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>> This is Bil, resource center manager with national spinal cord injury association. And welcome to the NSCRA Webinar intro to implanted neuroprosthesis for people with SCI/D. Please note that if you require closed captioning, the directions for closed captioning access are listed in your question box panel. I will be your moderator for today's Webinar. Presented by Jennifer French, Dr. Anderson-Erisman, and Ms. Megan Moynahan. There will be questions at the end of the presentation, approximately 45 minutes in. So please ask your questions through the question box during the Webinar and we will get to as many as possible at the conclusion of the actual presentation.

Now, for introductions. Jennifer French sustained a spinal cord injury in 1998, resulting in C6-7 incomplete quadriplegia. She is an active user of functional stimulation implantable system that she first received in 1999. She also represented team USA at the 2012 Paralympic games in the sport of sailing. As a user of neurotechnology who has reaped its benefits she is cofounder and Executive Director of a nonprofit organization Neurotech Network. She currently serves on the advisory boards for the FES for cerebral palsy project at Stanford, the Brown University institute for brain science, and the advanced platform technology center for Cleveland, Ohio in Cleveland, Ohio.

Dr. Anderson is a research Professor and director for education for the Miami Project to Cure Paralysis at the University of Miami, Miller school of medicine. Her research is focused on translational investigations and bridging the gap between basic science, clinical science, and the public community, living with spinal cord injury. Her training spans a spectrum of SCI research through cellular and molecular studies through whole animal and behavioral studies and human clinical research now as a faculty member at the University of California Irvine and also at the

University of Miami. Her currently projects focus on aging-related changes in bladder health after SCI, determining the minimum amount of exercise and locomotor training required for clinical trials for SCI/D and identifying with facilitators and barriers through clinical trial participation from the SCI clinical perspective. In addition to pursuing her own research regarding chronic injury she serves as a scientific interface to the public for the diverse array of research being conducted at the Miami Project, and is now also managing the first cellular transplantation clinical trial.

Megan Moynahan is Executive Director of the Institute for Functional Restoration, a nonprofit organization based at Case Western Reserve University at Cleveland, Ohio with a mission to restore function to people with spinal cord injuries by creating sustainable inertia model for new technologies. The IFR brings technologies out of research, and into commercial availability for people with spinal cord injury by identifying those that are viable solutions for patients, and then navigating them through the pathway through availability outside of clinical research, using funding that comes from a culmination of grants and philanthropy. She holds a bachelor's degree in biomedical engineering from Johns-Hopkins University and a master's degree in biomedical engineer from Case Western Reserve University. Please pose any questions you have during the presentation. And we will now hear from our first presenter, Jennifer French. Jennifer.

>> Jennifer: Thanks, Bil for the great introduction and thank you for attending this Webinar. We will be talking about accessing to implanted neuroprosthesis along with Dr. Anderson and Megan Moynahan. Let's dig into our presentation that we will be talking about today.

As Bil mentioned there is a question box that's over on your screen. So if you have any questions during the Webinar, please pose your questions there. I also want to encourage you, if you have any ideas for future Webinars to please post them there as well so that will help guide us into what you would like to hear in the future. And also, to let you know that this presentation is provided in PDF form. It will be available -- actually, it is available on the Miami Project website, on the Neurotech website, as well as the NSCIA website. So please don't feel that you have to scurry down notes during this or try to copy everything that you see on these slides. You will be able to access that PDF format along with all the hyperlinks that we will be presenting today.

So, first, I'd like to introduce you to each of our organizations. My name is Jen French, Executive Director of Neurotech Network, a nonprofit organization, focusing on the education and advocacy to access neurotechnology devices, therapies and treatments. And we focus for people living with impairments, their caregivers and the medical community who care for them.

Kim, would you like to introduce the Miami Project? I don't hear Kim, but she's with the Miami Project. The Miami Project is dedicated to finding more effective treatments and ultimately a cure for paralysis resulting from spinal cord injury.

And Megan, would you like to introduce the IFR. I don't seem to hear Megan either. But the IFR, again, is committed to the mission of restoring function for people with spinal cord injuries by creating a sustainable commercial model and for neuromodulation systems. That's part of accessing these devices that she will be introducing later today, in this Webinar. So those are the three organizations that each of us represent. Again, there are links to our website so you can learn a little bit more about each one of our organizations.

