LINDSEY: …for joining us this afternoon for our webinar about Functional Electrical Stimulation. My name is Lindsey Whitcomb, and I am a social worker for the National Spinal Cord Injury Association, and will be your moderator for today's presentation.

Today, the webinar is one of several that National Spinal Cord Injury Association will be hosting, and all of our webinars will be archived and found on our website at www.spinalcord.org. Today's webinar will provide an overview of neurotechnology and FES applications, specifically for paralysis. Resources will be provided to learn more about this emerging field of technology as well as a description of recent research findings and development in neurotechnology applications for paralysis, the application of neurotechnology devices in the areas of cough assistance, hand function, trunk stability, standing and walking, as well as other information and resources.

We are pleased to have Jennifer French, the Executive Director of Neurotech Network and the Cleveland FES Center here with us today to discuss this exciting topic. As a result of a snowboarding accident, Jennifer became a quadriplegic from a C6-7 incomplete spinal cord injury in 1998. She is an avid user of Functional Electrical Stimulation system. In November 1999, she received the implantable Stand and Transfer system provided by the Cleveland FES Center, MetroHealth Medical Center, and Veterans Affairs. Jen is the first woman to receive such a system. Residing in St. Petersburg, Florida, Jen volunteers at the local sailing center, serves as a chairperson on the Committee to Advocate for Persons with Impairment for the City of St. Petersburg, and is a state-trained paramentor for spinal cord injury. She will also be representing Team USA at the 2012 Paralympic Games in the sport of sailing.

As a user of neurotechnology who has reaped its benefit, Jen is the co-founder of our 501(c)(3) nonprofit organization, the society to increase mobility doing business as Neurotech Network. The organization's focus is to educate and advocate to and for persons with impairment, their caregivers, and healthcare professionals regarding neurotechnology.

We will have time today at the end of the presentation for questions, and please use the Questions window to write in any questions that you may have, and we will do our best to get to them at the end of the presentation. If you are unable to, Jen will be able to follow up with you each individually via the email that you used to sign in for today's webinar. So without further ado, I'd like to turn the presentation over to Jennifer at this time. Thank you.

JENNIFER: Thanks, Lindsey. That was a great introduction. I really appreciate it, and it's a pleasure to be here today.

You know, it's a little interesting as today is actually my 14-year anniversary of the accident when I went off the embankment on my snowboard, so I'm now 14 years post-injury. And reflecting on that time, 14 years ago, we actually called the National Spinal Cord Injury Association, and they helped my friends and family and for all of us to understand what spinal cord injury is about. So it's a real pleasure to be here today and to be able to give back to an organization that helped me so much in those early stages and beyond. So, it's a great time to be here.

But I want to thank you all for attending. We are going to go through this whole presentation on functional electrical stimulation and neurotechnology. So let's dig into it, and let's learn about what we are going to talk about today.

So first I want to introduce you to two organizations. The first is the Cleveland FES Center. They're a research center that actually develops technology that improves the quality of life of individuals with disabilities through the use of the functional electronical stimulation and enabling the transfer of technology in the clinical deployment. So they actually do a lot of the technology development, a lot of the technology research, if you will.

The second organization that I would like to introduce you to is Neurotech Network. And Neurotech Network is near and dear to my heart. It's a nonprofit organization for which I'm a founder. But our focus is really in education and advocacy for the access to these types of devices and therapies and treatments. And really, our focus is people with impairment, their caregivers, and the front line medical clinicians that take care of them. So those are the two organizations I would like to first introduce you to.

Today, we are going to go over about four main objectives. I'm going to give you an overview of neurotechnology and some of the main categories, some of the applications, and just kind of give you a flavor of it. And of course, give you some resources to learn more, where you can find out about these different types of technologies. And then we're going to go into some of the research side of functional electronic stimulation. And of course, we're going to end out this presentation with additional resources for you all to go and investigate more about this type of technology and whether it would be appropriate for you.

So what is neurotechnology? The definition, or the industry definition, I should say, is the application of medical electronics and engineering to restore or improve function of the human nervous system. So what in the world does that mean? That means way before we had cell phones and

computers and iPads and iPhones and whatnot, Mother Nature discovered that electrical signals provide the most efficient way of relaying information within the body. That's really in layman's terms. So in the most part, we have electrical activity happening within our body. And what neurotechnology really does is it capitalizes on that electrical activity to either help boost rehabilitation or the rehabilitation process, or to be able to modulate some systems within the body.

Here I'd like to show you on the bottom left-hand part of the screen are some of the health and economic impacts that have been researched and discovered over the years. So neurotechnology really has decades of research behind the technology. And here are just some of the areas where they've proven to make impact—such as long-term care cost reductions, independence, quality of life improvement, self-reliance, acceleration of rehabilitation—just to give you a flavor of what type of impact that the technology can make.

