

Working²Walk

Educating our Community - Engaging the Science



Photo credit: Tyler Croat

Science & Advocacy Symposium (Virtual)
October 22 - 24, 2020

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THIS YEAR'S APPROACH

Working 2 Walk 2020

The core focus of our Symposium is to bring those of you from the SCI community into the movement for curative interventions. We feel that advocating effectively in this space requires a three-pronged approach.

- We should strive for a broader understanding of our **Context** (educating ourselves on where the science has been, where it is now, what exactly is being done, and who is doing it),
- so that we can develop the most effective **Strategy** (built upon a solid and broad grasp of the Context)
- which allows us to have a more effective **Voice** (collaborative, coordinated and united) with which to advocate for curative therapies.

Working 2 Walk is organized around the above approach. Our intention is to stimulate a rich dialogue amongst the panelists who represent the key pillars of the SCI landscape: basic research, clinical research, clinical practice, industry and advocacy. Specifically, how each of us define a “win” and how we can strategize together to achieve a more coordinated effort.

We've grouped each session of this year's agenda in the following way:

- **Pre-Clinical Research:** broadly defined as research done in laboratory experiments and animal models
- **Clinical Research:** research performed with humans
- **Funders:** agencies or foundations that fund research of all kinds

- **Industry:** companies that are trying to bring a research discovery to a clinical product
- **SCI Advocacy:** SCI foundations/nonprofit organizations working to influence all the above stakeholders

Each session will deliver presentations from these leaders in each of those 5 core areas. We'll conclude with a panel discussion of representatives from these areas to explore this strategy question: **how can we structure this work so that everybody wins? And how can we in the SCI community work with our partners to achieve success?**

We need all of your voices in this conversation. So think about our approach and then come prepared to speak up. We have built in plenty of time to facilitate constructive conversation.

Finally, we realize that this work is demanding and difficult. It's easy for all of us to sometimes lose sight of the fact that we are a community of people with injuries and those that love them, those who research and treat SCI, and those who want to help us reach our goal. So, we've added 6 conversations with artists from within our community to remind us of what we can and will do together.



SCHEDULE OF EVENTS

THURSDAY, OCTOBER 22, 2020

Stakeholder Session 1: Clinical Research *Research performed with humans*

10:00-10:50 am

Exhibitor Visits & Networking

11:00-11:05 am

Opening Remarks & Welcome
Matthew Rodreick | Unite 2 Fight Paralysis

11:05-11:20 am

Regenerative Medicine: A Novel Autologous Cell Matrix Therapy Approach for Spinal Cord Injury
Stephana Carelli, PhD | University of Milan

11:20 -11:35 am

Exercise after SCI: Evidence for Health Benefits and The Need for More Research
Leslie Morse, PhD | University of Minnesota

11:35-11:50 am

Adipose-Derived Mesenchymal Stem-Cells (ADMSCs) for Patients with Traumatic Spinal Cord Injury (SCI)
Mohamad Bydon, MD | Mayo Clinic

11:50-12:20 pm

Panel Discussion with Question & Answer Session
Stephana Carelli, PhD | University of Milan
Leslie Morse, PhD | University of Minnesota
Mohamad Bydon, MD | Mayo Clinic
Christel Mitrovich | Unite 2 Fight Paralysis - Moderator

12:20-12:35 pm

Artist Interlude: Richard Bell | Painter

Stakeholder Session 2: Pre-Clinical Research *Research done in laboratory experiments and animal models*

12:35-12:50 pm

Using Dogs to Hunt Down Translational Obstacles in Spinal Cord Injury Research
Nicholas Jeffery, PhD | Texas A&M

12:50-1:10 pm

Degrading the Glial Scar to Promote Regeneration after Traumatic Spinal Cord Injury
Molly Shoichet, PhD | University of Toronto

1:10-1:25 pm

**Accelerating Translation with Porcine Models of Spinal Cord Injury:
An Invitation to Collaborate**

Candace Floyd, MS, PhD | University of Utah

1:25-1:55 pm

Panel Discussion with Question & Answer Session

Nicholas Jeffery, PhD | Texas A&M

Molly Shoichet, PhD | University of Toronto

Candace Floyd, MS, PhD | University of Utah

Sasha Rabchevsky, PhD | Unite 2 Fight Paralysis - Moderator

1:55-2:10 pm

Artist Interlude: Eric Howk | Grammy Award Winning Songwriter and Musician

2:10 -2:15 am

Wrap Up

2:15-3:30 pm

Exhibitor Visits & Networking

FRIDAY, OCTOBER 23, 2020

Stakeholder Session 3: Industry

Companies that are trying to bring a research discovery to a clinical product

10:00-10:50 am

Exhibitor Visits & Networking

11:00-11:05 am

Opening Remarks & Welcome

Matthew Rodreick | Unite 2 Fight Paralysis

11:05-11:20 am

The RESET Trial. Phase 1/2 Evaluation of the Safety, Pharmacokinetics, and Efficacy of AXER-204 in Patients with Chronic SCI.

George Maynard, PhD | ReNetX Bio

11:20 -11:35 am

The Up-LIFT Study – A Pivotal Trial Intended to Demonstrate the Benefits of Non-Invasive Electrical Spinal Stimulation Therapy in People with Neurological Deficit Following Spinal Cord Injury

Candy Tefertiller, PT, DPT, PhD, NCS | Craig Hospital

11:35-11:50 am

KCC2: Triple-Edged Sword for Paralysis, Neuropathic Pain and Spasticity

Joanna Stanicka, PhD | AXONIS Therapeutics, Inc.

11:50-12:20 pm

Panel Discussion with Question & Answer Session

George Maynard, PhD | ReNetX Bio

Candy Tefertiller, PT, DPT, PhD, NCS | Craig Hospital

Dave Marver, MBA | GTX Medical

Joanna Stanicka, PhD | AXONIS Therapeutics, Inc.

Traci Fernandez | Unite 2 Fight Paralysis - Moderator

12:20-12:35 pm

Artist Interlude: Ben Leclair | Videographer

Stakeholder Session 4: Funder

Agencies or foundations that fund research of all kinds

12:35-12:40 pm

Introduction & Explanation

Matthew Rodreick | Unite 2 Fight Paralysis

12:40-12:55 pm

Spinal Cord Injury Research: In, Across, and Beyond the NIH

Linda Bambrick, PhD | National Institute of Neurological Disorders & Stroke

12:55-1:10 pm

The Spinal Cord Injury Research Program – Engaging the SCI Community throughout the Research and Development Process

Melissa R. Miller, PhD | U.S. Army Medical Research and Development Command

1:10-1:25 pm

Creating A Roadmap For Spinal Cord Injury Cures

Jay Shepard | Christopher & Dana Reeve Foundation

1:25-1:40 pm

BEAT PARALYSIS: Together, We Can Get This Done

Jack Jablonski | Jack Jablonski Believe in Miracles Foundation

1:40-2:10 pm

Panel Discussion with Question & Answer Session

Linda Bambrick, PhD | National Institute of Neurological Disorders & Stroke

Melissa R. Miller, PhD | U.S. Army Medical Research and Development Command

Jacqueline Roche, MS | Congressionally Directed Medical Research Programs

Jay Shepherd | Christopher & Dana Reeve Foundation

Jack Jablonski | Jack Jablonski Believe in Miracles Foundation

Sam Maddox | Unite 2 Fight Paralysis - Moderator

2:10-2:25 pm

Artist Interlude: Freaque | Musician

2:25-2:30 pm

Wrap Up

2:30-3:30 pm

Exhibitor Visits & Networking

SATURDAY, OCTOBER 24, 2020

Stakeholder 5: SCI Community & Organizations

SCI foundations/nonprofit organizations working to influence all the above

10:00-10:50 am

Exhibitor Visits & Networking

11:00-11:05 am

Welcome & Opening Remarks

Matthew Rodreick | Unite 2 Fight Paralysis

11:05-11:20 am

Research and Advocacy in Australia

Perry Cross, AM | Perry Cross Spinal Research Foundation

11:20-11:35 am

Micro-level to a Macro-picture: From Minimal Functional Recovery to a Cure - What Can We Do?

Corinne Jeanmaire | endParalysis Foundation

11:35-11:50 am

North American SCI Consortium: Connecting the SCI Community

Kim Anderson-Erisman, PhD | North American SCI Consortium

11:50-12:20 pm

Panel Discussion with North American SCI Consortium

Perry Cross, AM | Perry Cross Spinal Research Foundation

Corinne Jeanmaire | endParalysis Foundation

Kim Anderson-Erisman, PhD | North American SCI Consortium

Barry Munro | Unite 2 Fight Paralysis - Moderator

12:20-12:35 pm

Artist Interlude: Jesse SiNZ | Graffiti Artist

Stakeholders 1-5: Strategy for Success

Representatives from the 5 areas above will explore opportunities for improving strategic collaboration

12:35-1:05 pm

Panel Discussion

Murray Blackmore, PhD | Marquette University

John Reilly | Jack Jablonski Foundation

Joanna Stanicka, PhD | AXONIS Therapeutics, Inc.

Rebecca Martin, OTR/L, OTD, CPAM | Kennedy Krieger Institute

Corinne Jeanmaire | endParalysis Foundation

Matthew Rodreick | Unite 2 Fight Paralysis - Moderator

1:05-1:35 pm

Question & Answer Session

1:35-1:50 pm

Artist Interlude: Reveca Torres | Multimedia Artist

1:50-2:00 pm

Closing Remarks

Matthew Rodreick | Unite 2 Fight Paralysis

2:00-3:00 pm

Exhibitor Visits & Networking

END OF CONFERENCE

CONFERENCE Tips

SPONSOR EXHIBITORS

Our sponsors help make Working 2 Walk possible - they also provide a tremendous array of resources, services and products for the SCI Community. Several of our sponsors will be available via our Virtual Exhibit Hall. Just click on the sponsor name to access their virtual exhibit space, where you can:

- Download sponsor information
- Watch promotional videos provided by select sponsors
- Converse with select sponsors via live chat

Please take a moment to stop by the Virtual Exhibit Hall and learn more about their unique offerings for our Community.

NETWORKING & DISCUSSION ROOMS

We've provided a Breakout Zoom Room where our attendees can participate in several Open Forum or Stakeholder-focused video discussions with one another, both before and after the Symposium.

GET CONNECTED



Twitter: @W2W_U2FP - #Working2Walk2020



Facebook: www.facebook.com/Unite2FightParalysis/



Instagram: @u2fp

A WELCOMING SPACE

Unite 2 Fight Paralysis is committed to creating a welcoming event. We seek to create an environment where everyone feels encouraged to participate. Please help us to nurture a space where we all feel included and where civility grows. Be sure to email the U2FP staff (conference@u2fp.org) if you hear or see anything that needs our attention. Thank you!

SPEAKER BIOS

A first-class line up of presenters from across the Scientific & Advocacy communities



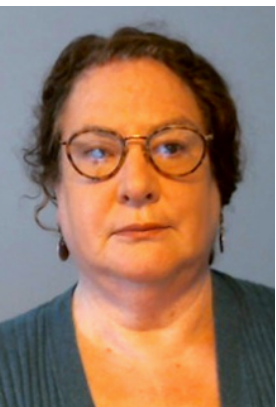
Kim Anderson-Erisman, PhD | *President, North American SCI Consortium*

Dr. Anderson-Erisman is the current President of the North American SCI Consortium (NAS-CIC). She is also a Professor in the Department of Physical Medicine and Rehabilitation at the MetroHealth Medical Center and Case Western Reserve University (CWRU) School of Medicine, Associate Director of the Institute for Functional Restoration, and Director of the Northeast

Ohio Regional Spinal Cord Injury (SCI) Model System based at the MetroHealth Rehabilitation Institute. She has lived with a cervical spinal cord injury for 31 years. Her research focuses on translational investigations and bridging the gap between basic science, clinical science, and the public community living with SCI. At MetroHealth-CWRU she is continuing her involvement in clinical trials with the team pursuing implanted stimulation devices for SCI and further developing her independent research efforts addressing issues important to people living with SCI with an emphasis on translational research to deploy treatments to the clinic.

Linda Bambrick, PhD | *Program Director, Division of Neuroscience in Extramural Programs, NINDS*

Dr. Bambrick is a Program Director in the Division of Neuroscience in Extramural Programs at the National Institute of Neurological Disorders and Stroke (NINDS) in the NIH. She manages a portfolio of grants and cooperative agreements in the areas of spinal cord injury, peripheral nerve injury, and axonal regeneration. Prior to joining the NIH, Dr. Bambrick served as a Program Manager at the Department of Defense leading the Spinal Cord Injury Research Program (SCIRP). In both positions her work has involved engagement in program priorities, application receipt and award management, and promoting coordination across funding entities supporting spinal cord injury research.



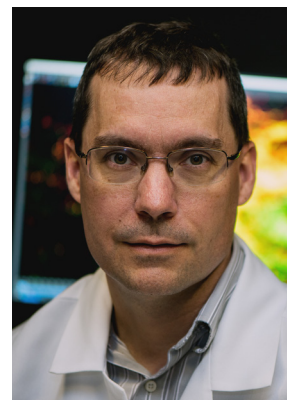
Richard Bell | *Painter*

There is much more to Richard Bell than his spinal cord injury which he suffered as a result of a motor vehicle accident in 2002. Although this tragic event left him a quadriplegic, it also resulted in him being an accomplished artist. The transformation from charcoal to paint was encouraged by his late and great uncle, Raymond Howell. Recognizing his talent from looking at his charcoals, Mr. Howell decided to mentor Richard in 1996. Later, during his recovery Richard began to experiment with applying his subjects to canvas in different ways. In a short amount of time, Richard had enough work to start entering into shows. He won his first award at the Beverly Hills artSHOW in 2016. He was then awarded a full scholarship to the Vermont Studio Center in the summer of 2018. Richard's work is on display in galleries and private residences internationally.



Murray Blackmore, PhD | *Associate Professor, Department of Biomedical Sciences, Marquette University*

Dr. Murray Blackmore received his undergraduate degree from Stanford University, and his graduate degree in neuroscience from the University of Minnesota. During his postdoctoral training at the Miami Project to Cure Paralysis, Dr. Blackmore studied axon regeneration and adopted High Content Screening methods to identify new gene targets to promote neural repair. Later, as a Research Assistant Professor at the Miami Project, Dr. Blackmore used a gene therapy approach to test these new gene targets for the ability to promote axon regeneration in the injured spinal cord. Dr. Blackmore is continuing this line of research at Marquette University, using viral delivery of genes to injured neurons in rodent models of spinal injury in order to foster repair.





Mohamad Bydon, MD | *Neurosurgeon & Medical Director of the Neurosurgical Registry, Mayo Clinic*

Dr. Mohamad Bydon is a neurosurgeon at Mayo Clinic in Rochester, Minnesota. He holds the academic rank of Professor in three Departments: Neurosurgery, Orthopedic Surgery and Health Services Research. He specializes in complex spinal surgery and spinal oncology as well as minimally invasive approaches. Dr. Bydon is Principal Investigator of the Mayo Clinic Neuro-Informatics Laboratory, which is leading

the CELLTOP Trials on the use of stem cells in spinal cord injury.