So a little disclaimer. The information that we're presenting in this session is not meant to replace the advice of your medical professional. You should consult a healthcare professional who is familiar with your specific case. And we highly suggest that you work with an informed medical professional familiar with your case. So the information that we're providing for you today, please feel free to take that to your medical professional and be able to work with them on your specific condition.

Now, so what are we talking about today? So what we're talking about today, first we're going to introduce you to implanted neuroprosthetics and talk about the difference between a therapeutic effect and prosthetic effect in terms of application and talk about the neurostimulation, the -- and brain computer, brain machine in your case applications and introduce you to -- also we will go through some of the pros and cons with what people with spinal cord injuries, and disorders as well, as to what their decision process is, and when they're looking at getting an implanted neuroprosthesis and a little bit of basics about clinical trials and how to access it, how do you get plugged into these types of neuroprosthetics.

At this point we would like to poll the audience. We would like to toss out a poll to you all to answer this quick yes or no question. So are you aware of neuroprosthetics before you entered this it Webinar? So please go ahead and answer that poll question either yes or no, if you were aware of neuroprosthetics before you logged into this Webinar, so we can kind of gauge the audience and your knowledge out there. Take a few minutes just to allow you all to give your responses.

>> I'm back on.

>> Jennifer: Great. We have Kim back on with her mic and she will be joining us and talking about BCI. I think our poll is just about done. Do we have the results possibly coming up?

So the poll results are in. So it's just about 50/50. So about 57% of you have heard about neuroprosthetics before this and about 43% have not. That helps us gauge this audience's learning about it, and want to learn about it. And then those of you that have heard about it and just want to learn more. So let's dig into some of the details of what is an implanted neuroprosthetic.

First what is a neuroprosthesis. It is a device that connects with the nervous system to replace a supplemental function. When we talk about implanted devices, these are devices surgically implanted into the body. For the applications we talk about they use electrodes, or sense neural activity that can be applied to either a nerve or a muscle. So the pictures that you see here are some of the various types of implanted electrodes. So some of these are recording electrodes. And this square is called a electrodal array in some of our applications.

It's key to note that some of these devices also have a lot of the implanted neuroprosthetics have the internal control unit. The device may be encapsulated or implanted in the body but there is an external control unit for the user to have control over the device inside of you. For instance for the Vegus nerve stimulater for seizure or seizure management they typically have a external magnet or an external device using stimulation for drop foot that you may be familiar with, usually have a remote in your pocket so you can control the device. So the take-home message about implanted neuroprosthesis, it is able to restore function not only for acute conditions but chronic conditions as well. That's the key point.

Some people say I'm five years, 10 years, 15 years after my injury. Am I eligible for this type of technology. The answer is, in many cases yes. So we want to be able to introduce this to -- technology not only to new spinal cord injuries but those that have chronic conditions and those with other conditions as well.

So what does neurotechnology really offer? It offers functional restoration today. It's impacting people's lives today. For thousands of people impacted by neuroprosthetics it provides restoration of sensation, site, hearing, or even movement, seizures, chronic pain, and ability to communicate with the world, just with the use of thought. And really what you're seeing in front of you right here are faces of neurotechnology users. There's a wide array of neurotechnology center being used by people, that are implanted, inside the body. Today what we're going to focus on is neuroprosthetics and how they apply to people with acute and chronic spinal cord injury, as well as applications for other disorders that result in paralysis such as ALS, multiple sclerosis and TBI.

One thing we want to stress is the difference between the therapeutic effect and -- [Audio Skipping] -- a prosthetic effect. When we talk about a therapeutic application the key thing is it restores voluntary motor control through a temporary treatment. What do we mean by that? It means it restores function that remains after the stimulation or after the application is done, for a period of time. Meaning that you use it for a period of time, you turn off the device, and then your voluntary control remains. That's a therapeutic application compared to a prosthetic application where it's really used to replace the loss of neuromotor function through intervention.

Typically with a prosthetic effect is the capability of the device gives function to somebody when they turn it on to be able to perform a task when they're actually using the device.

Today we're focusing on that prosthetic application. So let's dig into some of the applications. First is our hand grasp function. This is what you're seeing is an example of an implanted device. He's playing there with his daughter. This is a device that's in clinical trials. This particular one is in trials in the United States but there are also some being investigated in Canada, U.K., Europe, as well as Australia.

