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## Ototoxicity Monitoring Programs: Addressing Existing Barriers

Presenter: Irina Linkov Middleton, AuD, CCC-A

- [Christy] It's my pleasure to welcome back Dr. Irina Middleton. Dr. Middleton is an audiologist at Jefferson Otolaryngology, where she primarily works with both adult and geriatric populations. Today she's gonna be discussing ototoxicity monitoring programs and how to address our existing barriers. I'll hand the mic over to you, Dr. Middleton.

- Thank you. Thank you very much. Let me advance the slide over for everybody. There's the disclosures for everyone to review, and I wanna go in before we jump into the full topic, a little bit about myself. I'm Dr. Middleton. I'm a clinical audiologist with Jefferson Balance and Hearing Center. Before continuing to the learning outcomes of today's course, I do wanna take a moment to thank everyone for taking the time to attend today. I also want to extend my gratitude to AudiologyOnline for inviting me back again to share information on this topic. As a clinical audiologist, I work primarily with the adult and geriatric populations. In a busy ENT setting. I conduct comprehensive audiologic evaluations, hearing aid evaluations, fittings with verification measures, hearing aid checks.

In addition, I have experience with tinnitus evaluations and management. In more recent years, I have taken a more active role within research for the audiology team and our ototoxicity monitoring program for our department, specifically pertaining to ototoxicity monitoring. And collaboration with patient care teams, which includes our head and neck physicians, nursing staff, oncologists, schedulers, I was able to assess our existing process to identify possible barriers which hindered effective adoption of the Ototoxicity Monitoring Program and help it evolve and grow. And so this is what we'll be discussing today, and I'll be showing some data that we've been able to track over the years since we've implemented a more formalized structure. So the learning objectives today, firstly, we're going to discuss the recommended schedule of ototoxicity monitoring for different drug classifications.

We'll also identify testing protocols for ototoxicity monitoring, as recommended by the American Speech Language and Hearing Association and the American Academy of Audiology. We'll also be able to describe the importance of ototoxicity monitoring in patients who are scheduled to undergo or are undergoing treatment with ototoxic or vestibular toxic medications. And we will identify possible existing barriers for ototoxicity monitoring and discuss how to incorporate strategies towards updating existing practices within our own clinical setting. So general information about ototoxicity. So toxic medications can directly affect the auditory nerve and or the vestibular nerve. It's important to be cognizant of the various symptoms which may arise while undergoing a treatment plan involving medications with oto- or vestibular toxic properties.

Ototoxic pertains to any drug that can cause damage to the ear. Vestibular toxic medications will cause damage to the vestibular system, so patients may experience dizziness imbalance symptoms as a result. Common symptoms that are caused by ototoxicity. Irreversible hearing loss, sensation of fullness in the ears, tinnitus, hyperacusis, and or dizziness. So the importance of monitoring for ototoxicity. So firstly, it does aid in early identification of otologic changes. It also allows for the opportunity for intervention when appropriate to mitigate further damage and improve quality of life post-treatment. Implementing rehabilitation measures such as amplification and counseling of communication strategies which result from hearing impairment will promote improved quality of life for patients post-treatment and help mitigate further ototoxic damage resulting from these chemotherapeutic agents.

Sorry. This is a drug class of different types of medication which can have ototoxic, vestibular, or both ototoxic and vestibular toxic symptoms that can arise. Very common in patients who are receiving chemotherapy for, like, head and neck. That's what we deal with most in our practice. Cisplatin and carboplatin are very commonly used. Cisplatin has higher tendency of ototoxic symptoms that can arise, but this is a general

reference chart that's really good to kind of just keep an eye on. If you have a patient reporting certain medications, this can indicate for you, is this something that they should be worried about. Is there a certain type of schedule that they should have? I do have, I think I missed it in the last slide, but there is a three-part poll that I would like to kind of present to everybody.

The first question is, within what setting do you currently practice? A hospital medical ENT setting, private practice, school system, or none of the above? The second question, with what age group do you work with? Adult, geriatric, pediatric, a combination of both? And within your clinical practice, do you perform ototoxicity monitoring? Yes or no? I'll give a moment for everyone to go through this. Okay, so results from the poll. The first question being within what setting do you currently practice? About 38% work within a hospital medical ENT setting, 29% in private practice, 7% in the school system, 26%, none of the above. For question two, with what age group do you work with? 60% work with adult or geriatrics. 7% pediatrics, 33% in combination of both.

And in terms of within your clinical practice, do you perform ototoxicity monitoring? It was 50 50. So 50% yes, 50% no. So thank you so much for participating and completing that poll for me. Moving to the next, we're gonna be reviewing testing protocols. Okay. So per the American Speech Language Hearing Association and the American Academy of Audiology, the testing protocol for ototoxicity should be minimally inclusive of tympanometry, distortion product otoacoustic emissions, comprehensive audiologic assessment, and high frequency assessment through 16 kilohertz. You can go up to 20. It's also in ASHA and AAA's information breakdown. But it's not going to be clinically significant on your findings if your equipment isn't calibrated up to 20,000 hertz. You can go up to 16,000 hertz. ASHA does also suggest the inclusion of click and tone burst auditory brain stem response testing for patients undergoing platinum derivatives, such as indicated like cisplatin and carboplatin.