Stephana Carelli, PhD | *Group Leader, Pediatric Research Center, Department of Biomedical and Clinical Sciences, University of Milan*

Stephana Carelli is a group leader at the Pediatric Research Center "Romeo ed Enrica Invernizzi" foundation, Department of Biomedical and Clinical Sciences, University of Milan, Italy. She served as aggregate professor of pharmacology at the faculty of medicine, University of Milan. Her current research interests include: (1) role of RNAs in epigenetic mechanisms and functions in neurodegeneration/regeneration and in the programming and re-programming of stem cells fate; (2) regenerative medicine for curing neurodegenerative diseases such as spinal cord injury and Parkinson's disease, focusing on both cell therapies (adult mouse neural stem cells and human mesenchymal stem cells) and on the neuroprotective action of erythropoietin; (3) application of advanced cell manipulation technologies in regenerative medicine. Dr. Carelli has co-authored many publications and holds one patent in this field.



Perry Cross, AM | *Executive President and Founder, Perry Cross Spinal Research Foundation*

Perry Cross AM, broke his neck in a rugby accident that changed his life forever, 26 years ago. At the age of 19 he was severely injured in a rugby union tackle and told he would never walk again. Paralyzed from the neck down, relying on a ventilator to breathe and requiring 24/7 medical care, Perry quickly had to adapt to the profoundly difficult and devastating situation. Perry was left a C2 ventilated quadriplegic. Amidst the heart-break, terrible grief and pain somehow Perry carved out a new lease on life and within a few years, became one of the world's most inspiring motivational speakers and spinal research advocates – with one mission, to find a cure for paralysis. He has since dedicated his extraordinary life to helping others by raising millions of dollars for medical research and increasing the awareness of spinal injuries through his Foundation, The Perry Cross Spinal Research Foundation.



Dr. Candace L. Floyd, PhD | *Associate Professor and Vice Chair for Research in Physical Medicine and Rehabilitation, University of Utah*

Dr. Floyd is an Associate Professor and Vice Chair for Research in Physical Medicine and Rehabilitation at the University of Utah. Dr. Floyd's research focuses on the use of porcine models of traumatic brain injury, spinal cord injury, and neuropathic pain to advance discoveries and translation in preclinical research. She is a certified Good Laboratory Practice (GLP) professional. Dr. Floyd serves as a Councilor and co-Chair of the Communication and Outreach Committee for National Neurotrauma Society. She also has previously served as President, Vice President, and Security/Treasurer of that Society. She has served on the Program Committee for the Society for Neuroscience. Dr. Floyd currently serves as the Treasurer and Board Member for the Brain Injury Alliance of Utah. Dr. Floyd has received numerous awards, including the UAB Graduate Dean's Outstanding Mentorship Award. She is actively engaged in efforts to increase inclusivity and founded the National Neurotrauma Diversity Fellowship Program.



Freaque | *Musician*

Freaque is for the derelicts, the heretics, the tree stumps, and those who live on the fringes of society. A tattered voice, made of strung out words, hung to dry over broken chords on his mother's piano.

"Broken Puppet" was created in his childhood dining room, on the piano he played for 11 years before a spinal cord injury took away his hands. In a wooden womb of darkness, he took what he had and rose above a society that constantly tells us we are not enough, that we're only worth the possessions we own, the money in our bank accounts, and our body's abilities.

His music is also used as the soundtrack for his production, *A Cripple's Dance*, a live music and dance production created and performed by people with Spinal Cord Injuries and abled bodies.



Eric Howk | *Grammy-Award Winning Songwriter and Musician*

Eric Howk is an Alaskan born, Pacific Northwest based songwriter, multi-instrumentalist, producer, touring musician and entrepreneur. He has been a T-4 level complete paraplegic since 2007, and since that time he has performed at thousands of shows in hundreds of cities internationally. He has more than 20 gold and platinum certified album sales from all over the globe, with over one billion verified radio spins.

In 2017, at the 60th annual Grammy awards, he was nominated for the Portugal. The Man song *Feel It Still*, and won a Grammy for 'Best Pop Duo/Group Performance'. He has been featured on *The Tonight Show*, *Late Night with Conan O'Brien*, *The Ellen DeGeneres Show*, *Good Morning Britain*, *The Today Show*, and *The American Music Awards* among others, while appearing on the soundtracks of over 50 major productions. He has no cats.



Jack Jablonski | *Jack Jablonski Foundation*

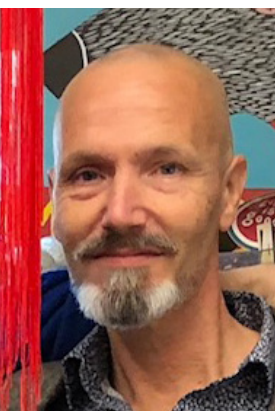
In December 2011, at age 16, Jack Jablonski was hit from behind during a high school hockey game. The resulting injury (C5) left him with complete paralysis below the shoulders. Jack graduated from the Annenberg School at USC in 2019. He lives in Los Angeles and works with the NHL's LA Kings as a communications coordinator where he also hosts a podcast and works as a radio analyst. Recently, he started coaching the LA Kings U14 Junior Hockey Team. Inspired by Jack's determination to "skate again," volunteers established the Jack Jablonski BEL13VE in Miracles Foundation in 2012, on the first anniversary of his injury, to support research that will advance recovery for everyone living with a SCI. Last year the foundation dropped 'Believe in Miracles' from its name because the miracle we once hoped for has become the science we believe. Paralysis is no longer permanent; recovery is possible.



Corinne Jeanmaire | *Founder, endParalysis Foundation*

Corinne Jeanmaire sustained a complete spinal cord injury (T10) as a consequence of a car accident in 2001. Since 2014, after a career in the field of Purchasing and Sustainability Management, she has dedicated all her productive time to help find a cure for chronic spinal cord injury, and created the endParalysis foundation. The foundation (www.endparalysis.org) focuses on accelerating research towards curing chronic SCI through funding targeted research projects and through promoting an integrative, collaborative and goal-driven approach in SCI research. Corinne participates in various cross-functional taskforces aiming at accelerating research towards SCI recovery and works in close co-operation with various other organizations worldwide. She has also been actively contributing to the establishment of the new website, www.scitrials.org, which provides lay information for patients and their families to search, locate and better understand all clinical trials potentially applicable to them.





Nicholas Jeffery, PhD |
Professor, Neurology & Neurosurgery, College of Veterinary Medicine, Texas A&M University

Nick Jeffery qualified as a veterinarian from the University of Bristol (UK) and has a PhD in Neuroscience from the University of Cambridge (UK). At various times, Nick has worked as a full-time veterinary clinician, a laboratory scientist and as veterinary school faculty, including investigation and treatment of spinal cord injury in dogs for more than 30 years. In 2013,

he attained a Master's degree in Clinical Trial design and analysis from the University of London (UK). Nick has recently completed two clinical trials on novel therapies for spinal cord injury in which dogs were models for the condition in humans. He is currently Professor of Neurology & Neurosurgery in the College of Veterinary Medicine at Texas A&M University. His current research interest is the reliability and reproducibility of laboratory investigations and translation of interventions from laboratory to clinic.



Ben Leclair | Videographer

Ben Leclair is a 27-year-old former professional wakeboarder from Quebec, Canada.

He is currently a videographer and brand ambassador for Amysystems wheelchairs, the Wings for Life Foundation, and O'NEILL.

Ben sustained a spinal cord injury in November 2016 in Florida. He was diagnosed a c3 complete quadriplegic. He's been working hard on his rehab ever since and has made significant improvements, giving him the chance to get back to video editing and slowly

back to filming. In addition to filming and editing videos for a living, Ben also works in marketing and research development with Amylior to help improve quality of life for power wheelchair users.

Rebecca Martin, OTR/L, OTD, CPAM |
Manager Clinical Education and Training, International Center for Spinal Cord Injury (ICSCI), Kennedy Krieger Institute

Dr. Rebecca Martin is the Manager of Clinical Education and Training at the International Center for Spinal Cord Injury (ICSCI) at Kennedy Krieger Institute and an Assistant Professor at the Johns Hopkins School of Medicine in the Department of Physical Medicine and

Rehabilitation. Dr. Martin received her Bachelors of Science from Boston University in 2001 and her Occupational Therapy Doctorate from Rocky Mountain University in 2008. As the Manager of Clinical Education and Training, she is responsible for program development, staff training, and oversight of the clinical research program. Dr. Martin speaks nationally on topics related to Activity-Based Rehabilitation; she has taught many continuing education courses in the areas of neurological pathology, rehabilitation, and research. Her current research is in novel applications of electrical stimulation to restore functions lost to spinal cord injury.



Dave Marver, MBA | Chief Executive Officer, GTX Medical, BV

Dave Marver is CEO of GTX Medical, BV. He is an accomplished chief executive with a broad range of experience gained leading public, private, and emerging companies in the US and Europe. He has sector expertise in medical technology, wearables, consumer technology, and health monitoring. Mr. Marver is also an experienced board member with multiple successful exits under his governance. Dave spent almost 15 years with Medtronic in a variety of leadership positions around the world. Representative roles included VP Sales for Medtronic's Cardiac Surgery business, VP Marketing and interim Business Unit Leader for Medtronic's CRM business in Europe, and VP Strategy for Medtronic's Diabetes business. Later, Dave served as CEO for Cardiac Science Corporation, a NASDAQ-listed company with 600 employees that was #2 in the world in AEDs and #1 in the US in stress test treadmills. He then founded and ran a high-profile sports technology start-up, raising \$90M and developing two TIME Magazine Inventions of the Year. Dave has been an advisor to the World Bank's International Finance Group and a member of the Health Industry Distributors Association Board of Directors and Duke University's Health Sector Advisory Council. He has guest lectured at the graduate business schools for Duke University, University of Washington, and University of California at Los Angeles. Dave earned a BA from Duke University and an MBA from University of California at Los Angeles.



George D. Maynard, PhD | *President & Chief Scientific Officer, ReNetX Bio, Inc.*

Dr. George D. Maynard has over 29 years of pharmaceutical and biotechnology research and development experience spanning new drug discovery, preclinical, and clinical development. His efforts have advanced new therapeutics for the treatment of disorders of the central nervous system, respiratory diseases, metabolic diseases, and immunologic disorders and include development of small

molecules and protein therapeutics. Dr. Maynard currently serves as President and Chief Scientific Officer for ReNetX Bio Inc. Prior to joining ReNetX Bio, Dr. Maynard served as Vice President of Early Development for Neurogen Corporation. He has conducted discovery research at Hoechst Marion Roussel and DuPont. Dr. Maynard earned his Bachelor of Science degree in chemistry from Marietta College and his PhD in organic chemistry from Ohio State University.



Melissa R. Miller, PhD | *Program Manager, Spinal Cord Injury Research Program, Congressionally Directed Medical Research Programs*

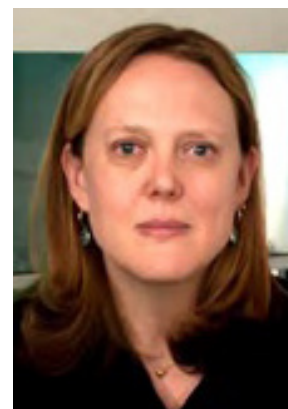
Dr. Miller currently serves as the Program Manager for the Spinal Cord Injury Research Program, Congressionally Directed Medical Research Programs (CDMRP), U.S. Army Medical Research and Development Command. She previously served as Science Officer for both the Spinal Cord Injury Research Program, as well as the Peer

Reviewed Cancer Research Program within CDMRP. Dr. Miller attended Seton Hall University where she earned a Bachelor of Science degree in biochemistry. She holds a PhD in Cellular and Molecular Medicine from the Johns Hopkins University School of Medicine, received in 2012, where she identified novel small molecule modulators for ion channel targets. She completed a post-doctoral fellowship in physiology examining the role of ion channels in human fertility and reproduction at the University of California, Berkeley.



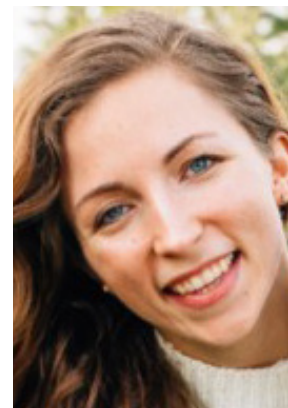
Leslie Morse, MD, DO | *Department Head, Department of Rehabilitation Medicine, University of Minnesota*

Dr. Leslie Morse, DO, is Chair and Professor in the Department of Rehabilitation Medicine at the University of Minnesota School of Medicine. Her research, as well as her clinical focus, is the care of individuals with SCI, with a long-term goal of developing mechanism-based therapies to prevent and treat secondary health complications after injury. To that end, she is studying the impact of exoskeleton-assisted ambulation on bone health, neuropathic pain, and quality of life after SCI (a clinical trial supported by the Department of Defense). Dr. Morse completed her medical training at the University of New England and her residency in PM&R at Boston Medical Center. Author of more than 80 publications, she has received several national best-paper awards and presented her work nationally and internationally. Dr. Morse's research interests include spinal cord injury and osteoporosis, neuropathic pain, therapies for bone health in SCI, health benefits of exercise in SCI, and biomarkers of neurological recovery.



Jacqueline Roche, MS | *Consumer Reviewer Administrator/Patient Advocate, Department of Defense Congressionally Directed Medical Research Programs*

Jacqueline serves as the Consumer Reviewer Administrator (CRA) from General Dynamics for the Spinal Cord Injury Research Program, Congressionally Directed Medical Research Programs, U.S. Army Medical Research and Development Command. As a CRA, she coordinates consumer reviewer involvement. Consumer reviewers act as lay experts on their disease, injury, or condition, bringing their experience and perspectives to the evaluation of research grant proposals.





**Jay Shepard | *Chairman,
Christopher & Dana Reeve
Foundation***

Jay Shepard served as Executive Chairman of Versartis, Inc., since early 2014. In May 2015, Mr. Shepard joined Versartis, as President and CEO. In 2018 when Versartis merged with Aravive, Mr. Shepard became CEO of the newly formed company until January of 2020 when he retired. Mr. Shepard was an Executive Partner at Sofinnova Ventures until May 2015. He has over 35 years experience in the

pharmaceutical, biotechnology and drug delivery arenas. Previously he served as President and CEO of NextWave Pharmaceuticals (acquired by Pfizer), Ilypsa (acquired by Amgen), and interim CEO of Relypsa (Ilypsa's spin-out company, which was acquired by Galenica). Mr. Shepard has participated in or led over 16 product launches by preparing markets and establishing sales and marketing operations, having served as Vice President of Commercial Operations at Telik and Alza Pharmaceuticals (acquired by Johnson & Johnson). He currently serves as Chairman of The Christopher and Dana Reeve Foundation and is on the board of directors of Esperion Therapeutics, Inc., Inovio Pharmaceuticals, Inc., and Craig Hospital, a world-renowned center for specialty rehabilitation and research for people with spinal cord injury and brain injury. Mr. Shepard holds a B.S. in business administration from the University of Arizona.