So what types of applications go with neurotechnology? There is a lot of them. And this just kind of gives you a bit of a flavor of what type of applications there are. Of course, we can't go into all of them today. And if there are any that truly interest you or you want to know more specific topics, please let the organizers know, and we will be happy to put something else together for you. But we're just going to focus on some of the applications today.

But now I'm going to go into some of the categories of neurotechnology, and to try and break down this big category, if you will, or this big area of neurotechnology. So the first category is neuromodulation. So really, when you look at neuromodulation, it's the application that modulates an existing neural system to bring or return it to normal effect. So really, it's modulating, if you will, some type of system within the body. An

example would be spinal cord stimulation systems used for chronic pain. They really don't cure the pain, but what they do is they help modulate the pain for the person that's actually using that system.

The second category is neural prosthesis. So just like we think of prosthetics for amputees, neural prosthetics actually are an application that uses the neural system to replace or supplement lost function. And we're going to see some of that today as well.

The third category is neural rehabilitation. So we all know what rehabilitation means. But really, this is using technology that helps, if you will, boost or restore or aid the recovery process that's already happening within the body.

And the final category is called neurosensing or neurodiagnostics, and this is really devices that monitor or give a good view or a better view, if you will, of the activity that is happening within the neural system. So such common tools like EEG and EMG, and even you may have heard about some brain interfaces that are actually using neurosensing to sense the activity within the brain.

So what types of applications are there? This is a bit of a busy slide, but I'm going to walk you through it just so we can give you some examples of the different types of categories. In the upper right-hand side, you'll see neuromodulation and some common uses of neuromodulation—for instance, are deep brain stimulation. That's a device used and FDA approved for Parkinson's disease, essential tremor, dystonia, and now used for severe depression. Sacral nerve stimulation, it's this little picture over here on the far left. It's used for overactive bladder for modulating the urinary system. And then, of course, there is spinal cord stimulation that

was mentioned earlier in terms of modulating or regulating for chronic pain.

In the upper right-hand corner, these are some examples of neural prosthetics. So for instance, this picture right here shows you some of the hand and wrist stimulation to give some gross hand function, if you will. Also, the diaphragm pacing system is a system that is approved for spinal cord injury and ALS to allow people to breathe off of a ventilator and be able to, if you will, breathe independently, or breathe when using this system, if you will, instead of a ventilator. And finally, drop foot stimulation. That drop foot syndrome is very common amongst stroke survivors and/or people with incomplete spinal cord injury, and this is a system using electrical stimulation to be able to improve the gait or walking.

In the bottom left-hand corner, you'll find neural rehabilitation, some examples of that. FES cycling has been around for a long time. That's an example that fits into that category, neural re-education systems, which is this boxy thing right there in the middle that uses EMG and surface stimulation to be able to re-educate or improve with the rehabilitation process, mostly for upper limb. And also the robotic assisted walking. There's been a lot of press, if you will, about the exoskeletons, and that also fits into that rehabilitation category.

And then finally in the bottom right are some of the neurosensing or neurodiagnostics area. EMG communication uses some of the muscle sensing to be able to control environmental controls or even a computer. The middle picture with this woman with weights is using EMG to be able to monitor movement. This is where your physical therapist can make sure that you're doing your proper exercises at home and you're actually using the correct muscles. So that's a way of being able to monitor using

EMG. And then finally, EEG interfacing – this has been commonly used for epilepsy. But this actually is an interesting picture where they have been using EEG in military situations to be able to understand some of the brain activity for military training.

So that really gives you some of the examples of neurotechnology. I'll give you some resources at the end where you can learn much more about these and some of the others in those categories.

So let's move on to FES or functional electronic stimulation. So we've mentioned the Cleveland FES Center at the beginning, and it is really a consortium between Case Western Reserve, the V.A., and MetroHealth Medical. And when we look at functional electronic stimulation, it is really the application of electrical stimulation to restore function. So it can be used in the therapeutic purpose and for the replacement of lost function. So as I just showed you those categories, really, when we're looking at FES, it can fit into almost two of those categories. It can fit into the neural rehabilitation category, and it also can fit into the neural prosthetics category. So again, here is some technology that can go in between those two categories. And we're going to show you some of those examples today as well.

But let's first go into some of the technology to give you a basis of the technology that we'll be talking about. So when we talk about external technology, we're talking about things that are outside of the body. That means it's not implanted or a surgical implant. So it's on the surface of the skin, if you will. EMG, it's that middle picture where you see that person's foot. Those are actually EMG sensors to be able to sense muscle movement or voluntary muscle movement. So EMGs might be able to pick up muscle movement that might not necessarily be visible, but there's actually neural activity happening within that muscle. Also, surface

stimulation on this upper right-hand picture, you can see those pads that go on the surface of the skin. This is a picture of an upper limb rehabilitation system that's being tested for stroke survivors. And then over on the far left-hand side is the percutaneous nerve stimulator. Again, it's on the surface, but it's a deep tissue, if you will, a stimulation technology.

