Date: April 10, 2014

Event: NSCIA Webinar Series

Consumer: United Spinal Association

This text is being provided in a rough-draft format. Communication Access Realtime Translation is provided in order to facilitate communication accessibility and may not be a totally verbatim record of the proceedings.

>> Good afternoon, everyone. Thanks for joining us today for our Webinar titled can I walk again the latest technology on motion therapy. I am Lindsey Elliott a spokesperson for the United Spinal Association. Today's Webinar is one of several that NSCIA will be hosting. It can be found at www.spinalcord.org. Today's Webinar session will address the latest in technology as relates to motion therapy. Topics covered will be locomotion treadmill training, exoskeletons, FES and more. This Webinar is directed towards consumers with spinal cord injury and is for healthcare providers. The application will focus on technologies for spinal cord injuries but may also apply to other conditions with lower limb paralysis such as MS or traumatic brain injury. We are pleased to have our presenters today.

Jennifer French became a quadriplegic in 1998 from a snowboarding accident. She has a implantable stand and transfer system which she first received in 1999. Jen represented team USA at the 2012 Paralympic games in the sport of parasailing. As a user of neurotechnology she is cofounder of a 503 company, to educate and navigate to and for persons with healthcare impairment. Regarding neurotechnology. Ms. French is the executive director. Dr. Anderson-Erisman is a research associate Professor and director of education at University of Miami Miller school of medicine. Her research as focused on bridging the gap between basic science, clinical science and the public community living with spinal cord injury. Her training is a spectrum of research from cellular and molecular studies to whole animal and behavioral studies to human clinical research while a faculty member at the University of California and Irvin and now the University of Miami. She completed study relating to the validity of the spinal cord independence measure in the U.S. healthcare setting. Her

current projects focus on aging related changes and bladder, after spinal cord injury, determining the minimum amount of exercise and motor training required for clinical trials regarding spinal cord injury and identifying facilitators from the SEI consumer perspective.

In addition to her own research she serves as a scientific interface for the public being conducted at the Miami project and is managing their first cellular transplantation clinical trial. We will have time at the end of today's presentation for questions. Please feel free at any time today to use the question chat box and we'll do our best to get to your questions at the end of the Webinar. You will be able to contact them directly with questions we may not get to. I would like to turn the presentation over to Kim and Jen. Thank you.

>> Thanks for the introduction, Lindsey. We're both really happy to be here. Thank you all for attending this Webinar. As we mentioned we will be going over the different types of therapies that are available for different types of motion therapy. Before we get into this, you do have opportunity to ask questions during this Webinar. If you look on your screen you will see a similar screen and there you can type your question in and we will have type at the end to address those questions. If we do not address your question specifically, Kim and I will be happy to follow up with you after this Webinar.

Also, for those of you that might be taking notes, we have a PDF version that is available on the Neurotech Network website, on our home page and also at the national spinal cord injury association website, the Webinar website they will have the PDF up as well so you can have access to the links that we will be going over and the other resources that we will be providing for you.

So let's dig into this topic. We want to introduce you to both our organizations. Kim, if you can talk about the Miami project.

>> Kim: The Miami project is a research center within the University of Miami. And it is dedicated to finding more effective treatment and ultimately a cure or a combination of cures for preventing and reversing paralysis due to spinal cord damage.

>> Jen: The Neurotech Network, we're a nonprofit organization and we focus on education and advocacy of neurotechnology devices, therapies

and treatments for people with impairments. We also talk to their caregivers and medical professionals who care for them. We typically focus on medical technologies that interact with the human nervous system thus then the definition of neurotechnologies.

So we have to throw out a disclaimer to you before we get into any further details. But it's part of what we have to put in here. The information presented in this session is not meant to replace the advice of a medical professionals. You should conduct the healthcare professional familiar with your case and address your concerns and condition. We highly suggest that you take this information from this Webinar to a trained medical professional familiar with your case to discuss options that are best for you prospect so now that we're done with the disclaimer, we can get into the nitty-gritty of what we're going to be talking about today. So we will be touching on a couple of different topics. First we're going to talk about -- if we're talking about trying to walk again the question comes up, will it be before like my injury, will it be before I acquired my condition. We're also going to address the technologies that we'll be talking about today for a therapeutic effect versus prosthetic applications. So we'll be addressing that for you to kind of set the difference between those two.

We will be talking about both the benefits and risks that you need to consider when looking at these types of systems, and also talking about the technology, and supporting research behind this technology. And finally, we'll close out this session on how to access this type of technology, and the programs that are available around the country. So, Kim, could you go on to start talking about if it would be like before your injury.