We don't do this in our clinical setting, but there are suggestions to be able to incorporate this for this population. In terms of testing schedules, they are different based on the type of drug patients are being treated with. So chemotherapeutic drugs like cisplatin, the recommendation is to retest with every cycle of chemotherapy. With carboplatin, retest every two to four cycles of chemotherapy. And it's different with aminoglycoside antibiotics that they'll ideally weekly will retest one to two times per week in extreme cases. Typically, testing should be done at baseline. If they miss the baseline prior to administering the drug, then testing should be completed within 24 hours of the initial dose. Now with this, you know, generally it sounds very excessive, like to be monitoring them so frequently, and sometimes that's part of why patients are not seen beyond the baseline testing because with their work schedules with just how sick sometimes the medication can make them, it's not always realistic or possible for patients to come in so frequently.

But knowing what the recommendations generally are are good to have and to encourage to come in for the testing or as soon as they start to notice any changes. So typically, you'll have your baseline, you'll do the test battery that we reviewed, and typically, it's patients who are enrolled to be, you know, chemotherapy with or without radiation, they'll meet the inclusion criteria to be referred for baseline testing. This is the schedule that we roughly have for head and neck patients, but this is kind of what you wanna structure to follow. During treatment, follow-up testing should be scheduled within 24 hours of the next cycle of treatment with cisplatin. Within 72 hours with carboplatin through the course of their treatment.

Any significant changes, you'll wanna immediately report to the referring physician, the oncologist, following ASHA's guidelines. Post-treatment monitoring. You'll wanna complete testing again within six months. So the other important thing that has come up in our protocols, in our processes was always the question of, with every repeated

exam, are we repeating, you know, distortion product emissions? And our general rule of thumb is if you have any responses on that test battery that are still present at that baseline, continue to do it as patients come back because you may not identify any changes on the audiogram, but you can easily track and see the changes in the emissions results. So it's good to continue it, and at the point, if there's nothing there, then to repeat it, you're gonna get the same finding.

That's when you can defer on that test. In research, when we were trying to identify, you know, how can we make our process, our protocols more efficient. You know, we look at research. What is research sharing and telling us? So one of the articles that I had found talked about research and our role as audiologist as part of an ototoxicity monitoring program. In this article, it's entitled Clinical trials, ototoxicity grading scales and the audiologist's role in therapeutic decision-making. The objectives of that study was to define clinical trials, adverse effects for monitoring from the perspective of the audiologist. Looking at audiologist's involvement throughout the entire process, not just in that moment in time where we're seeing this patient for testing.

And so the conclusion, in terms of where we come in as audiologists, they determine that our role in therapeutic decision-making goes beyond just administering the audiogram. So clear communication to stakeholders in auditory, sorry, in ototoxicity monitoring is paramount. There's other studies that also support the involvement of audiology beyond the testing. And so that's this another article that had it. Ototoxicity management and investigation into doctor's knowledge and practices within and the roles of audiologists in tertiary hospital. So the aim was to determine our role within the management of ototoxicity and determine if they should expand our role to share information with patients and other professionals. So they surveyed 90 participants to assess their knowledge of ototoxicity. And so when they looked at the overall results, they determined knowledge about ototoxicity was lacking.

Ototoxicity risks were not fully disclosed due to lack of timing and insufficient knowledge. And while the audiologist's role was determined to be important, few referred to audiology for monitoring. And so the conclusion was that our role in this process should be expanded. It's a must. Expanding the role includes provision of continued professional development activities, advocacy for their role in the hospital to raise awareness among physicians of the importance of ototoxicity monitoring. So when we go into different barriers, lemme see. So before I do that, actually, in terms of the participants in the study who were surveyed, it represented interns, medical officers, registrars, consultants in the neonatal intensive unit, intensive care unit, ear, nose, and throat, and internal and family medicine departments.

So when we look at barriers, we're looking at, you know, what variables exist within clinical workflows that could potentially interfere with successful adoption or implementation of ototoxicity monitoring. You know, this can range from location access, limitations to staffing, maybe something with equipment, poor referrals. There could be a variety of different types of barriers. Per the research, when we're looking through it, a lot of what was consistent was inconsistent referrals, scheduling, location, space, staff limitations, collaboration, communication between disciplines, education of importance of ototoxic implications, patient access, education, and audiology inclusion. Now barriers may look different depending on the type of practice and the structure that's in place. But these that are listed, they were key of what has been cited.

