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Healthy Ears for Lyric Wearers:  
A Review of Key Contributing Factors  
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Presenter: Michelle Wiebke, AuD  
AudiologyOnline.com Course #33644  
Partner: Phonak

- [Michelle] Good morning everyone and welcome. Thanks for joining today's course on healthy ears for Lyric wearers. I'm Michelle Wiebke, the Lyric clinical manager and I'm happy to be with you this morning. This presentation is a combination of a few things, but there is a bit of a summary of the Phonak Insight, the Lyric Clinical and Medical Review by Jacob Johnson, who is our Lyric medical director. And you can actually find that document in the resources of this presentation as well as an overview of the slides, so that's down on your screen in the left where you see the handouts. If you have any questions as we go along, feel free to type those in and I will do my best to answer those. And without further ado, we'll dive right in. So today we will cover a few outcomes. We're gonna review the history, development and ongoing innovations of Lyric as they relate to the safety and efficacy of an extended wear hearing device. We're gonna look at some clinical presentation patterns and recommendations on how to maintain your health in your patients that are wearing Lyric.

So the first stop is the history of Lyric. The Lyric research and development team was founded in 1998 to develop the technology and techniques for hearing device that would safely reside in the ear 24 hours a day, seven days a week, for up to four months. The critical success factors for development of this device included utilizing materials and design that would enable safe placement in the ear for an extended period, as well as long battery life and a low-power circuit. So there was lot of clinical trials that were undertaken, and Lyric was cleared by the FDA in 2002, and the first devices sold to patients in late 2007. Since 2007, the technology have undergone many major improvements. The original Lyric 1 fit about 50% of ears anatomically, so one of the key initiatives for Lyric 2 development was to decrease the device size in order to increase the fit rates. You could fit more of your patients. And when Lyrics 2 was released in 2012, the fit rate improved to 75% of appropriate candidates. And then in 2014, Lyric 3 further improved on successful form factor of the previous generation with a new lower-power circuit and additional sizes to help with comfort and feedback. So you can see that whole process as we go along, and as of today, the most current version available is Lyric 3, but you can see there's been a couple of updates to Lyric 3

since 2014. So since the commercial launch of Lyric in 2008, or late 2007, over a million and a half fittings have taken place, and with over 10 years of clinical data and monitoring and more than 320,000 Lyric fittings alone in 2017, Lyric has continued to show that it's a safe and effective hearing solution for patients with mild to moderately severe hearing loss. So putting this out there because every now and again we get questions of is it safe? And , excuse me, the paper that's attached with Dr. Johnson's summary you'll see that it is a very safe product, and we look at all of these fittings over these years to really make sure that it is safe. And what we're seeing popup over the years continues to be things that we're expecting or we can handle, but we're gonna look at this a little closer for some of the issues or concerns that you might run into as you're fitting Lyric in your practice. So from its inception, when we were looking at that whole history, it was understood that by the Lyric design and research team that the device would need innovative technology to have an extended wear hearing aide that could reside in the ear, a warm, humid, acidic, oily ear canal, while also maintaining the natural help of the ear with comfortable and safe placement.

So the three key principles that guide the design for the Lyric devices to be able to live in the ear is first to avoid excessive pressure. So we don't want the Lyric device to exceed the the venous capillary pressure of the skin in the ear canal. If that were the case, the excessive pressure might interrupt ear canal blood flow and possibly affect skin integrity, so that's one of the key design intents. Second is that the Lyric placement shouldn't impede the ear canal at the filial migration, and should also allow for adequate moisture vapor transfer, or breathability. When the Lyric device is in the ear, the medial ear canal has a range of relative humidity from 55 to 95%, and if we don't have appropriate breathability then that moisture vapor can't transfer through that Lyric device and may lead to a moistier or what we'll call non-infectious otitis externa. So we'll look at that also much more in-detail in this presentation. And then the third is that the device should be able to reside in the bony portion of the ear canal as much as possible to avoid the inherent motion of the cartilaginous ear canal. That repeated motion over the ear canal skin could lead to irritation but also, maybe more

practically, you see in the clinical that a lot of that cartilage movement can lead to migration of the device or sometimes even feedback with that motion. So getting the steel in the bony portion and having the device reside longer in that bony portion is the goal. One of the ways we can see how the research and development team has improved Lyric over the course of its lifespan is by looking at these CT scans. So the first one you see here, this is Lyric 1 and an image of a CT scan of Lyric 1 in the ear canal. And you can, let me pull my little pointer out, can tell we have sort of the bony part of the ear here versus the cartilage, which is gonna be your more-gray in this area. And with the Lyric 1 it was that two part device, and you can see the entire device was certainly not in a bony portion. You were lucky if you got a bit of that first part into the bony portion of the canal. So we certainly had room for improvement from Lyric 1. And here we see Lyric 2, so the redesigned Lyric 2 and 3, in fact, module, is much more condensed than it was in Lyric 1, and then you can see it here sitting more in the bony portion, so our bone is a little clear on this image as well versus the cartilage, which is in that gray. And the Lyric 2 or 3 device is sitting much more in that bony portion, which is in fact meeting one of their key development initiatives when it came to Lyric. All right, so now that we've seen kind of how that design in the overall shape and size has advanced, let's look at some of the other parts of the actual device that lends itself to this innovative design of Lyric.