>> Kim: Okay. There we go. So I'm going to give just a little bit of background first about locomotor training and how that impacts and interacts with some of the different types of devices and techniques that are out there for walking function. And the main principle behind locomotor training is to provide the injured spinal cord with incoming information that will stimulate the remaining spinal cord network, even after the connections with the brain are damaged. And I have a picture here, that can help explain this, just a little bit.

So if you look at my mouse, over here, we have the brain. And it is connected to your spinal cord. If you look at this arrow right here, down

in the lower part of your spinal cord is a series of reflex circuitry that is involved in walking, or locomotion. And if you have a spinal cord injury anywhere above this region -- so if your spinal cord was injured anywhere up here -- you would lose the information from the brain, that sends control signals for walking, but you would still have this reflex circuitry down here, in the lower part of your spinal cord. It's in the lower thoracic area of your spinal cord.

Sot important thing about reflexes are that you don't need the brain to control them. They're very fast, and they're meant to be helpful, or protective. Now, you do need information from the brain, in order to voluntarily control them. So one good example I like to give is, when you're at the doctor's office and the doctor hits your knee with a hammer, and your leg kicks out. That's a reflex that does not involve your brain. Because the information comes from the hammer, hitting your knee, straight in through your spinal cord and straight back out to your knee, to make that muscle move.

Now, your locomotor reflexes are similar to that and you need your information coming down from the brain in order to make voluntary movement with those. But as long as the spinal cord's damage does not hurt these reflexes, they're still going to be there and importantly you can still engage them for locomotor training. That's what we're going to talk about in body weight support training in a couple of minutes.

Now the next question is, if you regain walking, either because you have a incomplete injury or because you participate in a clinical trial that has electrical stimulation or a repairative technique will that walking about like before. And the answer is, quite honestly, it's probably not going to be exactly like before. And the reason for that is a couplefold. First, the circuitry of the spinal cord is incredibly complex. You may have heard people relate the spinal cord to a large telephone cable that goes across the country. Yes, it is similar to that. There's lots of small wires within a big cable. But they're not just straight lines going from one place to the next. There's a lot of interconnections there, kind of like a computer circuitry, that kind of changes as we change. And reorganization is very possible.

So this diagram here can give us a little bit of a visual about what that means. So if we look where my mouse is -- and I have an arrow to point to this -- this side of the diagram, you could consider to be the normal

spinal cord, in a diagrammatic way. And also some people have spared tissue, or spared nerve fibers around the outside of their injury, that still travel all the way up and down the spinal cord. So you can see that that looks kind of nice and neat. But then there's a couple of things that can happen spontaneously as well as with different types of intervention. And that is illustrated here.

Above the injury site, you can get nerve fibers that are not injured, to start to sprout and give off branches that can bypass the injury site, depending on how big the injury is, and go below the injury, and start to create some function.

You can also get nerve fibers that are damaged, but can spontaneously regenerate themselves down below the injury. And then, also, you can get sprouting of neurofibers that are below the injury. So all of these types of sprouting, we call plasticity, meaning that there's flexibility in your spinal cord circuitry. And, over time, particularly with motor incomplete injuries, people get changes in their spinal cord that kind of compensates for the loss. And you can regain some motor function, but it's not necessarily the same circuitry that it was, preinjury.

And that's actually a good thing, because it means that we do not have to exactly replicate the spinal cord, in order to get functional recovery. But it also means that the way that you regain walking may not necessarily be the same way as it was preinjury. and that lead us into our next slide, which asks dear or brings up the topic of whether or not regaining walking function will resolve everything.

I used to think that if I could regain walking then everything else would be fixed as well. That's not really the case. Because the nerve fibers, that are responsible for you to be able to do movement, either of your arms or your legs, or any other kind of muscle, are not the same nerve fibers that enable you to feel, or the nerve fibers that elicit pain. And similarly, the nerve fibers that produce bladder and bowel and sexual function are different. The nerve fibers that control your temperature and blood pressure are different as well. So we may be able to do different types of interventions that regain walking function, but the other symptoms are not necessarily guaranteed to come along with it. So that's something important to remember.

And another thing to point out, finally, here, is the efficiency of movement.

Many people get very efficient, and are very independent, using their wheelchairs. And when you start to transition from ambulating or walk instead of using your wheelchair, it may be very slow and difficult and require a lot of energy. These are all important things to consider, when thinking about devices for locomotion.

Now, I'm going to hand it back to Jen.

