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>> Bill: Good afternoon and thank you for joining us today for our webinar entitled, breakthroughs and stem cell therapies. My name is Bill, Director of National Spinal Cord Injury Resource Center and I'll be your moderator for today's presentation. Today's webinar is one of an on-going series that National Spinal Cord Injury Association will be hosting and all of our webinars will be archived on our website, www.spinalcourt.org. We have time at the end of the presentation for questions. Please use the question's window on the bottom right corner of your control panel to write in any questions that you have and we'll do our best to get to them. If we do run out of time, on the last slide the presenter's contact information will be presented if you wish to follow up with your questions. May I also call your attention to the directions, access our closed captioning capability at the bottom of your webinar control panel. Our presenters today are Jennifer French and Dr. Anderson-Erisman. Jennifer French became quadriplegic from C6-7 spinal cord injury in 1998. She is an active user of the functional electrical stimulation implantable stand and transfer system. She first received it in 1999. She also represented team USA at the 2012 Paralympic games in the sport of sailing. As a user of neuro technology that reaped benefits she's also the co-founder and Executive

Director of the nonprofit organization, Neural Tech Network. She currently serves the Brown University institute for brain science and the advanced platform technology center in Cleveland, Ohio. Dr. Anderson-Erisman is an Associate Professor and Director of 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 spectrum of SEI research of molecular studies to whole, animal and behavioral studies in human clinical research as a faculty member at the University of California Irvine and now, the University of Miami. Her current project focus on aging related changes in bladder health after SCI, determining the minimum amount of exercise and local motor training required for clinical trials, targeting chronic SCI and identifying the factors and barriers to clinical trial participation from the SCI consumer perspective. In addition to pursuing her own research regarding chronic injury, she serves as the scientific interface of research being conducted at the Miami Project and is now also managing the first cellular transplantation clinical trial. And now, I would like to hand it off to miss Jennifer French and Dr. Kim Anderson-Erisman for their presentation today.

>> Thank you, Bill, thank you for that great introduction and thank you all for coming to this webinar. We do want to let you know a few things before we get into the details. The PDF for this presentation will be available on the National Spinal Cord Injury Association's website and their webinar archives on the Miami Project website as well as on the Neural Tech Network website. It will have links and all of the slides. For those of you who are trying to write fast be able to have access to that PDF.

Also, during this presentation if you come up with any other ideas of what you would like to see for webinar, please write those in to -- on to your screen so we can take that as feedback for what you would like to see in the few turned and what type of topics with you like to see. So there is a lot going on in the world of spinal cord injury research. What we're going to be focusing on today is stem cell therapies, specifically for spinal cord injuries. We want to keep it focused but again if there is any other ideas that with you, you have would like to see presented in the webinars please let us know. During this presentation you're going to see on your screen that there is a questionnaire I can't. So as Bill mentioned if you would like to pose questions to us please type them in. We will be able to address those at the end of the presentation and again if we're not able to get to your questions during this time period our e-mail addresses will be available at the end of this presentation to follow up with us. First I would like to introduce you to both organizations. Kim, do you want to introduce the Miami Project?

>> Kim. Yes, Miami Project is research center based within University of Miami and awful their faculty are dedicated to finding more affective treatments for spinal cord injury to ultimately lead to significant improvements and functions.

>> Jennifer: Thanks, Kim. And I'm from the Neural Tech Network. We're a nonprofit organization and we focus on education and advocacy of neuro technology devices, therapies and treatments foe people living with impairments, also directed to their caregivers and medical professionals as well. Just so you're aware of the two organizations that we both represent. There are some disclaimers that we have to go over real quickly in regard to this presentation. We wanted to let you know that the

information presented in this session is not to replace advisement from your medical professional. You should consult a health professional about your concerns and conditions. In presentation we're going to discuss experimental and experimental devices and therapies and biologics that are not approved. We do want to let you know about that. And also Neural Tech Network and representatives we do not endorse, rate, sale, prescribe or administer any products or procedures or services. We highly suggest you take the information that we're giving you today and to talk to a medical professional that is familiar with your case. Okay. We are done with the disclaimers and now let's get on to the guts. We have seen a lot happening in the media and just recently this past week we've seen the headlines of talking about different types of cells. And all things really creating all to pay attention to the research that has been going on. For those of us that are in wheelchairs of course it builds excitement but we want to caution whenever you see anything in the headlines you want to be able to look at it from a key perspective and take it into the context of what it really is. One of the concerns of course that comes up with all of the hypothesis that comes around the media is that there is really kind of this global industry of unproven stem cell intervention and what is called stem cell tourism. We're going to touch on that later. We want to make it clear that any one that is thinking about getting cell transplantation or participating in a clinical trial there is really you need to do your homework before you do so. So just always keep in mind that what we see in the media is something to be able to help educate us but also to be aware of -- be a little skeptical as well.