So we have the core module and battery design, so the Zinc-air battery custom designed to nest into that Lyric 3 core module, and each Lyric battery is evaluated through a series of verification tasks to ensure performance and safety that meets the specifications required for extended wear application. And that little battery, you can see it, I left my little pointer out, is about the size of a grain of rice so it's really very, very small, and it is housed just at the bottom of the Lyric device. The sealed design is also very much a big part of this process. The Lyric polyurethane seals are hydrophilic and flexible. The flexibility of the seals allows for more comfort in the fitting, but then also keeps from exceeding that venous capillary pressure that we discussed a couple slides ago. Each of those seals is tested in production to ensure that it doesn't exceed

that venous capillary pressure, and the foam itself is open-air cell, allowing for that moisture-vapor transfer that we discussed as well. So the three principles we talked about earlier, avoiding the excess pressure, breathability and device placement in the bony portion of the canal, they've been accounted for in this device development. But they are still the principles that maybe bring you guys the most challenges in your actual fittings, so whether it's the seven sizes that we've got on the screen here now on our most Lyric 3 product, or parts of this, we're still gonna transition now and talk about what it is that you're seeing in the clinic with ears and what you can do to help your patients continue to wear Lyrics successfully, especially as it relates to working with these design principles. Let me turn my little pointer off and we'll move on. So the first step in maintaining good ear health starts at accessing your candidates. So our research and development team does their part in trying to make these adjustments and updates to devices, to meet the core needs for the device for an extended wear product, but some of it comes back to us in fitting the device to actually maintain the candidacy advice that Phonak is setting forth.

So using this candidacy form to make an informed recommendation is really the foundation to starting your patients off for success. As you may know, medical clearances recommended for the patients that may have uncontrolled diabetes, take prescription blood thinners, have immune deficiencies or compromised immune systems, if they're wearing an implantable medical device, if they have a bleeding disorder or are under the age of 21. Lyric is also contraindicated in patients with previous head and neck radiation, and any active middle ear issues such as TM perf, cholesteatoma or PE tubes, but Lyric is only contraindicated for those patients, so head and neck radiation or active middle ear issues. Again the section that you're seeing above there, these are your medical clearance folks, so you can fit those patients, and we'll talk a little bit more about some other steps that you might take for some of those medical clearance folks to make sure you're getting the best fit for them. So starting with this as your foundation to make sure you're getting the best candidates as far as medical, is really important to getting the most use out of your

Lyric device. And we wanna really consider the entire patients, so it goes way beyond just what's on the form. You wanna ask more questions to get a picture of that entire patient. So for compromised immune system, how is your general health? Do you have recurrent infections? Do you have issues healing? Are you on antibiotics regularly? Generally, the types of immune system issues that you would be concerned about, lupus, advanced rheumatoid arthritis, HIV, organ transplant, they're pretty significant issues, and the patients gonna have an indication that they have a compromised immune system. They've talked with the physician about what steps they need to take that you really wanna understand what's going on with that patient if you're gonna fit them with Lyric. Similarly, and probably one you run into maybe more often is prescription blood thinners. You wanna ask, do they bruise or bleed easily? And if they do bleed, is it difficult to get the bleeding to stop? If they're taking coumadin or warfarin they'll generally have their blood tested monthly for the clot factor, or INR. You don't necessarily need to know what number is good or bad, but are they doing that? Are they in charge of their health? And are their levels stable? Or are they working on trying to get those levels to a stable point still? And if they take Aspirin, what dosage and how often? We know a lot of our patients will just take a baby Aspirin or something, kind of self-prescribed. It's really still important for you to know that. If a patient is taking Aspirin, that does not contraindicate them. That does not require a medical clearance, but it is still really useful information for you to know because they will likely have a little more of a bleeding response than someone not taking Aspirin.

So asking more questions can really help you to get that full picture of the patient, and if that's important, as we'll see later, 'cause when we, Dr. Johnson's research has shown that patients that have poor overall general health generally are gonna run into more issues when it comes to wearing Lyric than those that have better health. So you wanna really be able to assess that entire patient in order to understand the situation and give them your best support as the Lyric fitter. So now that we've discussed some of those questions, you can ask to determine your appropriate candidates for Lyric. Let's look at some of those challenges that you may be running into with your Lyric

fittings. So the clinical presentation pattern, so this is built on, again, some of the work Dr. Johnson has done in looking at the data that we collect on all of our Lyric fittings. And there two temporary skin issues that occur in some of our Lyric users. Generally, they're gonna resolve by removing Lyric and letting the ear rest, but those two different presentations are discomfort or pain and non-infectious otitis externa. So that's what we're gonna look at for the next several slides, are both of these. But this is pulled, again, from Phonak monitoring the Lyric user profiles, device quality and status of Lyric users ear health, and we monitor this regularly in our quality reviews. So let's take a look closer at discomfort and pain. So when it comes to discomfort or pain, this is typically something that you're gonna see in the first week or two of placement, maybe even the first couple of days, especially for new users. The reason for getting discomfort or pain generally comes down to a traumatic insertion, maybe not quite the right size. Poor placement in the ear, or motion or pressure may be from that overactive cartilage. Maybe poor cerumen management prior to insertion, and that could be leaving cerumen in there, or maybe just having irritated the ear by taking cerumen out prior to putting Lyric in, and then always, patient manipulation of the device.