**Molly Shoichet, PhD, O.C., O.Ont., FRS |
*Professor of Chemical Engineering & Applied
Chemistry and Biomaterials & Biomedical
Engineering, University of Toronto***

Professor Molly Shoichet holds the Tier 1 Canada Research Chair in Tissue Engineering at the University of Toronto. She served as Ontario's first Chief Scientist in 2018 where she worked to enhance the culture of science. Dr. Shoichet has published over 650 papers, patents and abstracts and has given over 400 lectures worldwide. She currently leads a laboratory of 30 and has graduated 200 researchers. Her research is focused on drug and cell delivery strategies in the central nervous system (brain, spinal cord, retina) and 3D hydrogel culture systems to model cancer. Dr. Shoichet co-founded four spin-off companies, is actively



engaged in translational research and science outreach. She is the recipient of over 50 prestigious distinctions. Dr. Shoichet received her SB from the Massachusetts Institute of Technology (1987) and her PhD from the University of Massachusetts, Amherst in Polymer Science and Engineering (1992).

Jesse SiNZ | *Graffiti Writer*

Jesse SiNZ has been a graffiti writer for over 20 years. He was injured "on the job". While out one night doing a couple of buildings, he fell off of a 50-foot roof and broke his neck, C 3/4. As he learned from doing grout work how to accept and change things, he applied that same principle to his art. 10 years later he is still doing the same thing - graffiti writing - with the same passion, but in a different way. Jesse believes this shows the resilience of the human body and what we are capable of doing. He strives to teach people and help them learn their craft to keep them on the positive side of this crazy world.



**Joanna Stanicka, PhD |
*CEO & Co-Founder, AXONIS Therapeutics, Inc.***

Dr. Stanicka has been studying signaling pathways that regulate the phenomenon of cell growth and death, and mechanisms of cancer, neuroprotection, and neuroregeneration. She led a genome-wide CRISPR screen in vivo to identify novel axon regeneration and neuroprotection mechanisms in central nervous system after injury in Dr. Zhigang He's laboratory at Boston Children's Hospital. Throughout her career, she has been interested in how specific genes/proteins lead to disease development and applying this knowledge to develop novel treatments for patients. By using her strong multidisciplinary training in genetics, biochemistry, cell biology and neuroscience, she is determined to develop treatment for spinal cord injury, and other currently incurable neurological diseases. In only the last 12 months under Joanna's leadership, AXONIS received state and federal non-dilutive funding, and secured \$4M seed financing. She also won a Boehringer Ingelheim Innovation Prize and Massachusetts Next Generation Award for a woman-CEO in life sciences.





Candy Tefertiller, PT, DPT,
PhD, NCS | *Executive Director
of Research and
Evaluation, Craig Hospital*

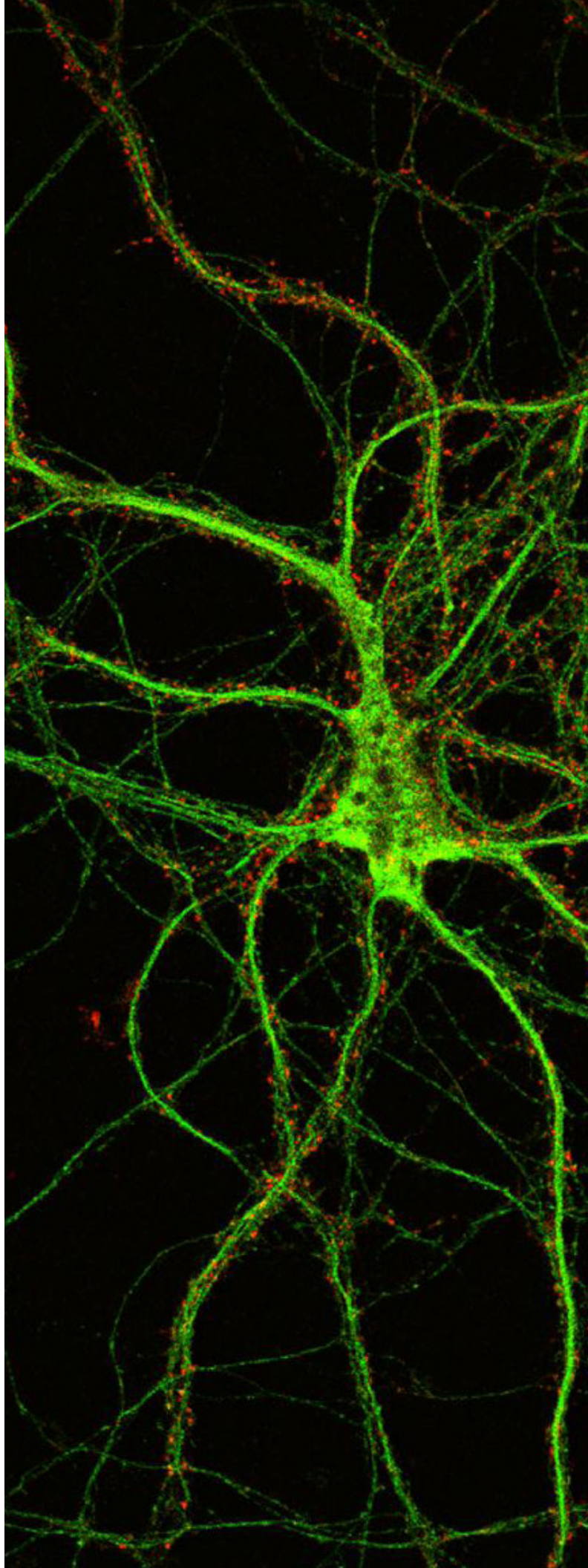
Candy Tefertiller, PT, DPT, PhD, NCS is the Executive Director of Research and Evaluation at Craig Hospital. Candy received a B.S. in Biology from Mount Olive College, a Master's degree in Physical Therapy from East Carolina University, a Doctorate of Physical Therapy degree from Rocky Mountain Health

Care University and a PhD in Clinical Sciences from the University of Colorado. Dr. Tefertiller has been working in the field of neurological rehabilitation since 2000; she became a certified neurological clinical specialist (NCS) in 2007. She has been involved in numerous lines of research and has focused much of her career on research and program development promoting recovery after neurologic injury or disease. Dr. Tefertiller is currently the Co-Project Director for the Rocky Mountain Regional Brain Injury System.

Reveca Torres | *Multimedia Artist*

Reveca Torres was injured and paralyzed in a car accident at the age of 13. After completing degrees in Fashion Design and Theatre Arts, Reveca worked as a costume designer and simultaneously worked with various organizations doing disability advocacy and peer support. She started a nonprofit called BACKBONES after realizing that

years of interaction and friendship with others living with spinal injuries (SCI) had made a significant impact in her own life. Reveca is co-director of ReelAbilities Film Festival Chicago and has curated touring photography and art exhibitions that showcase the work of people with disabilities and bring awareness to disability rights. She uses painting, illustration, photography, film, movement, and other media as a form of expression and a tool for advocacy and social justice.



SPEAKER Abstracts

NORTH AMERICAN SCI CONSORTIUM: CONNECTING THE SCI COMMUNITY

Kim Anderson-Erisman, PhD | *President,
North American SCI Consortium (with: Jennifer
French, Barry Munro, Sasha Rabchevsky, Bill Fertig,
Teren Clarke, Jennifer Wolff)*

The North American SCI Consortium (NASCI) was developed by the community for the community through grassroots efforts. Officially launched in 2018, NASCI's mission is to bring about unified achievements in research, care, cure, and policy by supporting collaborative efforts across the SCI community. To achieve this mission, NASCI will identify gaps, communicate resources, and be a conduit for collaboration between the community of people living with SCI and the many stakeholders. Since its inception, NASCI has 1) grown to over 300 members across geographic North America with a collective reach of over 500,000 individuals living with SCI and support persons, 2) developed a Project Review Committee and approved 13 projects placing 48 individuals with SCI in the translational process, 3) successfully advocated for the inclusion of people living with SCI in the research process at the SCI 2020 conference, 4) conducted a needs assessment of the SCI community to understand the widespread preferences and challenges faced by our community, and 5) began a capacity building program to further enhance community engagement. The role that NASCI plays within the broader strategy of promoting restorative treatments is 3-fold. First and foremost, to understand and bring voice to the diverse community living with SCI. Their everyday challenges must guide the strategy at all stages. Second, to promote the engagement and placement of people with SCI and their support persons throughout the entire translational process. Third, to facilitate the exchange between organizations and connect stakeholders. Living with SCI, understanding SCI scientifically and clinically, and translating restorative treatments to clinical practice is too complex for a single organization to complete. We must harness our individual roles and move forward together.

SPINAL CORD INJURY RESEARCH: IN, ACROSS, AND BEYOND THE NIH

Linda L. Bambrick, Ph.D | *National Institute of
Neurological Disorders and Stroke, NIH*

Spinal cord injury (SCI) is a whole-body injury with impact throughout the lifetime of the individual and with effects reaching from the individual through the community. Approaches to address SCI similarly need to stretch from the biology of injury and recovery through studies of systems in acute and chronic injury and with consideration of both individuals and communities.

In this presentation I will describe, with some examples, the multiple levels of SCI research supported by the NIH, how different institutes of the NIH work together, and how we are engaging with other funding entities. I hope to encourage the ongoing discussion of how cooperation can move research forward through translation to improve lives.

ADIPOSE-DERIVED MESENCHYMAL STEM- CELLS (ADMSCS) FOR PATIENTS WITH TRAUMATIC SPINAL CORD INJURY (SCI)

Mohamad Bydon, MD | *Neurosurgeon & Medical
Director of the Neurosurgical Registry, Mayo Clinic*

In the United States (US), more than 17,000 people each year suffer a spinal cord injury (SCI), a debilitating condition resulting often in partial or complete paralysis of the body. Due to limited regenerative capacity of damaged neurons, clinical trials have yet to identify an effective strategy to improve neurological function in affected patients. Regenerative treatment using cellular therapy is a novel option that is being employed increasingly for various diseases. Stem cells, one of the most frequently investigated cellular therapies, have garnered much popularity due to their regenerative potential. Among potential reservoirs for stem cells, adipose tissue has been recognized as one of the safest and most feasible options. To date, there have been no clinical studies in the US investigating the role of adipose derived mesenchymal stem cells (ADMSCs) for patients with blunt-traumatic SCI. The overarching objective of our phase I clinical trial was to investigate the safety and feasibility of adipose-derived stem cell injection among patients suffering SCI. Our study included 10 patients with traumatic SCI who presented to us within 1 year of injury. For each patient, fat tissue was harvested at the baseline visit, followed by culturing of stem cells in a good-manufacturing-practices (GMP) facility. After expansion, each

patient was injected with ADMSCs. All patients were followed up to a year for any adverse events as well as neurological improvement. We observed no serious adverse events for any of the 10 patients enrolled in our phase I. Moreover, most patients demonstrated improvement in their neurological status following the injection, although the extent of improvement varied significantly for each patient.

REGENERATIVE MEDICINE: A NOVEL AUTOLOGOUS CELL MATRIX THERAPY APPROACH FOR SPINAL CORD INJURY

Stephana Carelli, PhD | *Department of Biomedical and Clinical Sciences, Pediatric Research Center "Romeo ed Enrica Invernizzi," University of Milan, Italy.*

No effective therapies are currently available for spinal cord injury. Human stem cell transplantation is a promising central nervous system tissue repair strategy in patients with SCI. In animal models, activated human adipose (fat) tissue has been demonstrated to survive after transplantation in vivo, promote neurogenesis and neuronal regeneration, and improve functional outcomes. The French patients' association Neurogel en Marche decided to evaluate the safety of this procedure in people with chronic SCI. The group supported and organized a Phase I clinical trial, which was developed in collaboration with the International Spinal Cord Injury Treatment Center at the Tongren Hospital in Kunming, China. Twelve subjects (9 men and 3 women; 6 French and 6 Chinese) affected by chronic SCI underwent intraoperative liposuction. Treatment involved removal of spinal instrumentation, laminectomy, and clearing of the gliotic (scar) area. The exposure of the damaged area of the cord was followed by the implantation of the autologous adipose tissue derived matrix along with erythropoietin, administered at 24, 48 hours after surgery and then again at 3 and 6 weeks. After a mean period of 15 days after surgery, patients started an intensive rehabilitation pro-

gram of 36 hours per week. All subjects tolerated the procedure well and there have been no serious adverse events to date (18 months post-grafting). Moreover, in some subjects more than two levels of neurological improvement were detected using ISNCSCI motor scores. Our results support the safety of autologous adipose tissue matrix transplantation into the SCI site plus EPO treatment. We observed significant signs of potential efficacy in all the treated subjects to warrant further exploration of activated fat matrix in a Phase II study, and also for addressing the acute phase of injury. Neurogel en Marche (France) organized the study and covered the costs.

RESEARCH AND ADVOCACY IN AUSTRALIA

Perry Cross, AM | *Executive President and Founder, Perry Cross Spinal Research Foundation*

The Perry Cross Spinal Research Foundation was started 10 years ago and aims to facilitate, collaborate and initiate the connections and research required to find a cure for paralysis. The project supports and funds The Spinal Injury Project (SIP) at the Menzies Health Institute Queensland and the Griffith Institute for Drug Discovery at Griffith University; we are working towards a human clinical trial. We are working on cell therapies that can be complimented by other technologies such as electrical stimulation, bionics & rehabilitation. We collaborate with Griffith University, Making Strides Rehabilitation Centre, and Australian Spinal Cord Injury Research Collaboration (ASCIRC). The obstacles faced by the Foundation: Finding adequate funding for medical research has always been difficult and this continues to be the case as it is a very competitive field. Governments nationally and jurisdictionally have no dedicated funding programs, and despite the high costs and devastating impacts of spinal cord injury, it has never been identified as a priority for investment in research. Our goals:



- Empower the SCI community to fundraise and contribute to the research and have their voices heard.
- Create awareness of SCI and generate further funding for medical research.
- Produce an “Australian Roadmap for Spinal Cord Injury Research” to be presented to the Commonwealth Minister for Disability (NDIS), and other potential funding bodies at the State/Territory level, and philanthropic organisations.
- Change rehabilitation protocols in Australia.
- Launch a Human Clinical Trial

ACCELERATING TRANSLATION WITH PORCINE MODELS OF SPINAL CORD INJURY: AN INVITATION TO COLLABORATE

Dr. Candace L. Floyd, PhD | *Associate Professor and Vice Chair for Research in Physical Medicine and Rehabilitation, University of Utah*

The road to translation of a new therapy from the bench to the bedside is a difficult one and the success rate for development of new therapies to treat spinal cord injury remains unacceptably low. One of the goals of our research program is to accelerate the pace and improve the success of translation of new therapies. To achieve this goal, we utilize a porcine model of spinal cord injury in both male and female animals. Importantly, we have selected highly-translational experimental parameters (bottom-up approach) and paired these with clinically-relevant outcomes measures that we have back translated from the clinic (top-down approach). This talk will discuss the advantages for using a porcine model of SCI as a translational accelerator for novel treatments for SCI. I will discuss the importance of sex as a biological variable and how porcine models more closely model humans than rodents. I will overview anatomical similarities between pigs and humans. I will discuss the advantages of a pig model in understanding immune responses after SCI due to the similarities between human and porcine immune systems. I will describe how the pig is a good model for understanding sensory alterations after SCI. Lastly, I will invite collaboration and input.

BEAT PARALYSIS: TOGETHER, WE CAN GET THIS DONE

Jack Jablonski | *Jack Jablonski Foundation*

For the first time, a medical treatment conceived and developed over decades of laboratory research is demonstrating recovery results for people living with chronic paralysis.

Called spinal neuromodulation, researchers reported this breakthrough with the first patient in 2011, and then three more in 2014. In 2017, Mayo Clinic confirmed the validity of those recovery results. Dozens of studies have followed.