There has been a lot of progress going on. As I mentioned earlier. With the research for spinal cord injury. And a lot in terms of stem cells. The

progress of stem cells but as we go through the research and see it in the media, for every question that might be answered, sparks a whole plethora and even though we have made quite a lot of progress and science there are a lot of questions not such as what types of cells are the most advantageous and how long to do the transportation how long after the injury and where to do the transport along the spinal cord and also how to protect from cell rejection. So there is a lot of still unanswered questions and that is really what the research is focusing on is focusing on how to answer those types of questions. So we're going to dig a little further into this but first we want to take a step back be able to have a better understanding of the spinal cord and what happens during a spinal cord injury and with that, I'm going to hand it over to Dr. Kim Anderson Erisman.

>> Kim: Thank you. I wanted to mention I had a spinal cord injury myself. It has been for 25 years. There has been a lot of change in the research field in the last 25 years and a lot of understanding and it is a very exciting time but it is also can be kind of a confusing time trying to decipher what is throughout in regards to clinical trials and what are stem cells and what do they mean. So let's talk first about what happens inside your spinal cord after you have an injury. In this diagram right here, it is a good example. So you have the primary damage that happens right in the core of the spinal cord. And that would be from whatever the mechanism of your injury was. If it was a car crash. If it was a fall. A gun shot. Or if it was from a surgical procedure. Anything like that, that causes the primary damage. You can't reverse that on its own but something that happens after the primary damage is called secondary damage. This can take hours to weeks to occur. But it is basically your body's response to the primary damage and initially it causes extra injury why we call it

secondary damage. But then ultimately it ends up walling off the injured tissue from the rest of the spinal cord. So that the injury site does not keep on progressing and getting bigger. And we also know that in addition to that damage, there are some nerve fibers called axons that get cut or severed and power House of the cell body may not need damaged and it might be in the brain or might be lower down in the spinal cord and it is sending axons up or down the spinal cord. The axons get cut but cell body is still alive. You don't need to replace the cell. You just need to regenerate the axon fibers. That is another target of repair.

And then we also have the inhibitory scar tissue which I think many people are familiar with. And there is -- there is a lot of research on how to get rid of that inhibition. We have many types of cells that die. With stem cells one of the big areas we're looking at is how to replace the cells that die.

So what are some of these targets then for clinical trials and therapy? In red here you can see a decompression surgery, you can see hypothermia, you can see two drugs, Riluzole and minocycline. These are all strategies that are called neuro protectants and they're trying to prevent that secondary damage from occurring. Those actions are coming in very, very early after injury. And by preventing some of that secondary damage, the host is that you can spare tissue, which means you can spare function and people can be higher functioning level as a result of that.

However. After that neuro protective window ends, there are still other strategies that are out there for repair. And if you think about the scar tissue right here, you probably have heard a lot about the no go antibodies and there is another called cethrin that inhibits the row activity. These are targeting trying to get rid of the scar tissue area. Another one is called conjointnace that dissolves the scar tissue without damaging any of the

healthy tissue. And then you have heard about the electrical field stimulation or the epidural stimulation. It can help stimulate growth or regeneration of nerve fibers. Then it is cell pre placement strategy. Sorry about that. And then so with the stem cell, there are -- there is a little bit of information we know about stem cells and it can be given early, early after injury to try to target some of that inhibitory damage. That is occurring. But the rest of the stem cells are really looking at cell replacement strategies. Let's get into stem cells. You may or not realized that all are the same. And what is the true stem cell versus a progenitor cell. First a true one is unspecialized cell. Touser more specialized function. So there are very few there are some development but the key is that they can self-renew and divide indefinitely. Now a progenitor cell is similar however, it is more specialized. So it can divide but it cannot divide inner definitely. Just like -- opposed to it stem cell. And usually a progenitive cell will not be able to make as many different types of cells as stem cells. Can they will make a specific type of cell. So, for example, I have written down here an oligodendrocyte. That is a type of cell that makes more progenitor cells and more oligodendrocyte cells and the oligodendrocyte cells form the myelin inside the spinal cord. And so I have another image here. If you see here this is what happens. What gets done here is pregnancy is developed in a female. So in very, very, very early stages of that fertilized egg, there will start to be division of cells. And when it gets to this area right here in the red rectangle, it is called the blast toes. There are 600 cells total in that fertilized egg. If you look right here where it says the inner cell mass, that is the area of the blast tow cyst that contain embryotic stem cell. That is the only place you can get embryonic stem cell from. What has been done in the research

