

**Centers for Disease Control and Prevention**  
**EARLY HEARING DETECTION AND INTERVENTION**  
**Special Topics Teleconference**

**July 10, 2007**

**Roughly Edited Transcript**

*Auditory Brainstem Implant (ABI):  
An Option for Some Individuals with Hearing Loss*

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**John Eichwald:** Good afternoon, this is John Eichwald with the CDC EHDI Program. I welcome you to our teleconference. Thank you all for calling in today.

We have a very great call planned for today related to auditory brainstem implantation. I'm very pleased to introduce Krista Biernath, who most of you know. She's a Medical Officer here on the CDC EHDI team. And Krista, you may or may not know, is a recent recipient of an auditory brainstem implant. We also have the benefit of having Krista's audiologist on the line, Steve Otto, who is associated with the House Ear Institute. I believe he's willing to take some questions at the end. I find this to be a real exciting call. As an audiologist and a colleague and friend of Krista's, this has been a real interesting experience to have someone this close to me receive this kind of technology. With that, I'm going to turn the time over to Krista.

**Krista Biernath:** Thanks, John. As John mentioned, this presentation is going to be on the ABI from the user's perspective. First I'm going to cover some basic technology and historical and medical aspects, and then I'll talk about the first six weeks as a user and what that's been like. As John mentioned, my audiologist, Steve Otto, who's the Chief Audiologist and Coordinator of the ABI Project at the House Ear Institute in Los Angeles, is on the line, and he's worked with many ABI users, so I feel very fortunate that he's agreed to help out with answering questions.

The first slide depicts a very brief overview of hearing. And I'm just going to go through this very quickly. Sounds enter the ear and are carried down the ear canal to the tympanic membrane, as seen on the left figure. When sound waves vibrate that membrane, the energy is transferred to the middle ear, which houses the ossicular chain. Sound energy then moves through the oval window of the middle ear to the inner ear, which is composed of two structures, the snail-shaped cochlea and the semicircular canals which are part of the vestibular system for balance. The fluid vibrations within the cochlea then activate the auditory receptor cells, or the hair cells, and transmit the electrical signals through the auditory nerve to the brain. And these signals enter the brain via a structure in the brainstem called the cochlear nucleus. This functions like a grand central station in routing signals to other parts of the brain. One other piece to mention is that the auditory nerve in exiting the inner ear joins with the nerve from the vestibular portion of the inner ear, and becomes the vestibulocochlear nerve.

The next slide shows the anatomy of hearing loss. Hearing loss typically occurs in one or more parts of the auditory system that's not working correctly. The figure on the left shows the location of a conductive hearing loss where the problem is in the outer or the middle ear and it prevents sound from being

conducted properly. Causes for this type of loss include things such as ear wax in the outer ear, otosclerosis, or otitis media with effusion. The figures that you see to the right and bottom show the anatomy of the sensorineural hearing loss. On the right shows a problem in the cochlea resulting from missing or damaged hair cells. This is one of the most common problems that cause a permanent sensorineural loss. The bottom figure shows a problem that results from the absence or damage to the auditory nerve, and can also cause a permanent neural hearing loss.

The next slide -- this is a picture of an audiogram. And as I will show pictures of some audiograms later in the presentation, I want to put this slide in as an overview of what it looks like. The audiogram is a graph showing the results of pure-tone hearing tests and each line from the left to right represents a frequency in Hertz (Hz) starting with the lowest pitches on the left side to the very highest on the right side. And then going from top to bottom, each line represents loudness or intensity in decibels. Lines at the top of the chart represent the very soft sounds, while lines at the bottom represent very loud sounds. This audiogram shows where some speech and environmental sounds are located.

The next slide: Since the EHDI community is very much aware of cochlear implants as a technology option for families with children with severe to profound loss, I'm going to spend the next couple of slides comparing cochlear implants with auditory brainstem implants. Cochlear implants can bypass a damaged cochlea and send electrical signals to the auditory nerve. But for a person with a fully working cochlea whose anatomy of the hearing loss is at the nerve level, a cochlear implant doesn't work. An ABI, on the other hand, is a device that bypasses the auditory nerve and sends the electrical signals directly to that structure on the brainstem called the cochlear nucleus. Currently there are approximately 37,000 cochlear implant users in the U.S and 100,000 worldwide. In contrast, there are approximately 300 ABI recipients in the U.S. and 600 worldwide. The first cochlear implant recipient in the United States received their device in 1961, and the implant was FDA approved for use in adults in 1985, and for children in 1991. In contrast, the first ABI recipient received her device in 1979, nearly two decades later. The ABI was FDA approved in 2000.