The problem. To keep the momentum going, the next step is to get this treatment into medical clinics as a new standard of care for people living with paralysis. Success depends on getting regulatory approval through the FDA, but so far, no organization has stepped up to lead the way. That needs to change. The time for waiting is over. Together, we can get this done.

The Plan. Since my injury almost nine years ago, more than 1 million people have had their lives touched by a friend or family member with an SCI resulting in paralysis, but only a fraction of these people knows how to help make recovery happen. We need their help – and they will help if we ask them, and show them the way forward.

To start, we need to achieve that first victory – not just in the lab for a few, but in the clinic for everyone.

Researchers are doing great work along many research pathways (e.g. nerve cell growth and cell replacement) that hold great promise for treatments that will provide even more restorative recovery from paralysis, but none are as close to clinical translation as neuromodulation.

The Result. Crossing the clinical threshold with the first recovery treatment will mark a tipping point in the cause of advancing paralysis recovery. When science we can believe in replaces the miracle every one of us hopes for, our cause will become a movement.

MICRO-LEVEL TO A MACRO-PICTURE: FROM MINIMAL FUNCTIONAL RECOVERY TO A CURE - WHAT CAN WE DO?

Corinne Jeanmaire | *Founder, endParalysis Foundation*

Spinal Cord Injury will become curable. It is not a question of IF; it is a question of WHEN.

This groundbreaking idea of 'when', not 'if' came up about fifteen years ago and offered the SCI community a promise that a new future was possible. The idea back then was that if we could just throw enough money at the problem we would get our 'cure'. Well, we know now that this approach isn't enough.

So, what can WE (i.e. all stakeholders, including the SCI community) do - either individually or collectively - to accelerate progress?

1. Individually, we can adopt a goal-driven approach focusing on the development and translation of repair strategies with a potential for human (chronic) functional recovery
2. Collectively, we can promote a more integrative approach, based on mapping the key injury and repair mechanisms and identifying the key gaps to recovery. This could take place in the shape of a virtual research network/platform and a flexible roadmap with identified priorities, selective goals, enablers and catalyzers.
3. Furthermore, we can promote the development of disruptive strategies that challenge the status quo and bring us closer to a CURE. Our presentation will review the individual approach taken by endParalysis with respect to the research project selection and funding. It will also discuss important macro level initiatives that require a collaborative effort by all key stakeholders and could advance research much further.

This presentation will review the individual approach taken by endParalysis with respect to the research project selection and funding. It will also discuss important macro level initiatives that require a collaborative effort by all key stakeholders and could advance research much further.

USING DOGS TO HUNT DOWN TRANSLATIONAL OBSTACLES IN SPINAL CORD INJURY RESEARCH

Nicholas Jeffery, PhD | *Professor, Neurology & Neurosurgery, College of Veterinary Medicine, Texas A&M University*

This presentation will review reasons for failure to translate interventions from laboratory to clinic, focusing on trials conducted in dogs. The lack of 'end-product' is a major frustration in spinal cord injury research, especially in view of the decades of work and billions of dollars expended. There are numerous apparently effective laboratory interventions and so the problem seems mainly to lie in translation to the clinic. Suggested translational obstacles are (implicit) lack of trust in reliability of laboratory results and uncertainty about what improvement of neurologic function in an experimental animal might imply if the same intervention were to be applied in humans.

Each year tens of thousands of dogs are treated by veterinarians in the USA for spinal cord injury and provide a potential translational model. Pet dogs undergo the same diagnostic tests and clinical treatment, including surgery, and often receive similar physical therapies as affected humans. Two of our recent trials have shown that intraspinal injection of olfactory ensheathing cell transplants and (in a separate study) chondroitinase ABC are safe and associated with clinically appreciable improvements in function. Despite these findings and the wealth of laboratory data that precedes these trials, both therapies have yet to be translated into humans. Why has the substantial evidence in favor of these therapies not resulted in clinical translation? Perhaps neurologic improvement in dogs is no more persuasive than that previously available from laboratory animals? If that is so, why is that?

The conflict between 'explanatory' (i.e. strictly defined and laboratory-orientated) and 'pragmatic' (i.e. more like 'real-life') trials might be relevant and so a solution might be to conduct more pragmatically-oriented clinical trials in dogs, in which the outcome can more easily be related to everyday life for spinal cord-injured people. Such results may, perhaps, be more persuasive than previous laboratory-centered outcomes?

THE RESET TRIAL. PHASE 1/2 EVALUATION OF THE SAFETY, PHARMACOKINETICS, AND EFFICACY OF AXER-204 IN PATIENTS WITH CHRONIC SCI.

George D. Maynard, PhD | *President and Chief Scientific Officer, ReNetX Bio, Inc.*

ReNetX Bio, a privately held, clinical stage company in New Haven, CT, is evaluating a human fusion protein known as AXER-204 for the treatment of chronic SCI in a first-in-human Phase 1/2 clinical trial enrolling patients with chronic cervical injuries with significant but incomplete loss of hand and arm function. AXER-204, based on Yale University research from the laboratory of Dr. Stephen Strittmatter, binds three key axonal growth inhibitors present in myelin. Blocking these inhibitors changes the environment in the CNS, promoting axonal growth and recovery of motor function demonstrated in preclinical models of SCI. Investigational New Drug (IND)-enabling development and safety studies were completed and clinical testing is underway at five major treatment and rehabilitation centers in the United States following Food and Drug Administration (FDA) and Institutional Review Board (IRB) approvals. The mechanism of action for regeneration with AXER-204 will be discussed along with key efficacy data in preclinical SCI. The design and objectives of the clinical trial will be presented.

Team members

George Maynard, PhD (Presenter), President & Chief Scientific Officer, ReNetX Bio, Inc.

Erika Smith, MBA, CEO, ReNetX Bio, Inc.

Craig Hackett, PhD, VP Process Science & Manufacturing, ReNetX Bio, Inc.

Crista Adamson, PhD, Director Clinical Engagement, ReNetX Bio, Inc.

Stephen Strittmatter MD, PhD, Founder & Scientific Advisor, ReNetX Bio, Inc.; Professor of Neurology and Neuroscience, Yale University School of Medicine

Funding sources

Wings for Life

NIH NINDS & NCATS BrIDGs

ReNetX Bio, Inc.

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THE SPINAL CORD INJURY RESEARCH PROGRAM – ENGAGING THE SCI COMMUNITY THROUGHOUT THE RESEARCH AND DEVELOPMENT PROCESS

Melissa R. Miller, PhD | *Program Manager, Spinal Cord Injury Research Program, Congressionally Directed Medical Research Programs*

The Spinal Cord Injury Research Program (SCIRP) was established by Congress in fiscal year 2009, in part as a response to the high rates of spinal cord injury (SCI) observed in Warfighters returning home from duty. To this end, the SCIRP has invested over \$200 million into research and development efforts guided by the vision to advance the treatment and management of SCI and ameliorate its consequences relevant to injured Service members.

SCIRP focuses its investment into areas of SCI inquiry that address critical gaps in SCI research, patient care, and quality of life. To address these gaps, funded projects utilize an array of approaches. The majority of SCIRP projects, though, involve drug or device interventions, including exoskeletons, invasive and non-invasive stimulation devices, and therapeutics targeting regeneration of the spinal cord or treatment of secondary health effects. Both chronic and acute SCI are investigated within the SCIRP portfolio, which primarily consists of projects within the translational and early clinical phases of the research and development continuum. These phases of research rely on pioneering volunteers to test new interventions, devices, and diagnostics.

However, research participation is only one way people with lived SCI experience can engage with the SCIRP program and SCIRP-funded research. People with lived SCI experience are asked to participate in grant application review, submit their own grants, or consult on research projects to ensure that the needs and wants of the SCI community are being addressed and met by SCIRP-funded research. The SCIRP believes that capturing and integrating the unique perspectives and experiences of people with lived SCI experience throughout the entire research and development process will lead to better and more impactful outcomes for people living with SCI.

EXERCISE AFTER SCI: EVIDENCE FOR HEALTH BENEFITS AND THE NEED FOR MORE RESEARCH

Leslie Morse, MD, DO | *Department Head, Department of Rehabilitation Medicine, University of Minnesota*

Dr. Morse will discuss the need for more robust and rigorous research on the effects of exercise, including Activity Based Therapy, in the SCI population. She will provide a summary of the current state of this research and make some suggestions toward improving our knowledge base, and maybe some assumptions that need to be challenged. Dr. Morse is currently working with U2FP's Activity Based Exercise workgroup. The group is composed of representatives from multiple community centers across the US. The group, in partnership with Dr. Morse and her team, is working to develop a research program to define the health benefits and public health impact of exercise in the SCI population.

CREATING A ROADMAP FOR SPINAL CORD INJURY CURES

Jay Shepard | *Chair, Board of Directors, Christopher & Dana Reeve Foundation*

Throughout the last 40 years, spinal cord injury (SCI) foundations and funders have supported hundreds of projects without a globally coordinated research agenda that spans bench to bedside. Further, government and non-profit continue to make significant annual investments in SCI research, but the increase in scientific understanding has not yet impacted the SCI community – there are zero approved therapies in the clinic today. Currently, no individual stakeholder is playing the “orchestrator” role in the SCI R&D ecosystem. To address this gap, the Christopher & Dana Reeve Foundation is applying learnings from its decades of research funding, lessons from other therapeutic fields and a commitment to cross-sector collaboration to generate a technical roadmap to guide the field forward toward translational care improvements using combinatorial therapies. From epidural stimulation to cell regeneration to gene therapy, spinal cord injury (SCI) medical breakthroughs are reaching a tipping point. However, the field requires a platform from which

to accelerate and synergize efforts so that every opportunity to further the most promising science is afforded. The Reeve Foundation envisions four primary building blocks to enable the field to collectively deliver on a more ambitious R&D agenda: a high caliber team of passionate scientific experts to drive R&D; capital raising model designed to provide sustained funding; a governance and operating model that facilitates a highly disciplined, yet agile approach to funding, scientific review and identification of promising new technologies; and an alliance of strong partners working together toward a shared vision: to fully understand the scientific underpinnings of the most significant therapeutic approaches and maximize their outcomes to co-treat with multiple modalities and restore function for SCI survivors that were previously thought to be impossible.

DEGRADING THE GLIAL SCAR TO PROMOTE REGENERATION AFTER TRAUMATIC SPINAL CORD INJURY

Molly S. Shoichet, PhD, O.C., O.Ont., FRS | *Professor of Chemical Engineering & Applied Chemistry and Biomaterials & Biomedical Engineering, University of Toronto*

Team: Marian Hettiaratchi, PhD; Matthew O'Meara, PhD; Nitzan Letko-Khait, PhD; Tobi Führmann, PhD; Malgosia Ip (née Pakulska), PhD; Andrew Pickering, BSc; Samantha Payne, PhD

Affiliation: Department of Chemical Engineering & Applied Chemistry, Institute of Biomedical Engineering, Donnelly Centre, University of Toronto

Area of SCI Inquiry: After traumatic spinal cord injury, the body responds by creating a glial scar that provides both a chemical and physical barrier to axonal regeneration. Chondroitinase ABC (chABC) is a potent enzyme that has been shown to degrade the glial scar.

Problem: Notwithstanding the promise of chABC, it is a fragile enzyme that degrades easily. Moreover, chABC requires local, sustained delivery.

Solution: We have re-designed chABC to be both more stable and more active over 1-week while at the same time demonstrating a method for local and sustained delivery.

Methodology: Using computational biology, we predicted a series of mutations and then tested these experimentally for thermal stability and biological activity using known strategies. We also tested a new delivery strategy for local release.

Mechanism: ChABC is known to degrade the glial scar and promote plasticity in the central nervous system. This may account for some of the promising results.

Clinical Prospects: While ChABC alone has not provided significant functional benefit in animal models of traumatic spinal cord injury in the past, this may be because it has had limited activity and stability. Our newly designed ChABC and its local delivery are promising for further study.

Human Application: In order to test this new molecule in clinical trials, it will first have to be tested in pre-clinical models.

Chronic Solutions: For chronic spinal cord injury, I would expect that ChABC would have to be delivered with another regenerative strategy, such as transplanted cells.

Funding Sources: We are grateful for funding from the Canadian Institutes for Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) of Canada, the Krembil Foundation and the Canada First Research Excellence Fund (CFREF) to Medicine by Design.

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KCC2: TRIPLE-EDGED SWORD FOR PARALYSIS, NEUROPATHIC PAIN AND SPASTICITY

Joanna Stanicka, PhD | *Chief Executive Officer & Founder, Axonis*

Refined voluntary movement in an intact spinal cord is a result of a balance of activity between excitatory neurons, which promote electrical signals, and inhibitory neurons, which help halt transmission of these electrical signals. Spinal cord injury (SCI) dramatically impairs voluntary movement and sensation below the level of injury. The majority of SCI individuals possess residual spared neural tissue around the injury site, but often suffer complete paralysis. KCC2 is a CNS potassium/chloride co-transporter that regulates neuronal inhibition. Loss of KCC2 after SCI, and other neurotraumatic disorders such as stroke and traumatic brain injury, leads to dormancy of spared tissue and other SCI co-morbidities, such as neuropathic pain and spasticity. Restoration of KCC2 reactivates the spared neural tissue, leading to robust recovery of stepping ability in severely paralyzed mice, and also alleviates neuropathic pain and spasticity. AXONIS is at the therapeutic candidate selection stage for developing the first oral KCC2 drug to improve quality of life of both acute and chronic SCI individuals. To validate translational potential, the designated compound will be tested for locomotor recovery, and treatment of neuropathic pain and spasticity in animal SCI models.

THE UP-LIFT STUDY – A PIVOTAL TRIAL INTENDED TO DEMONSTRATE THE BENEFITS OF NON-INVASIVE ELECTRICAL SPINAL STIMULATION THERAPY IN PEOPLE WITH NEUROLOGICAL DEFICIT FOLLOWING SPINAL CORD INJURY

Candy Tefertiller, PT, DPT, PhD, NCS | *Executive Director of Research and Evaluation, Craig Hospital*

Improved upper extremity (UE) function has been identified as a top priority among individuals with spinal cord injury (SCI). There is no currently approved therapy indicated for restoration of UE function following SCI. Non-Invasive electrical spinal cord stimulation (NESS) has recently been introduced as an intervention that may restore or improve UE performance. Eight pilot studies in chronic SCI (n=52) have been conducted using NESS (LIFT System, GTX Medical, Inc.) and have demonstrated improvements including but not limited

to the following: UE strength and function, voluntary activation of lower extremities, improved walking speed and endurance, improved bladder control and decreased spasticity. However, this therapy has yet to be evaluated in an FDA regulated market entry trial.

Proposed mechanism includes using an electrical stimulus to activate dormant but viable neurons contained within the injury site. Reactivating these dormant neurons in combination with intensive training strengthens these networks and allows even weak supra-spinal signals to activate previously lost voluntary motor function below the level of the injury.