field to use embryonic stem cell for different medical diseases and studies is that they have taken out the inner cell mass and from a blastocyst that has been destroyed and typical way they get this is a couple it has a -- in vitro fertilization that we're trying to do to have children. They will normally fertilize several eggs and freeze them. Once they have a number of children that they want, we have to make a decision and they either continue to freeze those fertilized eggs and they have to pay to do that every month. Or they decide to get rid of them. And if they get rid of them they can either donate them to research or they can just totally destroy them. It is their choice. And, so, some people have decided to donate those fertilized eggs that they're no longer going to use to research. And that is how the embryonic stem cell line has been developed.

This is where it destroys. It is a lot of controversy; however, the embryonic stem cell the early stage of development are truly what we call pluripotent. They can make every single cell in the body. The danger of the embryonic stem cells for medical treatment is that they can have high probability of forming a tumor. So that is dangerous. And there needs to be regulation how you use embryonic stem cells and we'll go into one of the trials that uses them.

The next area you see in the picture is where you get specialized cells forming. For example, heart muscle cells, and now you can have stem cells in the heart muscle and these are often called adult stem cells and you can get these from yourself. But they are restricted. They can only make part muscle tissue. They can't make nerve cells. And they can't make liver cells. So you can get adult stem cells in these different specialized tissues and there are people that are studying them and I'm going to talk about some trials with them as well. But they are not

powerful as the embryonic stem cells because they're more restricted in what they can make. So I hope that was not too confusing and if you have questions that come in to that I'll be more than happy to talk about that. So let's go ahead and go into our clinical -- our potential for benefit and then into our clinical trials.

So like I mentioned, stem cells have a lot of potential for spinal cord injury or diseases and other diseases because they have the ability to test -- to replace lost cells. Due to the injury or disease. But we need to be careful that we understand what they're doing and we refine the cells and we test for them appropriately in animals before we subject humans to different types of risk.

The other thing is that they can be particularly related for spinal cord injury, they can be a platform for axons to regenerate on and kind of create a bridge in the injury site. Axons don't like to grow in error in liquid. They like to grow on some kind of tissue. So we can use stem cells in that regard as well.

Like I mentioned earlier, the -- it may be very beneficial in that early time period after injury where they can limit some of the inflammation that is occurring inside the spinal cord. Stem cells can also be used to promote blood vessel formation which is very important for the stem cell tissue.

And then also stem cells can release different things like growth factors or cytokines that are beneficial to creating a healthy environment in the injury science -- in the spinal cord to enable other types of interventions to repair.

Like I mentioned a couple of time, this involves risk. Some of the risks are no matter how much we study animals or cellular model. In the laboratory and preclinical studies there is some an Your Honored questions.

Because there is always going to be a certain amount of unknown. There

is going to be a certain amount of risk related to that unknown. And there are really no well defined gold standards protocols for humans with spinal cord injury. Because this is a relatively new area of clinical research. It is really uncharted territory. And you have to hear me talking about really trying to define the path that we feel more doing this. Also if you're talking about putting stem cells or any kind of cells into the actual spinal cord, then there is going to be the risk of causing additional damage. Just by simply putting something in the spinal cord. And so that risk of additional damage may or may not cause a loss of existing function. But in these early stages of the clinical trials, we cannot rule that out. So it is definitely a risk that people need to be aware of. There is the possibility when you do the spinal cord you could do neuropathic pain that was not there previously. And it could be worsen. This is because you're changing this circuitry in the spinal cord. And then finally like I mentioned. For some stem cells there is high risk of forming tumors. For example, embryonic stem cells if you put in pure population, stem cells, other stem cells like the adult stem cells have less of a risk. It definitely something we need to be aware of when we're making a decision to participate in a cell based let's get into the current trials that are out there. You may have heard about a trial conducted by a company named Geron and it is taken over by a company called [NAME] and Geron was using an embryonic stem cell line. They were not transplanting pure embryonic stem cells. They were taking cells from that embryonic stem cell line that had been pushed into a direction to become a good dendrocyte progenitor cell and all the dendrocyte progenitor cells were transported into the spinal cord. Now, what they're targeting with that type of intervention is re-myelination. Of de myelinated axons so around the rim of the injury you can have some