So I have another poll that I wanna include here to kind of gauge everyone's experience with what barriers they've had. So what barriers, if any, have you identified within your clinical settings that may have hindered full adoption of an ototoxicity monitoring protocol? So there's a few options, like listed in the slide. Inconsistent referrals, scheduling, location, space, staff limitations, collaboration, communication between disciplines, education of importance of ototoxic implications, patient access

and education, lack of audiology inclusion, or not applicable. Okay, so to review some of the answers that we have. For what barriers, if any, have you identified within your clinical setting that may have hindered full adoption of an OTM protocol? 38% said inconsistent referrals, 29% scheduling, 4% indicated it was location, 2% space, 21% staff limitations, 42% collaboration and communication between disciplines, 35% said education of importance of ototoxic implications, and 17% said patient access and education.

31% lack of audiology inclusion, 25% nonapplicable. So it seems from the result of the survey, the big ones that have come up across different settings in everyone's experience has been the collaboration and communication, education importance of the implications of ototoxicity, and inconsistent referrals. Those are like top three that I'm seeing. So what we did essentially, you know, we had a test battery that's always been in place. We knew what schedule we should have been following, and that's what we did. But if we wanted to make sure that the protocols were being adopted effectively, what we did is kind of look at what is existing to see if we're noticing any of those barriers that we cited. So within our practice, ototoxicity was established in this type of structure.

Audiology followed standard testing protocols, but not all patients fit criteria for ototoxicity monitoring were being referred 100% of the time. The way in which the barriers can be addressed and resolved, you know, was different from our site locations. Oh, I'm so sorry that jumped. I did not anticipate that. My bad. But this represents what our process looked like initially. It started with observation, and then if there was a patient who was referred or labeled with adjuvant radiation plus chemotherapy, that prompted the oncology nurse navigator to send a task and benefit verification checking for baseline testing to get the patient scheduled. So how these patients are essentially were referred from our internal practice is through our head and neck physicians from a weekly meeting that they have called tumor board.

So that's where all cases of patients are reviewed based on the surgical findings, you know, scans, and it's determined there what patient, what these patients are going to have done, whether they're going to be observed, have surgery, chemotherapy, radiation, chemotherapy with radiation, that's where the decision is made. And so once this specific note was made for these patients, they had an oncology nurse navigator take over from there and task the right people to get patients scheduled. But again, it wasn't happening consistently 100% of the time. And audiology's involvement was from the testing standpoint, we weren't part of the decision or the collaboration. And so once we identified the workflows, we evolved the process a little bit more to then look a little bit more like this.

So barriers were taken into serious consideration while reviewing existing workflows with all involved stakeholders. The goal was to improve access for patients, ensure patients were appropriately referred, and to ensure tracking system was in place so that each step within the process was followed. The goal wasn't to impede workflows but to seamlessly integrate an improved process into patient care pathways. So the formal protocol takes into consideration key points which take place during the entire ototoxicity protocol cycle. So beginning with the initial recommendations from tumor board, which we referenced ASHA's and AAA's guidelines, there are key checkpoints that were built into the process to ensure accountability of everyone involved. So this includes tasking, insurance verification specialist, verifying benefits, verifying that patients have been contacted, scheduled when appropriate, and documenting when the test has been completed.

So tumor board meets, they meet every week, they determine the status of whether a patient should or shouldn't be referred based on the treatment type. They send out the results to me, and then, based on the recommended patients, I then send a task to our insurance verification specialist with a trackable phrase within our medical records

system. So it's very much automated. So we have an automated way of tracking it within our EMR, but then I also manually track it. Once the insurance benefit is checked, I update that status in our tracker, and then the patient is scheduled. Audiology is kind of signaled into knowing that patients are scheduled specifically for baseline testing based on what is written in the appointment note.

We have it very clearly written, "Head and neck baseline testing." So audiology will implement the protocol, test the patient, and send the results to the referring physician but also to me so that I can then update in our tracking system that the patient has been seen and they have been recommended for follow-up. So these are some of the barriers that we had discussed. The big ones that we encountered here, which was, you know, the collaboration between disciplines, educating on the importance of the ototoxic implications, patient access, patient education, and audiology inclusion. So our ways that we acknowledge those barriers, first and foremost, we developed a formal protocol, and it's led by audiology. So we're very much involved in guiding the decision-making in terms of how to integrate it into the workflows with the research supporting it.

There's now education on ototoxic properties and importance for monitoring to key stakeholders. Audiology is very much involved with that. We collaborate with them regularly. OTM tracking is something that we do to ensure successful implementation of the process. Again, audiology leads that. Patient access. At the time, we had six locations, so we made sure all locations were appropriately calibrated for the extended high frequencies, and they had been, but we did wanna make sure that it was there. We now have another location. So now patients have a seventh location where they can be seen if it's more convenient to where they're located. And then patient education about ototoxicity. We do talk to patients about that. We provide resources for patients so that they know what implications they can anticipate possibly.

It can be that they don't have issues at all, but in the event that they do, they have an awareness of that now. Within our tracking, you know, when we say we have a tracking system in place, we have, it's in an Excel sheet that we're looking at every individual part of the process. So we're tracking the tumor board date, when patients met, patient information, the referral type, the recommended treatment. We're tracking the smart phrase usage. That way we have on the backend an automated way to identify it and whether the tasks are sent, whether the tasks are being verified, if the patients are being contacted. Eventually, part of, you know, this is an ever-evolving protocol.