So for discomfort or pain, you can always run into a hematoma or an abrasion that may develop on the skin of the canal of the wall from any of those types of traumatic insertion, sizing error type of things. But most of these skin issues are gonna resolve within seven to 10 days of rest, and typically don't require any medical intervention. One of the interesting findings, there was a research study done just last year by our research and development team and they looked at ears and found that ear health issues were observed most often in the posterior portion of both the right and left canals and the medial and lateral regions. So a lot of this is due to the trajectory of the ear canal, and then just how the device is contacting the wall on insertion. So we'll talk about some best practices to try to help you decrease that irritation and improve overall your health issues for your patients. But in talking through discomfort and pain, you can probably recognize that a lot of this is traced back to clinician technique or

skill with insertion, except for that patient manipulation. So having your methodical placement of the Lyric device, and keep up your practice, will help to decrease these occurrences. We can see that same principle displayed here, so while this shows removals in 2014, the premise still exists today in 2019. This is another view of some of the monitoring that we do at Phonak, and this data has shown us that Lyric providers with over six months of experience have significantly less patients with abrasions than those that have less than the six months experience. We also see from this that fitter experience, as the fitter experience increases, the need to let the ear rest due to irritation within the first week or two after Lyric fitting significantly decreases. So this is the saying, the more experienced you are the less irritation that you'll run into, and I don't think that should surprise most of you. But it really does make sense, because for any new process or procedure there's a learning curve that requires training and sustaining the activity, and Lyric evaluation and fittings are not different. You must be committed to implementing the process for using Lyric for you and your patients, to really provide your patients with that best experience. Woo, went too far.

So what can you do if you have patients who have abrasions or hematoma, or this response to discomfort or pain? So if it's an abrasion or hematoma, you're gonna let the ear canal rest seven to 10 days. Ask the patient to come back for reexamination. If everything looks good, refit a Lyric device. If the patient had been manipulating it, you're gonna talk with them and encourage them to not manipulate the device, although sometimes those patients don't tend to like to fess up that they were manipulating it. And while you can have the patient remove the device, sometimes you can get an abrasion or hematoma from removals, so most practices prefer to have patients come in. And if you run into some ear health issues, or some irritation upon removal that you can't put a device back in directly for a patient, some clinics will schedule proactive removals and use a little lubrication or loosen the seal to promote those device removals being comfortable in order to be able to put a device right back in in that same appointment as well. When it comes to bleeding, this I would expect to be a little more rare than an abrasion, but if you do have an occasional bleeding ear



you can use some cotton with lubricant or Afrin on the area to help stop that bleeding. And your goal here is to try to keep as little blood in the ear as possible. I mean, you're not gonna go crazy and irrigate, but you really wanna try to keep that blood, kind of use the Q-Tip or cotton ball to kind of dab it up. Once you've gotten that bleeding stop, rest the ear. Again, maybe seven to 10 days. Have them come back, make sure everything looks good. If you have a really large scab, you're probably not gonna wanna insert over top of that, so you're gonna wanna give that ear time to heal even from that scab, and then reinsert when the ear is free of that breathing, and bleeding and abrasion.

All right, now let's transition to the non-infectious otitis externa. And again, this one I'm sure you've run into at least once. It does occur somewhat frequently, as my experience has shown in being a trainer out in the field prior to joining the Lyric team as the Lyric clinical manager. But what non-infectious otitis externa is, it's gonna generally occur two to three weeks, maybe four after the patient's device was inserted. The patient might report that their device is weak, or not functioning correctly, and once that device is removed from the ear then you see something like is in this picture here, kind of white and a lot of debris, and that's that non-infectious otitis externa. So the differentiation that we make here, why are we calling it non-infectious otitis externa is that this debris that you see in the ear is not associated with canal swelling or significant pain or any kind of strong sense that would tell you that there is infection present. It's really just a buildup of moisture in the keratin debris of that skin just becomin' swollen with moisture. Once the device is removed from the ear, it generally will dry out quite quickly and be right back to its normal healthy self. We're gonna talk a little more about the differences between this and infectious, 'cause there's been research on the microbiome of the ear canal and what types of some cultures, what they have found prior to wearing Lyric and even after wearing Lyric, but this is a presentation that you've likely run into. So looking at that study, and how can we say with such confidence that what you'll run into is not infectious otitis externa? We know those external symptoms of when it's an infection you're really gonna know. There's

gonna be a swelling or a significant pain, especially once the Lyric is outta the ear, and that's just now what you run into. But also, this culture study that was conducted by our Lyric research and development team, in coordination with the San Francisco Audiology Research Center, showed that many patients when they were actually, when their ears were cultured, they already had positive cultures for bacterial or fungal parts in their ear, prior to even wearing Lyric, so they already have that. That's very normal for us to have some bacteria or some amount of fungus not growing out of control, right? But this is all around us; it's on our skin always, and so when we culture we find that. Even after a patient maybe ran into ear health, there was no correlation that the bacteria or fungal results that were found prior to wearing it were then translated to why that patient then had an ear health issue. So the majority of subjects that were in this didn't have detectable bacteria fungal growth from this microbiome study or their cultural data.

So this just tells us that it's not generally going to be an infectious type of an issue. You're just getting this buildup of tissue from the moisture that maybe isn't able to vent as we would like it to. And we can say this might be on a quiz if you're going for CEUs, that in this study both groups had normal healthy ears, but both groups also had normal bacterial growth as well. So again, it's not uncommon on a culture to find that there was bacterial already in the ear prior to wearing the Lyric device, and as a rule when it comes to this non-infectious otitis externa, oral or topical antibiotics are generally not needed unless you really see those true signs of an infection. There's significant pain, there's cartilaginous swelling, there's a significant odor with the ear, and then of course you would have referred the physician if they were seeing this infection, might go ahead and prescribe if needed. But let's look at a couple of ear canals and be able to kind of differentiate what we're seeing in these images. So first one here, not sure that you have seen this really when it comes to Lyric, but when you see this, this is definitely not gonna be your non-infectious otitis externa. This is gonna be that canal swelling, and if you were seeing this you would certainly, in my mind, want to refer because this is likely causing the patient a fair bit of pain and this is

gonna be that swelling with that ear canal. And here, this is gonna be a wick that has been inserted for this otitis externa in a patient. And you'd hope that the patients mention this to you versus you just ran into it during your otoscopy. And if so, generally this patient's already under physician care, and just proceeding with their treatment plan would be the right course of action, and certainly you wouldn't wanna be, and wouldn't be, inserting Lyric at this stage on this ear. Here is another image of our non-infectious otitis externa. It's a little bigger for you to see here, and in this case, the ear is a little more red, and in some cases you will find that on these non-infectious otitis externa ears, that's where you tend to get your bloody ear as well. But the skin issue is already kind of compromised when it's all moist that way, so that's been my experience as a trainer is I've seen some of these bloody ears in combination with the moisture, but once everything dries up, clears up, ear looks really great and healthy with just time and air getting to it.