nerve fibers that are still connected but they have lost their myelin and myelin is what is considered to be the installation of the nerve fibers. And all the dendritic sites are cells and then they go on to form all the dendrocytes and then myelinate those nerve fibers that are there. And so in their first trial, which was a phase I trial, they only enrolled people with complete thoracic injuries and the transplantation had to be done within 14 days of injury. They did interspinal injections. That means that they injected the stem cells into the spinal cord. They gave steroids and all of those individuals had to be on a temporary immunosuppression. Drug paradigm. Because the cells are not from their own body. They cannot be from their own body. Now, what they did is they enrolled five out of the 10 people that they allow them to enroll. The company Geron posted the stem cell trial because of financial reasons. In 20 Asterius therapeutics took over all the rights took over the data and now they're monitoring the individuals that they had to have cells injected previously and they now have approval from the FDA to begin another phase I trial. From what I understand right now, they will be focusing on cervical injuries but they're still going to focus on early time points after injury. Within the first couple of weeks. You can learn more about that trial as it gets registered on clinicaltrials.gov. Another study involving skin cell is using human fetal central nervous system stem cells. This is run by a company called stem cells, incorporated. Based out of California and CNS for central nervous system and SC for spinal cord. And this is the clinical trial dot gov number you can look up and read more about it. Now, they're not using embryonic stem cells. They're actually using human neural stem cells and nervous tissue stem cells that were derived from fetal brain tissue. They created this into a cell bank basically. They don't have to

get new cells every single time. And they are targeting two areas. And now these cells have the ability to replace neurons and you may be able to replace some of those nerve cells that have been lost at the actual site of injury and allow more of the functional change. And so in their first trial, they -- they enrolled people with thoracic injury and complete and incomplete and this was kind of a semi chronic. People were three to 12 months post injury. And they -- this also involved injections of inside the spinal cord and involved immunosuppression temporary and these cells you cannot get from your own body. People were followed very intensely for one year and more of a long term monitoring for four years. They already enrolled all 12 of the people that they had approval to enroll. And some of them are still in the first year of follow-up. At least eight or nine of them are past that one year follow-up. And they first let me mention that in those individuals, probably about half of the 12 have regained a significant amount of sensory function. And, so, that is good information. And nobody had any serious adverse effects or any loss-of-function. So that is really important as well. And, so, this has given the company confidence to begin a phase II trial that is going to be multi-center in the United States. It is on clinical trials dot gov as well and this is registered number. They are going to be doing three cohorts of people and they're really going to be focusing on cervical injury. So for those people that have what we call an Asia A injury, they can be three to 12 months post injury. But if they have an Asia B or an Asia C injury, which are different versions of incomplete, they can actually go out two years post injury and qualify for the trial. But like I mentioned it is restricted to the cervical level 5-7 because they're really trying to look at motor change. It is much easier to see a motor change in the cervical

spinal cord than in the trunk where the thoracic cord is. This will also involve intra-spinal injections and temporary is me know and follow-up for one year. There is information on this on our website as well. So the last trial that I want to talk to you about briefly, it is a trial involving human spinal cords neural precursors and unlike the stem cells trial, they were looking at human neural cells derived from the brain and this company is taking a neural cell that lives -- that is derived from the spinal cord. So a little bit different. And by a company called Neural Stem, Incorporated also based out of California and registered on clinicaltrials.gov and this is their registration number. They're going to do a phase I safety trial. This is their name and NSI-556 that they give their stem cell project. These are cells derived from the human stem cell of an eight-week-old fetus that was aborted. So they derived the cells one time and they will keep on propagating them forever. They do not have to go to any more tissue. To get these cells.

These ones are targeting growth factor replacement and potentially nerve cell replacement. This is two of the potential areas where you can replace cells but you can also be kind of a mini pump and pump stuff out against the environment. We don't know the results of that trial. I'm going to leave it here and pass it over to Jen. I'm going to give to it Jen]

>> Jennifer: Thank you foregoing over those specific clinical trials.