>> Jen: Thanks, Kim. Now we're going to talk a little bit about the difference between a therapeutic application versus a prosthetic application. So when we think about therapeutic application, it's really focusing on the rehabilitatative process that's really designed to facilitate the process of recovery from injury or illness or disease. When you think about these types of technologies that will introduce you to, when we talk about a therapeutic effect it's a recovery effect or a rehabilitative effect. It focuses on restoration and recovery, focuses on voluntary control, and also with a community orientation, to be able to eventually use this technology from a therapeutic standpoint and then take it away so that you can have voluntary control. That's kind of framing the world of therapeutic effect.

On the opposite hand these technologies can be used for a prosthetic effect. Like we think of prosthetics for amputees, these types of technologies can work as a tros thet tick application in which it's a tool to compensate to replace for a lost function. So for instance if you have paralysis in your lower extremities, a type of technology might be able to use, to compensate for that, to be able to give you some type of movement. But if you try to take that away, that movement won't be possible. So it really focuses on improving your health conditions, as a compensatory measure, and also as a means of prevention of other ancillary medical conditions that can come along with sitting in a wheelchair, but also in terms of performance as well.

So, again, therapeutic applications are in terms of being able to use it for recovery, to be able to use the technology, take it away, and be able to regain or have that -- control, whereas a prosthetic application is where it will be used to replace a lost function that uses a compensatory measure, where you would need to use it all the time, if you want to still have that function. That's the difference between those two applications.

So when we talk about the benefits of walking, there's a whole -- of

benefits. We will touch on some but we will also talk about the risks as well. When we look at the benefits of walking -- [Audio Skipping] -- that has been a spinal cord injury -- paralysis, it does help to reduce spasticity. Research has shown that walking will improve cardiovascular performance as well as pulmonary movements. You've seen it in terms of circuitry, in terms of circulation throughout the body -- there's also evidence of walking -- management of bowel, just as -- [Audio Skipping] -- how it was before, but still the bladder control can help in terms of --

>> This is Lindsey. We're having trouble with your audio. I don't know if you're on a headset or if you can switch over maybe to your...

>> I am --

>> You're breaking up.

>> Is that better?

>> No. It's not any better.

>> Okay. Can you try to call back in.

>> I will.

>> That might help. I'm sorry, everyone. If you can just bear with us. I want to make sure everybody can hear the a audio. Let's give her a minute to call back in.

You can leave it off, Jen. Just hang up the phone and use the audio number. If you see the audio...

>> Jen: Is it possible to hear me now?

>> Yes. Much better. I hope everybody agrees. If not, let me know and I'll let you know, Jen, but you sound much better. Thanks.

>> Jen: Great. Sorry about that. Would it be helpful to go back a bit into the explanation of the therapeutic versus prosthetic? Was I scratching then?

>> Yeah. You started to. Yeah, why don't you just cover that one more

time. That would be great.

>> Jen: Okay. I'll reiterate quickly about therapeutic versus prosthetic. Again to reiterate this slide -- sorry to you for that technical glitch. The therapeutic effect is when we use the technology from a recovery focus. The idea is you would use this technology to gain recovery of -- control, take technology away and you would remain to have that -- control whereas for prosthetic use it is replacing the use of a lost function or paralyzed limb. So that technology would be a compensatory measure or be used all the time if you take that technology away, you would still have that limitation. That's the difference between those two applications.

Looking at the benefits of walking, we did touch on reduced spasticity, cardiovascular and pulmonary health improvements, circulatory improvements, improvements in bladder and bowel. Kim had mentioned that will it be like it was before that your bladder and bowels return to the way you remember before your injury. More than likely not. But with walking, there has been evidence that it would improve your bladder management and bowel control.

Again, pressure sore preventions, from that sitting all the time in one position, and also mental health as well. And we're also seeing in terms of musculoskeletal health in terms of the improved health of not only your muscles but also your bones. So all of these benefits have been documented and researched and -- in published research, looking in terms of using the technologies.

When we look at the risks, there's also inherent risks associated with using technologies as well that you need to consider before either joining into one of these therapies and/or clinical trials. One of them of course is the obvious, the potential for increased falls and bone fractures. As we know, people that have been paralyzed for long periods of time have higher propensity for osteoporosis. With that comes the higher possibility of bone fractures when you have a fall. That's definitely something to consider when you're looking at these technologies.

Also, your sit-to-stand might increase with lower blood pressure. Those of you, those people that might be using wheelchairs for long periods of time and are not used to standing, if you go from a sit to a stand your blood pressure might drop significantly, almost to the point where you might pass out. That's something to keep control of and to be able to

monitor if you look at these types of systems.