So this can look really yucky, especially if it's the first time you've seen it live in person, but our experience has been that it really does resolve on its own by just letting the air, the ear get air, excuse me. And our last image here looks like something's growing, kinda like mold on bread, and certainly it's what it kinda looks like, right? So some fungus growing in the ear, but since as an audiologist I'm not going to diagnose, I'm just gonna refer this for a physician to be able to make that discussion. So we talk a lot about this non-infectious otitis externa, but I think that's because you'll likely be running into it somewhat frequently. And maybe you've struggled really with how to manage it, so let's talk about the reasons that you may be having this non-infectious otitis externa occurring. So when it comes to our ear canals, and especially in the ear design concept with Lyric, it's important for a significant amount of moisture vapor to transfer through the seals. The mechanism for that venting is the seals alone, and there are some variables in some patients' ears that can really reduce the appropriate venting of the actual seals of the device. So the devices are designed to withstand a typical amount of this transepidermal water loss, or TEWL as you see there, because the skin, and the skin in our ear canal is very normal in this fact that it's constantly

releasing moisture. That's why we have to have this moisture-vapor transfer through the seals. But some conditions maybe increase the amount of moisture in a patient's ear canal, or maybe a patient just has a lot more moisture being secreted than someone else. Some of the situations that may increase the moisture would be an increase in the middle ear, or in the humidity in the middle ear or eardrum, maybe from allergies. So if there is an increase in moisture in the middle ear space that's gonna be secreted through the TM, therefore being down, in-between the device and the TM in the external ear canal. So if you patient has significant allergies that might increase the moisture that's gonna be just enough to cause the seals not to vent. Funny story about this, I recently had a cold but I went to the urgent care and when the nurse practitioner looked at my ear she said I had bubbles behind my ear drum, and I kinda looked at her and I was like no, 'cause my experience has been that not all nurse practitioners or general care doctors are always sure of what they're looking at. My ears felt fine, I was like no, I don't have any bubbles behind my ear drum. But it certainly stands to reason that the histamine response could have increased the moisture in that middle ear space for me, and she could've been seeing that.

So that's very much a factor when it comes to Lyric, for sure. Anyone that's having significant impact by allergies may have increased moisture, therefore causing maybe this non-infectious otitis externa. Other things that can cause it, skin health issues or irritations or abrasions. So our skin heals by sending moisture to that affected area, so that clear serous fluid. If there's irritation or an abrasion in the canal, maybe it was from inserting Lyric, the patient manipulated the device, maybe cerumen removal, ultimately our skin's natural response is to heal that trauma and send fluid there to heal it. In that case, we might be creating excess moisture that the seals can't vent appropriately, and then you might run into this non-infectious otitis externa. A poorly fitting device can also cause it. More frequently we see this in those really small ear canals, where an extra-extra small or an extra small as the device fit, but it's a really tight fit. And if the device is fit really tightly, that alone can reduce the ability of the seal to vent, so if it's just a super snug fit, especially in the bony portion, then you're just not able to get as

much of that moisture-vapor transfer through that seal as you would anticipate. Another situation you may run into, is maybe you up-sized a patient because they were having feedback. Feedback's gone, everything's just fine, the patient says it's comfortable, and when you're looking at the device, the lateral seal may look okay, but it is entirely possible that the medial seal of that device is now fitting really very tightly, similar to what we just discussed above. And that medial seal may not be allowing the venting that you're expecting. You'll recognize this when your patient who's done very well never run into moisture in the ear, or this non-infectious otitis externa, all of a sudden after having an up-size, now you can get some of this moisture accumulating in their ear. If that's the case, the way you can evaluate it, is to use a Lyric sizer of the size you up-sized to. Remove that lateral seal and go ahead and place the sizer in without a lateral seal. That will allow you to look at that medial seal in the ear canal, and then you can really get a better estimation of if that's a really, really too tight of a fit in the medial portion that might be causing this moisture accumulation or non-infectious otitis externa to occur for your patient.

So another reason, there's a couple more. There's many reasons, so sometimes it's kind of tricky to pinpoint, but another reason you might see this non-infectious otitis externa is if there's too much external canal moisture, so don't misunderstand this. This isn't a case that, in the shower, water ran into my ear and got stuck between the device and my TM. But when I say too much moisture this is too much moisture from showering three times a day, or being in the sauna, having a lot of sweat or humidity, and that's leading to the lateral seal becoming saturated with moisture. At that point, the seal can't perform as expected to vent between that medial portion between the TM, so there, that buildup of moisture really prohibits the normal moisture flow from the medial portion of the ear out and may be a cause for that buildup for your patient. And lastly, another part of it could be lubrication. If it's been necessary for you to lubricate the ear canal on insertion for your patients, then you wanna be sure you're using as little as possible, because adding that increased moisture, whether it's from glycerine or steril water, could be enough to send that humidity level in their ear canal