Because she talked about clinical trials we do -- we had one other last thing on this clinical trial was follow-up for one year. Then long term follow-up for four years. Just to add that in. But as we're talking about the trials we want to help in the terms of the understanding of what a clinical trial is. So when we look at clinical research, clinical research is kind of this big bailiwick if you will in terms of researching human subjects

instead of preclinical studies and it focuses on patient oriented research looking at mechanisms of disease, therapeutic interventions and actual trial which we'll go over a little bit now a second. And the development of new technologies. Really these studies or clinical researchers is focused on epidemiology or behavioral studies and also outcome for research for health service research. Focus in a little more clinical research the clinical trial. And Kim had just gone over quite a few of them. We need to understand what the perspective is a clinical trial. It is designed to answer a very specific question when it comes to biologics or behaviors or some type of intervention. So when she had mentioned some of those trials doing certain types of injections they're trying to really study what happens when we put that injection into a human being. And also for clinical trials it is used to see if there is a new biologic. Those are always key terms when it looks at a clinical trial. It is safe. Efficacious and affective. But also some of the long term goals for clinical trial is really to provide scientific evidence to be considered in terms of change what our standards of care are as well as our health policy. This is until drugs and behavior and how do we get -- diagnose diseases or injuries. And of course how we treat them. Therapeutic means can be. One of the things is to be careful in terms of what are the risks of unapproved clinical trials. So as Kim mentioned some of the risks of stem cells there is also risks for other in general in terms of unapproved clinical trials and specifically when we look at stem cell and stem cell replacement it is very easy. Very easy procedure to reproduce those cells. Universal there is some untremulous clinics out there looking at offering this type of treatment that is really not a valid treatment in terms of providing evidence for the benefits of the procedures. So and be aware what the risks are unapproved trials. And

increased long lasting pain and muscle spasticity. Loss-of-function. A very big risk and you can increase your disability. And there is complications that is the role of the FDA and the US and other regulatory agencies but also and really requiring the evidence to minimize those types of medical complications that can happen as well as that. That is the important role. Of the regulatory agencies. Also risk of health insurance and coverage in case of a complication it happens if it is unapproved trinal trial. Also exclusion from any future spinal cord injury clinical trials as well. So just because you join unapproved trial you -- that might exclude you from going into another trial later on. L might be some unscrupulous clinics and that created what we call stem cell tourism. We want to make you aware of how to pull out some of these or beware if I have a question whether it is a case of stem cell tourism. So what is that? It is really a stem cell tourism or medical. Travel for the purchase of unproven stem cell therapies. And these unproven treatments hold significant risks that we just went over. There is also no evidence yet that those stem cells have a reparative effect on chronically damaged stem cell tissue. Kim mentioned these trials are early stations and trying to gather that evidence to see if it does actually have a comparative affect. And, so, that is one of the key things and we go into some of the questions to point out as well to ask to see if it is a valid trial. One of the biggest area to snuff out whether it is valid or not or tourism it is unethical to charge people money for any unproven risk medical intervention. So if you or your family member or friends are being asked to pay for an experimental treatment, it is probably not a clinical trial. That is one of your biggest barrier red flag to walk away from that treatment or go away from that treatment if you will. Also be very aware of trying to sell hope for money. We have been in

wheelchairs for a long time post spinal cord injury. Really you want to be on guard. Terms of people trying to sell you we want to be secured and with we were before our injury. But also be aware which is another red flag when it comes to types of treatments because if there is no oversight meaning there is no follow-up after the treatment. As well as if there is no reporting afterwards. Those are just two other key red flags to be aware that those are not valid or not true clinical trials. There are serious questions to be aware of that you should ask if -- for any clinic or any treatment that you're looking into. Again you should not be concerned or to be aware of what you're getting yourself and your body into. What the procedures and what are the expenses. Key question is to ask what is actually being studied. So, for instance, when Kim went over those clinical trials they went over exactly what type of cell that they're using. And how they are studying. And you also want to ask the key questions to the researchers to the investigators of why do they believe that this intervention is being tested. That is actually affective. So that means that they have done some pre-research before they're going into the human into you being a participate and you want to be able to know what that evidence is that they have looked at. They want to understand the risks and side affects that might come into it and any benefits of those trials that they have compared with other treatments. So we call this comparative studies because as you may have seen in some of the trials that Kim talked about they said there might be three cohorts. That means there is three different groups that they're looking at and compare how the effects happen. For compared to those who have not and try to keep them into those -- into the comparative studies to see what impact there may have been. And so it is key question to ask. What are also again