Next application is for breathing. Breathing is a fully commercialized

device allowing those with higher level injuries or higher level conditions to be able to breathe using this device rather than a ventilator. So it's replacement of a ventilator. There are three main companies that have commercialized this device, either using diaphragm pacing or stimulating the -- to be used around the world. We have a hyperlink to the Neurotech Network for breathing systems to find out more about this device. [Audio Skipping]

A device -- (something is wrong with the audio.)

The next device -- [Audio Skipping] in the U.K., Canada and China as well as Brazil and the Middle East. There are three companies that are commercialized bladder and bowel management devices. Two are available in the U.S. and again there's -- to our fact sheet there. So I understand that I'm breaking up. So I think it may be best if I log back on. If you -- I believe it happened last time. If I log off and log back on. If you can bear with me for just a second to make it so I can fix my microphone.

I think I just tried to fix it. Hopefully I'm able to hear me a little better now. So we go into this. My apologies for that technical problem.

So we talked about both hand-breathing cost and bladder in the previous slides. Now I want to go into a couple of other applications, one talking about trunk posture and pressure sore prevention. That's showing the first picture on the left is actually without stimulation. The picture on the right is with stimulation. This device is in clinical trials in the U.S. and there is no commercial availability at this time.

The next device when we talk about standing, it's using stand and transfer. Here's a diagram of the device and someone using it. This is in clinical trials in the U.S. There are trials in the E.U. and Australia. These devices can use application for both muscle and nerve based. I want to talk also about the epidural stimulation. We've heard a lot in the press about epidural stimulation allowing a few users, that have been able to stand. I wanted to stress that this application is almost another way of using the stimulation, where they're applying it to a nerve rather than a muscle. But, again, if they're using it as a prosthetic device and the therapeutic effect has yet to be proven. So, again, we're looking at epidural stimulation for standing. That's a application of a neuroprosthetic device for standing but there's also application using muscles as well.

And finally, to round that out you want to talk about walking devices as well, some using muscle based implanted devices being investigated in the U.S., E. U. and Australia and are typically provided for those with some voluntary movement, that have voluntary motor control and being able to supplement the motor control that they have. That's on the left.

On the right-hand side is drop foot stimulation. We have several that are internal but is being investigated in the U.K. to implant that device, to have an implanted drop foot stimulation. In fact I've interviewed two participants in the study and both have MS and have found benefits from it. But again it's also the implanted side is still in clinical trials. So that rounds out some of the neurostimulation application.

What I'd like to do is hand it over to Kim, to talk about some of the brain computer and brain machine interfaces. Kim.

>> Kim: Thank you. So now we're going to switch gears just a little bit. The devices that Jen was talking about were primarily implanted in -- not into the brain, but into other areas of the body and muscles. And now we're going to talk about how we can actually use the brain to sense information, or to sense thoughts, and be able to translate that into some kind of action. So the brain computer interface and brain machine interface has been around for a little while. And some people may have seen some things on the news about it. But the idea is to take an electrode array, like Jen showed you earlier, and like in the top two pictures here. These are really magnified examples of what these arrays are. And what happens is the neurosurgeon will implant this little tine array into really particular area on the top of the brain. And that area usually -- they put it in different areas, depending upon different functions. But usually, it is the area where movement planning occurs. And the idea is for the electrodes to sense the electrical activity that's in our brain, when we're planning to make a movement, and then that is recorded and, quote unquote, decoded so that the thought in electrical activity becomes an output for a device.

So the example that I'm showing you here is for a trial called Braingate 2. And in this particular set of studies, they are using an electrode that is sensing thoughts for controlling a computer cursor or other assistive devices that are external. In the example that you see right in the center picture, on the right, with this gentleman, is -- right here is where he's got

the wires that are detecting the signals and decoding it, connected over to this massive computer system, where, by his thoughts, he is controlling actions on the computer.

And another portion of this study involves individual using their thoughts, with same devices, to control an external robotic arm. And in this situation, this woman is controlling the robotic arm to bring this -- grab onto this cup, bring it over to her mouth so she can drink out of it and bring it back to the table.

This is called Braingate 2. There are a couple of locations in the U.S. that are conducting the clinical trial. For example in Boston, in Stanford, California, Cleveland, Ohio, and Providence, Rhode Island. You will be able to access this research on clinicaltrials.gov that we will tell you about later to get more information about that clinical trial.