When we talk about implanted technology, now this is a technology that is actually implanted inside the body. It takes a surgical procedure to have these devices implanted into the body. But I know some people get a little worried when we talk about implanted devices. But really, we like to think of this as the pacemaker for the body. So we have thousands of people walking around with pacemakers today, and we think nothing of it. So really, this is the same, in essence, technology, but it's being used in a different manner.

So to introduce you, we have the implant of the IST, or the implanted stimulator. It's this picture over here on the upper right-hand side that is implanted and has different types of leads that come off of it. And those little leads that come off of it connect to electrodes. And here we're showing you two different types of electrodes. And the very bottom right is this fish-like looking, hook-like looking electrode that is called an intramuscular electrode. And also, this little spiral is called a spiral cuff electrode. Those are two different types of electrodes. The intramuscular electrode typically goes right into the muscle, whereas the spiral cuff will wrap around a nerve, if you will, to be able to control a large group of muscles and more selectively.

And finally, there's -- with all these implanted devices that I'm showing you over here on the right-hand side, there's this little box on the bottom,

and this is the external control unit. This is how the user would control these types of systems.

So what's coming down the pipeline? I just want to give you a little peek of what's coming into the future. There's something called a network neural prosthesis that is currently being developed. So we're very familiar with computer networks where we have a hub and we have different computers coming off of it. So in theory, this is the same thing is we would have a little hub that you see in the hip here, and we would connect different modules to it. So you would connect the module for shoulder, one for some EMG signals, one for some hand functions, et cetera. So you can add different types of modules, if you will, into the body. Now understand, this is still in its very early stages, but it is something that is coming down the pipeline in terms of technology.

So let's start looking into some of the applications and how does this apply to people like you and me, and people that are actually using these types of technologies and how it impacts them. So, here are the six different types of applications or research applications that we are going to go over today. The first one is called the cough restoration. So really, this cough restoration system was designed to be able to offer a more natural cough. It's really focused towards those that have an impaired cough, if you will. The system is designed to be able to use independently, to have different types of stimulation parameters. And what they're looking to do is to provide different types of cough, if you will—we have the clear-your-throat cough and sometimes those deep coughs, so different types of coughs for people—and also to reduce the need of a caregiver to provide that secretion clearance.

If you look over on this picture on the right-hand side, you'll see that basically the system is to implant electrodes along the spinal area. And

you have an implanted receiver, just like I showed you earlier, in the other earlier slide, and then there's an external control unit. So the system is designed where there's implanted electrodes and a receiver and an external control unit to allow somebody that's implanted with this device to be able to cough.

So really, the candidates for these types of cough systems are individuals with cervical or high thoracic levels of spinal cord injury or those that have an ineffective cough due to paralysis of the muscles. So really, it's looking to provide another or an alternative solution for someone to have a coughing system. And then, of course, this is one of our -- the gracious users of one of the cough systems. And just below that is the investigator, Dr. DiMarco, and the contact information where you can find out more about this study.

Moving on to upper extremity or upper limb or hand grasp. Basically this type of study is to provide hand grasp function for a variety of activities of daily living: eating, shaving, writing, brushing your teeth, opening a wallet, answering a cell phone, things that we do every day for people that don't have that hand function, to be able to provide this through this type of technology.

Now, when you look at this photo that's over here on the right-hand side, you'll see it's very similar to what you saw in the cough. You have electrodes that are implanted inside the body that go over to a receiver—that's up in the shoulder area—and then there is an external control unit to allow the user to be able to control the system.

Also, in this diagram, which is an option with this system, is to use EMG to be able to control the device as well. So who are these users? Here's two great pictures of people who are both quadriplegics, and this type of

system is providing them hand function. So here on the left-hand side is a young lady who is using her upper extremity FES system to be able to apply her makeup. And over here on the right-hand side, excuse me, is another gentleman who again is using his electrical stimulation to be able to hold the razor and shave himself independently. Both of these two individuals would not be able to do this activity without the use of their electrical stimulation device. So below here are the investigators, Dr. Kilgore and Dr. Peckham, and again, the email contact information if you want to find out more about this type of study.

Now, pressure sores. We know pressure sores are -- people that are immobile or typically wheelchair users or in one position at a very long time are susceptible to pressure sores, and it's a big issue for people. And there is an FES system, if you will, that they're using to be able to prevent pressure sores. So the regimen, if you look at the picture, is very similar, again, to the devices that we saw before. There are implanted electrodes. There is a receiver and an external control unit. But what it does is it stimulates the muscles that are within the gluteal area to be able to relieve or exercise, if you will, those muscles we sit on every day. So really, it's designed to have a dynamic alternating bilateral stimulation for a weight shift, if you will, and also look to be able to use this for a long period of time—for instance, for over six months.