We always have to stay on top of it to see, you know, what's working, what's not. And so now we also track if patients are not being scheduled, why? You know, what reasons influence that? Is it because they simply don't want to? Is it that they prefer to go somewhere closer to home? Do we not accept their insurance? We look at every little piece that's tracked. And so if we look at it in phases, we can almost break it down that in phase one, it's the tumor board is when they're meeting. Then, the phase two, we check the benefits, then patients are scheduled, and then we complete their testing. And so the biggest question was, if we're looking at this at a glance, how successful has this been since we, you know, became more involved and part of that collaboration process?

And so what this looks at is a glance in time at a fiscal year. So it represents about three months, I believe it was April to June. So in 2021 is when we became more involved with the process. Even though we had the testing schedule in place, audiology became more involved addressing the barriers in 2021. So before audiology kind of led the initiative, you can see that I don't have the exact numbers on here, but if we compare fiscal year '21 to '22, the number of patients who met the criteria increased substantially and continue to increase even this year alone. One of the biggest things that changed from when audiology kind of took over the tracking and

the guidance of it is that in 2022 and 2023, 100% of the patients who met the criteria to be referred for ototoxicity, 100% of them were accurately referred.

Versus in the past, many, like 38 or so, were referred, but only like, I think it's seven or five actually who were actually referred, even though a lot more met the criteria. So we see that over time it grows, the referral rate is more accurately captured. Not as many are scheduled, but again, part of that isn't so much because patient, because we're losing them to the follow-up, it's because, again, we're tracking potential reasons. Like, again, maybe patients don't want to come in, maybe they've already had it just somewhere closer to home, maybe the patient passed away. Those are various reasons for why not 100% of them get scheduled, but 100% of them are contacted and several attempts are made to try to talk to patients about what the recommendations are.

So if we look at it from a yearly glance, I don't have 2023 'cause we're still ongoing with it. But from 2021, 112 were referred, and then 180 were referred in 2022. So it increases because now more are being identified that meet the criteria. 83 tasks are sent in 2021, 183 are sent from 2022. And the reason why there's more is that while we track where the referral source coming from, majority of them are from the internal tumor board, but patients still come to our practice who are being referred from an outside physician. So we do track the the process for them as well. So that's why you'll see more potentially being scheduled or more being seen or verified than how many internally were referred.

But you see that 120 were scheduled in 2022, 49 of the 112 that were referred were actually scheduled. Three were missed. So the more we add, we might see a little bit more missed, but again, we look at why, and that's represented in the next slide. So the biggest reason that it really comes down to was patient refusal, they didn't want to, or they wanted to schedule closer to home. Those were the two big ones in 2021.

They've remained the biggest reasons in 2022. Very few of the insurance wasn't accepted, so they went somewhere in network, somewhere closer to home. And then the very, very small one is that patient passed away before we can even contact them to get them scheduled.

But we do look at all those things. We're also tracking if patient's scheduled and then canceled. So that also can happen. But the key with it is that as long as we're maintaining that contact and we're tracking the system itself, and we're consistent, then it can work. It's just a matter of identifying what barriers potentially are in your setting and how can we, you know, more efficiently address them if it's feasible, 'cause sometimes there's roadblocks that can't be avoided. But these are just some ways that we were able to do it here, and the way that we were doing it, we're seeing the growth in numbers, and it's been a phenomenal thing. So some key points about this, you know, the collaboration, the communication, education, physician education, and patient education, those are big.

Accountability is also very important. Everybody plays a key role into this being successful. So if everyone is on top of what their portion is and they're held accountable, and they're verifying, again, that consistency, it can be very successful. So part of what we do, weekly follow-up at those key checkpoints, you know, patients are referred every single week. So for example, when I'm adding to the tracker every single week, I'm also looking back, I'm looking back at previous ones that were added in to see is there anywhere in this tracking process that something was not done. So then we can evaluate how can we help that process be better. How can we make it efficient and help the workflows rather than, you know, complicate or hinder them? So that is what I have. We can start with, if anyone has any questions, we can open the floor for that.

- Thank you, Dr. Middleton.

- Yeah.

- [Christy] We have a question here from a member. They mentioned they get doctor referrals for monitoring for aminoglycoside administration. And sometimes the patient is in the ICU and is too ill to come to the clinic. Do you have any suggestions for continued care? And they also mentioned they have a portable audiometer, but it has limited frequency.

- Limited frequencies. I mean, so the best that I can maybe suggest in this situation, realistically, if a patient is in the ICU, they can't come to the clinic, whatever information you're able to get is still information that is trackable. Even though you have limited frequencies, you can still see are there changes to the frequencies you're able to assess and monitor from each time that you're coming in. So, like, from week, if it's week to week, if you have, you know, 10 decibels at one frequency that you're able to test and then, you know, three weeks later it's suddenly dropped to 30 decibels, that's still trackable. Any information you're able to realistically acquire, it is still beneficial. So as long as that patient is not able to get to you and you're able to, without issues, get that portable audiometer to that patient, it's still critical information. Do you have a portable tympanometry or a portable emissions reader?