In the next example that I have for you, we have similar -- a similar concept, where there is an array of electrodes in a particular area of the brain, being used to sense thought for controlling an external robotic arm. And the difference with this trial is that they are testing a couple of different electrode arrays than the Braingate. And this is good because we need to advance technology, and test multiple types of devices and arrays so that we can develop and improve those to be the most useful.

You can see here, this particular individual is controlling this robotic arm to make movements in this board. Put things in it, take things out of it. This is being done in Pittsburgh and is also in the clinicaltrials.gov website. There are a couple of trials this California doing similar things with different arrays to use thought to control a computer screen and cursor or use thought to control a robotic arm.

The next thing that we want to move to, though is how do we actually use these types of sensing information to actually make our own muscles move. And there's an example here of a study that's being done out of Ohio State University in Columbus, that is -- in a company where they have an array implanted in a particular part of the brain. They have what they call a forearm cup that provides external stimulation to the muscles of the lower arm and hand, to try to stimulate movement of your own muscles. And so the person makes the thought to make a movement with their arm, and the device will sense that, and do its decoding to send that information to a computer. And then the computer sends the signal

to the electrical stimulation system around the outside of the arm, to trigger and stimulate the muscles.

So ultimately we want to be able to make this so that we don't need any kind of external devices. We could potentially use the types of implanted devices that Jen was talking about to trigger internal stimulation of the muscles and have that controlled by thought.

Jen. We will -- I'm wondering if Jen is having some technical issues. We are going to do a kind of pro and con on why or why not to get an implanted device.

>> Jennifer: I'm here.

>> Kim: Okay. So I'll let you start.

>> Jennifer: Okay. We want to bring you through the decision process of the pros and cons that people with -- that might be considering when they're looking a the getting an implanted device. When we're looking at for a device, the question is well what else is available for functional restoration. When I got implanted I looked at the clinical trials and found this was one device that would be able to provide function on a daily basis.

>> Kim: And on the opposite effect, if you were considering why shouldn't I get an implanted device, one question might come through of mine is fear that it would interfere with biological therapies in the future.

>> Jennifer: Another consideration is how the device -- that I found the device early post-injury and you're still adjusting to your actual injury. So when I was implanted, I was a year and a half post-injury. And I was still kind of adjusting.

>> Kim: And in my own case, I actually had never heard about implanted devices until I was actually 15 years post-injury. And at that point, I was so engrained in my routine of my life that I didn't want to take any downtime to consider this type of an intervention.

>> Jennifer: Another possibility or a pro for the implanted device is that you're allowed to use it independently. You can use it at home or in the community and I don't need another person to help me use the device.

>> Kim: But in the opposite effect you might think, well what if I can't operate the device by myself and what if I have to have somebody there to help me use the device. And that might be an increased cost for me. That's one question that might come into your mind.

>> Jennifer: Another thing to consider as well, well, I have other devices implanted inside of me. For many of you who have spinal cord injuries, rods or cables have been implanted inside of you, some might already have ITB pumps or other devices. People walk around with pacemakers in their bodies all the time. So there are other devices implanted inside the body. Why not one more.

>> Kim: But to be the devil's advocate, I already have too many surgical scars. Why would I want more, to get more things implanted into me.

>> Jennifer: When we're looking at implanted devices, it's actually very portable so it's a device that you can take with you. Many devices, you can move around the community. For instance the breathing device, you can take it anywhere very easily as well as other neuroprosthetic devices. They're portable.

>> Kim: What about if the external unit has to be worn on the outside. I might have a concern about carrying that around, or possibly about somebody seeing that. And I might be hesitant about that.

>> Jennifer: Another consideration for the external appearance is not that obtrusive. They have small controllers that are not that obtrusive.

>> Kim: Then my opinion is what if the external box is obtrusive and I don't like looking at it and don't like it being there. That might prevent me from moving forward.

>> Jennifer: Another consideration too is there's limited downtime post-surgery. They have advanced these technologies far enough that someone isn't down for the surgery for very long.

>> Kim: But in reality I'm so busy with work and with my family and all the activities that I do, that I don't -- or so like I can't take the downtime or commit to the exercise and training or rehabilitation that maybe associated with any of the devices afterward.

>> Jennifer: Another consideration is these devices are reliable. They've been researched for years and you get what you expected. Typically before you go into surgery working with these types of implanted devices that we've shown today are really -- you get what you expect. You're told what to expect up front.