A prospective, multi-center trial will be conducted in the US and elsewhere using NESS therapy delivered by the LIFT System. The Up-LIFT Study protocol will include an 8 week wash-in period of massed practice training (MPT) focused on UE recovery followed by an additional 8 weeks of MPT+NESS in individuals with chronic cervical SCI. The primary effectiveness endpoint of the study is a composite measure that will assess both strength and functional performance changes resulting from NESS using: UE motor score (UEMS-ISNCSCI),

Graded Redefined Assessment of Strength, Sensibility and Pre-hension (GRASSP Prehension & Strength), Capabilities of Upper Extremity Test (CUE-T), pinch force and grasp force. In addition, improvements made during the MPT only phase will be compared to those achieved during the MPT+NESS phase. A series of surveys will also report observational and patient-reported outcomes related to other co-morbidities and activities of daily living following NESS.

While pilot studies have shown promising early outcomes, a larger scale prospective study like the Up-LIFT study has been designed to capture improvements in functional mobility and independence in individuals with chronic SCI to maximize quality of life. If successful, the study results would support FDA clearance of the first device therapy indicated for the restoration of sensory and motor function in people with SCI.



LEADERSHIP TEAM

The Board & Staff of Unite 2 Fight Paralysis

BOARD OF DIRECTORS



Mike Burris – President

Mike (of Colorado Springs, Colorado) received his B.A. from the University of Iowa and has an M.S. in Systems Management from the University of Southern California. Mike has more than 35 years of experience in the world of space exploration. He served as an Air Force intelligence officer from 1977-1982. After he left the Air Force, he went to work at Science Applications International Corp. (SAIC) before retiring as an Assistant Vice President at the end of 2011.

During his career, he worked on several space related activities such as the building of the Air Force's Consolidated Space Operations Center, the Air Force Satellite Control Network, NASA's X-43 hypersonic research vehicles, and the replacement for the Space Transportation System. Prior to joining the U2FP Board he served on three boards; he served 10-years as a school board member for the Lewis-Palmer School District #38 in Colorado during the 1990s, he was a member of the International Astronautical Congress (IAC) Space Transportation Committee from 2004-2011, and he is currently a member of Rehabilitation Institute of Chicago (RIC) Foundation Board. In July 2009 while body surfing Mike suffered a C4 incomplete SCI that, although he is ambulatory, still impacts him today. Being on the U2FP Board provides him the opportunities to advance the goals of our community and advocate for all of us to live our best possible lives.



Barry Munro – Secretary

Barry (of Toronto, Canada) is the Chief Development Officer of the Canadian Spinal Research Organization and the Ontario Neurotrauma Foundation; he also serves as director of the American Spinal Research Organization. In 1987, Barry sustained a spinal cord injury in a diving accident, which resulted in quadriplegia. He has sat on multiple boards advocating for people with disabilities and particularly spinal

cord injury research. Barry graduated from law school in 1994 and was called to the Bar in 1996. He practiced personal injury law for over 10 years. His legal experience combined with 30 years of practical experience living with a spinal cord injury make him a formidable advocate for the disabled community. Barry has dedicated his life to assisting people living with disabilities and improving their quality of life.

Michele “Shelly” Towle

Michele (of Bismark, North Dakota) is the Assistant Director of the Spinal Cord Injury Program at DP Clinical, Inc., located in Rockville, MD. Michele has 19 years of experience in SCI clinical research. She became a study coordinator starting in 1999 when she began working with spinal cord injured patients enrolled in clinical trials. Through this early experience she came to understand the impact of a spinal cord injury, not only for individuals but also for their families and communities. From 2003, Michele moved on to monitor and manage SCI clinical trials for DP Clinical, a Contract Research Organization (CRO) specializing in Spinal Cord Injury (SCI) Phase I-IV clinical programs for pharmaceutical, biotech, and medical device companies. Over the years, Michele has seen many SCI clinical trials halted due to slow enrollment and the prohibitive cost, leaving SCI patients without a potentially beneficial new therapy. Research needs to succeed, and there remains a need for meaningful contribution to the efforts in spinal cord research. Michele advocates for better-designed protocols and validated efficacy tools to be used in clinical trials. Having worked with many talented people with SCI and other experts committed to research, Michele asks, “how can I as a non-scientist help to advance research and clinical trials that will provide a breakthrough for spinal cord injuries?”





Alexandar “Sasha” Rabchevsky

Alexander “Sasha” Rabchevsky (of Lexington, Kentucky) is a tenured Professor of Physiology at the University of Kentucky, College of Medicine and is a core member of the Spinal Cord & Brain Injury Research Center. He is paralyzed himself, T5 complete, as the result of a motorcycle accident in 1985. His research efforts have ensured continued extramural funding while gaining him international recognition as a leading expert in both mitochondrial dysfunction and autonomic pathophysiology following spinal cord injury, particularly the development of a hypertensive syndrome termed autonomic dysreflexia. It is the latter condition that he himself experiences on a regular basis, and his studies have advanced our understanding of how to monitor and treat such an insidious disorder. He has and continues to serve on various study sections, both federal and private, is associate editor and reviewer of various scientific journals, and his distinct studies have been funded by the National Institutes of Health, the International Spinal Research Trust, the Paralyzed Veterans Administration, the Craig H. Neilsen Foundation, the Commonwealth of Kentucky, and the University of Kentucky.

Traci Fernandez

Traci has owned and operated numerous organizations throughout her career and has held executive positions at several Fortune 500 companies. Currently, Traci is a Founder and Managing Partner at TRYAbility in Chicago. TRYAbility provides Intensive Activity Based Rehabilitation services to individuals with Paralysis. TRYAbility’s mission is to help patients optimize their recovery, maintain long term health and foster a connected community. Prior to TRYAbility, Traci was a Founder and President of

3C Compassionate Care Center. As a founder of 3C, Traci successfully opened and operated two of the largest Medical Marijuana dispensaries in Illinois. Traci also was a Founder and President of Operations at iGenMedia, an application software and development company. Before opening iGen, Traci held Technical and Executive roles at Arthur Andersen, IBM and the Tribune Company. Throughout her career, Traci has excelled at both technical and executive positions and was twice awarded Employee of the Year for her contributions.



Traci received her bachelor’s degree in Information and Decision Sciences from the University of Illinois. In addition to working with U2PF, Traci founded the United Paralysis Organization after becoming paralyzed in 2008 from Transverse Myelitis. Since founding the charity, Traci has worked as an advocate, raising monies to find a cure for neurological conditions and promoting therapies for those with Spinal Cord Injuries.

Christel Mitrovitch

Christel Mitrovich is a proud San Diego native and graduate of San Diego State University where she earned her MS in Exercise Physiology. Christel is Director of Operations for Reneu Health, Inc., a Southern California team of clinical kinesiologists specializing in restorative exercise and activity-based therapies. Since beginning her career in 2002, Christel has helped to advance the field of neuro-recovery and expand the reach of post-traditional rehabilitation services through her leadership and educational development of new practitioners. Christel has worked side-by-side top researchers and practitioners in the field of SCI rehabilitation, logging several years as a Facility Director for the NeuroRecovery Network and lending her expertise to numerous research projects. Over the years, Christel has worked closely with countless patients and their families and made many friends in the SCI community. She has dedicated her career to advancing the field of neurorehabilitation, working to develop and bring new treatment options to those fighting paralysis. Christel is honored to join the Unite 2 Fight Paralysis Board of Directors and looks forward to contributing all she can to find a cure.





Matthew Rodreick

Executive Director

Matthew (of Minneapolis, Minnesota) entered the SCI community after his son Gabe sustained a C5 injury while body surfing in Costa Rica. After leaving his position as Emergency Department Operations Supervisor for the Fairview Health System, he and Gabe traveled the world in search of the best therapeutic options, only to end up back in Minnesota advocating for cure research. Matthew led a coalition of

Minnesota SCI community advocates and researchers to leverage the state legislature in pursuit of public funding for SCI research. In 2012 he made a short documentary film featuring then Minnesota Viking punter and Twitter celebrity Chris Kluwe, spending a day in a wheelchair. The screening of "Chris Kluwe Rolls A Mile In Someone Else's Wheels" kicked off their 2013 legislative campaign. The bill was passed in 2015 as the MN SCI/TBI Research Grant Program, and Matthew is now working with advocates in Washington and Pennsylvania to pass similar legislation. He credits U2FP and Working 2 Walk with providing the knowledge, focus and energy to see the real possibility of an end to the debilitating effects of paralysis.



Sam Maddox

Scientific Advisory Board Director

Sam Maddox (of Los Angeles, California) is former Knowledge Manager and spinal cord injury research writer for the Reeve Foundation. He is the author of several books related to chronic health and paralysis, including four editions of the Paralysis Resource Guide, published by the Reeve Foundation. In 1992 Maddox wrote the first comprehensive history of spinal cord injury research, *The Quest for Cure: Restoring Function After Spinal Cord Injury*. He wrote and

published the widely acclaimed resource book *Spinal Network*, and is founder of *New Mobility* magazine. Maddox was a panel member on The Consortium for Spinal Cord Medicine, which develops and disseminates evidence-based clinical practice guidelines to professionals and consumers. He is currently writing and producing books as a resource for the newly injured: *SCI: First 90 Days*. He has been a

reporter for many magazines, including *Time*, *Money* and *People*. Maddox is a graduate of the University of Colorado, where he taught in the School of Journalism.



Jake Beckstrom

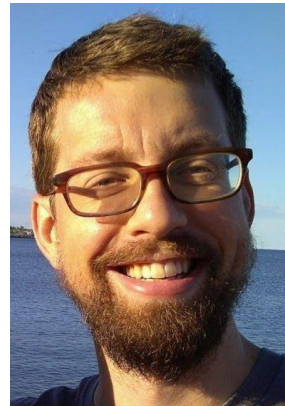
Cure Advocacy Network Manager

Jake Beckstrom is from Watertown, Minnesota. At the age of 16, Jake had a diving accident in a backyard pool and sustained a C4-6 spinal cord injury. A lifelong love of hunting, fishing, and the outdoors led him to pursue a path of environmental sustainability. He received a B.S. in Environmental Science at Southwest Minnesota State University, and in 2015, he received a law degree and master's degree in Environmental Law and Policy at Vermont Law School. Jake is eager to use his experience in public policy and advocacy to work with the Cure Advocacy Network to lobby for smarter spinal cord injury research funding and find a cure for paralysis.

Ryan Romine

Program Manager

Ryan (of Minneapolis, Minnesota) has worked in managerial and administrative roles at mission driven organizations for the last 15 years. He has a strong background in communications, customer service, and project management. Impressed by U2FP's vision to end paralysis rather than simply accommodate it, Ryan is honored to lend his efforts in the comprehensive fight for a cure.



Kathy Christopherson

Finance Manager

Kathy Christopherson (of Minneapolis, Minnesota) was born and raised in New England. She enlisted in the US Navy as a medic after high school and moved to the Minneapolis area with her husband after being discharged from the service. Kathy attended the University of Minnesota and earned a Bachelor of Science degree in Accounting. She has worked in accounting management for the last 30 years - half of that time with non-profits serving



disabled and refugee clients. Kathy believes that there is nothing more satisfying lending your efforts to a mission-driven organization, even in a small way. She is honored to be part of the Unite 2 Fight Paralysis family and our mission to find cures!



Jason Stoffer *CureCast Host*

Jason Stoffer lives in the Rockies of Northwest Montana with his wife and three children. He has a B.S. degree in Natural Sciences/Biology from the University of Alaska, Anchorage. Jason's love of outdoor adventure led him to work and play there as a mountaineer, long distance hiker, wild-land firefighter, search and rescue technician, EMT, and Law Enforcement Officer. A single vehicle rollover on his

commute to work one morning resulted in an L1 Spinal Cord Injury (SCI) and paraplegia. He has now turned his energies toward SCI cure advocacy and participates as a co-host on the CureCast podcast.



Kelsey Peterson *Social Media Strategist & Contributing Writer*

Kelsey Peterson (of Minneapolis, Minnesota) received her BA in dance in 2008 from the University of Montana, and has since pursued choreography, as well as teaching dance and yoga. Since her spinal cord injury in 2012, she has been pursuing other creative endeavors. After working on the board of Get Up Stand Up to Cure Paralysis out of Minneapolis, she has

embarked on her film-making journey with SUBMERGED (currently in post-production). Kelsey hopes that her personal reflections on what it's like to live with a SCI will help incite action, and inspire others to join the movement to finding cures more quickly.

Alina Garbuzov *Contributing Science Writer*

Alina Garbuzov (of San Diego, California) attended Brown University for her undergraduate degree, where she studied Neuroscience and Molecular Biology. After Brown, she moved to California to attend Stanford Graduate School. During her PhD studies she fell while rock climbing and fractured her L1 vertebra. Alina was able to re-start school and complete her dissertation in the field of stem cell biology and genetics. After her fall, she came to the realization that in order to keep doing science she needed to align her personal interest and her work focus. Her personal experience and the people she met through adaptive sports created a new, deep drive to contribute to a field with many promises, but still no therapy in the clinic. Alina recently started a post-doctoral position in the lab of Mark Tuszynski at the Center of Neural Repair at UCSD Medical School. She is bringing expertise in molecular biology, stem cell biology, and bioinformatics to a lab that specializes in stem-cell based treatment for SCI. She also hopes to contribute as a patient and to be a voice for the SCI community in this top research lab. She feels passionately about science communication and wants to help her community understand the latest science to drive smart decision-making both for personal health and for setting research goals.



ABOUT Unite 2 Fight Paralysis

In the spring of 2005, just 6 months after the passing of Christopher Reeve, six “bionic women” organized the first Rally in Washington on behalf of the spinal cord injury community. Three of the women – Pam Bailey, Susan Maus, and Betheny Winkler – had spinal cord injuries or disease themselves. The other three – Faye Armitage, Suzanne Poon, and Marilyn Smith – all had sons with spinal cord injuries. Their collective determination to fight for a cure led to the historic Washington Rally.

Motivated by the knowledge and energy gained at the Rally, Susan, Betheny and Marilyn founded Unite 2 Fight Paralysis (U2FP) in late 2005, and a unique advocacy organization was born. In 2006 U2FP introduced the Working 2 Walk Science & Advocacy Symposium, bringing research scientists, clinicians, investors, SCI survivors and family members together for the first time. This annual conference continues to foster knowledge, collaboration and power for all of the stakeholders committed to achieving a cure for spinal cord injury.

Through the Working 2 Walk Symposium and its other outreach programs, Unite 2 Fight Paralysis has had an enormous impact in the community. We have promoted:

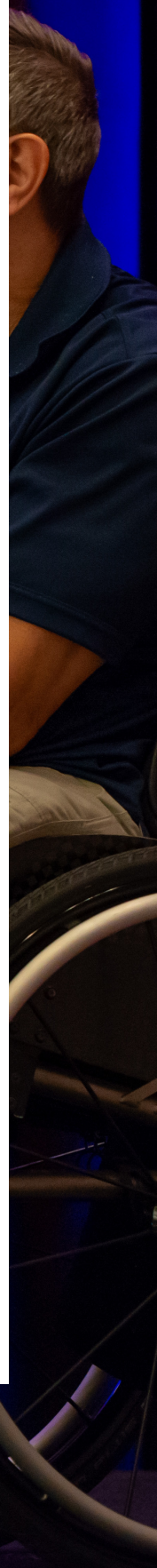
- Increased collaboration among research scientists;
- A committed advocacy effort that led to passage of the Christopher & Dana Reeve Paralysis Act;
- Partnerships between scientists and investors;
- Ongoing dialogues between researchers and those living with spinal cord injury;
- Individual and collective fundraising campaigns by community members to support research;
- Development of a strong core of community advocates who are empowered by their knowledge and support for each other;

Working in partnership with SCI Sucks, in 2012 U2FP created its first Scientific Advisory Board (SAB), comprised of experts in the field of neuroscience who evaluate research targeted toward repair of the chronic spinal cord injury. The SAB began work on November 1, 2012, and to date have reviewed over \$9 million in targeted research funding. Their reports offer educated, reliable guidance for community members to provide financial support for research.