Also, you might be limited by contractures and also in your joint health. So another of very high propensity for people that are long-term wheelchair users are contractures and potential arthritis in the joints. So that might be a limitation in terms of using these technologies.

Also, there has been evidence, in terms of -- from a mental health standpoint of setting unrealistic expectations can lead to lower quality of life. That's something to really consider before you look at joining in or participating in any of these types of technologies, is to really take a step back and set some realistic expectations of what you expect out of the technology, and what you expect to achieve.

And finally, there has been evidence that, in some of these using some of these technologies, people have experienced increased chronic pain. It might be from a lot of different reasons that we don't necessarily know why. But one that we do know, which is very obvious, is in terms of shoulder pain. So using these technologies, you're using your upper body much more. They have had evidence of increased shoulder pain. But also there's been an increase in chronic pain as well and we're not quite sure how that -- and why that occurs. But it is something to consider before taking part in these technologies.

So we've talked about the risks, we've talked about the applications, now let's get into the nitty-gritty of talking about the different types of technologies. So Kim will -- technologies. Kim will introduce us to body weight support systems combined with repetitive motion therapy and then I will address exoskeletons and electrical stimulation. I would like to hand it over to Kim.

>> Kim: There are a couple of different ways that you can do this. And the main principle that underlies all of them is to provide body weight support. So no matter what kind of system you're using, you're typically wearing a harness that is attached to something overhead that can help bear some of your body weight in the event that you are not able to do that on your own. And particularly in the beginning, when you start training, most individuals require 100% body weight support. Once they go through different lengths of training, then your body starts to be able to support some of its own weight, and that support from the system can be reduced.

So let's talk a little bit about some of the ways that you can do body weight support locomotor training. Here are a couple of examples of training protocol that we refer to as treadmill based manual assist. So if you follow my mouse here, you can see the harness that is around the individual, and you can see there's a harness in this picture as well. Both individuals are on a treadmill here. The harness is connected to an overhead system that's bearing the body weight. The treadmill is used to create a force that will activate the -- that walking circuitry that I described you to you earlier that's in the lower part of the spinal cord, that reflex -- circuitry. With manual assist, as you see this therapist here and over here, manual assist is where another person manually moves your legs, and helps initiate the walking pattern.

So this picture right here is very good. You can see one therapist is on the left -- the right leg, another therapist back here is on the left leg, another therapist is in the back, supporting the hips, and a fourth person is operating the control system, and the treadmill. So in the beginning, when you first start doing this type of locomotor training, the therapists have to do a lot of work, to physically move the legs, and make that stepping pattern occur.

With increasing numbers of weeks of doing this, even if you don't have any movement in your legs, that you can control, this starts to trigger those reflex patterns in your spinal cord for locomotion. And once you get used to that, then the therapists actually have to do less and less. The key is that the treadmill has to be on. If you don't -- if you're doing locomotor training without any control of movement.

Another way that you can do locomotor training is, on the treadmill, having electrical stimulation to trigger the movements. So you can kind of see on this picture, this person has different electrodes on their legs. We have another picture of that here. These electrodes are placed in specific areas, so that, when electrical stimulation is provided, you get this stepping pattern of your muscles, so that being on the treadmill, you can actually do stemming without as much -- stepping without as much assistance from a therapist and therefore you're relying on that electrical stimulation.

Another way that you can do body weight support locomotor training is actually utilizing a robotic system. This is an example of the loco mat

which is the most common and popular robotic assist for people with spinal cord injuries and disorders. As ugh see, we have the body weight support system. We have the treadmill for stimulation. And then what you see are these robotic arms wrapped around the individual's legs, and around their foot. And it's all controlled by this computer system here.

So this computer does all of the stepping movements for the individual. And you can see here, you only have one therapist that's needed to operate this. So this robotic system was actually developed by a company, to really try to reduce the burden on therapists of providing body weight support repetitive locomotor training, particularly for the individuals with motor complete injuries, or very, very weak motor incomplete injuries. And in the hospital setting, there is a trade-off between the number of therapists to patients that is available. And so that is why this robotic system was developed.

Now, there is another type of body weight support training, and that involves overground locomotor training. This is particularly used for those individuals that have at least a little bit of motor function in their legs, after injury. Here's one example. You can see you still have the harness, and it is supported by a system in the ceiling. So you still have that body weight support. But this individual has a little bit of motor function, and he has to do all the stepping over ground, rather than on a treadmill. Here is another way that you can do overground training and this is where the system actually follows you along. And this can really monitor a lot of different things, with your stepping.