>> Kim: And as an opposite, what if I end up having too high of expectation of the device, and I might be disappointed by the results that I get. So they may be a benefit but they may not have met my expectation.

>> Jennifer: And finally, you know, consideration for an implanted device is it really aids to decrease incidence of secondary conditions. Those of us living with paralysis were faced with osteoporosis, pressure sores, scoliosis and these other secondary conditions that we fight on a daily basis and this can help you combat those types of conditions.

>> Kim: One reason maybe not to get an implanted device is what if restoring one function, for example hand -- and one arm, is that going to give me enough benefit to outweigh the downtime that I might experience as a part of the device trial?

>> Jennifer: So in summary, you can see on this slide we're looking at a lot of the considerations for and against implanted devices. And I think pretty much forward to you all really helps in the decision process of whether you are a candidate or it's a device that might be for you and some of the considerations that you need to see going forward.

>> Kim: So now we're going to get into a little bit about clinical trials and I'm going to give you one bit of information, before Megan comes in. And that is to just explain a little bit about the difference between a clinical trial, and healthcare. So a clinical trial is a research experiment. It's in humans. And it has a specific goal. Therefore, there's very strict protocol that must be followed, and there is an end point to it. So that the results can be analyzed.

Sometimes, in early stage trials, the goal is just to test safety and not necessarily benefits. Now usual healthcare on the other hand is healthcare or monitoring of a condition or a specific health condition. And the treatments can be very flexible because it is based on an individual's own health status. And ultimately all of those decisions are meant to

benefit the individual, either to not let the disease progress or to actually improve health. So there is not necessarily a strict protocol. It's more of a individualist type of care. So there is a big difference between a clinical trial and usual healthcare.

>> Thanks, Kim, for the introduction to the clinical trial side of things.

This is Megan Moynahan. Thanks for the slides that led up to this point. One of the reasons why we want to focus on clinical trials is for the most part, at this point, if you're interested in having neurostimulation technology, you have to get them as part of a clinical trial. As Jen pointed out, there are a few marketed products out there but not very many. If this interests you on getting involved in a clinical trial is sort of the next step.

Do I have access to the -- advanced slide? There we go. So continuing on with this idea of the clinical trial, I want to draw your attention to clinical trials.gov. This is a great place to identify some existing clinical trials that may be looking for patient enrollment for people with spinal cord injury.

Clinical trials are research involving human volunteers. And the goal here is to add to the medical knowledge so they can advance their thinking. It will be led by a principal investigator who will pull together a team of people that will help them, that may include doctors, nurses, social workers or other healthcare professionals. And all of these trials have to have funding to be conducted because they're not done as part of usual healthcare. They have to have funding from some place and it is typically a company or federal agencies. So you see volunteer groups to help in clinical trial research.

So as the clinical studies participant it is important to understand a little about how the study is going to proceed. And you would be presented, if you were interested in this, with a summary of the protocol, to understand what will be expected of you, or what the study's all about. The protocol will have basic information about why are they conducting the study, who may participate in the study, the eligibility criteria, how many people they're looking for, what kinds of tests, procedures, or investigatal devices will be applied, how long is the study going to last, and what kind of data will be gathered about each of the participants.

Just to give you a sense of sort of the rigor around this, no clinical trial can proceed without some sort of oversight by an independent group. For clinical trials that involve investigational or new medical devices or new drugs, it's the FDA that has oversight over that. So these clinical protocols would not exist if it weren't for the oversight board at the FDA would have approved it and the surgical procedures, investigational research for the RID for a hospital to oversee approval of clinical trials. So they don't exist in isolation but usually are well vetted.

If you're interested in joining a clinical trial, there are some basic questions that are worth asking of the investigators. It's really important to get to know as much as possible about what is being studied. So you can feel comfortable about what is going to be done to you, as a participant in that trial. So you'll want to know why do the researchers believe the intervention being tested is going to be effective, how do the possible risks or side effects and benefits of the trial compare to those of current treatment that's out there, are there going to be any out-of-pocket costs, and how for example if the study is designed to compare two different treatments, how will it be determined which intervention is actually the better intervention. So these are sort of basic questions that you might want to think about if you're thinking about joining a clinical study.