The Cure Advocacy Network was established in 2016 following the successful passage of the Minnesota SCI/TBI Research Grant Fund. U2FP supports, trains and leads advocates to initiate state legislative efforts to fund SCI research across the United States. We have initiated these efforts in 5 states (Minnesota, Washington, Pennsylvania, Ohio, and Wisconsin) and have secured funding in 4 so far (Minnesota, Washington, Pennsylvania, Ohio). We have will have added almost \$12M by the end of 2020, with 61 people with chronic injury having had an intervention.

Through the years Unite 2 Fight Paralysis has stayed true to its roots. We are governed and staffed by people who have a personal connection to paralysis; we live with it every day. We don't spend a lot of money on marketing or fundraising or salaries. We focus our time and energy on understanding the science, and bringing key players together who can advance the best therapies as quickly as possible. We are the Voice of the Cure.

Unite 2 Fight Paralysis is a 501c3 nonprofit organization, and donations are tax-deductible to the full extent of the law.



VOICE OF THE CURE A U2FP Vision

WHAT IS THE CURE – DEFINING THE VISION

Unite 2 Fight Paralysis uses the tagline, “Voice of the Cure”. What does the word “cure” mean to us? Our vision of a cure includes:

1. Restoration of one’s fully functional and healthy body, including relief from pain and spasms, return of bowel, bladder and sexual function, and recovery of normal sensation in addition to motor control. Once cured a person should be able to live independently, free of assistive devices, caregivers, catheters, etc.
2. Belief that curative therapies will come in stages, and support for advancing research into each stage as it becomes more promising.
3. Understanding that recovery will come through combinations of therapies that may vary just as much as the nature of spinal cord injuries. To this end we promote and support collaborations amongst scientists, investors, advocates, clinicians, and regulatory agencies.
4. Commitment over the long term to successive stages of recovery by helping to build the capacity necessary to optimize that recovery while refusing to be satisfied until all bodily functions are restored.

WHAT IS THE CURE – NAVIGATING THE VISION

U2FP fights for a cure for the invisible ones, the severely disabled, the families who support them, and everyone who believes that it’s possible, and more importantly urgent, to restore health and opportunity to these compromised lives.

A cure does not mean that a person receives a “magic potion” injection one day and is up and running around the next. We know that after any kind of intervention to stimulate regeneration, extensive rehabilitation will be required to properly connect the motor and sensory pathways and restore function.

Let us never forget about those with complete injuries and little or no return, those who cannot use their hands or live independently, those who have no family support and are shuffled off to nursing homes, those on ventilators who require 24/7 assistance, those who do not have the time and/or money to spend the hours necessary to maximize recovery.

We don’t want to start a “pity party”, but we do want to increase the awareness of these realities by bringing our community into effective relationships with critical decision-makers. We believe this is the best tactic to demonstrate:

- that paralysis is a progressive and burdensome condition,
- that research science shows great promise and needs financial support,
- that restoring function will save millions of dollars for SCI survivors, their families, and society.



SCIENTIFIC ADVISORY BOARD

The U2FP Scientific Advisory Board (SAB) is directing dollars from SCI foundations to research that is Relevant to Chronic Injury, Replicable, Translatable and Innovative.

Relevant to Chronic Injury Giving preference to chronic injury research allows for a greater impact to the vast majority of individuals currently living with a spinal cord injury.

Replicable Research needs to be replicated in order to move toward clinical trials. We want to identify opportunities to replicate research that shows promise for innovative treatments.

Translatable Research that is applicable to the chronic injury and has the potential to move from animal models to human trials.

Innovative We wish to identify research that is asking bold questions with conservative interpretations, rather than conservative questions with bold interpretations.



Phillip G. Popovich, PhD, Chair Dr. Popovich is the Chair and Professor in the Department of Neuroscience and Director of the Center for Brain and Spinal Cord Repair at Ohio State University. His laboratory is an interdisciplinary research group dedicated to studying the complexities of CNS injury, inflammation and tissue repair. Inflammation can have devastating consequences in the spinal cord, and the lab is striving to develop novel therapies that will manipulate or over-ride normal immune function. In addition, the Popovich lab performs

replication work for the NIH. Replication is a core principle of the scientific method. To establish validity, the results of an experiment performed by one group of scientists must be evaluated by an independent group of scientists. The second group attempts to repeat the experiment of the first group, based on the original description. If the outcomes are similar, replication has been achieved and the first experiment is validated. Dr. Popovich's work in the replication process will bring a detail-oriented perspective to evaluating scientific projects.

Cure research can be overwhelming and confusing. Many smaller foundations want to fund promising research, but lack the scientific expertise to vet their funding decisions. The U2FP Scientific Advisory Board is here to fill this gap. We make that expertise available to these important members of the paralysis community.

Moses V. Chao, PhD

Dr. Chao is a Professor of Cell Biology, Physiology, and Neuroscience, and professor of Psychiatry at the York University School of Medicine. He is the former President of the 42,000-member Society for Neuroscience (SFN), made up of the world's leading brain and spinal cord scientists. Dr. Chao's lab at the Skirball Institute of Biomolecular Medicine focuses on the study of molecular neurobiology and understanding the mechanisms that lead to a. the generation of neural cells and their targets, and b. the mechanisms that allow axons to project to their targets, form synapses, and signal to one another. Dr. Chao believes strongly in the necessity for more discovery science to solve the challenges of neurodegenerative disease and trauma. He brings a wealth of knowledge and experience in the field of neuroscience to our Advisory Board, and we appreciate his service.



Keith Tansey, MD, PhD

Dr. Tansey earned his BS and MS in Biology and Biomechanics from Stanford University and his MD and PhD in Neuroscience from the University of Texas Southwestern Medical Center. He then completed his Residency in Neurology at Washington University in St. Louis and then Fellowships there and at the University of California at Los Angeles in Neurorehabilitation and Spinal Cord Injury Research. He was board certified in Neurology and then subspecialty board certified in Spinal Cord Injury Medicine and Neural Repair and Rehabilitation. Dr. Tansey serves on the Board of the American Society for Neurorehabilitation and as a Board Officer for the American Spinal Injury Association and the International Society for Restorative Neurology. He recently published a book, "Neurological Aspects of Spinal Cord Injury" with two colleagues from Heidelberg Germany.





Dr. Tansey has grants to study neural plasticity after spinal cord injury in animal models and humans from the National Institutes of Disability and Rehabilitation Research, the Department of Defense, the Veterans Administration, and the Neilsen Foundation.

Steven Kirshblum, MD

Dr. Kirshblum is nationally recognized for his work in the area of spinal cord injury rehabilitation and research. He joined Kessler Institute in 1990 and currently serves as Medical Director of the West Orange campus, as well as the Director of

the Spinal Cord Injury Program. Dr. Kirshblum received his medical degree from the University of Health Sciences/Chicago Medical School and completed a residency in physical medicine and rehabilitation at Mt. Sinai Hospital in New York City, where he was a chief resident. He became board certified in 1991 and was one of the first physicians in the country to receive special certification in spinal cord injury medicine in 1998. One of the most widely respected physicians in his field, Dr. Kirshblum has delivered more than 500 lectures nationally and internationally. He is the President of the Academy of Spinal Cord Injury Professionals, Chair of the International Standards Committee for the American Spinal Association and a member of numerous advisory boards and foundations for spinal cord research.

Brian Kwon, MD, PhD, FRCSC

Dr. Kwon is the Canada Research Chair in Spinal Cord Injury and a Professor in the Department of Orthopaedics at the University of British Columbia (UBC). As a surgeon-scientist, he is particularly interested in the bi-directional process of translational research for spinal cord injury – both “bench to bedside” and “bedside back to bench”. He has worked extensively on establishing biomarkers of human SCI to facilitate human trials and is leading a national biobanking effort in acute SCI. In his laboratory he has developed novel preclinical

small and large animal models of SCI that can serve as the testing ground for therapeutic strategies and for conducting bedside back to bench translational studies. He has also led initiatives to establish a framework for how promising therapies for SCI should be evaluated in the laboratory setting prior to translation into human patients.



John Houle, PhD Dr. Houle is a professor in the Department of Neurobiology & Anatomy at Drexel University College of Medicine, and director of the Spinal Cord Research Center. Prior to coming to Drexel, he taught at the University of Arkansas for Medical Sciences (UAMS), also serving as the director of the Division of Cellular and Molecular Neurobiology and the Neuroscience Research Core Facility at UAMS. Dr. Houle has long been interested in neurotransplantation strategies to promote structural and functional recovery after spinal cord injury. Research in his laboratory is designed to examine multiple aspects of the neuronal and glial cell response to spinal cord injury, with the intent of designing a combinatorial treatment strategy for regeneration leading to functional recovery. Dr. Houle’s career has been a pursuit of understanding how the regenerative response of injured neurons is regulated, why some neuron groups are strong regenerators while others exhibit very limited regenerative effort, and how we might enhance regeneration in acute and chronic injury conditions.



Paul Lu, PhD Dr. Paul Lu is an Associate Adjunct Professor of Neuroscience at the University of California San Diego (UCSD) and a Research Health Science Specialist at the Veterans Administration San Diego Healthcare System. His research, motivated in part by his own spinal cord injury, focuses on neural stem cells. He explains that injured neurons of the host nervous system regenerate into stem cell transplants, forming neural connections. In this way, the injured spinal cord forms new relay circuits through the injury site to partially restore function. Dr. Lu received his PhD in molecular biology from the University of California Davis, and performed his post-doctoral research in the laboratory of Dr. Mark Tuszynski at UCSD. While much basic work remains to be done with this neural repair strategy, Dr. Lu and his colleagues hope to translate this work eventually into humans with spinal cord injury.



Navigating

THE WORKING 2 WALK SCIENCE PRESENTATIONS Sam Maddox

Unite 2 Fight Paralysis' annual Working 2 Walk (W2W) Symposium will be held online this year, from Thursday, October 22 through Saturday, October 24. This is the place to get up to speed on the state of science to restore the injured spinal cord.

We will provide some background and context, define the problems scientists are addressing and their rationale for doing so. They have come a long way in understanding the biology of spinal trauma. But progress is not on a fast track; there is no treatment close to being approved for either acute or chronic SCI in humans. However, there are some exciting possibilities on the horizon, including some projects now in clinical trials, and some new biotech start-ups hoping to monetize their optimism.

You are the Symposium

One of the unique features of Working 2 Walk has always been that this is not just a research science show-and-tell, but a research science interaction. While the symposium is online this year, all participants are still encouraged to be part of the event. **The SCI community has an important role to play in keeping things moving: to remind the scientific community – with your voice and your presence – that there is urgency for treatments.**

You will still be able to mix it up with the scientists, and vice versa. Scientists very much want to meet members of the SCI community and their families. It humanizes and motivates their work. The meeting is set up so you can ask any question of any other participant – especially the esteemed scientists. There's also a Networking Room where you can chat with other participants and share insights. So don't be shy, if you don't understand something, ask!

To help frame these discussions, it can be helpful to reduce spinal cord injury to a general range of problems researchers are trying to solve. It is also important to keep a wide view: discovery science is only part of the solution. Therapies start out as ideas that have to be funded. Then, if something pans out with animals, they have to be translated to humans, which means they have to navigate clinical trials, governmental approvals, commercialization and insurance reimbursement.

Let's start with the most basic question: What does an injury actually do to the cord? (*Note: We recognize the medical value of acute SCI treatment development, however our focus is on chronic injury.*)

Three research categories:

The spinal cord is usually injured by high impact, a force that exceeds the protective armor of the backbone. There are also numerous ways the cord can be damaged without trauma (congenital, tumor, stroke, disease, surgical error, etc.). Some nerve cells in the impaired zone die right away – they're gone. Nearby, others are in peril, and many succumb hours and days later as the injury site becomes toxic. Could we **REPLACE** lost cells or rebuild the mangled cord structure to encourage recovery?

Some spinal cord cells survive trauma but lose their axons, or long extensions akin to wiring. Many of these cells attempt to recover and send out axons but get stuck. Could we unstick the cells, bump up their power, **REGENERATE** them, and then direct the axons to reconnect appropriately?

Many cells and cell networks in the injured spinal cord are alive but disconnected from the primary information circuits between brain and cord. Can we **REJUVENATE** the spared parts, tapping into inherent self-repair mechanisms, or perhaps the innate smartness of the spinal cord itself?

Replacement

Cell transplantation is a potential strategy we all seem to get; it's easy to imagine a new cell replacing a missing or broken one. Of course, it's not that easy. Which cells are best to use, what's the right timing to transplant them, where is the best place to put them, what about the immune response that wants to eat any new cells up, and what are the cells actually doing once introduced to the host? This leads us to stem cells, and much reason for optimism, and for caution: because these cells are capable of growth they are capable of too much growth.

In recent years a number of SCI-related cell replacement trials have been undertaken. The Miami Project, for example, has tested implants of Schwann cells (a support cell from the peripheral nervous system). Schwann cells appear to nourish the native cord cells but don't replace them. Other labs have published positive results transplanting olfactory cells, taken from the nose area. Stem cells have already implanted in various forms in several human clinical trials for SCI, mostly for acute patients but also for injuries considered chronic.

It's too soon to know what to expect regarding recovery (sample sizes are small) but in FDA-regulated trials, stem cells appear to be safe, and some stem cell efforts have reported benefits to participants.

At this year's Working 2 Walk, we will meet **Mohamad Bydon**, a neurosurgeon at the Mayo Clinic in Minnesota. He published encouraging results from a study last year that injected 100 million stem cells into the spinal fluid of 10 patients; the cells were derived from each patient's own abdominal adipose tissue (fat cells), important because this avoids any immune response or ethical issues. One patient became a "super responder." Chris Barr, 53, broke his neck surfing in 2017 and was what's called AIS A – complete injury, no motor or sensory function below lesion level. He later improved to AIS C – some motor and sensory function below his injury, including some ambulation. But after the stem cells, Barr got way better, including speedier walking. You might recall he was on ABC's Good Morning America being interviewed by Christopher Reeve's son, Will.

Some patients did not respond at all to Bydon's stem cells. Barr's result is cool but not the main point: why do the cells work in some and not in others? The Mayo team doesn't know, and they also don't know exactly what the cells are doing. The working hypothesis is that adipose derived stem cells support spinal cord cells, reduce inflammation, increase blood flow and limit formation of cysts. Maybe the stem cells also encourage cells in the cord to regenerate. Bydon wants "to better delineate who will be a responder and why patients respond differently to stem cell injections."

Note: Another very cool thing about the Mayo study is that a major part of its funding came from the state of Minnesota. Prodded by activists in the SCI community (organized as Get Up Stand Up to Cure Paralysis, and initially led by Matthew Rodreick, now Executive Director of U2FP) the state passed legislation in 2015 allocating \$1 million for SCI and brain injury research. The next year, they added \$6 million more. Minnesota's success has become a template for U2FP advocacy developments in other states, including Pennsylvania, Ohio and Wisconsin. Almost \$12 million of grassroots money has been funded by states so far. To learn more, or to get involved in your state, see the Cure Advocacy Network page at u2fp.org.