understand what your out-of-pocket expenses are and out-of-pocket costs will be. Always make sure that you ask that as a very direct and pointed question. How will they do that again in are they going to split into it cohort and placebo and how they compared that to see if the treatments they are studying are going to be affective safe and efficacious. And there is a document out there and give you the link to this at the end of the presentation. And kind of a checklist criminal trials human studies. We mention a lot of clinical trials are listed on clinicaltrials.gov but that does not preclude you and something that you want to be involved in this. Checklist is a great tool to be able to use. So splits these questions into categories. So, for instance, safety, what your possible benefits might be, what the clinical trial protocol is which means what are the procedures that you will be going through when you enter into this clinical trial. And some of the other questions are payments and costs which we mentioned earlier. The participation and other trials. How that will impact you. And also any of the preclinical or prior clinical evidence that they have. And again some of the key questions of how they came to the point where they're going to start trying this treatment in humans. Finally, an independent a testament of the treatment and the investigator to look into their backgrounds to see what experience they have in terms of working with these types of interventions and also working with people with spinal cord injuries or other conditions if that is what you're looking for. So that questionnaire is actually is available in this document called experimental treatments for stem cell injury. It is available in version 2. It is what you should know about experimental treatments so that document actually doesn't only just go into clinical trials but it goes into other treatments as well. That booklet is downloadable on this link. Available on the Miami Project website.

Also available on the ISCOS, or International Spinal Cord Society which is a collaboration between researchers and clinicians from around the world that are all working on spinal cord injury research and spinal cord injury interventions. Those are two great resources that you can use. We've also mentioned clinicaltrials.gov and some of those trials Kim went over gave you a specific number you can look up to be able to find more about those trials. Also to look into some of the other trials that are existing out there in the world. Now, again, we went over the questions that you should answer just because a trial is listed on clinicaltrials.gov does not preclude you of doing the homework. Going through the checklist to make sure that that trial is right for you. That concludes our presentation about break through stem cell therapies. Here is the contact information for Dr. Kim Anderson Erisman as well as the contact information for myself. I believe we've left some time to be able to answer some of the questions that might be out there. So we would like to hand it back over to Bill to see what type of questions we can answer from our audience.

>> Bill: Excellent, Jen and Kim. We do have some questions that have rolled in. We'll get right to them. One of them I believe you addressed pretty well at the time of the question. It was before you started addressing it and it is. What is your take on going to Panamá for stem cell therapy? I believe that there was a large fee involved with this. If I'm correct in this.

>> Kim: I can tell you a little bit about that because the Miami Project actually a few years ago was trying to communicate with the people in Panamá and see what they were doing and tried to find out look at their records and things like that. And they're not really using very characterized stem cell type. They're really looking at taking [NAME] stem

cell that I mentioned which you can get from a bone marrow biopsy. And they were injecting them into the veins intravenously or intrathecally into the fluids surrounding the spinal cord but the data for those stem cells is really only for early after injury to try to reduce the inflammation and they were giving these to people with chronic injury with many different types of injuries and -- and they were charging people several thousand dollars. So I would fought recommend anyone to go do that. In Panamá or anywhere else that were doing a similar thing as that.

>> Bill: Thank you Dr. Anderson-Erisman for directing answering that question. Next question, after what number of years do you think any of this would not benefit a para or quadriplegic? Is there is number of years that presents a time window for any and all stem cell trials or does it depend on trial?

>> Jennifer: I'll try to address it and Kim you can chime in as well. It really depends on the trial. Some of the trials for instance that Kim mentioned are looking at very early post injury. Some are looking at chronic. So the type of intervention that they're looking for really depends on what the trial actually is and how they define the parameters around it meaning exclusion and inclusion criteria. There is no defined date if you will for a number of years post injury that is very specific of whether it will benefit or not. Kim, I'm sure you want to add to that.

>> Kim: Yeah, I'll just add a little bit. The two trials that aisle mentioned that were in chronic injury they were going out to one or two years. I think that is the state of the field right now. We're slowly feeling more comfortable because we're doing more clinical trials and so we're getting more safety information so we're slowly expanding out the time window that we can go chronically. One of the biggest things that might preclude

is you that, you know, if you had some kind of complication in your spinal cord with a number of things post injury some people develop problems and that might be something that would prevent you from being in a trial depending on how the trial is designed. But just having the length of time is going to continue to expand out further and definitely the more that we learn about interventions trying to deal with the scar tissue as well, that is certainly going to be.