And on the next two slides, this is a really nice document that goes into a lot more detail here. This again exists as a PDF at the website. You will be able to find this and print it out and look at it in more detail. These are examples of more detailed questions that you might want to ask before you think about taking part in a clinical trial, things about benefits, the protocol itself, payment and costs, what -- participate in other trials, how evidence is going to be evaluated, and, the assessments of the treatment and the investigator. So these are sort of the basic ideas that you might want to think about asking.

So, again, I'll put in another plug for clinicaltrials.gov. You might want to use terms such as implanted prosthesis, generation, neurostimulation and neuromodulation define these types of technologies we're talking about today.

So now we want to quickly go through and talk about what my organization is doing. I am the Executive Director of the Institute for Functional Restoration based out of Case Western University, a nonprofit organization. And our mission is to restore function to people with spinal

cord injury by creating a sustainable commercialization model for these neuromodulation systems that we're talking about. And our philosophy is we want to help people today, even though research is going to continue to hopefully develop more in the future. So we also know that we have to learn from a somewhat painful history in order to create the sustainable business model, that ends up being the more important piece in the whole equation here.

So just to give a little bit of an idea of the kinds of functions that we're hoping to restore, we would like to develop technologies to help people with hand graphs, trunk control, bladder continence, functional standing, stepping, and respiratory functions, for example cough. And this flowchart that you see is a construct that shows you how technology has moved from early ideation all the way through clinical trials to commercial sales. Just a very simplistic view of a complicated process to help you see right now we have a lot of technologies, hand, trunk, bladder, you know, cough, all around here, in early human clinical trials. If you want access to them today, you would have to take part in these studies. But we do have past history with products all the way through the market of commercial sales. I want to talk about what we've learned from that experience.

My organization is wanting to take these through the pipelines through clinical trials through commercial availability to people. So we have a complex history that we've already lived through. Some people may already be familiar with the neurocontrol freehand system that came out in 1998. And we see that now with behind sight a great product that restored hand function to people with cervical level injury but a failed business model because despite having this technology get out there and become commercialized, the company itself could not sustain itself. A few years later it went out of business. What happens when that happens is it leaves people without any access to any kind of follow-up. So there were people out there with the original freehand system. Some people's units are still working but some people's units are not working anymore and there's no recourse for them to get any kind of assistance.

So you want to learn from this example and make sure that when we do this again that we can resolve some of the business limitations that existed the first time around. There's something that you want to think about that none of us has access to all the great medical technology out there. We only have access to the ones that do well in the marketplace. And the

problem is when technology fails to achieve success in the marketplace it's the patients who lose out. The second time around we want to make sure we get the business considerations downpat.

The great news is because of those previous examples we know the exact pathway to get through clinical trials, FDA and through reimbursements to make these products a success. The last remaining challenge for us is to figure out the high cost of technology and the fairly small market potential. So the way we're tackling this is to create Institute for Functional Restoration. Ultimately it will become a for-profit/nonprofit hybrid model, and the nonprofit and the for-profit will sort of function together to complete final stages of commercialization.

Where we are right here are raising funds right now to bring those technologies from the previous slides through the pivotal clinical trial and FDA approval and hopefully to a for-profit partner. So I think at this point we have our second polling question. Can that come up? Here we go.

So here's our quick poll. So after listening to the Webinar, at this point would you consider getting an implanted neuroprosthetic? The choices are yes, no, or don't know and need to learn more.

>> Jennifer: This is Jen. It looks like our polling is still in progress. So we're going to give you a few more minutes to contemplate that question now that we've gone through our agenda in terms of what are implanted neuroprosthetics, what are some of the neurostimulation systems out there, the brain computer and machine interface as well as some of the pros and cons and some of the considerations you need to think about before you want to get an implanted neuroprosthetic. Megan reviewed the basics of clinical trials and also the model they're working on to make these accessible for those devices that are moving out of clinical trials into commercialization and we have some of those commercial devices out there as well. Just a few more minutes of the polling questions and let's see if the results will be coming in soon. And we will move on with a couple more slides to round out this Webinar.

So our results are in. And a lot of you, which is good, they say there's 57% say I don't know, I need to learn more. That's a good thing. Because I think one of the big things that you need to consider, this is a big consideration in terms of -- or big decision, if you will, in terms of getting an implanted device and those types of things to consider. So I

hope you'll review this Webinar again as you try to learn more about these devices and that also leads us into one of our last slides. We want to leave you with some resources to learn more. A lot of you have said -- over half have said I need to learn more and I really don't know.