Regeneration

It wasn't until the 1980s that any real hopes began to emerge for restoring function after spinal cord injury. Age-old dogmas held that the brain and cord are a single set of wires – once damaged they can't be fixed. Not so! Scientists showed that spinal cord nerve fibers (axons) could indeed grow and reconnect again after injury if the area near the damage is cleared of growth-blocking debris and perhaps nourished with growth additives. This remains an active area of research today; indeed, the injury environment can be made more hospitable to the survival and growth of axons. Also, surviving spinal neurons might also be genetically rejiggered to grow with an urgency they once had, when we were babies.

A major issue in regenerating spinal cord nerves is the formation of a scar-like barrier that seals off the damaged spinal cord. Spinal cord nerves avoid this area. Could it be cleared away? This is now a busy research area, including budding commercial efforts, as enzyme drugs or peptides appear to digest or neutralize the scar so nerve cells can cross the barrier. In animal experiments, significant function has been restored after application of a scar-eating molecule called Chondroitinase, nicknamed chase. Chase is not clinically useful yet – it's too unstable at body temperature and may have to be dosed repeatedly.

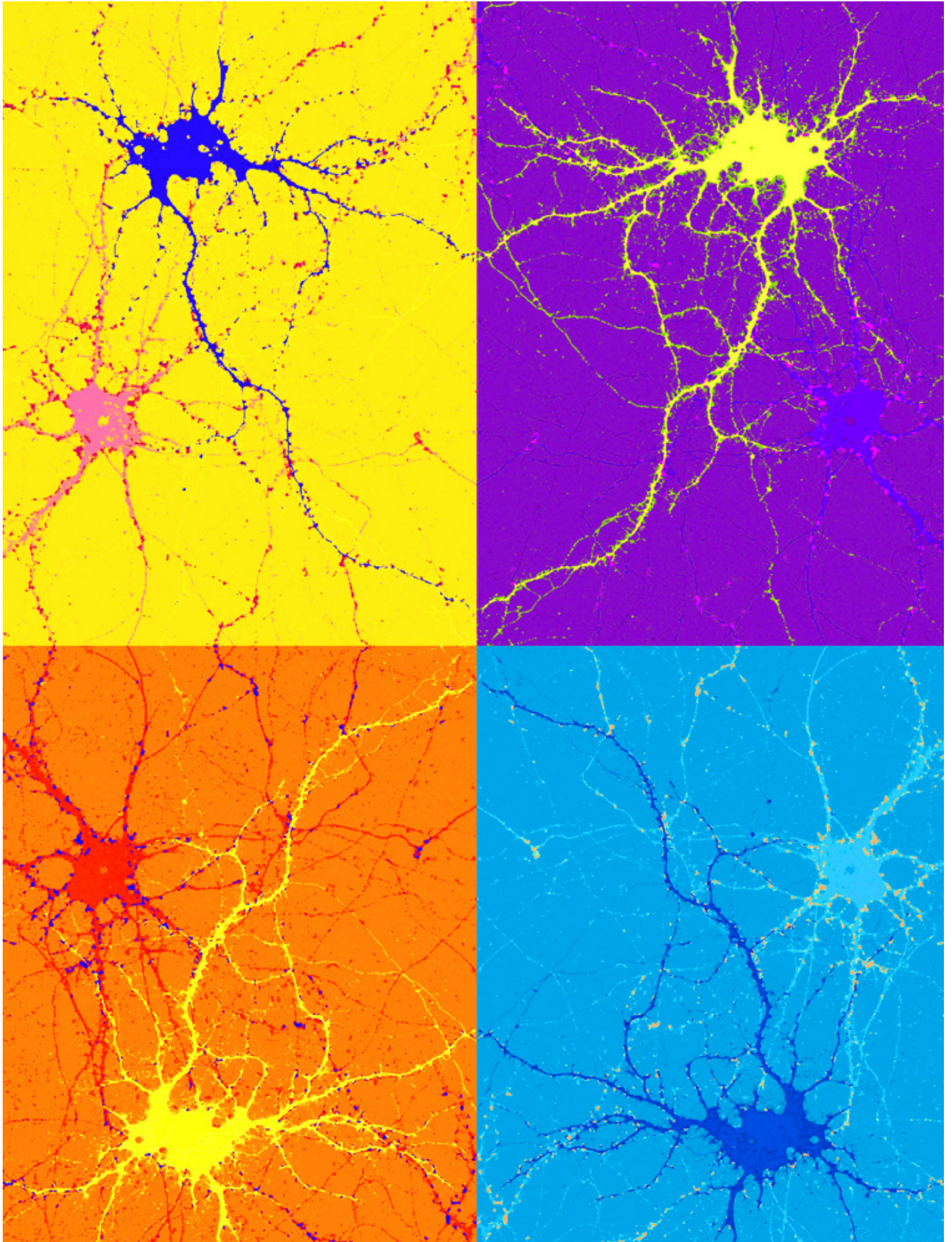
Working 2 Walk 2020 features two researchers who study chase and its limitations, in very different settings. Both have an eye on human follow-up. **Molly Shoichet**, the Canada Research Chair in Tissue Engineering at the University of Toronto, has found ways to modify chase to be less fragile. She also suggests that delivering the molecule along with another regenerative strategy, such as transplanted cells, might be the answer.

Nick Jeffery is a veterinarian and Professor of Small Animal Clinical Sciences at Texas A&M University. He has had very encouraging results in a double-blinded randomized controlled study of intraspinal injection of chase in chronically paralyzed dogs. These dogs represent a naturally occurring injury model that is highly relevant to humans. One wonders why this hasn't been more widely discussed. You can ask him.

We will also learn about a regenerative clinical trial now underway hoping to modify the injury area and promote recovery in people with limited arm and hand movement. Presenter **George D. Maynard**, Ph.D., President and Chief Scientific Officer of ReNetX Bio, Inc., will take us through the process of commercializing a molecule they call Axer-204, or "nogo-trap." This molecule acts as a decoy to block out inhibitors, thus allowing axon growth.

Scientists very much want to meet the SCI community. It humanizes and motivates their work.

Candace Floyd, a physical medicine and rehabilitation professor at the University of Utah, joins Shoichet and Jeffery on the first panel of the conference. Floyd studies the basic biology of SCI and will add her experience with larger animal models (e.g. pigs) to help refine preclinical studies of potential therapies - such as chase - toward human use.



*Synaptogenesis by Lin Ning, Neurobiology, Stanford.
First place, 2016 Stanford Neuroscience Institute's Art of Neuroscience competition*

Neurogel en Marche Association is an association of paralyzed people based in France. In 2004 the association bought the patent to a synthetic bio-material called Neurogel – the stuff was said to act as a substrate to help injured spinal cord cells recover and grow. A European clinical trial for chronic SCI had been planned for many years. Neurogel en Marche persisted, and in 2018 got a trial approved for 12 patients in China. They dropped Neurogel and opted for an activated fat cell compound; the spinal cord is surgically opened so glial scars and adhesions can be cleaned up. The fat cells fill the cavity. Early reports via the famous medical journal *Facebook* indicate that there was some recovery. **Stephana Carelli**, a researcher at the University of Milan (working with a team called House of Miracles)

Science, money and promising trial results are not enough – a treatment has to be approved, then paid for.

was involved in the Neurogel en Marche trial. She will tell us how a committed community based group can pull off a clinical trial.

One of the more compelling regeneration stories in recent

years was the discovery that gene modification could take the “brakes” off spinal cord axon growth. The Zhigang He lab at Harvard deleted a molecule called PTEN in the spinal cord of injured animals. This rebooted robust axon growth in critical sets of long axons that start in the brain and course the length of the cord, and which are the key to major motor function (grasping, walking). **Bob Yant**, a California guy living with C5 SCI, heard about this, liked the possibilities, formed a company to develop and commercialize the gene technique, and now here we have Axonis, for real.

Joining us at Working 2 Walk 2020 is **Joanna Stanicka**, Ph.D., CEO of Axonis. Stanicka will talk about potential treatments but also about what it takes to bring a product to market. Axonis first hopes to test a molecule called KCC2, which has shown a regenerative effect to restore stepping in paralyzed mice.

Rejuvenation

It wasn't that long ago that rehabilitation just meant learning to compensate for lost function, using devices and tools. Now we know that rehab – in the form of physical therapy and activity based exercise – can on its own facilitate recovery. Certain forms of patterned activity (e.g., stepping on a treadmill) appear to wake up dormant nerve circuits in the spinal cord, and for some people this seems to unlock some degree of function.

Why is it we hear about these new rehab techniques helping people, but they are not widely available? Part of the problem is that rehabilitation as a field has not convincingly justified itself with cold, hard data. It's time we got organized. U2FP has over the past several years helped specialized SCI fitness centers form the Association of Neuro Activity Based Professionals (ANABP) to share knowledge, set some basic standards and establish proof

that activity based therapies actually work. Once the case is made for medical value, it should follow that they be covered by Medicaid, private insurance, etc.

Working 2 Walk presenter **Leslie Morse**, who heads the Department of Rehabilitation Medicine at the University of Minnesota, has agreed to be the principal investigator to study participant data from ANABP member centers; the goal is to establish the public health impact of activity-based exercise. Morse is with us on a panel with Drs. Bydon (Mayo) and Carelli (Milan). They'll be talking about running clinical trials and validating research.


The biggest story in restoring function has been the development of spinal cord stimulation. In several labs in the U.S. and abroad, people with SCI have been implanted with an epidural spinal cord stimulator in their back. In the SCI trials, many participants have seen significant voluntary recovery of function, including the ability to stand, plus benefits in cardiovascular health, bladder and even sexual function. Investigators have found that the benefits of spinal cord stim don't necessarily require an implanted device. A skin surface stim method has been tested, with good results.

The possibilities of spinal cord stim have fueled interest in the biotech device world. Fledgling California company NeuroRecovery Technologies was bought out by a European start up, GTX. Meanwhile, there's another new west coast start-up, SpineX, that hopes to get its noninvasive device approved. Clinical trials continue all over the U.S. and abroad.

Joining the Working 2 Walk 2020 program is Dr. **Candy Tefertiller**, Executive Director of Research and Evaluation at Craig Hospital in Denver. She's here on our Industry panel (with Maynard of ReNetX and Stanika of Axonis) representing GTX, a spinal cord stimulation company founded in the Netherlands by scientist Gregoire Courtine. GTX is in position to lead the stim field in the coming years to develop both implanted and noninvasive units. A multicenter clinical trial is coming soon for GTX's noninvasive unit; the trial is focused on incomplete cervical SCI. Tefertiller will oversee participants at Craig. Also joining the Industry panel discussion will be **Dave Marver**, CEO of GTX.

Funders

Science, money, promising trial results and new companies are not enough – a treatment has to be approved, and then it has to be paid for. These topics are fundamental but not always fully appreciated in a research field that has never seen an idea run the gauntlet from lab to clinic. Working 2 Walk's Funders and Advocates panel (Friday



afternoon) will discuss strategies for financing research by way of government grants and charity support.

Linda Bambrick is a Program Director at the National Institute of Neurological Disorders and Stroke (NINDS). She manages the portfolio of grants and cooperative agreements for spinal cord injury, peripheral nerve injury and axonal regeneration.

Melissa Miller runs the Spinal Cord Injury Research Program, Department of Defense (DoD), Congressionally Directed Medical Research Programs.

Jacqueline Roche is a consumer reviewer and patient advocate for DOD.

Jay Shepard is chairman of the board of directors of the Christopher & Dana Reeve Foundation. He has a daughter with a spinal cord injury.

Jack Jablonski was spinal cord injured playing hockey. He now operates an SCI-specific nonprofit, The Jack Jablonski Believe in Miracles Foundation, which funds promising research.

Community

U2FP is a community-centric organization. Working 2 Walk presents three advocates from around the world on the Saturday morning session.

Perry Cross is Executive President of the Australia-based Perry Cross Foundation. He is a C2 ventilated quadriplegic injured in 1996.

Corinne Jeanmaire was paralyzed almost 20 years ago. Over the years Corinne, from the Netherlands, has been a familiar face at Working 2 Walk. She operates the endParalysis Foundation, which supports SCI science.

Kim Anderson-Erisman is a spinal cord injury scientist who herself lives with an SCI. She is the Director of the Northeast Ohio Regional SCI Model System at MetroHealth Rehabilitation Institute in Cleveland, and is also President of the North American Spinal Cord Injury Consortium (NASCI).

Wrap-Up Panel

The final discussion of this year's symposium will explore strategies for creating a sort of "Cure GPS," so we know where we are, and where we are going. This segment, moderated by U2FP's Executive Director, Matthew Rodreick, includes representatives from science, advocacy, funding, and industry.

Murray Blackmore, Marquette University

Corinne Jeanmaire, endParalysis Foundation

John Reilly, Jack Jablonski Foundation

Joanna Stanicka, Axonis

Rebecca Martin, Kennedy Krieger Institute

What Now?

All of this brings us back to you. We believe that bringing all of us together in a single symposium and toward one shared purpose is a necessary step toward finding our way forward and ultimately realizing **U2FP's vision: Every person has equal access to treatments that will restore health and independence after spinal cord injury.**

- To learn more about our work please visit u2fp.org
- To learn more about the Cure Advocacy Network, contact Jake Beckstrom, jakebeckstrom@u2fp.org
- For more info about the Science Advisory Board, contact Sam Maddox, sammaddox@u2fp.org
- To find out about Team U2FP, contact Ryan Romine, ryanromine@u2fp.org
- To reach Matthew Rodreick, contact matthewrodreick@u2fp.org



*Shelter in Place by Geinene Carson
Part of 2020 Art of Neuroscience exhibition, Netherlands Institute for Neuroscience*

SciTrials.org

WHAT IS SCITRIALS.ORG?

Clinical trials are an essential part of the path to bring treatments to the Spinal Cord Injury community. Before SciTrials.org, users would have to search through hundreds of thousands of trials on ClinicalTrials.gov on every medical problem. It would be hard to find trials that were relevant to them, and have to do this on a regular basis. SciTrials.org provides the community with a way of finding clinical trials that are relevant to each individual in the fastest way possible by enabling individuals to:

- Search via location and injury details
- Receive email updates on new trials of interest to them
- Find answers for the most common questions about trials
- Access clinical information distilled into everyday language
- Apply to clinical trials quickly and directly in the web site

WHO CREATED IT?

SciTrials.org was created by Niall El-Assaad, Corinne Jeanmaire (endParalysis), and members of the North American SCI Consortium (NASCI). This new tool has also been tested by members of the SCI community and endorsed by several SCI organizations.

WHO IS IT FOR?

The system is for people living with a SCI and their family members to find clinical trials that interest them with capabilities to apply for the trial. Additionally, it is for Investigators to help increase recruitment requests for their respective trials. It is also a source of reliable and easily accessible information for all clinicians in the field of SCI. The aim is to balance the needs of both communities. Resulting in more people participating in trials, and trials having more candidates to find better matches.

WHAT DOES IT DO?

The tool collects all available clinical trial data applicable to spinal cord injury on a global basis. It makes the trials easily accessible (through our basic and/or advanced selection tool)

depending on the user's situation (e.g. chronic or acute, high or low injury, complete or incomplete) and wishes (type of trial, goal). It also makes the information from the investigator much more understandable as it provides an "overview" which describes the key data about the trial in lay language. It makes it possible for the user to receive information about new trials automatically or to easily ask more information from the investigator for a given trial.