There are three manufacturers with cochlear implant models approved for use in the United States. These include the Advanced Bionics Corporation, Cochlear Limited and Med-El. There's only one ABI model approved for use in the United States, and that's manufactured by Cochlear. Med-El also has a model, and from what I understand, that device is not FDA approved for use in the United States, but is used in other countries. Finally, in the United States, the cochlear implant is approved for use in children 12 months of age and older, while the ABI is approved only for persons 12 years of age and older.

On the next slide, as the Nucleus 24 ABI with the SPrint speech processor manufactured by Cochlear is the only model approved for use in the United States, I'm going to compare its technology with that of its cochlear implant counterpart. These pictures show the internal and external components of the devices. On the left, the external components of the current Nucleus cochlear implant system are the microphone, worn at the ear level, the speech processor, also worn at the ear level, and the transmitting coil. The internal components, those which are surgically implanted, include the receiver and the electrode array, which is implanted in the cochlea. So how does it work? Sound waves travel through the microphone to the speech processor, where sounds are digitized into coded signals. And these coded signals are then sent to the transmitting coil, which is positioned on the scalp behind the ear. The transmitting coil on the scalp connects to the implanted receiver through a radio link, and then electrical signals are sent down tiny wires to the electrode array.

In contrast, the external components of the ABI, as seen on the right, include a microphone, also worn at the ear level, a body-worn speech processor, and the transmitting coil with the receiver and electrodes being the internal, or surgically implanted, components. As with the cochlear implant, the sound travels through the microphone to the speech processor, with coded signals traveling to the transmitting coil, receiver, and finally the electrodes. But instead of the electrode array being implanted into the cochlea, the main difference between these two devices is the electrodes of the ABI, which are mounted on a rectangular silicone carrier, are placed directly over the cochlear nucleus in the brainstem. Initially, the external components of the Nucleus cochlear implant and ABI systems were identical with the body-worn processors. But recently, an ear-level processor has been approved for use with the Nucleus cochlear

implant system, and I understand that the ear-level processor is now awaiting FDA approval for use with the ABI system.

The next slide shows a comparison of the electrodes used with the cochlear implant and the ABI systems. The picture to the left shows the electrodes with the cochlear implant system are placed along a long, thin pre-curved electrode array that is designed to fit inside the cochlea. In comparison, the ABI electrodes, shown on the right, are mounted on the carrier, which is designed for placement over the surface of the cochlear nucleus.

On the next slide, the ABI was pioneered at the House Ear Institute in Los Angeles, California, by Dr. Hitselberger and Dr. House. The first ABI recipient, Marilyn Davidson -- and she's shown here with Dr. Hitselberger -- received her implant in 1979. And as an ABI recipient, as I think about this, I'm in awe of what she did. Basically, she was approached by Drs. Hitselberger and House, and she was asked to consider a procedure where electrodes would be placed on her brain and then electrical signals would be sent directly to her brain, and then maybe she would hear something, or maybe she wouldn't. They really couldn't say, because it had never been done before. And I could just see her saying something like, "Sure, let's go for it," and I'm not sure if I would have done the same thing. But fortunately, for the rest of us, she did, and she paved the way for the rest of us. Ms. Davidson's first implant consisted of a ball electrode which soon, as I understand it, became unstable, and it had to be explanted. She then agreed to re-implantation with a two electrode array, and from what I understand, she is in her late 70s, and continuing to successfully use the ABI. The first recipient of the multi-channel, 8-electrode ABI received his implant in 1992, and the model currently being used was FDA approved in 2000. And I left out a very important piece of ABI history. The Penetrating Auditory Brainstem Implant, or PABI was designed to use not only electrodes placed directly over the cochlear nucleus, but also microelectrodes penetrating into the structure. The first PABI recipient received her device in 2004 -- and I'll talk about the PABI in a few minutes.

The next slide: Currently there are 11 centers in the United States that implant ABIs. I put this slide in to give you the Cochlear Ltd. website that provides contact information for each of these centers.

The next slide. Who are candidates to receive the ABI? The FDA approved ABIs for use in a very select group of individuals. These are persons who have neurofibromatosis type 2, they have bilateral tumors on their auditory nerves and are 12 years of age or older. It's important however to remember that these indications are only for the United States. Other countries have differing regulatory requirements, and therefore, different candidacy indications.