Let's review our resources slide. And we've mentioned Neurotech Network earlier. We provide a lot of these free resources for you on our website. We worked with the national spinal cord injury association to develop an education tool for specifically for spinal cord injury and that's available for free on our website. Also available on spinalcord.org and spinal cord central through their resource as well.

You can also learn a lot of education pieces that Kim has mentioned. We mentioned here today in this Webinar at the Miami Project website as well as the others. A couple others, Megan and I talked a few months ago and that's available on YouTube. And we have that link for you. Also we've mentioned some of the key centers about electrical stimulation and we have a link to the Cleveland FES center as well as the Southberry FES research center that's in the U.K., that does a lot of this type of research with these types of devices.

We also mentioned there are some commercially available devices as well and we want to give you those links. One is the devices breathing assistance devices, and the three companies that are available in the U.K. that are available. We have the links there to learn more about those. Any other commercially available devices, to learn about urinary incontinence, we have a research page on that. The two that are available is the Medtronic interstim for fecal incontinence as well. Finally the Finetech Medical offers a bladder control device that is available in the U.K. and Europe and other areas around the world.

So I hope that rounds out some of the resources that you can go ahead and learn more about these implanted neural prosthetics. Now we'd like to leave it open for any types of questions that might exist that we can address for you, that might have come up during the Webinar. I'm going to go back down to that last slide to you can -- so you can get our contact information. There's contact information for Dr. Kim Anderson-Erisman, for Megan Moynahan, as well as for myself, both our websites and e-mail addresses. So if we don't get to your question today you can e-mail us your questions and we will make sure to get them answered.

I'd like to hand it over to Bil for any questions that might be out there.

>> Bil: Thank you. We have some great questions so let's get into those with the time we have remaining. For whomever feels comfortable to answer these on the panel, can this technology restore sexual function? Who would like to answer that?

>> Jennifer: There's a device out there that's been primarily used for bladder control and it's available through -- in Europe through Finetech Medical that's used for urinary incontinence. They give it one, two, three, for urinary control, bowel control and sexual dysfunction. There's also some sexual function being investigated as they're looking into more of these urinary devices, finding it ancillary to those devices but those are still in investigation. But the commercially available device in Europe and beyond.

>> Bil: Thank you. I think this maybe best for you as well but others can jump in as needed. Can a C6-CI use the stand and transfer system?

>> Jennifer: That actually depends on -- it depends on a couple of things in terms of your peripheral nervous system and how well it's used. Being in the study for how long I have been, I use the stand and transfer system, and I am a C6-7. There's another one that's a C5. He uses it with his caregiver to make transfers easier so there is no need for a Hoyer lift during transfers.

>> Bil: A practical application.

>> Jennifer: Yes. So it's to see -- a specific person you want to see if you meet all those specific criteria in terms of your peripheral terms in terms of contractures. Yes there are people using it that are C6 and even C5 injuries.

>> Bil: Thank you. Can Braingate 2 arrays control a robotic arm attached to a wheelchair? Who would like to field that?

>> Kim: I can handle that one. The Braingate 2 array one of the things they are testing already is the control of a robotic arm. In that particular situation it was mounted to a table because of all the equipment that's involved in this level of testing. But potentially, you could envision that a robotic arm attached to your wheelchair is something that could be

created. And then packaging the Braingate software or the decoding technology in a -- system so that it can go around with you, maybe in a little bag or backpack on your wheelchair, so that you can operate the robotic arm while you are moving around with your wheelchair.

>> Bil: Thank you, Kim. This may be for Jennifer again. But correct me if I'm wrong. Jennifer, if I understand it correctly, you're the the only panelist with an actual implantable device so correct me if I'm wrong on that. How many weeks/months did it take to adjust to the implanted device until it became a fully functioning part of your routine?

>> Jennifer: That's a good question to adjust to the device. When we look at my case because it's standing it's a little more complicated. So before I answer that question directly from my personal experience I have to say that some of these devices that we saw today there's a very quick turn around time. For instance for cost, people are using it within two or three days of implantation and the same thing for breathing. So I think that's -- depending on the device the turn around time for when it can become functional. From my personal experience, it was a bit of a longer period of time, where you need to -- once you are surgically implanted with the system there is a recovery period where they want the electrodes to encapsulate inside the body. That's about an eight week period. They may be able to decrease that but that's the protocol at this point in terms of not being able to use the system and then there's a three month period where you can do passive exercise. You want to be able to build up those muscles to get to a functional stand. Once you get to a functional stand, at that point it's about a month or so to work with the physical therapist to get comfortable with it and before they release you into the community. So there is some several weeks involved in being able to build up your muscle tissue and be able to get to a functional stand. But I've been using my system for the last 15 years. So it's -- from that -- the way I look at it is those few months of commitment have paid off over a 15 year period.