- [Christy] And while we're waiting for the attendee to reply back, there is another question here, if you're ready for it, Dr. Middleton?

- Absolutely.

- [Christy] Do you ever incorporate tinnitus or hyperacusis assessments in your monitoring of these patients?

- For ototoxicity, not particularly, not at this time, but if you were looking to implement something for tinnitus monitoring, I do suggest the emissions for every patient and extended high frequency. That's gonna be the same thing that you track for that population base. And then there's a question, "Why don't you test the same day after treatment? Could do?" So you don't wanna just limit the test battery. So if all you have is tymps and audiometry, you know, you use what you can. If you have emissions, you definitely wanna make sure you can have that in there. But same-day treatment if you've missed the baseline, and if you've missed the baseline before administration of treatment, then do it.

Absolutely. If you can do it the same day, you should, but then make sure they're coming back within that timeframe to monitor during. Let me see, yes, the anonymous attendee said, "Yes, we have tymps and OAEs too. OAEs were absent at baseline." Okay, perfect. So all important information. So if they're absent from baseline, they're gonna stay absent, they're not gonna come back. So in terms of the what you can realistically do each time you can get there to do follow-up, always run a tymp. And even though, again, even though it's limited frequencies, that's still information, that's still a picture into what's going on, and trackable changes that may or may not happen as they get new doses.

There's another question. "How often do you see cisplatin therapy change in dose or to another therapy due to hearing loss identified?" So that's the other part of it. So we can track changes, but medication on our end that we've seen, they're not gonna change the medication type if there's changes on the audiogram. Ideally, that is what sometimes is recommended. If you're seeing significant changes, then there's the potential consideration from the physician to change to a different drug. But that's not what we see here. Not in our population base. So patients who come in who are being treated with cisplatin, they likely stay on that medication regardless of the changes we find on the audiogram, unfortunately. But they are, I'm not sure there's.

TC says, "But they are available then." I'm not sure what you mean by that. If you could expand? Then there's is, "Is tinnitus monitoring via questionnaire, should this also be done to identify need for follow-up?" So tinnitus monitoring, there's a couple different, there's a couple different questionnaires that you can use to incorporate for tracking patient's perception of tinnitus. One that I've used with tinnitus patients is the TRQ, and every single time that they come in, I administer it, so that way we get a picture of how they are in time from the last two weeks and then we monitor, like, that I monitor their score and potential improvement. You also wanna get their subjective perception of what their tinnitus awareness and disturbances.

'Cause sometimes you might have, like, relatively stable responses on the TRQ, but maybe their disturbance level or awareness level has gone down with time. So you can, you can absolutely try that for patients with tinnitus that you're monitoring. "What degree of loss are you typically seeing in adults with cisplatin at the end of their treatment?" So some that I've seen is, like, moderately severe. So this is the unfortunate part. We know what the protocols are. Come at baseline, during treatment, and post. We're seeing that, with implementing our protocol, patients who should be referred for their baseline testing, we see them, we see them all. But the other part of it now is that continuation. Whether they're coming at the end of their treatment and that's where we're not, like, I'm not seeing that, and we're working on constant collaboration to see that improved.

So right now I have patients who have been monitored in the very beginning, but they're either not done with their treatment yet or they haven't come back. So where they are at the end, I don't have it yet. Not for a lot of the patients who we've seen, unfortunately. Question. "Do you see a significant portion of post-radiation eustachian tube dysfunction with mixed hearing loss? If so, do your ENTs treat it? Here they say, generally, it does not help place a PE tube because of more chance of constant

drainage." So medical insight into whether a PE tube is warranted, I leave that to the discretion of the physician because it's not within my scope to make that type of judgment.

But again, what I can say is that we haven't, I haven't seen many patients from post-treatment because that's the next piece that we need to help improve and expand upon. All the appropriate people are coming in, not as many are coming at the very end of it. So I can't comment on that one yet, in terms of what I'm seeing post. But, you know, I haven't seen many coming in that have, like, hearing loss complaints. It's usually, like, an oral fullness eustachian tube issue that starts during their start of treatment. And this is patients who never had a baseline, who didn't know, because they're not internally coming from tumor board. "On the day of treatment, they are captive audience."

And so again for TCM getting pieces of what you're sending. So I know that, like, previously you had written, like, "Why not do it the same day? On the day of treatment, they're a captive audience." Again, if that's the time that you can do it, that's the time that you should do it, as long as everyone's on board and you can get patients scheduled, but they should still ideally be coming back. That's the thing, the next piece of it that needs to happen. Patients need to be consistently aware that during treatment, monitoring is something that should be happening, not just once at the start.