Well, actually, they did a study where they had some users stimulating these gluteal muscles for a six-month period, and I wanted to show you this diagram. If you look over on the left-hand side, here are some muscle -- this is the muscle tissue that has atrophied in the gluteal area. After six months of stimulation, over here on the right-hand side, you will see that same muscle; but look at how much it has grown or it has developed, if you will, by being able to exercise that muscle. So this is a system that's being worked on to prevent pressure sores, and Dr. Bogie is the chief

investigator or the principal investigator in this study, and there's the contact information for her.

Now, looking at the trunk control –really, when we look at trunk control, we always think of your core muscles. We talk about yoga and Pilates and everybody talks about their core. But those people with paralysis might not have those core muscles, and it makes it very difficult, for instance, to be able to reach for things, to be able to bilateral -- or using both hands to reach for something, if you will, without falling over. And we end up using things like belts and straps and constraints so that we don't fall over in our wheelchairs. So really, the system that they're looking to design, or that they have designed, is to be able to provide a stimulation system that can be independent in terms of forward and lateral bending, transfers and maneuvers, reaching, to improve spinal alignment, and again, for pressure sore prevention, because really you're stimulating some of those gluteal muscles as well.

So looking into what system has been designed for this, over here on the right-hand side you'll see a diagram of the trunk FES system. And again, it's the same technology that I showed you earlier. You are using implanted electrodes—you'll see those in the diagram—that go over to a receiver that's implanted in the abdominal area. The targeted muscles are listed here for the muscles that are being implanted. And then there's an external control unit, the same one that I showed you earlier.

So really, the other two bullet points are—I'll show you some pictures that have a little bit more meaning to this data, but it's really about erecting this spine and being able to have that hip tilt, if you will. For some of us, you see we'll slouch in our chairs. But using this stimulation system, they're allowed to see at least a 20-degree tilt difference as well as a

workspace difference meaning that the area in terms of being able to use your arms and your trunk system mutually.

So let's really see what it does to people. So here's actually a picture of me. So here I am sitting on a mat without any stimulation. And you can see that I'm slouching. I am a C6-C7 injury. So let's show what happens when we turn on the stimulation and in terms of spinal alignment. You'll see how much straighter you are actually sitting and how much more upright sitting using the stimulation with the trunk and posture system.

Let's show you another one where we mentioned earlier about the workspace. So here's a picture of -- again, I'm sitting there without any stimulation on and I'm trying to hold a box above my head, and you can see how I am slouching. But also, it's really hard to be able to hold up with the two hands. So the next picture we'll show you is using the stimulation system, how much I am more erect and being able to put that box out further away from me to, again, expand that workspace. And the principal investigator in this is Dr. Triolo, and the contact information is spelled out as well.

Let's move on to standing and transfers. So as we're moving along into these FES systems, I hope you're starting to see a theme in terms of the same technology that I introduced you to before we're applying for different uses. So here again is the stand and transfer system—a little bit more elaborate, a lot more muscles that are being implanted. But again, if you look at this diagram that's over on the left-hand side, you'll see the electrodes that are being implanted into these targeted muscles, they all are rooted into a receiver that's, again, in the abdominal area. And that is all implanted inside of the body. And then there is an external control unit that controls the system, if you will. So some of the benefits of standing and transfer systems is really -- if you're looking at transfers to higher

surfaces—I know for me when I travel, those hotel beds seem to get higher and higher and make it harder to transfer independently; and being able to stand up and transfer is a benefit of this system as well as for reaching objects that are outside of reach from the sitting area, as well as environmental access, if you will. Doorways are not always wide enough for a wheelchair, and we all know that sometimes the world isn't as accessible as we would like it to be. But there's also psychological benefits of being able to stand up and hug a loved one, and the physiological benefits, again, of standing, even just using this in the standing frame. But still, for these types of standing systems, it's a lot of weight bearing. But more importantly, those muscles are contracting against the bone while you are weight bearing.

Of course, there's limitations to this system as well. The standing duration is limited because your muscles will fatigue. And there's no control for balance, so there needs to be a use of something to be able to control balance; and you'll see that I typically use a walker. It requires some upper body extremity support, so again, to be able to handle that balance. And it also takes a surgical procedure, which we showed you with those implanted devices.

So let's show you a picture of what a standing system actually looks like. So this is a picture of me. I am sitting in my wheelchair and with a walker in front of me. And you'll see right where around my hip and my waist, there is that control unit to be able to control the system. So just to be able to turn it on, I get into place to be able to get into the standing mode. And finally, when the system is on, you pop up and standing with the walker. So the electrical stimulation is actually stimulating those muscles. It allows me to stand on my own using my own muscles. And I'll be standing using a walker. So that's actually the stand and transfer system

that they introduced to you. And Dr. Triolo is the principal investigator, and there is the contact information for this as well.

Now stepping -- the final system that I am going to introduce to you is the stepping system. And really, this is more focused towards those that are incomplete spinal cord injury, for those that have some volitional movement in their lower limbs. And really, it is kind of designed to be able to augment what type of stepping that someone might have already. So really, they customize this type of system to the individual that actually is going to get the stepping system implanted. So for instance, the previous slides I showed you some of the targeted muscles that they are implanting with these electrodes.