>> Bil: Thank you. The next question's been in the news recently. Epidural stimulation is very promising in terms of return of function after SCI what are the current findings on epidural stimulation and when it will be available for commercial use. I think clinical use might be more appropriate but commercial use was the question.

>> I can take a little bit of a stab at that. This is Megan. It's always

hard to predict a little bit how long things will take. But what we know about that program is that they are at the early stages of human clinical trials. And so what stands before them, you know, between this point and commercialization are, you know, an assessment of the early clinical phases, a large scale pivotal clinical trial where they can show that this is a technique that can be used by many different clinicians and many different hospital settings. In the process of doing that they will establish how it will fit into the healthcare paradigm, the piece that remains unanswered. And then it requires a commercial partner to actually bring it through to commercial viability. And, again, I think they may discover that they're faced with the same situation that others have discovered at that point, which is there aren't that many large companies that are trying to pull these things through the commercialization. So we don't know how long it will take. We're all very excited to see how that is progressing but it's a difficult pathway to commercialization for a sophisticated technology intended for this small market.

>> Bil: Thank you, Megan. We have had actually a flood of additional questions. I'm prioritizing them as we go but I'll get as many out to the general audience as possible.

The next, is there anything available for what is considered complete paraplegia? My son does have some pain and feeling down one side, due to a crushing-type injury. Anything new in this area?

>> Jennifer: I'll be happy to address that. I think a lot of those neurostimulation devices that we presented today apply to complete paraplegia as well as incomplete. I think one, in terms of the neurostimulation that we presented in terms of of incomplete, would be the walking system, where they're using it for C and D where they have some voluntary movement. We're looking at A and B that don't have that motor function. A lot of those devices apply in that case. So for instance the trunk system, the standing system. So understand that a lot of these neurostimulation systems, when they're muscle-based and even some that are peripheral nerve based, they're based on the peripheral nervous system and not the central nervous system. Even though you may have a spinal cord injury to your central nervous system, if the peripheral nervous system is intact, that's what these rely on.

>> Bil: I have been evaluated and approved for a freehand device. Are they still looking for candidacy for this procedure, the freehand device at

McGee Rehab?

>> This is Megan. The freehand system is not on the market anymore. For commercial use in the U.S. So I don't -- maybe, Jen, you can help out. But I don't know how it could be available at an investigational either.

>> Jennifer: [Audio Skipping]. So it might be -- system that might not be -- [Audio Skipping] -- I'm not sure what they're using at McGee specifically for upper extremity but it might be another -- freehand might be a newer -- device. I think the key thing would be to look on -- trials.gov for more.

>> Bil: Thank you. This unfortunately will have to be the last question this afternoon due to time constraints. Any additional questions can be directed to the panelists, and by use of their e-mail that is on the screen. The question, my urologist -- they have an indwelling catheter for 10 years. Is neurotechnology a real option for me in terms of bladder voiding over the next year or two, or should I go with a urinary diversion?

>> So this is Megan. I'll say it is our discussion to have with a doctor -- yeah, with your regular physician. And maybe -- in exploring what investigational or commercially available bladder systems are out there armed with some of that information maybe help make a decision directly with your doctor.

>> Jennifer: If I could add to that answer. On the resources page, we have Neurotech Network has options. I would encourage you to look at those resources and bring those resources to your doctor so they can look at what's available and how it might fit into your case, specifically.

>> Bil: Great. Thank you. Jennifer French, Dr. Anderson-Erisman, and Megan Moynahan, thank you very much for your time and your great and voluminous information. All remaining questions can be addressed directly to the panelists through the e-mail that is listed on the last slide. And this presentation will be archived in it its entirety at www.spinalcord.org within approximately one week. There, you can also review our upcoming presentations of NSCIA Webinars. Again, Jennifer, Kim, Megan, thank you very much for your presentation today. And this will conclude the Webinar intro to implanted neuroprosthesis for people with SCID. Thank you.

>> Thank you. It's great to be here.

>> Thank you.

>> Thank you.

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