The next question, "Should 250 to 8,000 hertz testing be offered to these patients if high?" Yes, yes. If you don't have extended high frequencies, you should still be offering the standard test battery. Absolutely. "Are patients receiving hearing aids during treatment or at the end of their treatment?" So that is a very tricky one. 'Cause some patients might have, like, a short stint with treatment, or they might be going on for, like, maybe, you know, worst case, a year or maybe less. I don't know, 'cause I'm not, I don't have their active therapy plans to know how long they're there. But

generally, generally, what we know is the sooner you initiate oral rehabilitation, the better outcomes for these patients. But the other side of the coin is what happens if, like, halfway through their therapy, their hearing aid candidates and word recognition scores are still good, but a year from now they've completed it, it's been over six months.

Now that toxicity has really impacted their word recognition, and so now they should be in, like, a CROS or BiCROS, not hearing aids. That's what's really tricky, and you really should use, you know, the judgment in the moment based on what you know about their therapy plan and just really stay on top of monitoring those changes. That one's a hard one. "Do you test only the sensitivity range of ototoxicity during treatment, or do you test all the high frequencies? What is considered an extreme case of aminoglycoside? Meaning do you need to retest?" So extreme case, so do I, so first part of that question, "Do I test sensitivity range during treatment or do I test all the high frequencies?" I test all of them.

There are modified, you know, approaches that you can take, like for the sensitivity range. That way, when you're getting people in, you can do it a lot faster. But for consistency, we make the time, we test all of it to see potential changes across the board. "What is considered an extreme case of aminoglycoside antibiotic, meaning do we need to test?" So really, patient. So I mean the Gentamycin, those ones are, like, are the big ones. I had a patient who was coming in every single week because she was receiving IV with Gentamycin every single week for an infection that she had. And her infectious disease specialist was aware of the potential effects.

And so every single week she was coming in. If the patient is experiencing sudden changes to their hearing, that, I think, would be extreme. Like suddenly you came in, say, Monday, had their test. Tuesday, Wednesday they had, like, their treatment administered. Friday they're saying, "Something's wrong, something's wonky, I'm

experiencing a sudden loss, or suddenly I have this ringing in my ear." That's extreme. I haven't seen very many for that, but I think that is what I would classify as extreme.

"Do you ever administer quality of life questionnaires? If so, which ones?" I have not personally. Adding questionnaires for patients for hearing aid evaluations after all this is something that we're constantly in the process of doing, like the CoC, but I don't, so I don't have ones to recommend at this time.

"What are the main reasons for patient refusal?" So that we haven't expanded on, but some patients simply don't want to. Some people they don't wanna know, they don't wanna know if they have a problem with their hearing because they're too focused on making necessary arrangements and plans for their, they're trying to make, you know, the plans for, they're about to undergo chemotherapy, they're potentially gonna be out of work. They have everything that needs to, you know, that they're prioritizing above where their hearing is. So, I mean, that's the biggest one. They have too, too, there are higher things on the list that they're prioritizing over knowing where their hearing is. That's probably the big, big one for patient refusal.

"Do all audiologists on staff conduct the monitoring? Do you have externs and train them?" So we do have externs and so, as externs gradually become proficient in diagnostics, you know, they do perform it, but it is mainly the audiologists on staff who conduct the monitoring. "At any given time how many are on your caseload?" So I don't have my tracker on me, but I can say, for example, in terms of how many are referred, one week we can have seven people, seven patients who are referred. Another week, it could be only one patient who met the criteria to be referred. Then it's a matter of once everything is verified, we contact them. So sometimes we might see maybe three or four get scheduled at one location, but we have seven sites.

But what I'm noticing is mainly it's, like, our center city location where patients get scheduled, and then the small handful that choose at one of our satellites if they wanna

stay and be tested by our practice. So it's not, it's not an extreme amount of patients at one time for ototoxicity compared to how many we see day to day for just general routine visits or ear issues or dizziness, or tinnitus. But they do come up. For me, not as many, but downtown they do come up more frequently. "When does a patient graduate from the monitoring program? Who decides that?" The physician. So I mean, especially the physician, because they, especially the oncologist and the physician who collaborate on the patient care, they know when that last dose is gonna be.

So once that last dose is administered, then, from a technical standpoint, the post audiogram should happen at least six months within that six month timeframe. Once we have that, they've, like, technically graduated from the program. But then it's general, you wanna keep staying on top of it, have your hearing checked every year or sooner if changes occur. "Can you go back to the barrier slide? Could you tell us, could you maybe tell us some personal experience with each of these barriers and what we should expect when starting our own program?" So let me go back. This one? Hold on. So this is the barrier. So some that I've, so that I've come across. So the inconsistent referrals.

So the big one, you know, with the example of the fiscal year, that small moment in time, that small moment in time where like 37 met criteria, only five were actually referred. So, like, those referrals, you know, that was a big one. Scheduling. Once a task was sent, what happened? Was the patient contacted? There was no way of knowing what happened beyond that initial encounter. So now we look and expand into that. Space and staff limitation was never an issue. So the biggest ones, again, was the education of importance of ototoxic implication, audiology inclusion, the inconsistent referrals, and the scheduling. Those were the big ones that I'd encountered. But I think I lost the rest of that question.