The difference with the stepping system is that really they look -- the investigators look at how that individual is stepping already independently, and what muscles they can stimulate to be able to improve that gait and to make it more of a more functional gait, and also one that doesn't require as much effort, if you will. So really looking at being able to -- for somebody to be able to use it in the environment, in the household, and as a community ambulator. It is not designed as a system to replace the wheelchair. It's more of a system to be able to supplement. So, for instance, there's a user that he uses a wheelchair when he is out in his environment and goes to work, but he uses the stepping system when he's at home to get around his house. Or he uses it to leave the wheelchair outside or in his car and being able to take steps and go into a restaurant and be able to walk into a restaurant, have dinner, and then walk out to his vehicle. So it's not designed to replace the wheelchair but to supplement it, if you will.

And here's a picture of one of our gracious users of the walking system. And some people say: well, how do you control it? He has this little

control box around his waist that you've seen before. And at first, they had designed the system so people would click every time they wanted to take a step. And what the investigators ended up finding out is that no, people really don't want to have to do that click. They want to be able to have a more natural gait. And that's where they put in the EMG control. So really, they're looking at taking sensors to be able to sense when you want to move that muscle, and then going ahead and activating the stimulation system to be able to allow a more natural gait, if you will. Stance times and speed have improved by using the EMG systems; and also its dynamic stability is still to be determined on this study, understanding that it is still in the research phase. But again, Dr. Triolo is the principal investigator in this study, and the contact information is down below.

So I've told you a lot, and I really introduced you to a lot of different FES systems and to give you an overview of neurotechnology; but I think this slide is probably one of the more important ones in the presentation for anyone that is considering participating in an FES program. I think a very important point just to understand is that not all programs and not all devices or treatments or therapies are appropriate for all populations or all individuals. We all have -- we all know that spinal cord injuries, there are never two that are exactly alike. And all of us have different anatomies. So it's very important to be able to understand that a device or a therapy might not work for you, but it might work for the person next to you. However, it's very important to be able to be properly screened by someone that is trained to use electrical stimulation and be able to understand the different types of parameters associated with that.

Another key thing in participating with any type of FES program is really understanding the difference between implanted and external stimulation. So I showed you earlier the technologies, the enabling technologies, and

we started off by showing you the external stimulation. So the pads that you put on your skin or the EMG sensors that are put on your skin, those are all external. Those are outside of the body. FES cycling, for instance, is very common where you can put those electrodes onto your skin, and then there's nothing that actually protrudes the skin or is implanted into the body versus an implanted device—and we showed you a lot of implanted devices today. But again, those take a surgical procedure; and of course there are risks associated with that. And you should be well aware of what those risks are, but also the benefits that go along with it as well. Again, we've had thousands of people walking around with pacemakers and implanted devices into their bodies, so implanting an FES system is very similar to that.

Also, to participate in any FES program, you really have to understand the commitments, the commitments of the participant -- that would be yourself if you want to participate in FES program, and the family and/or the caregiver. There is definitely a time commitment when it comes to using electrical stimulation. For some of these stimulation systems, there is an exercise time period before you can actually get to functional use. So it's not always an instant gratification that you can turn on a system and you'll suddenly get function. There is a time commitment that's involved.

There is also -- understand what the out-of-pocket costs and/or what any type of reimbursements there might be. So every FES program is different. Not all of them are the same. There is no blanket for what the costs are for an FES program, but it's very important that people look into what those will be before they initiate any type of program.

And also understand that there are, of course, risks; and it can potentially be dangerous if it is not used properly. So for instance, if there is

peripheral nerve damage within the body, surface stimulation may not respond to -- you might not respond to the electrical stimulation, and/or look out for skin damage if you end up burning the skin if it's not properly used. Infections are always a risk for implanted devices, albeit a pacemaker, a FES system, spinal cord stimulator, but it's something that you need to be aware of before you participate in any type of implanted FES program.

And finally, looking at the potential danger of over-stress or over fatigue to the muscles – just as marathon runners can do damage to their muscles, you can do that using electrical stimulation as well; so that's definitely a precaution and something that people need to be aware of before joining any type of FES program.

Really, it's a quality of life impact. I know I mentioned some of the key quality and economic impacts, but I think we can look at all the data. But the most important thing is when we look at the people that actually use these types of systems. And here is really a collage of a lot of different users using a lot of different types of electrical stimulation in different ways and how it impacts people's lives personally. There is a lot of stories that go along with that.

So today I'd like to thank the Cleveland FES Center, who is part of a consortium of Case Western Reserve, the V.A., and MetroHealth Medical for making this presentation possible. And finally, I'd like to leave you with some key resources to take away with you. So we did introduce you to the FES Center. A lot of those applications, the implanted applications that I showed you near the end, the cough system, upper extremity system, pressure sore prevention, trunk control, standing, and stepping are all programs within the FES Center, and you can find those at their website at www.fescenter.org. A lot of those are in clinical trials as well, and you

can find out about different types of electrical stimulation programs not only going at the FES Center but also at other clinics around the country and around the world at clinicaltrials.gov, which can really give you an idea of what types of research there is out there for electrical stimulation.