And then another way that is becoming very popular in the hospital setting is this device that's known as the zero G or zero gravity device that provides body weight support, and it moves along with basically zero effort. And you can induce -- you can do locomotor training with that as well. The main goal behind all overground training is that you're not doing the treadmill, and you are enabling your own body to initiate the steps, and control the gait.

Now I want to tell you briefly about a research study that compared all four of those types of locomotor training that I just described to you. So they had the manual assist on the treadmill, they had the electrical stimulation on the treadmill, they had the loco mat robotic treadmill training and then they had the overground locomotor training. Four different groups. Everybody that went into the groups was all the same

at the beginning. They were people that had spinal cord injuries that were chronic, and they had at least a little bit of motor control in their legs. Though everyone was using a wheelchair as their primary mode of angulation or mobileity.

What they did was they went for a 12 week period of time they did locomotor training five days a week for one hour a day. I'm going to show you a graph that shows changes in walking speed. This was measured before the 12 weeks of locomotor training and then after the 12 weeks of locomotor training occurred. And what you see is an increase. So up here, on this side of the graph, we're having increasing speed of walking. And then we have the pretraining assessment, and the post-training assessment. And there's a couple of things to note.

First, everybody improved a little bit. So that's really important, because we know that if you have at least a little bit of motor function, no matter how long post-injury you are, you can do body weight support lock-o motor training and get a little bit of gain. Now those that enjoyed -- improved the most are here on this green line. And that is the group that did the overground locomotor training. The red line is the group that did treadmill training with stimulation. The blue line his the group that did the manual assist treadmill training. And then the purple line is the group that did the Lokomat robotic locomotor training.

Now, what we actually see a very similar response here, in regards to the amount of distance that people can walk. And what we think is happening, in this particular setting, with people that have motor -- injuries, is that the overground locomotor training, which is the group that had the greatest improvement in speed and distance, the overground locomotor training is actually providing more input to your spinal cord.

For example, when you make all the mistakes in the beginning because it's so hard to do the locomotor training, all of that mistaken information goes into your spinal cord and your spinal cord actually learns from that. And over time, it corrects the reflexes and the gait cycle. That's how you get improvement. And that is very important concept because we know a lot about this in animals, in regard to spinal cord learning. And we didn't know a lot about this in humans. So the important thing is that your spinal cord can learn just like your brain can learn, and it can adapt to in-coming information to improve the functional output.

One last area that I'm going to talk to you about is whole body vibration and locomotor training. This is a vibrating platform right here, where my mouse is. And we provide a certain set of vibration whole body vibration protocol, which you can see down here at the bottom. It's actually pretty short. This says 45 seconds of whole body vibration, and one minute rest period, 45 seconds of vibration, one minute rest, and two more bouts, his just like that.

So individuals that were in this study did four weeks of whole body vibration, three days a week, following that protocol. Then they had walking assessments either before they started the vibration, off after the four weeks of vibration. And in this particular group, it was individuals that did overground locomotor training. What they found was that the whole body vibration, prior to doing the locomotor training, significantly reduced the amount of spasticity in one of the leg muscles, the quadriceps is the muscle in the front of your leg. And, also, this graph here shows that the assessments, before the whole body vibration, compared to the assessments after four weeks of whole body vibration, showed improvement in a couple of different walking assessments.

So we have improvements in speed, improvements in stride length, how long of a step you take; and improvement in the cadence or the rhythm of walking. That's very important because many people that have motor incomplete injuries have spasticity in their legs that interferes with their voluntary control. So the whole body vibration can reduce that and improve the locomotor training. Now I'm going to hand it over to Jen.

>> Jen: Thanks, Kim. So now we're going to address exoskeletons. We've seen it in the news media and they've really come out of the woodwork, if you will. There's quite a few. There's actually five different types or concepts of exoskeletons. Exoskeletons came out of a military application that is now being designed from a medical perspective. So who's right for these types of exoskeletons. It's really focused on people with lower body paralysis or impairments, could be strokes, spinal cord injury or MS. They're not really designed to replace the wheelchair but provide people mobility options. So if you look at each one of these types of devices, you'll see that there's kind of a similar component to them.

There's almost a skeleton that you wear outside of your body, along your lower limbs. There's joints, both typically in the knee and the hip, some

have it in the ankle. But those actually have actuators with them. It's more, if you will, assisted walking, similar to what you saw with the Lokomat that Kim showed early why are, these types of devices are outside of the treadmill, if you will, and be able to go overground in a lot of different types of settings.