The next slide. What is neurofibromatosis type 2, or NF 2? It's a neurological disorder found in approximately 1 in 40,000 people. It results from a mutation of chromosome 22, and is autosomal dominant in inheritance. Approximately 50% of the individuals with NF-2 inherit a mutation, while the other 50% are affected through spontaneous mutation. Typically, NF 2 is clinically detected in the second or third decade of life, but it can be diagnosed during childhood. And NF 2 is characterized by benign tumors, or schwannomas, on the central and peripheral nerves. The hallmark of this disorder is the growth of these tumors, bilateral schwannomas, on the vestibulocochlear nerve resulting in hearing and balance deficits.

The next slide. Schwannomas are an overgrowth of normal cell, also call Schwann cells that normally cover both the peripheral and the central nerves. Over time, these tumors can grow and begin pressing on the brainstem, and not only traumatize the vestibulocochlear nerve, but can also damage other nerves around the area, such as the facial nerve and the nerves associated with swallowing and breathing. So while these tumors are small and causing very few clinical problems, they can be watched carefully using imaging techniques. Eventually, however, they have to be removed, and when they are removed, the vestibulocochlear nerve is usually severed, especially in larger tumors, and then the patient becomes profoundly deaf.

The next slide. The ABI is designed to bypass that severed nerve. During surgery, once the tumor is removed, the ABI electrodes that I showed a few slides ago are placed directly over the cochlear nucleus.

The electrodes are then activated during the surgery to test for signals. However, in order to allow resolution of any swelling in the area over the receiver that would prevent transmission of the signal, the ABI is typically not activated for something like 6 to 8 weeks. At activation, each electrode is tested, and the recipient reports if he or she perceives auditory sensations. Since the electrodes are placed superficially over the cochlear nucleus, some of the nearby nerve fibers may be stimulated resulting in non-auditory sensations that are perceived by the recipient. These can include such things as dizziness, slight sensations of eye movement, and tingling sensations over different parts of the body. These sensations typically disappear over time. Electrodes that produce only non-auditory sensations or that produce auditory sensation with intolerable non-auditory sensations reported by the recipient are not used during mapping.

Even after years of use, ABI recipients are not expected to get the same quality of sound that cochlear implant users typically do, and the reason for this is partially due to the layout or geography of the nerve endings in the cochlea as compared to that in the cochlear nucleus. In the cochlea, the tonotopic layout allows predictable pitch ordering, whereas the layout in the cochlear nucleus can be quite variable depending on individual anatomy and slight differences in array placement.

The next slide deals with outcomes. The study reporting outcomes used for the 2000 FDA approval is outlined here. This study was carried out using patients who were implanted with the Nucleus 22 ABI device. That was the model that was used just prior to the one that's currently being used. A total of 90 subjects implanted with this device were followed. Eighty-two percent, or 72 of these subjects, were able to perceive auditory sensations. Of the 90 users, 60 had at least three to six months experience with the ABI. One third of the individuals were implanted during surgery to remove the first side tumor, while 2/3 received the implant during surgery to remove the second side tumor. This is important to keep in mind because those with the hearing remaining on one side are often less likely to rely exclusively on the ABI. On testing, 65% of the individuals could recognize more than 50% of environmental sounds presented to them in a standardized format, while 85% showed improvement over time on open-set sentence understanding with lipreading. But only 12% showed a great improvement without lipreading. This again highlights the important fact that ABI users are not expected to achieve the same quality of sound as cochlear implant users, and that expected results are improved lipreading and sound awareness. And finally, in this study, 44 of the subjects completed the post-operative questionnaire regarding their experience as users. Just over 60% of the subjects who received the ABI after the removal of their second-side tumor reported using the device on a daily basis for 10 hours or more. Eighty percent reported that they were receiving some benefit using the ABI, and 70% of them said they would recommend the ABI to others

The next slide shows a study done with tumor versus non-tumor patients. Currently in the United States, individuals with the loss of function of the auditory nerve but without NF-2 and bilateral tumors are not candidates for the ABI. In other countries, however, where regulatory requirements are different, these patients are candidates. It's thought that recipients with tumors may have poorer outcomes than recipients without, due to trauma of nerve endings in the cochlear nucleus from pressure that the tumor places on that structure. At the University of Verona, Italy, between 1997 and 2006, 80 patients received ABIs, and that included 26 with tumors, and the remaining without. All but one patient reported auditory sensations when the implant was activated. Speech recognition was by far better in non-tumor recipients than those with NF-2 after one year. However, most all recipients reported overall better communication and sound awareness. Recently in this country, House Ear Institute and the University of North Carolina Department of Otolaryngology have been selected as the two co-investigator centers in the newly approved FDA clinical trials of non-tumor ABI recipients.