over sort of that normal range that it's able to be vented through the seals. So there's several different reasons that really could contribute to why you might be running into this non-infectious otitis externa in the ear canal, and likely that was not even a conclusive list. There would likely be a few things that sneak by on the sides or just aren't as typical as those cases that I discussed. But one of the interesting things too is, at Phonak, we've looked at humidity in ears to try to get an understanding if we can determine from the beginning if a patient's gonna be someone who might have more issues with this than others. What this study looked at, excuse me, was humidity readings, they were humidity sensors put on Lyric sizers and placed into the ear. So they did it at a baseline, so prior to Lyric insertion, and then at followup appointments, and they left that in there for a while until they would see the humidity sort of level off, and what they found is that patients with less stability in regard to ear canal humidity measurements had a greater incidents of ear health versus those with more stable longitudinal humidity measures. So what this tells me is someone who yep, is gonna get a slight increase in humidity when we start to put a Lyric in their ear, but their skin and their health is so intact that it's able to manage that and go ahead and continue to vent properly, is gonna do much better than someone that doesn't always keep that humidity in check, or their skin or their health isn't able to always regulate as well. One other unique finding was that it was very common to see a difference in humidity between ears.

So if you've run into that patient that everything's fine on one side, but they always have this moist ear or this non-infectious otitis externa occurring on their right side, that's not a real bizarre finding. It is not uncommon for one of our ears to have a bit more humidity than the other. The other thing you're seeing here on this slide is the differences in size. So you see here that the smaller the size, the more likely it was to have a higher humidity, so that goes to what I was saying in this previous slide. If you have those extra-extra small or extra small patients wearing that device and it's just a real, real tight fit, then they're likely getting more moisture trapped because that seal isn't able to effectively vent as maybe a larger size that has a lot more foam and just

surface area to vent that moisture out. So what can you do, and what are our recommendations for this non-infectious otitis externa? The first, and the key here, is really just to let that canal dry prior to putting a device in. I always liken it to the floor in front of the ear canal have been disturbed, so there's been trauma to the ear even if there's no bleeding, or any cuts or abrasions, right? But something has changed to that skin, and you really wanna make sure you give that canal a good amount of time to rest before putting a device back in. It's not uncommon to put a device in too quickly with this, and then you get this moisture or this non-infectious otitis externa occurring again rather quickly. So you wanna make sure you get the ear nice and dry, then put a Lyric back in. And again, you wanna try to determine what might've caused this to occur for your patient. And as a summary of what we discussed before, it could be that over-lubrication, maybe excess medial moisture from allergies, moisture from skin healing from trauma, poor fit of the device, etc cetera. So you'll see all of those there, and you'll be able to reference this in the slides that are attached here if you wanted to come back and look at what maybe some of those reasons were that patients maybe ran into this.

So I mentioned we would talk about some best practices. So our best practices to try to help you avoid these two main clinical presentations are seen here. So first and foremost, if you do run into patients that are having repeat ear canal issues, transitioning to a daily wear device would be warranted. Now, sometimes your patients give you a bit of push back on that. We do recommend your audiogram, a tympanogram, doing your medical candidacy evaluation, and then even further, taking the step to go ahead and document the ear canal and taking a picture with your video otoscope. That's all recommended prior to fitting Lyric, and even doing that on an annual basis. We'll talk a little more about the TM part, the tympanogram part, in a couple of slides as well. We also recommend that you instruct the user to return if they have discomfort or pain. That's not new news, but making sure that you're staying on top of that and adjusting the device, resizing, replacing if you do run into that, and reminding the patient that they shouldn't be manipulating the device themselves in the

ear. We touched on the lubrication when it came to non-infectious otitis externa, but generally it's not needed for Lyric placement. So the vast majority of our top Lyric accounts aren't using lubrication at all. They may use it in just a few ears that are just known to be very dry ears, or when you look in you can tell that the skin is just a lot more dry. So they may use it then, but the rest of the time they're not. If you do need to use lubrication, just be sure you're not using a lot of it, and that you're not saturating the seals or getting it on the microphone or receiver, which would cause device malfunction. Another best practice comes around removing the device. Again, your patients can remove the device themselves, and some of your patients do quite well with that. If you have a patient who's had repeated ear issues, you may decide to have them come in. You do the removals, you can really manipulate and control that situation to try to reduce any issues that might be coming from removal.

Our recommendation for removing the device, especially one that is providing a lot of resistance when you're starting to remove it, is to use your Lyric slider forceps. You may need to add lubrication to the ear canal. You might saturate the seals at this point, you're ready to take it out anyway. To saturate the seals to try to help loosen it from the canal walls, you might also take a thin metal curette to gently break the seal between the device and the ear canal skin. So sometimes those seals for some patients or skin types just like to stick a little more than others. Using that curette can sometimes help break that seal. And then, with your slider forceps and that alligator tip, grab that handle of the device and slowly with your circular motion bring the device out of their ear while the patients kind of opening and closing their jaw to help break that seal as well. Let's take, again, another look at some pictures. Think pictures are always quite helpful. So another best practice tip is that your ear is really clean, no cerumen or debris in place. So this is really very important for ear canal health, and in this set of images there are really only two ear canals that are ready for Lyric insertion. I'll give ya second to look and see if you find them. The first one is here. Arrows pops up in a funny place, but that would be your first one. That one looks quite lovely, ready to go. The second one would be this one, although you may notice a pretty significant



difference between the two. The second one is a bit more red, or vascularized, and that's really important to note as you're working with Lyric. Some patients just have a more red vascular look to their ears prior to even having a device in at all. If you know that about a patient, then the redness or vascularization's not problematic, but I would encourage you to note it, or that's where having that video otoscope picture of the ear canal prior to even having a Lyric inserted is helpful in documentation, especially if you're working with multiple fitters in your clinic so that you're all on the same page about what's normal for a patient. But if this kind of redness or vascularization is not the typical for this patient, you might decide to wait a couple of days before you put the Lyric in the ear to let this ear settle down. That's an option that you would have.