For these devices, you'll see that most of them require some type of assisted device, crutches, a walker, et cetera. There is one, however, the REX bionics designed to use without that type of assisted device. And you'll also see that some of them are working on incorporating electrical stimulation into it as well, but that is still very much in research stage. So when we look at exoskeletons and how they can be applied right now they are being applied in terms of a prosthetic effect or prosthetic application. Typically they're for people with lower level injuries with some type of trunk control and usually for paralysis to be able to walk with a reciprocating gait, to be upright, but they've also found that they're trying to achieve a walking proficiency, to be able to use it from a limited perspective out in the community.

Also there's been a high degree of performance variability in their research between different types of users. So again it's something that you really -- if you're interested in these to go and try, not an understanding that there might be some variability between from one user to another. These exoskeletons, there's a lot of clinical research going on as well and that clinical research is also looking at it in terms of using an exoskeleton for therapeutic application.

For instance, to being able to improve gait or gait rehabilitation for people that have incomplete injuries that might already have some type of voluntary walking or voluntary muscle control, and being able to use this for a prosthetic effect.

They're hoping that these types of walking will lead to better muscle strength and quality of that walking, but also more so to benefit people that might be -- have voluntary walking already, without the device, but to be able to improve that walking ability. So that's really what's being explored today.

So how can these be accessed. Right now, in Europe and in Israel and a few other parts of the country, for instance, REX is out of New Zealand, there are countries that you are able to get access to this device, to buy it

personally. But in the U.S. it's still not approved outside of the advisement or the... lost the word -- advisory of a trained therapist. So from an FDA perspective it's not a take-home device, if you will in the U. S., without having a trained therapist available, while using it. So more so, you're going to find these devices in clinics. All of those websites you can go to and learn and there's a lot of variability amongst those five but those are the main five exoskeletons that are available.

I also mentioned they are working on a hybrid device to be able to use these exoskeletons along with electrical stimulation to be able to potentially help with balance, and also with the stimulation or muscle bulk or recovery. Again that would be -- also they're looking at it potentially for prosthetic effect but also a therapeutic effect but again that's very much in research and in clinical trials.

Moving on to electrical stimulation we will touch on a couple of different things in terms of electrical stimulation but the first is drop foot stimulation. There's four commercial devices that are available today. And all of these devices are using what's called electrical stimulation, but it's external stimulation. So they're pads placed on the skin, in an area, in the lower part of the leg. All of these are focusing on the dorsiflexion and plantar flexion of your ankle. So typically these types of drop foot stimulaters are to solve a problem which is very similar to what it's called, drop foot. Drop foot is very common among stroke survivors, people with MS, incomplete spinal cord injury, where they mute use an AFO device where you can use stimulation to be able to lift the foot during the gait process.

All of these have surface stimulation, and they have a sensor that would be able to turn the stimulation on, of when to flex the foot. There is also a thigh device that you can see in the upper right that is also using electrical stimulation to stimulate the quad, and the hamstring, within one leg. So, again, this is to improve gait that already exists.

There are -- it is approved in the United States, for -- those different type of applications I mentioned, stroke, MS, cerebral palsy, traumatic brain injury, incomplete spinal cord injury and is reimbursed by Medicare for incomplete spinal cord injury on a case by case basis for private insurance.

What they've been able to find in their research is that this type of stimulation, they were able to find improvements in the quality of gait, the

prevention of falls, increased strength and endurance, and also increased walking speed. Those are some key factors in terms of looking at applying this device to improve a syndrome called drop foot. One thing we'd like to note about these drop foot stimulaters is they come out of the box from the factory with certain type of parameters in them.

So those parameters can be changed. One parameter, for instance, of frequency or pulse with, those don't necessarily fit maybe an individual that might be using it. So the parameters can be changed. And I think that's a key thing when we're looking at applying this type of stimulation is to be able to adjust those parameters and customize it for each user and that's what these devices allow you to do so. So you might try it out of the box, it might not work properly but the key is to adjust those parameters to be able to fit your specific body anatomy.

In the UK currently and in parts of Europe, they are testing or in clinical trials with implanting a drop foot stimulation system. So taking these surface electrodes and implanting them inside the body and having them implanted controller inside the body so all of that will no longer be external but that is in clinical trials right now in Europe and the UK.

Looking at other electrical stimulation devices or alternatives, we'll first address some of the commercial devices. One of them which has been on the market for quite some time is called the parastep system. This system is FDA approved and CE marked and is reimbursable, and it's designed for those with T and L level injuries. It's a hybrid between bracing system and surface electrical stimulation. So as you see, this user here, they have some bracing on their limbs but you'll also see some of the wires going to those surface electrodes that are placed strategically on their lower limbs and that provides a reciprocating gait as well.