The next slide. The question that is very pertinent to the EHDI community is: What are the outcomes for younger users? In this study that looked only at 21 users ages 12 to 19, 19 of the subjects perceived auditory sensations on activation. Of these 19 young users, 11 used their ABIs regularly; two of them still had hearing on the second side, and therefore did not use their implants; two were non-users due to uncomfortable non-auditory sensations; and four became program dropouts, with one returning much later. Currently, implantation in children younger than 12 years of age is not approved by the FDA. But in other countries where the regulatory indications are different, a handful of children have received ABIs

with some success. Most of these have been at the University of Verona. However, I believe one young girl about 3 years of age was recently implanted at the University of Melbourne.

The next slide. The penetrating auditory brainstem implant that I mentioned before is a modification of the ABI. Recipients of the currently used surface-electrode ABI don't generally receive the level of benefit that a cochlear implant recipient does, in part because the surface electrodes don't usually have extremely selective contact with the different pitch regions of the cochlear nucleus. This newer device, the PABI, uses a combination of surface electrodes and microelectrodes that penetrate into the cochlear nucleus, with the purpose of this being to produce a more localized stimulation of the cochlear nuclei than is possible with the regular ABI. The first recipient received her implant in 2004, and I believe there's been a total of 10 recipients of this device during its clinical trial period. From what I understand, the outcomes with this device have varied, and are not what was initially hoped for. From what I understand, plans for further work in this area are being carefully considered. However, the PABI research has clearly demonstrated that the penetrating microelectrodes can provide hearing sensations at lower levels of electrical stimulation than the larger surface ABI electrodes.

The next slide. This is the part of the presentation about the personal experience that I've had using an ABI. I received my implant in March of this year, and it was activated only about six weeks ago, which as you've heard is a very, very brief time for an ABI user. As Steve, my audiologist, says, for improvement, think years and not months, and it hasn't even been months yet. But here is a little of what this very early time has been like for me. This is going to be from my perspective as a non-audiologist, so please don't expect too much technical information.

Before I get started, I want to talk a little bit about the words "hear" and "hearing" and the new meaning they've taken on for me. Before my activation, I was adamantly against using those words to describe the sounds around me once my ABI was activated, because I would not be perceiving sounds in a natural way, through my ears, cochlea, and the auditory nerve, et cetera. But that got very old very quickly. It was very awkward to say, "Hey, honey, think I perceived someone at the front door. "Can you please check?" So the words "hear" and "hearing," slipped back into my vocabulary, and it bothered me, So I decided to go to the dictionary. And the Oxford Dictionary defines "hearing" as "the act of perceiving sounds," so I cut myself some slack, and you'll probably hear me using those terms during this part of the presentation.

The next slide. When it was time to start thinking about removing my second tumor, a personal physician suggested that I talk with Dr. Derald Brackmann to learn more about the ABI. And after a lot of discussion and thought, I decided to go forward with it. I had my surgery and subsequent activation done at the House Ear Institute in L.A. My team of professionals included Dr. Brackmann, my otolaryngologist, Dr. Hitselberger, my neurosurgeon, and my audiologist, Steve Otto. Steve has been incredibly patient with me and my anxieties, including my questioning even the day before the surgery about whether or not this might be the right thing for me. And I give Steve a lot of credit for simply saying, "It's your decision." There were other members of my team who are not shown on this slide, simply because I wasn't able to locate the pictures. Dr. Michael Stefan was my internist, who takes over the post-operative care for many patients. And I've never had the luxury of having an internist take over care from the surgeons and I partially credit this for my relatively smooth recovery. Dr. Weldon Selters is an audiologist who was involved with monitoring and testing during the surgery itself. And Dr. Joe Kutz is a fellow who was involved with the surgical team. After my surgery, I returned to Atlanta to resume my typical activities for two months, with absolutely no sound.

