection control procedures, along with FDA's safety communication, to determine on a case by case basis, if the benefit of using the 3T heater-cooler device, in a particular situation, outweighs the risk.

As we are coming to the close of this call, we wanted to give you a few reminders. Please share the information from this call with members of your organization, to heighten awareness. And take the necessary steps to mitigate infection risk to patients. If you suspect bacterial contamination of your heater-cooler device or suspect that your patients may have contracted an infection through use of a heater-cooler device, we encourage you to report the adverse event to both the heater-cooler manufacturer and also to MedWatch, FDA's online adverse event reporting program, at FDA.gov/MedWatch.

Please visit the FDA's heater-cooler Web page to view our communications along with other resources provided by other government and international

public health regulatory agencies. We will continue to update this Web page with more information as it becomes available.

Finally, I thank you for taking the time to participate in today's call and I hope I've clarified the agency's recommendations on this important public health issue. I will now turn the call back over to Helene.

Dr. Helene Clayton-Jeter: Thank you. As I mentioned in the opening of the call, (unintelligible) available one hour after the call ends. And will be available until December 1, 2016. No password is required. The phone number for the United States and Canada is (800) 677-9149. And for international callers, please dial 1 (203) 369-3408. If you have additional questions, please feel free to contact (unintelligible) Division of Industry and Consumer Education or DICE at DICE@FDA.HHS.gov. This concludes today's stakeholder call. Enjoy the rest of your day.

Coordinator: This concludes today's call. You may disconnect at this time.

END