This is more of garments designed to have electrical stimulation or surface stimulaters embedded into those garments. Those are two types of commercial devices. There's also a lot going on in terms of research and research devices. So one is implantable neuroprosthetics being involved at case western -- and the -- center and these are designed to be able to maximize volutionary control. It's looking at, in clinical trials, of individuals that have incomplete spinal cord injuries that already have some voluntary movement. What they're doing is applying electrical stimulation to be able to improve that gait to allow a person to be more ambulatory in the community. And again these are implanted electrodes,

surgically implanted into the body, to be able to improve gait.

We've also seen, when looking at these types of devices in terms of electrical stimulation, when we look at it compared to traditional gait, meaning that we're looking at electrical stimulation gait versus traditional gait training, we've been able to find, and research has concluded that FES has signs of increased spinal cord injury independence measures so we have been able to find some improvement for people using these electrical stimulation, as well as over the ground walking reduced pain, and improved mental health.

Now, there's also been a lot of press recently regarding epidural stimulation and that is a research that's being done at the University of Louisville sparked by the latest research coming out about epidural stimulation applied to four different subjects. They all had spinal cord injuries in AIS level A or B, and with the stimulation on, the research has been able to find that they've been able to regain some volutionary control, some movement of their paralyzed limbs and have been able to stand but not walk as of yet. So -- again, this is epidural stimulation. It's electrodes placed into the spine. When the stimulation is on, they've been able to show some volutionary control. This again is a limited clinical trial. There were only four subjects in it. The research team is currently looking at increasing the number of subjects in that study right now. But again it's in clinical trials and we'll go over a little bit more how to find out about that, as well as other clinical trials.

And at this point, we'd like to go into how to access those. So how do you access these types of technologies. We went over body weight support systems, exoskeleton, electrical stimulation, and we all say wow that looks like it costs a lot of money. Well, these technologies can be very expensive but there are alternatives to be able to access the technologies. One is that you can personally purchase the devices. Some of them you can. But also, there's clinical and post-rehab programs designed to be able to give you access to the technologies. And also there's clinical trials. And we'll go over each one of these -- or more so the clinical programs and post-rehab programs as well as the clinical trials.

If you're looking to personally purchase them we had the slides where you could see the links and you can contact the companies directly. Also, in the case of being able to try these technologies, I think we do want to stress is neurotech network does is the best is to be able to able to find

where these technologies can be accessed, to find a trained professional, and someone that you can advise, that is specific to your condition. And we typically ask people to look at the manufacturers. They have a find a therapist or find a doctor in your area where you live.

So how do you access these. There are post-rehab or clinical programs. These are programs that go beyond the outpatient or in-patient experience and allow you to have access to these types of technologies and the types of therapies that we discussed today. There's a list of of different types of locations where you might be able to find them, and see if you can be appropriate and be able to join these types of hospital programs.

The hospital affiliated programs again are affiliated with the hospitals, or with rehab facilities, and you typically have access to trained people.

Also, there are stand-alone programs and these programs are not affiliated with the hospitals, but they do give you access to different types of technologies that we address. And also, to be able to get -- to join these types of programs, like on a -- type basis and also you will have access to trained -- personal trainers or people that might be more familiar with your condition.

So before we go into -- into anymore, we'd like to hand over to Kim to be able to talk about clinical trials.

>> Kim: And actually, one thing that we want to do right before we go into clinical trials is actually give a poll to the audience, and it is really the audience's opinion about the exoskeletons, that Jen described, just a little while ago. So if you see the questions on your screen, go ahead and choose whichever answer is most relevant to your opinion. And let us know. And just a few minutes, we will... tie up the Webinar on clinical trials, and you will actually be able to display the results of the voting.

Jen, you want to say a couple of things while we're waiting for people to vote?

>> Jen: Yeah, actually, we can go back into a little bit of the access issue. So we're looking at the difference between hospital programs and those that are stand-alone. The hospital programs are typically done in their therapeutic gyms. They allow them after the therapeutic -- the time that they're actually doing therapy throughout the day. And you can get

access to these types of technologies.

The ones that are stand-alone programs can also give you access to those technologies. But they can also be available during the day, whereas in terms of many hospital systems, might not be able to be available when they're actually conducting therapy. I think those are two things to consider. But also to be able to shop around for these programs as well, to be able to see what the out-of-pocket expense will be, and what type of access you can get for the different types of technologies that they have.

>> Kim: So it look like we have our response to the poll now. About 72% of the audience felt that exoskeletons can be most efficiently and practical in the future to be used as a therapeutic device. That's important information that we can translate to the developers of these devices.