>> Bill: Thank you both in this case I have a couple of notes from the consumer. In this case it is a person who has been quadriplegic for approximately 27 years if that help with any background. Another question also do you know of any trials related to relief of pain in a person with a spinal cord injury? In other words, neuropathic no other pain related to the spinal cord injury. Any stem cell trials related to that?

>> Kim: Stem cell trials specifically focusing on pain. I'm not aware of. But all of the trials that I mentioned are evaluating pain as one of their measures because they're evaluating a lot of pain. Jen, are you aware?

>> Jennifer: I'm not aware of stem cell trials that specifically target pain. In the technology world there is quite a bit in terms of researching and also new devices that are coming out that are working on pain. As well as neuropathic pain. But so those -- that is definitely being addressed outside of the -- outside of a clinical trial. So I think it is more in the device world than you will see in the stem cell world.

>> Bill: Thank you both. And by the way, to remind that our resource center staff is happy to address pain related issues like this. We do have some resources if it gets into the technical expertise of miss French or Dr. Anderson Erisman we can draw upon their expertise if you have specific questions we can help with, don't hesitate to contact the resource

center. The next question for you, any thoughts on the BBC reporting on the case of Derrek Pidicka. I believe he is the Polish patient in London, England, being treated with olfactory transport. Just in the news.

>> Kim: I didn't you that was going to come up. The news has very exciting information about that. But I think that we all know to be careful about what we interpret from the news. What he had done is based on preclinical data. Based on environmental anal data and he got several different things done at once kind of. So he had a very aggressive rehabilitation program that he did for several months prior to his transplantation and then for several months after his transplantation. That is one. But then he had a portion of his nose cell which are actually coming from the olfactory bulb and taken out and cultured and tissue processing facility for a couple of weeks and getting a specific type of olfactory stem cell. Kind of like support cell basically. He had those transported into his spinal cord and at the same time, they took some segments of one of the nerves in his ankle and created a little bridges across the injury site in its spinal cord. Then they put the olfactory cells on either end of that. In addition, they cut away a lot of the scar tissue. That is a little controversial. And then one other characteristic of his injury was somewhat uncommon to the majority of spinal cord injury type. It was a big impact on the spinal cord. And he actually had a stab wound that was a very clean wound if you could consider it. It had a very small area of distance between the two injured ends of the stem cell. And so it didn't -- I didn't have a very big gap that it to do go across is what I'm trying to get to. I did they are thinking about enrolling in more people and it is important to see what is the result of that. The result are of this case study are actually being published in a reputable scientific journal so that is

good. It gives us information in that way. To each individual.

>> Bill: The next question is hopefully we have time for a couple of more here. There are international stories about stem cell research overseas using adult stem cell from a patient's nasal cavity. The reason we have not seen more research in this area is because there is not a cell line being created that a company can make lots of money off of. Are there any way to promote such research here in the US?

>> Kim: Reason why they cannot create a cell line it is otologies. We did not go much into that but those have a whole other set of pros and cons. And there is research that is being done in the US and in Canada and in Australia and other countries that is -- are investigating those types of cells. And I think that it will take academic university medical centers for clinical trials rather than accompany.

>> Bill: Unfortunately we're not able to take any more questions. There are a couple of questions remaining. Any remaining questions please consider directing them to Jennifer French or Dr. Anderson-Erisman directly to get your answer. On behalf of national spinal cord injury association, I would like to thank miss Jennifer French and Dr. Anderson Erisman so much follow sharing their personal experience and professional knowledge with us today on breaking news in stem cell therapy breakthroughs. Our next two webinars will be VA benefits for veterans dependents and Thursday, November 6 at 3:00 p.m. until 4:00 P.M. followed by veterans disability compensation appeals. Thursday November 20th. At 3:00 p.m. to 4:00 P.M. those are eastern time. To sign up and receive our webinar newsletter, visit us at www.spinalcord.org. Check out our "New Mobility" magazine which covers everything active wheelchair users need to know. Visit

www.newmobility.com to see what we're all about. Jen and Kim, thank you so much for your participation today. Your presentation. This now concludes presentation of the National Spinal Cord Injury Association.

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