Let's now take a look at just some other recommendations or general considerations for things you probably aren't seeing all that regularly, but that could pop up when it comes to Lyric wear. The first tier is an ulcer. An ulcer is a small break in the skin, so this can take weeks to heal and you may need to include the otolaryngologist to clean the debris from the base of the ulcer to promote healing. You always make sure this is one of the things why you really want that clean air canal, because if there's a significant amount of wax in the floor of the canal, or that you've put the Lyric over top of, that can cause excess pressure at the point of the wax, which then could lead to a break in the skin or the skin weakening. And if the wax is there, you're not able to see and visualize that the canal is healthy, so it's another reason why you really need to have a really clean canal when it comes to the fitting Lyric on your patients. Then I think we'll show, yep, so the other thing here is a medial bulge, or a growth. So this has been observed in a small percentage of patients. It can look a little bit scary as you're seeing in the images here, because it's very near the TM, or it seems to be a set-in growth. This medial bulge is a fluid-filled bulge. It's likely caused by irritation to that region of the ear canal. You wanna make sure you have a correct depth of insertion and correct device size for that ear to help you steer clear from this. If you do encounter it, then you need to refer your patient for your comfort level, go for it, but do let your otolaryngologist or the person, your patient that's gonna be seeing this

otolaryngologist know that this wasn't present when you first placed Lyric. So we wanna make sure that their patients not undergoing any unnecessary medical testing for more severe things like cholesteatomas, things like that, because they're generally just not gonna pop up in 30 days to the size that you would see here. And we've seen with this presentation that it does resolve with rest and without having something kind of irritating that area, so you can always just monitor it to make sure that the progression of healing is occurring, or refer should you feel more comfortable with that. When it comes to tympanic membrane issues, so the sounds like you might have tympanic membrane issues, but that's not really what we're saying here. We do every now and then, through our case reporting, get questions about this, or cases that come through that people think maybe Lyric caused a TM perf, but we definitely encourage you to do that tympanogram prior to fitting Lyric so you have that documentation of if the ear canal and the TM was intact prior to fitting Lyric.

From time to time if the patient had manipulated the device or somehow it got placed a little bit too deep, you might end up with a hematoma on the TM, but the TM is a very, it's a very resistant, it's a very resilient membrane. Takes a lot to really do much to it, so if you have that hematoma, giving it time to rest, make sure you resize prior to refitting is gonna be your best course. And when it comes to perforations, the key here is persistent. To date we've no cases of persistent perforations that have been reported. Cases that have been reported are acute cases. They've healed without surgical intervention, and in most of those cases, or the findings that our medical team has seen with those, is that the tympanogram prior to, or other notes prior to the Lyric fitting, or the history that the patient might've had with significant middle ear issues, led them to realize that there already might have been that small perf prior to placing the Lyric. It might've been missed or just not recognized prior to having the Lyric inserted. So sometimes those little perms can be hard to find if you're not using your proper magnification and illumination, but that's why we recommend doing that tympanogram prior to your Lyric fitting so you have that documentation of an intact TM and you don't have any concerns that Lyric had caught this, has caused a TM perf, as again, we

don't have concerns that it would. When it comes to middle ear issues, again this is not something that you should run into. This is not something that we see. There have been no cases of ossicular injury reporting. We just want you to know that if you have a patient that's reporting middle ear issues assess those complaints as you normally would. It doesn't mean that Lyric has triggered it. Do use your typical audiological judgment and take the Lyric out, perform your testing, refer if you need to, if there's something that come up while your patient's wearing Lyric but now they're having some kind of complaint. It's also important to note here that extended wear hearing aides, they're not related to eustachian tube dysfunction or otitis media, so the barometric pressure is also equalized by the seals of the Lyric device, so they're not increasing any of the issues or exasperating any of those middle ear issues that your patients may have already had prior to wearing Lyric.

Same goes for inner ear issues. No dizziness, tinnitus, sensorineural hearing loss or inner ear injury have been reported, so if your patients reporting something along those lines, again, use your audiological judgment. Take your device out and proceed with the testing you would need to, to make a referral for the situation to be evaluated. And as a side note, Lyric isn't contraindicated for your vestibular schwannoma or acoustic neuroma patients unless the patients already received radiation therapy for that. A couple of other generation considerations, if you've been doing Lyric for a while, you'll know our candidacy form has undergone some changes, but we know that Lyric is safe with a lot of data that we've looked at for ear health over the past 10 plus years. But for your patients that may have TMJ issues, there's no reports of Lyric making it worse, but if you already know your patient has TMJ issues you may wanna go ahead and use precaution in fitting them or maybe not fitting them if they already have associated ear pain with their TMJ. If your patient runs into trauma while they're wearing Lyric, then obviously try to remove the device if you're in that situation and access the ear canal and tympanic membrane as usual. And in very rare cases, you may run into a vaso vagal episode when you're examining the ear canal or doing cerumen management, performing audio, tympanogram, manipulating placing Lyric. If

this occurs your patient will kind of have the sensation of passing out, feeling warm, get nauseous, maybe get some stars in their eyes, some ringing in their ears and feel faint. So if this is happening, place the patient in a lying position with their head down and feed up, trying to get blood kind of flowing back to their head, provide reassurance, cool paper towels on his head or chest. They don't start to improve within a few minutes then certainly obtain appropriate medical support. But again this should be quite rare, but every now and again you may find someone who just has more of a tendency towards kind of passing out, or these vaso vagal episodes. I for one am one of those people so you would not wanna fit lyric on me, but the people that have to take blood sometimes don't like to do that on me either 'cause I can pass out for many, many a' thing.