Since we are running just a little bit short on time, I want to conclude here with a brief amount of information about how to access clinical trials. This website here, clinicaltrials.gov is a listing of different clinical trials ongoing throughout the world. The search terms are listed on the bottom. You can search for walking and whatever condition you're interested in. Locomotor training, exoskeleton, robotic therapy and walking, electrical stimulation and walking, or epidural stimulation, and a list of studies will come up, and then you can click on them, and read much more detailed information about each.

There is also a guide that can be used to inform people for clinical trials and the types of questions that you should ask. So they are pointed out here. You should ask questions about safety, about possible benefits, about the clinical trial protocol, what is actually going to be done, what's going to be measured, about payment, and cost, about whether or not you can participate in other clinical trials while you're in that particular clinical trial, what kind of evidence preclinical meaning -- evidence or clinical evidence, meaning prior human experiment is out there and independent assessment of the treatment and investigative.

If you go to this link down at the bottom of the page, you can download a copy of this entire guide for information on clinical trial participation, and read all of the details there. So I think we're going to open up for just a couple of questions. We're running short on time. We will be able to answer additional questions afterwards via e-mail.

>> Thank you both so much. We have several questions so we'll get to a few as we have time left to do. The first question, is there any science or technology available to help restore the use of the upper body, especially the use of hands in quadriplegics?

>> Yes, there is. We'd love to run a whole Webinar just on that but I will touch on a few things here, and so there are. There are, just as you saw some of the robotic and repetitive motion there's quite a bit of technology out there for repetitive motion therapy for upper limbs. Also the use of electrical stimulation, both external and implanted for upper limb treatments. If you go to the Neurotech Network website, and you look at our fact sheets for spinal cord injury we have a whole section dedicated to upper extremity technologies and there you will be able to find some of the repetitive motion therapies from a therapeutic standpoint and electrical stimulation used for therapeutic and prosthetic application as well.

>> Thank you. Next question, does Medicare cover any of the related therapy cost?

>> For a lot of what we've been covering today, there's several different types of devices that are in clinical trials so they are not covered under Medicare. We did mention the drop foot stimulation system. That is Medicare reimbursable for incomplete spinal cord injury. And I realize that some of these technologies are being developed in terms of being able to be reimbursed.

There's also been cases, in programs where they've been able to have post-rehab programs to be reimbursed. However that's again on a case by case basis.

>> Great. Thank you.

>> Sometimes the body weight support training can be reimbursed. It depends on how much you're progressing. But yes, it is a case by case issue.

>> Okay. The next question is, do they have to cut the nerve when they're implanting the stimulater?

>> No, they don't do that. You want to answer that, Kim?

>> Kim: Thanks, his Kim. That's an emphatic no, they do not. The key thing about the implanted electrical stimulation is it capitalizes on the peripheral nerve system that already exists in your body. So that's how, in layman's terms how the electrical stimulation works. When it comes to cutting nerves, they don't want to do that. That would be detrimental. They would like to keep the peripheral nerves and capitalize on them. When looking for implantable devices, for the prosthetic applications we have those are implanted electrodes but they do not cut the nerves.

>> Okay. And the last question I guess would be how do you think the vibrating platforms reduce the spasticity?

>> So we know a little bit -- yeah, we know a little bit about that. We don't know the exact mechanism. What it's working on, you have receptors in your body, that detect the vibration. And initially, when they do the vibration, it can actually be exciteory or stimulatory. But once you do it enough, it kind of -- you could think of it as depletes that activity, and then it causes it to settle down. So that you don't -- your body is not hyperactive anymore. And that is how you get the reduction in spasticity.

>> Great. Thank you both again so much. And want to remind everybody that the Webinar was recorded are, and it will be archived. You can find it on our website at www .spinalcord.org. You will have access to the PDF of the whole presentation. On behalf of the spinal cord injury association we would like to thank Jen and Kim for that wonderful presentation, for sharing your professional knowledge and personal experience in regards to motion therapy. The Webinar was extremely informative. Thank you for sharing your expertise with us today. Our next Webinar will be on March 17 at 3:00 PM eastern standard time we will cover transitioning from canes to walkers to wheelchair by a physical therapist and will explore the various devices and assisted equipment that a person may need as their condition progresses or changes and its impact on mobility. For anybody that doesn't already receive our newsletter you can sign off at our website which is www.spinalcord.org. You can receive our monthly newsletter, sign up for future Webinars we're having and join our membership that's free. Recently any members of ours who join the organization will now receive New Mobility magazine monthly for free. Anybody that would like to receive that, I'd encourage you to head over and become a member of the association. Thank you both again so much. And everybody, have a terrific day.

>> Thank you.