As mentioned earlier, I am a participant of the implanted Stand and Transfer system. You've seen that today. Just in the last year and a half, I was upgraded, if you will, and was able to blog about the whole experience of rejoining a clinical trial and what the process is and what a person goes through. And so I did a daily journal about that, and that is called the Stand By Me Journal, which can also be found on the fescenter.org website.

Over on the right-hand side, I want to introduce you to the Neurotech Network resources. If you go to neurotechnetwork.org, you will find a lot of the resources of neurotechnology, a lot of those examples that I showed you early on in the presentation, along with all those four different categories that we reviewed. If you go into our education section, you'll be able to find a lot of fact sheets not only about spinal cord injury but also about urinary incontinence in terms of pain management. There's a lot of different resources there, so I invite you to go there.

Also on that website as well, on the Neurotech Network website, you can see on our home page there is a link to this presentation, with this webinar, if you will. And if you go to that landing page, you'll be able to find this PowerPoint presentation and be able to review it again, if you will. And I also understand that United Spinal -- National Spinal Cord Injury Association will be providing this as well on their website.

And finally, I want to leave you with one final resource that is a key resource, if you will. Several years ago, Neurotech Network worked with

the National Spinal Cord Injury Association to develop the fact sheet on neurotechnology for spinal cord injury. And this fact sheet is actually in two parts. It's in an introductory part area that goes into a lot of the different areas of neurotechnology in applying to spinal cord injury, giving you an overview of all of those. And of course, that's much more than what we were able to present today. And then the second portion actually goes into some reviews of much more specifics of devices, how to contact, and websites that you can go to, to be able to learn more.

So where can you find that fact sheet? It's available at the National Spinal Cord Injury Association Resource Center. It's also available on Spinal Cord Central. And finally, you can find it on the Neurotech Network website on our fact sheet for spinal cord injury.

So I hope that left you with some resources to take away and gave you a good introduction to electrical stimulation, to neurotechnology, and how it can impact people with paralysis. So I thank you all for coming. I know we're going to stay on for some questions, so I invite Lindsey to come back on, and I'd love to address any questions that might be out there.

LINDSEY: Wonderful. Thank you, Jen, so much. That was a great presentation, and we do have some questions coming in. Again, for any of you that would like to ask Jennifer a question, you can use the Questions window. And you send your question in, we'll hopefully be able to get to them in the remaining limit that we do have on the line.

So we'll start with the question: Does FES work best for a recent injury? Or can it work for older injuries? I'm three years post-spinal cord injury and complete injury at C5-C7 with residual impairment, and especially fine motor control and balance when standing.

JENNIFER: Sure. Actually, that's a good question because one of the main misconceptions, I believe, when it comes to electrical stimulation is whether it will work for new injuries or people that have been long post-injury. Really, it is dependent more on your own personal anatomy. So it's a question of whether your peripheral nerves will respond to electrical stimulation. So I would encourage anybody that is looking at using electrical stimulation to be able to be tested with surface stimulation to see if their body responds.

And so it's not necessarily a factor of length of time post-injury. It's more of a factor of your own anatomy and whether there were any peripheral nerve damages at the point of injury or onset of the disability. So when people say, "Well, I'm only four years post-injury versus 14 years post-injury," that really doesn't make a difference. But what does make a difference as well is that, you know, your muscles may have atrophied. It will take a lot longer for those muscles to build up.

Again, it is not as easy as clicking a switch, but there's also some other things to look out for as well as—whether you have joint damage or there's contractures, and some other precautions as well. But, really, it's a matter of seeing whether the technology will work for you personally rather than a factor of how long it is post-injury.

LINDSEY: Very good. All right, this question kind of piggybacks on that one. How would FES work for hand and finger dexterity and strength for a person aging 66 and older with a spinal cord injury for 50 years plus? And is there a system to rent or purchase for personal rehab use, and is it covered by insurance?

JENNIFER: Ooh, that's a lot in a question. So I'm going to try to address each one of those. So for hand function, questioning about FES, I did show you an

upper extremity system that was in the research stages of the FES Center where they're providing hand grasp for functional use for ADLs. That provides -- I believe there are six different types of grasps within that program to be able to use for hand function. Now, understand that that system does not give fine motor skills, for instance, being able to play a piano, if you will. But there are users that use it to needlepoint, if you will, and to be able to use a computer. So there are some systems like that for hand use.

Now there are also, from a neurotechnology side, there are a lot of upper extremity ones. I showed you one earlier in the presentation that uses surface stimulation to provide gross hand function. And there's also a neural rehabilitation device that uses surface stimulation using EMGs along with surface stimulation, but that's more in a rehabilitation process rather than in a neural prosthetic or a functional use process. So I would encourage you to go to our website and the fact sheet page on spinal cord injury and look under hand grasp, and a lot of those systems are offered there.