So the other general considerations we have, the pacemakers, ventricular shunts, deep brain simulators. We know that the Lyric programming wand and the SoundLync have magnets in them, and we just wanna make sure that they're not interfering with an implanted medical device. So if you have a patient that has something that responds to, or an implantable device that responds to magnet, make sure that they're aware that the programming wand has the magnet and their SoundLync, maybe programming the Lyric device outta the ear before placing it, and then making sure they're keeping their magnets away from the medical device. And then MRIs, surgery, hyperbaric oxygen therapy, electroconvulsive therapy, these things are tests that would probably be in the best interest of the patient to have the device outta their ear. Certainly for kind of more standard surgeries we do just recommend having the patient discuss with the physician. 'cause if they have a hearing loss it's always important to hear what medical advice and what the medical team is saying, but it's always good that the physician and surgeon would know that the patients wearing a Lyric and what need to be done should anything come up, or if they have concern and wanted the device removed for that surgery. All right, now that we talked about just some of those general considerations, we're gonna move on to a few case studies to kinda close out our session today. And these case studies are just gonna be totally built on your

pictures. I think pictures are an easy, great way to learn about what you're seeing and what you should do, so that's what we are gonna dive into. So our first one here was a tourist case that showed up to your clinic, with the patient reporting that the Lyric died and when you removed it this is what you saw, and you were kinda like yeeek. The color of this would tell you that that didn't just appear in a week, which they said they were fit a week ago. So, and they confirmed that they didn't have any wax removed prior to having that device put in for their report to you. So obviously, we would wanna have this wax removed. This situation, it's could've been that, on insertion, wax could've actually got stuck on the medial portion of the device, causing the device to not function properly and die. In lesser cases, sometimes with a little less wax in this, what you can actually find, I forgot to mention this earlier, but as you're inserting the device it will actually snag on that, and then cause a bit of an abrasion. You may have seen it in the past where you just, by pushing the device in it, you see a little pushup of some of the skin or cerumen in the canal, and that can cause the irritation that can be an issue for some of your patients.

So wax is generally no good when it comes to Lyric, and in this case caused the device to fail prematurely and a patient who was out of town to visit your office. So this is the same ear, partially clean, so that debris was softened with mineral oil and cleaned with instrumentation and suction. If you don't feel comfortable cleaning the ear at the depth that it is, that is totally in your court to determine how you want to get the ear clean. This is an image that was provided by Dr. Johnson, so it may have actually been cleaned by him as he's an otolaryngologist, so it may be something a little more, a little deeper than maybe some of us would be prone to handle. And one final look with the canal completely clean with all of that cerumen removed, but as you see here this canal has now a more vascularized red appearance. This is gonna put you in a tricky situation, though. The patient's a tourist patient. If you've got this canal to this point do you wanna go ahead and put a device in? They certainly want you to, they're on a vacation, but as you recall, I'll click back, you can see the typical color of this patient's ear is not bright red. So you know that by removing that wax you've caused a little bit

of irritation, and maybe giving that ear a day or two would probably be the best course for them to not run into any issues as far as comfort or even increased risk from moisture buildup for that non-infectious otitis externa. All right, let's look at another case. So this is a lovely looking ear with the Lyric inserted. Nothing real surprising about the look, but the note here is it looks pretty good. It doesn't look super tight, and unfortunately, this was removed, that Lyric was removed because the patient reported reduced volume and this is what you found. So that doesn't look very good. You're starting to see a little bit of, sort of, a hematoma or bruise occurring there and some debris. This debris could be keratin. It can be a little bit of oil and wax in there. And ultimately, once you start to remove a little bit of that, that's where you're running into, in this situation, where you found that medial bulge, so this picture might look familiar. We saw it a little earlier in the slides, but that medial growth appeared and after cleaning that's what you recognized. And again, in about a week after that, that medial growth has now reduced in size significantly.

So I'm gonna flip between these, so this is prior where you're not getting a very good visualization of the TM, and then just a week later now you have a much better visualization of the TM. Things are starting to look much more normal as that food-filled pocket is starting to retract. But anytime you have that fluid-filled pocket, whether it be a medial bulge or a really large hematoma, it takes a long, long time for the skin to reabsorb that excess moisture in that bulge, whether it's that or a hematoma. This is a scheduled Lyric removal. So this canal looks pretty good. There's a little bit of debris that needs some cleaning up, but in this case you would have no problem going ahead and being able to refit a Lyric once you removed a bit of that debris. So I like showing this because most Lyric removables will be ready to go ahead and be refit right away. There shouldn't be any trauma or any kind of redness or issues, but you would want to remove this wax 'cause it could get into the receiver of the device or again, as we talked about earlier, be something that causes a little bit of excess pressure on the skin, not allowing the skin to, or just compromising the integrity of the skin of there's too much pressure because we put Lyric on top of the wax. In this case, we have a

patient who's device stopped working, and the patient, and you know that the patient manipulates the device, and the patients currently having difficulty removing the device. So this is one of those indications of okay, maybe I need to take some steps to try to remove this a little more gently, maybe filling the ear with some lubrication using the curette to pull it away from the canal walls. If the patient's having difficulty, chances are you probably have a little bit of that suction-y seal, and it's gonna be a little more challenging to remove it. And once that was removed you did find this. So this is one of those cases where you're like mm, this is not what I wanted to see. This is a combination of a few things, but keep in mind we knew that this patient manipulated their device. We knew that; they told us about it.