The next slide. This picture is of the gardens outside the guest house where we were staying. The House Ear Institute is located across the street from St. Vincent's Medical Center, where all inpatient services are provided. Adjoining the hospital is a guest house for patients and their families to stay during treatment. This garden was in front of the guest house, and this picture was taken the morning that my ABI was to be activated. This picture sort of describes my mood as we walked to the offices. I was trying so hard not to get excited, because I knew there was about a 9% chance of getting no sound, but still I felt like I was walking on clouds that morning.

The next slide. This was taken when I was hearing my first sounds. The initial part of the activation is to test each electrode. And we started at the very low-intensity stimulation for each electrode and worked up. For the first electrode, I could see a light blinking and the computer registering each increase in intensity and there was still nothing. I had a sinking feeling that was pretty unnerving. But then I thought I heard something, and I waited. And the next time, it was a little louder. It sounded like the tone that's used when pure-tone testing is done. I had a response to all 21 electrodes, but some of them were not auditory sensations. Activating 9 of the electrodes resulted in my calf muscle tightening, and one of them resulted in pain in my ear canal. So 10 electrodes were turned off. After testing each electrode and setting loudness thresholds, the electrodes were pitch-ordered. Two of the remaining 11 electrodes seemed to me to have pitches identical to that of two other electrodes and they were also turned off. So 9 of my electrodes were mapped. Steve indicated to me that he only needed approximately 4 to 5 electrodes to produce a good map.

In this picture, you can see that I'm wearing an athletic band around my head. Unlike cochlear implants, ABIs do not use magnets on the receiver to hold the transmitter in place. This is because NF-2 patients require frequent MRIs, or magnetic resonance imaging scanning, and anything magnetic will create a large artifact in the scans that will not allow important structures to be seen. Therefore a small piece of tape containing a thin metal disk is placed on the scalp over the receiver to hold the transmitter in place, and this requires shaving hair from a small patch of scalp. So in the event that a recipient does not receive any sound, Steve, ever so kindly, waits to shave the hair. Instead, he uses an athletic band to hold the transmitter in place.

The next slide shows my audiograms. After the ABI was mapped, we did speech recognition tests, which went fairly well, and then we also did a simple pure-tone test. And just to show you the difference, I've shown my audiograms over time. I lost all my hearing on the left side when my first tumor was removed in 1983. So the first audiogram shown here was testing my right ear in August of 2004. My hearing has definitely decreased after that time, but I don't know what it looked like after that, because I didn't get my hearing tested again prior to the surgery. And I can picture the audiologists on this phone call shaking their heads when I say this, but denial is a very powerful defense mechanism. It was really defeating to keep hearing the words, "It's getting worse." And so going to the audiologist became a lot worse than going to the dentist for me. The second audiogram was the two months between surgery and activation. You can see just the line at the very bottom. Basically, a jet plane could have flown a few hundred feet over my head, and there would have been no sound. The third one was done on the day of the mapping. And as you can see, it's above the level of many speech sounds, but because of the poor quality that I mentioned before, I can't understand speech without lipreading.

And the final slide. I've put together a collage of some of the things about my first six weeks with the ABI. First of all, everyone sounds like Donald Duck speaking in a monotone voice. Even our dogs sound like Donald Duck. A friend of mine recently asked me what Donald Duck sounds like, which I thought was a very intriguing question. But I keep forgetting to look for a Donald Duck DVD. In addition to the Donald Duck sounds, I sometimes hear what I call a splitting of sound with the monotone Donald Duck sound alongside a very faint sound of the person's actual voice. It kind of sounds like an echo. And with the exception of my husband, I've only heard it with female voices, and I almost always hear it when talking with my mother. Her actual voice is usually nearly as loud as the Donald Duck sound.

My dogs - while waiting for the ABI activation, I tried not to get my hopes up too high. And so I decided that if I could understand that our dogs were barking, I would be thrilled. And I definitely can hear them bark. And not only that, but I can also understand the difference between their barks, and I can hear them walking through the house. I had actually forgotten that walking is associated with a sound. Soon after I was using my ABI, I was home alone, and became frightened because I heard what sounded like footsteps, and it turned out to be one of our dogs.

I also have a clock that a good friend of mine gave me years ago, and it hangs in my study. I used to enjoy the sound of ticking and chime every half hour. But I stopped remembering to wind it because I couldn't hear it. After I started using my ABI, someone wound it up when I wasn't in the room, and when I returned, I couldn't figure out what the sound was until I looked at the clock.

Another sound that I've heard that I've had to go looking for the source is alarms. And I didn't remember that microwaves make a noise. I also hear the keyboard when I type, which surprised me. And chewing on my pencil makes a noise which makes me wonder how many people I've annoyed over the last several years.