So whether the systems are available for rent or to buy really depends on the system. So again, I'm going to direct you back to our website with the listings of the different types of devices—I believe there are six or seven of them listed there—to be able to investigate whether there are leasing options and/or purchasing options. And also understand that there are some devices that are within the research area that are not available for purchase. But again, it's in the research capacity, which is a little bit different involvement, if you will.

And finally, the question about reimbursement – reimbursement has always been a bit of nemesis for neurotechnology. There are devices that do get reimbursed, but there are devices that do not get reimbursed. So

really, it's a matter of investigating your own personal insurance and being able to inquire. It's very important to have—if you do want to take on an FES program—is to have a clinician that's going to advocate for you, and also be prepared to be able to advocate for yourself as to why you need that type of device and how important it is. So for instance, the drop foot stimulation system is being reimbursed by Medicare for incomplete spinal cord injury. That's an example. But that same system is not being reimbursed for stroke at this time through Medicare. So it's a matter of what device it is and how it's being used. So it's very individual, but I hope I at least addressed part of your question.

LINDSEY: A lot of questions are coming in regarding FES and multiple sclerosis. Is it effective? And how can somebody get more information about their situation?

JENNIFER: Sure. I appreciate those questions. And FES has been used for multiple sclerosis in a couple of different ways. I think some of the precautions in terms of multiple sclerosis is the fatigue issue. I had mentioned that in the considerations for FES programs. Persons with multiple sclerosis are more susceptible to fatigue, so that's definitely a key thing of awareness to be considered. Unfortunately, we do not have a fact sheet page on multiple sclerosis as of yet. We are working on it, and we hope to get it out to you all, and I truly appreciate that.

But I do have another resource for you. If you go to the Neurotech Network website, we have the central database of neurotechnology devices. And if you go and search that database, this is the first comprehensive database of neurotechnology devices and therapies and treatments. If you go there, there is an area where you can search for different types of conditions. And one of the condition options is multiple sclerosis. So I encourage you all, if you're curious about what type of

systems are specific for MS, is to go search our database and search under the condition of multiple sclerosis.

And of course, there are other conditions in there as well with ALS, with stroke survivors, for traumatic brain injury, et cetera. So that's another resource that you can use to be able to find out more about these types of devices.

LINDSEY: Okay. How often do the implanted leads require replacement?

JENNIFER: I think that's still a question. When you're looking at the devices that I showed you that are under research at the Cleveland FES Center, a lot of those are still in the research phase, so I think they're still learning how long it takes and how long they can stay in the body. I don't want to talk outside of the researchers, but I am sure that some of those electrodes have to do with how much they are being used rather than how long of a period that they need to be replaced.

There's more definitive answers, if you will, if you are looking at a device such as a spinal cord stimulator. Because those have been implanted so much, there is much more data on how often those need to be replaced. And each one of those organizations will have that information for you.

So typically, if you're looking at -- to kind of hone in on your question, typically if you're looking at something in a research stage, they really don't quite know how long those electrodes can be implemented and how long until they malfunction. So I think that's still a question.

But for commercial devices, a lot of that has already been researched, and it's more, I believe, in an area of how much it is being used. So for instance, if you are looking for stimulation devices that are on the

commercial side, I think that's a good question to ask for any specific device that you need.

LINDSEY: Do these systems only improve function while they are on, or does the neurological system itself improve due to the use of the system?

JENNIFER: That's a good question, actually. When you're looking at neural prosthetics -- I showed you those four categories of neurotechnology. When you're looking at neural prosthetics, that's basically what it is. It's providing function while the system is on.

So for instance, you saw the woman putting on makeup with her hand. And so that hand is contracted because she has the stimulation system on. If she turns that stimulation off, she goes back to being the way she was without it on and not being able to use that hand. The same thing you see when I used my standing system, for instance. I use a wheelchair. I can only stand when I have that electrical stimulation on. And when it's off, I'm back to having paralyzed muscles as I did when I was first injured. So that's the neural prosthetic side.

But the neural rehabilitation side is actually electrical stimulation being used for a different purpose, and that different purpose is for augmenting or improving the recovery process. So I know we see in some of the neural recovery network research areas where they are using electrical stimulation to aid or to boost their rehabilitation process or to assist with some of the voluntary movement that might already exist in a muscle and be able to help that muscle recover to a potential level.

So really, it depends on the capacity that you're using that electrode or that electrical stimulation. Whether it's being used for neural prosthetic device -- yes, when it turns off, then it's no longer of use or the limb is no longer

of use. Or whether you're using it in a rehabilitation process to be able to boost the rehabilitation process to bring on more voluntary movement.

LINDSEY: Okay. We have a listener from Germany, and they are wondering if these programs are only available in the United States. Or is FES in Europe? Do you know?