So if I missed any, I apologize. "Have you noticed a difference in patient acceptance in OTM depending on insurance coverage? In other words, will patients pay out of pocket?" Some have, yes. Some patients, like, if they don't have insurance, they can be self-pay, or patients who in are not in network with us, we give them that option if that's what they choose. The patients, you know, have been very open. Like, what the thought is if the program wasn't working, if it wasn't successful when we would reach out to patients, then no one would be scheduling, but they are. A lot of people, you know, they appreciate, "Okay, now this could potentially happen once I start my treatment."

I appreciate that they're coming in and being comprehensive in my care so that we know where things stand. So if something were to change at any point during treatment, we know where I was before I started to see if something significant happened. "Is it common for insurance to cover?" So it depends on patient's insurance. Insurance is a very wild thing. Some patients might have, like, a hearing test covered, some, depending on the plan, might not. And it's medical necessity. So, you know, they're being referred by the physicians that it's not our, it's not us saying you have to have this. We know that they should have this, but the physician refers them and orders this hearing test.

So if it's medical necessity and they have coverage for a hearing test, then it's billed to insurance, and it should be covered depending on the plan. "Would you consider the use of monitoring at home?" I don't know a lot about the reliability and the collaboration of apps on tablets. I don't know a lot of insight into that to say if I would ever consider to use that. So I don't know. "Do you have recommendations to prevent loss to follow-up in terms of the counseling aspect?" So to prevent loss to follow-up. So the best thing that we can do is, when the patients are in front of us, educate them on everything that you know.

If you don't have existing resources of ototoxicity, what it is, create a general patient handout that has all the information about what is ototoxicity, what are common symptoms, and what your recommendations are for patients to do if they were to ever notice it. The more information you can provide with the patient, I feel like that will help you with that, that, you know, potentially, like, that loss to follow-up aspect because there's only so much control that we have. But if we get ahead of it and we offer patients insight, I feel like that goes a long way. You're empowering them, you know? They now have all this information that they might not have been aware of in the past.

You know, in some of those research, you know, patients weren't aware of what could happen with the treatment. And so they just wanted to know, like, "If I knew this going in, at least I would have an awareness of what to what to look out for, what to expect." So that's what I would recommend to do. If you can create patient handouts and resources for patients, you're empowering them with all that information and that knowledge, so they know what to do as soon as they realize something is going on, they know who to turn to. "Do you work as a team to press the importance of audiology, to follow-up care, even with everything else going on in their care?"

So the physicians, so I work at one of our satellite offices, but I have constant access and communication with our physicians. So whether it's generalists, the otologist, the head and neck physicians, everyone is accessible. And so whenever something comes up that might need to be readdressed within the protocol, we meet, we talk about it, we make suggestions, and we collaborate together on how to enhance that patient experience to help improve the flow. And it's been really great. You know, the physicians have been really great to collaborate with. You know, in their tumor board, it used to come up as general discussion, and now, you know, in their tracking, they've even added, you know, a column specifically for ototoxicity monitoring referrals.

And that's a permanent adopted feature into their tracking. So when it's all said and done and they send it to me, it's there for me to know, it's not a guessing game. It's everyone who should have been checked, that I don't have to go back and say, "Hey, what about this person?" It's already there. And so it's been a great thing to see the collaboration element evolve. "What about patients who have returned for second round of treatment, and how are their cases in monitoring any different?" It's not. You're gonna follow the exact same protocol that you did from baseline. The only thing that might be different is if your emissions were absent across the board at baseline, you don't repeat it.

If you have, even if there was like three out of 12 that were present, still repeat it, 'cause maybe that three outta 12 will become zero out of 12. So everything's the same except for, potentially, the emissions, depending on where you were at baseline. "Have you been able to track if a patient refusal was related to their stage of cancer or type?" I have not tracked that. And part of that is I don't always have access to it. It's not in all their charts, all the specifics. There's some things that I can see, some things that I can't. We tried getting me access into what the regimen and treatment and dosage would be, but it's different department in terms of oncology.

And if they go to a completely different oncology center, I don't have access to it. So I haven't tracked that. The more you can track, the more patterns you can start to see emerge. So if it's something that you realistically can monitor and track, I would suggest it. You know, it doesn't hurt to be able to pick up on a potential pattern, as long as it works with your workflow and doesn't hinder anything that you need to do. "If you happen to miss the baseline test timeframe, is a test that is late better, is a test that is late better than none?" Yes. The thing is, even if a hearing test is done after treatment has been initiated, that very first test that you're doing, that becomes your baseline.

So, you know, a hearing test, to have that it's better than not having it at all. Yes. "What was the timeline you mentioned for the initial baseline?" So let me go back to that slide. It's right here. So if a baseline is missed prior to administration of the drug, testing must be completed within 24 hours of the initial dose. So that's, you know, ASHA and AAA, that's what their recommendations are in their literature and all their documentation. But going back to, you know, that previous question, it's good to have it at some point, even if it's a little late. "Please clarify testing timeline if the baseline testing has not been completed prior to the drug." So if you didn't do it, the sooner you can get them scheduled, the better.