So we're seeing maybe some hematomas from their manipulation or previous irritation that they were already causing, and then maybe that's caused that increase in moisture to cause this keratin or moisture-looking non-infectious otitis externa. Getting a lot of different things in this image, but lo and behold, once we give it a little bit of rest, two weeks after rest and a little bit of cleaning, that's what the ear canal looks like. So you get a drastic difference just in having the device out of the ear with a rest, and getting that skin back to its normal happy self. Here we have a case of dry blood after Lyric removal, so this is a trickier one in my opinion to kinda clean, 'cause it looks rather deep and on the TM, and the dried blood can really be very difficult. It will flake off versus coming off all in one. But you really do need to have this cleared prior to putting a Lyric in the ear, so if you needed to refer to have it cleaned then by all means go for that. And here's a lovely picture of it two weeks after removal, so a nice clear ear where there is no irritation or any kind of actual trauma to the site, but it was just dried blood in that area. So when we talked about a bloody ear before, this is one of those reasons why you really wanna try to make sure that you get the bleeding to stop so you're not getting a significant amount of dried blood left in the ear canal. Here we have an ear canal of an older man, so 97 years old, dedicated the Lyric, but more of a vulnerable skin type of patient. And this device was removed because it was weak, and what you're seeing in the ear is not super pretty, right? Another one of that kind of

moist. You see it shining back at you, sign of a break in the skin likely causing a little bleeding around in here. And, if my clicker will go, after one week you can tell that the ear is still healing and it needs to continue to rest. And I would encourage you, I'm gonna flip to the next slide, just look at the color of this slide versus this. And if you've been watching as we've gone along, so I'm back to this 97-year-old man, I'm going the one before, so here's a patient and now we're to our 97-year-old man, two images of his ear, you can just tell in the coloring that the skin is likely not as robust as it is for some of these other images. So as you're looking in Lyric ears this is the things you wanna be looking for, is robust skin quality, overall general health, because we know the more healthy the person is in general, the more healthy and more successful they'll be with Lyric. All right, so case number seven. This should be close to our, and it is our last one, and I know we're right outta time.

So this is a 50-year-old patient. Do note there was a preexisting TM abnormality, but upon removing the device we see some debris in the ear, sort of some significant buildup here, and after some cleaning this is where you kind of start to see a little ulcer. So the ulcer is a little bit of a raised area around just that skin that has been compromised, so this could have been from a buildup of debris, so just skin, wax, sitting there and then causing that skin to not get the right blood flow, air supply, and then kind of just degrading a little bit under that pressure. So that does need a fair bit of time to rest and heal, and it may require a referral should you ever run into an ulcer case like this. All right, so that's it with our case study pictures, but just a couple of things I wanna make sure that you can take away when it comes to Lyric. Lyric is the only product available that replaces hearing 24/7, except for cochlear implants, so it is a really great solution for patients. And you are unique individuals in group that can offer Lyric because not everybody can offer Lyric, so give your patients the opportunity to experience 24/7 hearing and not have to give up hearing 10 or 12 hours a day or more. You certainly wouldn't wanna give up breathing or having your sight for those hours of the day, so giving your patients the opportunity to hear 24/7 is a really great gift that you can give your patients. And as a reminder, to be good at something new,



you have to be dedicated to it and spend time to be proficient at it. Our medical director talks about when he first started doing surgeries back in medical school. We all have to start somewhere, but you wanna be dedicated to it. If you kinda start and stop you're not doing that first patient of yours any justice, right? You wanna make sure that when you start with your first patient you're giving it your same effort you can give your 50th patient, and if you're afraid you won't be successful. Don't be afraid. Good news when it comes to the Lyric and the ear is that it's skin and skin heals, so that's one of Dr. Johnson's more famous quotes. It's skin and skin heals, so you're really not gonna harm the patient. Should you encounter any of these kind of hiccups in your Lyric road, the great news is, is you are very capable in handling it, and hopefully you found from this presentation a few tips or tricks in some of the presentations that you might becoming across with your Lyric ears to hopefully get you over some of those humps and getting your patient back on the road to success. So that's all I have. If there are any questions that hadn't popped up, feel free to type those in or let me know.

And don't forget to pull your handouts, which are an overview of the slides, and then the Lyric Insight or the Phonak Insight on clinical ear health. Thanks everybody for joining us today. I'm not seeing any questions typed in, so with that I will let you all have the rest of your day and enjoy it. Oh, I did see a question. If you used a larger device to stop feedback, but encounter moisture issues, what should you do? So you might try, can be very tricky this situation, but the first is recognizing that maybe my increasing to combat feedback caused the moisture issue, and in this case, you might try going down back to the smaller size and trying the placement of the device in the ear. So sometimes the overall shape of the ear, you wanna try to match that kind of oval. So when we always tell you to put the device with the super indicator at the top you wanna make sure you're matching the overall shape of the ear, so you might try just some different positioning with the smaller size. With the bigger size, you might place it just a touch shorter. So if that medial portion was really causing just it to be really, really tight after you checked with your sizer and yep, the medial part is just

really a tight fit, placing it even a half a millimeter shorter might allow that seal to better vent as it should be, versus the tighter fit that you had a slightly, just a slight bit deeper of a depth. Thanks for the question. All right, thanks everybody for joining. If you need other Lyric help we always are here for you, your Lyric team at Phonak. You can always reach out to us via your rep or your trainer, and we are happy to help you any way we can.