Finally, I've had a very pleasant surprise in the past two weeks or so. One day, I began to absent-mindedly hum an unknown tune that I thought was my tinnitus, or the ringing in my ears. And my husband got very wide-eyed and indicated that was the music that was playing in the background. So I described it to him as a brass-sounding jazzy tune, and that's exactly what it was. I had never heard it before. We thought it was simply a fluke and would never happen again, but a few days later, I started humming a tune. The person I was with excitedly told me that it was a tune she was whistling. And I had never heard that one before either. So we went to the piano, and I'm able to pick out some simple tunes that are played very quietly in high octaves. But I'm not expecting that to improve or even to continue. But it was something that was really unexpected and exciting.

So that's an overview of what my six weeks have been like. The ABI experience, as I understand it, is not the same for everyone, and some people have had more success than I've had, and some people have had less. So if someone you know is a candidate, I would be more than happy to talk with them about what I've experienced. But I won't try to talk them into it because it may not be an option that others feel is right for them.

Before I open this up to questions, I'd like to introduce my audiologist, Steve Otto, who will be helping me answer questions. As I mentioned, he's the Chief Audiologist and coordinator for the ABI project at the House Ear Institute, and has worked with over 200 ABI recipients. He received his Master's degree in audiology in 1971, followed by post-graduate work at the University of Iowa. And among other career experiences, Steve spent a sabbatical year working as a Cochlear Implant Clinical Specialist for Cochlear Limited in Sydney, Australia. And upon his return to the United States in 1987, Steve became a Research Audiologist at House, and in 1989, he took his current position. So I'm very grateful that he's on the line to share his expertise. I will say before putting this up for questions, I am using captioning, and so there will be a slight delay. So I'll open this up for comments or questions.

**Steve Otto:** Krista, I have a question for you. I wonder, can you tell me a little bit more about how you think sound has changed from the first time I talked to you, and today. Has the sound quality changed?

**Krista:** Actually, the sound quality differs from day to day. It's very hard to understand people even with lipreading some days, and it's very frustrating. It just almost sounds like a continuous monotone sound, and I notice this especially when I'm really tired. Some days, I would say the quality is much better. And I would say the splitting occurs more often than it did initially and maybe a little less monotone.

**Steve:** Can I make a comment?

**Krista:** Yes, please do.

**Steve:** Well, first of all, I just want to say that I thought your talk was outstanding, and it would be great for everybody who is thinking about an ABI to hear your talk. So I thought you did a great job. And also, I want to say thank you to CDC for helping get the word out about the ABI. I'm always struck by the fact that lots of people with NF-2 do not know about the ABI. And so I appreciate your helping get the word out about the implant and what it can do. I'd also like to just say, if I can, that Krista is my idea of a perfect ABI candidate, and the reason is that she has the most important characteristic for being a great ABI recipient, and that is that she's motivated to use her ABI daily, and to take what she gets from her ABI and make the best of it. So I would say that the key to success with an ABI is just using it every day, because as I'm sure Krista will agree, at first, the sounds you hear with an ABI do not match what you see on the person's face. And I would say that's the most difficult thing for an ABI recipient at first. They often say that what they see on the face doesn't match very well what they hear. And on some of the tests, when I test lipreading only and sound plus lipreading, they actually may do better with lipreading at first

than they do with sound plus lipreading, because the sounds are not what they remember when they had normal hearing. So the key to success with an ABI is just using it every day, helping your brain to re-learn to use the new sounds, and connect those sounds with what you see on the lips. And ABI candidates can improve for 10 years or more, so it's important for people to stick with it, and, you know, sort of get over the hump, which happens, I would say, in the first month or two, because if you don't stick with it, then you can lose out on the very substantial improvement in performance that can occur several months down the road, and that can continue for many years. So those are the comments that I would like to make. And I want to thank Krista and CDC for allowing me to be a part of this teleconference. I really appreciate it. I'll turn this back over to Krista in case there are questions.

John: Do we have questions for Krista?

If not, I want to express my deep, sincere thanks to Krista for doing this teleconference. Also to Steve Otto for joining us and particularly those comments at the end.

Thank you all for joining the teleconference today. I hope you enjoyed it as much as I. And our next teleconference is in two months, and I can't remember the date. I wish everybody a happy rest of your summer. Thank you for joining us.

[END OF MEETING.]

## **Roughly Edited Transcript**

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