JENNIFER: Yes. Actually, there are a lot of programs that are going on over in Europe. In fact, the International Functional Electrical Stimulation Society, a lot of activity takes place over in Europe. And some of the big research centers are over there. I would invite that user to -- please, I'd like to talk to them separately to be able to provide some resources for where they are in their area for electrical stimulation clinics. So yes, it is very active in Europe.

LINDSEY: Okay. There's a lot of questions. I'm just -- "I have flaccid non-spastic paralysis and spinal cord injury. Could FES work for core muscles that are yet difficult to maintain? I don't believe it works for below my level of injury."

JENNIFER: So that's actually more of a personal question, so I think there are some other questions that need to be asked before I can answer that. But I would invite the listener to please -- I would like to follow up with them specifically, I think.

As a general answer, what I would like to provide to this is that really, there's a couple of things and considerations for FES programs. One is overall nerve damage, and the other one is really to look at where your level of injury is. Typically, the FES systems that we showed you today, the ones that are in the research stages, really rely on the peripheral nervous system. So lower level injuries where the peripheral nerves --

where you really start to branch off the spinal cord more in the lower level of the spinal cord, typically the peripheral nerves will not respond. So it really depends on the exact level of injury and what the injury type was. So, there's a lot more specifics that go along with it – but, again, to be aware of where it is on the spinal cord.

LINDSEY: Okay. How about FES when it comes to bowel and bladder control?

JENNIFER: Yeah, there's quite a few devices that are available for urinary incontinence. In fact, we have a whole page on it. There are implanted options. For instance, I showed you the sacral nerve stimulator, which is a neuromodulation system. That's an implanted system. It's also being investigated for fecal incontinence as well, so for bladder and bowel.

There is also a fine tech, which is a bladder control system, is available in Europe. And there is also the Urgent PC device that is also an implanted device. There are also external devices that use what's called the pelvic muscle stimulator or pelvic floor stimulator that might be available as well. So we really explain those types of -- there's a couple of different categories of urinary control stimulators. There's the sacral nerve, the tibial nerve, the pelvic floor, and then the direct muscle stimulation. Those are the four categories, if you will. And the fact sheet on our web page actually explains each one of those categories as well as gives you some resources for those devices.

There's also -- I would like to add that the Cleveland FES Center also has a program where they are doing a lot of research for bladder and bowel control, so that there is a research program over at the Cleveland FES Center as well for that.

LINDSEY: Okay. A couple more, maybe two more questions. Prior to sending a patient to the FES Center, are there labs, EMG studies, et cetera, that would be helpful for patients to get prior to their arrival?

JENNIFER: Yeah. I guess one of the key things before you look at going into the FES Center is really look at the programs and get in contact with that program director first. If you go to their website or if you email info@fescenter.org, your question will be routed to the correct program manager, and really find out what needs to be done before you pay a visit or whether you're a candidate for those programs.

One of the key things is to be able to have a clinician or a therapist locally that is willing to work with you and who understands your medical condition, because again, working with anybody that is within research, you want to make sure that you get your proper medical records to them and to be able to have somebody that's locally, for you, that understands your condition and what you'll be going through.

LINDSEY: Okay. And the last question, as we're running out of time, is: Can you have an implanted FES device along with an implanted Baclofen pump?

JENNIFER: That's a good question, and I'm not completely sure of that. I think it kind of depends on what system you're getting. So it depends on where the pump -- and the reason I say that is if you're interested, for instance, in the trunk system, there's electrodes that are implanted into the spine. It depends on where that pump was implanted. That might make a difference. So it really depends on the location of where that pump is and what type of system that you are looking for to have implanted.

Whether they will compete with each other, if you will, I don't believe that there is an issue. But, again, I think that would be a question you would ask the investigators if there's a program that you are looking into.

LINDSEY: Wonderful. Well, on behalf of National Spinal Cord Injury Association, I want to thank you, Jen, so much for your wonderful presentation, and for sharing all of your experience and knowledge with us regarding FES and paralysis.

And as I mentioned earlier, anybody that is interested, the PowerPoint presentation and a transcript will be available on our website: www.spinalcord.org. All of our webinars will be archived. And if you're not already a member of National Spinal Cord Injury Association, I urge you to join. Membership is free. Anybody can be a member, whether you're a caregiver, an individual with spinal cord injury, disease, or disorder, or a professional working with the FBIA/D population, it's free. Anybody can join. And that way you'll be on our mailing list and be aware of our upcoming webinars that we are holding in the next few months.

And to touch on that, our next webinar will be March 27th. The topic will be domestic violence and disability. And it will be, again, from 3:00 to 4:00 EST.

Well, thank you again so much, Jen. We really appreciate it. And for those of you who we didn't get time to answer your question, we certainly will be following up with you. Jen will get a copy of all of the questions and your email, so she will be able to get in touch with you individually.

JENNIFER: Excellent. Thank you so much. It's been a pleasure to be here today, and thank you all for attending.

LINDSEY: Thank you. /AT/pa/kbe/es