If they've already had treatment administered and they're coming in three or four days later, that's fine because at that moment in time, that will become your baseline, 'cause that's the first test you're gonna have on them. It's just you'll have to document in your notes that treatment had already started. "It sounds like you work at a really great practice." It's a great collaborative team that we work with here. It's been wonderful working with them. "What bit of advice would you give a busy ENT clinic that wants to incorporate monitoring for their patients? Where would you start?" So the first place I would kind of start is collaborate with the team to see what existing process is in place.

You don't know what needs to be addressed, you don't know what needs to be incorporated until you can see in front of you, almost mapped out, depending on, you know, I'm very visual. So once I met with everybody, I wrote things out, and then I drew a picture of it so I had a mental representation of kind of where things stood. But that's not how everybody, you know, that doesn't work for everybody. But if you can identify what current process you have in place, that's your starting point. You know, what is currently in place, what do they envision it looking like? And typically, I mean, they're coming in for a hearing test. So these patients, do you have set testing time slots, or do you work in a practice where they're sending you a patient without a concrete schedule of your own?

Because that's where you're gonna have to look at how can we best incorporate this if there's not a set schedule. Can you implement a set schedule in terms of how patients are scheduled? That's gonna be the biggest thing. First identify what the process currently is, because you don't know what needs to be enhanced until you see that for yourself. That'll be the starting point. "You mentioned patterns you happen to see in your patients. What is the most common pattern of progression we would see?" So as unfortunate as it is, it's a progressive loss. It's just happening, you know, a little bit on the sudden scale because ototoxicity, you know, once they get that initial dose, for example, with cisplatin, that's being absorbed and stays in the cochlea in that space, like, within an hour, that's where it stays.

It doesn't dissipate, dissolve, it stays there. There was another course in AudiologyOnline about this. It was wonderful. You know, if you can find it, I don't remember what it was called, but I would check it out. But you're gonna see the high frequencies, even if you're not seeing changes on the audiogram, you're gonna see changes in the emissions. Even if it's like the amplitude of the emissions that's suddenly dropping to some of the hair cells that are no longer responding, you're gonna see something somewhere on that result. And extended high frequencies, that's where it goes first. So you might see it in the extended high frequencies and the emissions before anything else. "Have you ever had a patient you were monitoring that developed tinnitus so bothersome, you cannot complete testing?"

Personally, I have not. But I prioritize, you know, patient comfort. And so if a patient just can't do it and they're debilitated, I defer. You know, we don't wanna put them into a more heightened state, a more stressful state, that will make their tinnitus so much worse. But I personally have not had that happen. "Are protocols different for pediatrics versus adults?" I don't work for pediatric, I don't work with pediatrics. But from what I was seeing in literature, I don't think it's very different. I think it's similar, but there is

information on this. If you do little digging and research, I think you'll find it's the same.  
"What would you like to see change in the future for the process of an OTM program?

What about patients with cancer? What's the most difficult barrier to overcome?" So what I would love, what I would love is for it to be, so what we know about OTM, patients should be monitored before, during, and after. I would love to see more of an adoption of the during and after. I love that we've enhanced the before and we've gotten the awareness out, but now we need to expand it to make sure that it's consistent across the board. And so that way we have more insights into the patient journey, and then we have more, you know, information to track what patterns are emerging. What can we anticipate because we have these patients consistently coming back that we can now identify and properly then, you know, give our guidance or recommendations for these patients from an audiologic standpoint.

Patients with cancer. So it's gonna depend on, you know, for their cancer, what type of treatment are they getting? So some treatments for cancer are not straight cisplatin, that's not straight, you know, otologic agents that are being used. But collaboration with the physicians would, you know, bring in awareness. You know, "Hey, if something that you're gonna be using with your patient has the potential to initiate and cause a hearing loss, here's what we recommend in terms of monitoring for them." And so that was the biggest barrier that we mostly had to overcome, wasn't so much, you know, we had the collaboration, we had the buy-in, and it evolved without a lot of roadblocks. It was just a matter of can we get someone to track it from start to finish so that it's consistent.

And so when, by doing that, by integrating audiology into that process, so, you know, not just in administering the hearing test but joining in that journey, then it made the program successful, and it continues to be, the numbers continue to grow, and the

referral rate internally is 100% from the internal referrals. So it's been a good evolution to kind of observe.

- [Christy] Thank you so much, Dr. Middleton. I think that concludes the Q&A. There's no more in the queue. And we would like to just thank you for sharing your wealth of knowledge on this topic. It's fascinating because I know most of our clinics, you know, don't ever get to, you know, put our time towards ototoxicity in monitoring. So we really appreciate you sharing that and just making it tangible for some of the other busy clinics out there.

- Yeah, I thank you so much for inviting me to talk about this. It's great to share it and to show, you know, how we can potentially address barriers to make it successful. We have all the foundations, it's just putting it all together to see where it could grow.

- [Christy] Thank you, Dr. Middleton. This concludes today's course. We hope you enjoyed it.

- Thank you.