WHAT TRIALS ARE INCLUDED AND WHAT IS EXCLUDED?

In the current platform we are importing all SCI trials that are posted on ClinicalTrials.gov. We are currently working on developing support to add trials from other trial registries from around the world. Trials are excluded from the platform if:

- they are not about spinal cord injury;
- they are not taking place at a University, Hospital, or Research Institution;
- they are trials that are asking for money for the research procedures or treatment.

Due to feedback from the community, we are initially writing lay-language overviews for the trials that are involving an intervention of some sort.

HOW IS INFORMATION PROVIDED IN THE SIGN UP FORM SECURED?

All information is protected by Google Firebase, which is a development platform provided and secured by Google.

WHO IS LIABLE FOR INFORMATION ON THE SITE?

All the information comes from publically available information on ClinicalTrials.gov or is obtained from the trial investigators. The trial investigators are responsible for the information they provide relating to trials.

The platform itself is covered by indemnity insurance under the American Spinal Research Organization doing business as NASCI.

SciTrialsFinder.net

WHY USE SCITRIALSFINDER.NET?

The goal of the SciTrialsFinder.net website is to allow individuals with spinal cord injury (SCI), their families and health care professionals to get common language information about clinical trials as developed by experienced clinical investigators (we call these curations or curated trials). We have started by curating trials looking for participants for studies of interventions targeting improvement of neurological and related functional outcomes, currently underway in North America, Europe and Australia. In addition to the curated trials, users can also read about all SCI related trials from clinicaltrials.gov.

KEEP IN MIND...

Clinical trials of spinal cord injury are conducted with the goal to advance knowledge of the injured nervous system and to generate ways to improve recovery and life after the injury. It is important to understand that trials are conducted because we don't know if an experimental method is or is not effective. Please keep this in mind as you review clinical trials that you may be eligible for.

Please help us improve our site by providing feedback at feedback@SciTrialsFinder.net





**For attendees who registered for Continuing Medical Education (CME) credits,
below is information on how to claim up to 10.50 hours of CME credits
for this year's Working 2 Walk Virtual Symposium.**

Accreditation Information

Accreditation: This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of University of Utah and the Nielsen Foundation and Unite 2 Fight Paralysis. The University of Utah is accredited by the ACCME to provide continuing medical education for physicians.

AMA Credit: The University of Utah School of Medicine designates this live activity for a maximum of 10.50 AMA PRA Category 1 Credit(s)[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nondiscrimination and Disability Accommodation Statement: The University of Utah does not exclude, deny benefits to or otherwise discriminate against any person on the basis of race, color, national origin, sex, disability, age, veteran's status, religion, gender identity/expression, genetic information, or sexual orientation in admission to or participation in its programs and activities. Reasonable accommodations will be provided to qualified individuals with disabilities upon request, with reasonable notice. Requests for accommodations or inquiries or complaints about University nondiscrimination and disability/access policies may be directed to the Director, OEO/AA, Title IX/Section 504/ADA Coordinator, 201 S President's Circle, RM 135, Salt Lake City, UT 84112, 801-581-8365 (Voice/TTY), 801-585-5746 (Fax).

Claiming Your CME Credits

Thank you for your participation in our course! Please complete the short course evaluation after you have completed your course sessions by following the link below. The evaluation should take less than 5 minutes. Once you complete the evaluation, the link will prompt you to claim your CME credit for this course. Thank you!

Instructions for Claiming Credit and Printing Your Certificate:

(Note: There will be a series of screens please follow the directions on each screen).

1. To complete a short evaluation, claim your credit and print your course certificate please go to the following link: <http://goo.gl/nrJKrN>
2. When prompted enter your email address. If you are a new user, select "new user" and complete some short identifying information about yourself.
3. Enter the password; if you do not have a password you will be able to create one.
4. Enter the following CME Activity code: 53128
5. Complete the short evaluation
6. Enter the number of credits commensurate with your participation in the activity, up to 10.50 which is the number of AMA PRA Category 1 Credit(s)[™] credits this activity is certified for.

If you encounter any problems please call the UUCME office at 801-581-6886.





This data sheet is a quick reference on demographics and the use of services by people with spinal cord injury in the United States (U.S.). Much of the information reflects recent data collected since 2015. Historical information reflects data collected since the early 1970s.

The National Spinal Cord Injury Database is a prospective longitudinal multicenter study that currently captures data from an estimated 6% of new SCI cases in the United States. The database has demographic and condition status data through 2019 for 34,130 people with SCI.

National SCI Statistical Center
515 Spain Rehabilitation Center
1717 6th Avenue South
Birmingham, AL 35233-7330

For Statistics: 205-934-3342
For Business: 205-934-3320
TDD: 205-934-4642
FAX: 205-934-2709
E-mail: NSCISC@uab.edu
Website: uab.edu/NSCISC

Incidence

Given the current U.S. population size of 329 million people, a recent estimate showed that the annual incidence of spinal cord injury (SCI) is approximately 54 cases per one million people in the United States, or about 17,810 new SCI cases each year. New SCI cases do not include those who die at the location of the incident that caused the SCI.

- **Data Source:** Jain NB, Ayers GD, Peterson EN, et al. Traumatic spinal cord injury in the United States, 1993-2012. JAMA. 2015;313(22):2236-2243.

Prevalence

The estimated number of people with SCI living in the United States is approximately 294,000 persons, with a range from 250,000 to 368,000 persons.

- **Data Source:** Lasfargues JE, Custis D, Morrone F, Carswell J, Nguyen T. A model for estimating spinal cord injury prevalence in the United States. Paraplegia. 1995;33(2):62-68.

Age at Injury

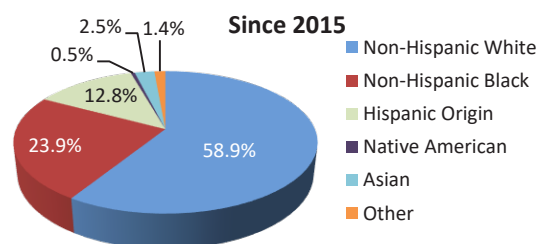
The average age at injury has increased from 29 years during the 1970s to 43 since 2015.

Gender

About 78% of new SCI cases are male.

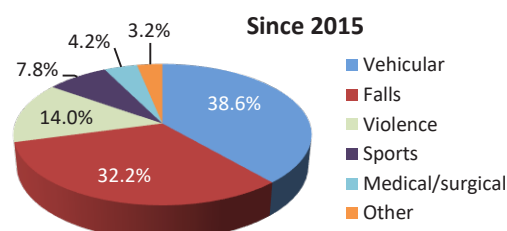
Race/Ethnicity

Recently, about 24% of injuries have occurred among non-Hispanic blacks, which is higher than the proportion of non-Hispanic blacks in the general population (13%).



Cause

Vehicle crashes are the most recent leading cause of injury, closely followed by falls. Acts of violence (primarily gunshot wounds) and sports/recreation activities are also relatively common causes. A customizable Leading Causes of SCI tool is at uab.edu/NSCISC.

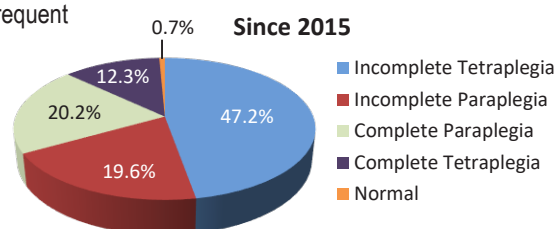


Lengths of Stay

Lengths of stay in the hospital acute care unit have declined from 24 days in the 1970s to 11 days recently. Rehabilitation lengths of stay have also declined from 98 days in the 1970s to 31 days recently.

Neurological Level and Extent of Lesion

Recently, incomplete tetraplegia is the most frequent neurological category. The frequency of incomplete and complete paraplegia is virtually the same. Less than 1% of persons experienced complete neurological recovery by the time of hospital discharge.



Education

Since 2015, about a quarter of persons with SCI have a college degree at the time of their injury, compared with 45% of people who survived 40 years of injury.

Education (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
High School Only	51.6	52.1	50.4	46.6	41.3	34.0
College or Higher	24.0	26.4	27.6	26.3	34.9	45.3

Occupational Status

Since 2015, 18% of persons with SCI are employed at year 1 post-injury. The employment rate increases over time to 32% at 40 years post injury.

Status (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
Employed	67.3	18.0	23.8	29.2	31.2	32.1
Student	8.1	7.3	2.8	0.9	0.4	0.0

Marital Status

Since 2015, the percentage of people who are married is relatively consistent up to year 40 post-injury, with single/never married status slowly decreasing and divorce status slowly increasing.

Status (%)	At Injury	Year 1	Year 10	Year 20	Year 30	Year 40
Single	44.6	43.1	37.1	38.1	33.5	24.7
Married	37.4	36.4	34.7	33.6	36.2	44.2
Divorced	8.6	10.8	20.1	19.7	21.3	21.6

Re-Hospitalization

Since 2015, about 30% of persons with SCI are re-hospitalized one or more times during any given year following injury. Among those re-hospitalized, the length of hospital stay averages about 18 days. Diseases of the genitourinary system are the leading cause of re-hospitalization, followed by disease of the skin. Respiratory, digestive, circulatory, and musculoskeletal diseases are also common causes.

Historical Lifetime Costs

The average yearly expenses (health care costs and living expenses) and the estimated lifetime costs that are directly attributable to SCI vary greatly based on education, neurological impairment, and pre-injury employment history. The below estimates do not include any indirect costs such as losses in wages, fringe benefits, and productivity (indirect costs averaged \$77,701 per year in 2019 dollars).

Severity of Injury	Average Yearly Expenses (in 2019 dollars)		Estimated Lifetime Costs by Age at Injury (discounted at 2%)	
	First Year	Each Subsequent Year	25 years old	50 years old
High Tetraplegia (C1–C4) AIS ABC	\$1,149,629	\$199,637	\$5,100,941	\$2,803,391
Low Tetraplegia (C5–C8) AIS ABC	\$830,708	\$122,468	\$3,727,066	\$2,292,479
Paraplegia AIS ABC	\$560,287	\$74,221	\$2,494,338	\$1,636,959
Motor Functional at Any Level AIS D	\$375,196	\$45,572	\$1,704,144	\$1,202,832

Data Source: Economic Impact of SCI published in the journal *Topics in Spinal Cord Injury Rehabilitation*, Volume 16, Number 4, in 2011. ASIA Impairment Scale (AIS) is used to grade the severity of a person's neurological impairment following spinal cord injury.

Historical Life Expectancy

The average remaining years of life for persons with SCI have not improved since the 1980s and remain significantly below life expectancies of persons without SCI. Mortality rates are significantly higher during the first year after injury than during subsequent years, particularly for persons with the most severe neurological impairments. A customizable Life Expectancy Calculator tool is at uab.edu/NSCISC.

Age at Injury	No SCI	Life Expectancy (years) for Post-Injury by Severity of Injury and Age at Injury									
		For Persons Who Survive the First 24 Hours					For Persons Surviving at Least 1 Year Post-Injury				
		AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent Any Level	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent Any Level
20	59.4	52.0	44.7	39.1	32.5	9.8	52.3	45.1	40.0	33.6	16.9
40	40.7	34.8	29.5	24.7	20.6	8.6	35.1	29.9	25.4	21.7	13.1
60	23.3	19.2	16.0	13.0	11.1	3.6	19.4	16.4	13.7	12.4	7.9

Historical Causes of Death

Persons enrolled in the National SCI Database have now been followed up to 45 years after injury. During that time, the causes of death that appear to have the greatest impact on reduced life expectancy for this population are pneumonia and septicemia. Mortality rates are declining for cancer, heart disease, stroke, arterial diseases, pulmonary embolus, urinary diseases, digestive diseases, and suicide. However, these gains are being offset by increasing mortality rates for endocrine, metabolic and nutritional diseases, accidents, nervous system diseases, musculoskeletal disorders, and mental disorders. There has been no change in the mortality rate for septicemia in the past 45 years, and there has only been a slight decrease in mortality due to respiratory diseases.

© 2020 Board of Trustees, University of Alabama. This is a publication of the National Spinal Cord Injury Statistical Center in collaboration with the Model Systems Knowledge Translation Center. The contents of this publication were developed under grants from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant numbers 90DP0083 and 90DP0082). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this publication do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government.

Data from the National SCI Database is from 29 federally funded SCI Model Systems since 1973. Presently, there are 14 systems and 5 Form II (follow up) centers sponsored by NIDILRR. For a complete list of current SCI Model Systems, go to www.msctc.org/sci/model-system-centers.

Document Citation: National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2020.

STEM CELL FACTS



INTERNATIONAL SOCIETY
FOR STEM CELL RESEARCH

The ISSCR is an independent, nonprofit organization providing a global forum for stem cell research and regenerative medicine.

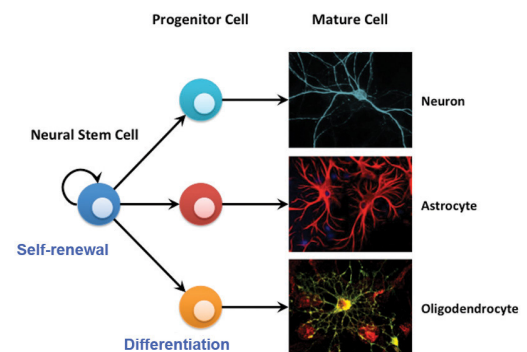
WHAT ARE STEM CELLS?

Stem cells are the foundation cells for every organ and tissue in our bodies. The highly specialized cells that make up these tissues originally came from an initial pool of stem cells formed shortly after fertilization. Throughout our lives, we continue to rely on stem cells to replace injured tissues and cells that are lost every day, such as those in our skin, hair, blood and the lining of our gut. Stem cells have two key properties: 1) the ability to **self-renew**, dividing in a way that makes copies of themselves, and 2) the ability to **differentiate**, giving rise to the mature types of cells that make up our organs and tissues.

TISSUE-SPECIFIC STEM CELLS

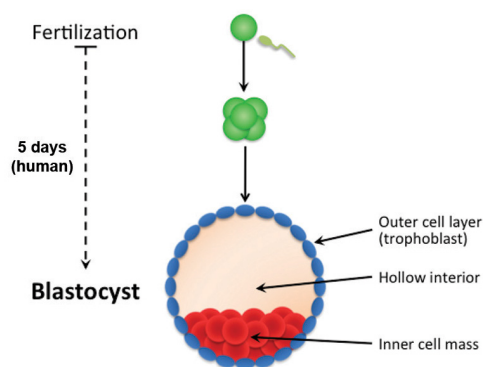
Tissue-specific stem cells, which are sometimes referred to as “**adult**” or “**somatic**” stem cells, are already somewhat specialized and can produce some or all of the mature cell types found within the particular tissue or organ in which they reside. Because of their ability to generate multiple, organ-specific, cell types, they are described as “**multipotent**.” For example, stem cells found within the adult brain are capable of making neurons and two types of glial cells, astrocytes and oligodendrocytes.

Tissue-specific stem cells have been found in several organs that need to continuously replenish themselves, such as the blood, skin and gut and have even been found in other, less regenerative, organs such as the brain. These types of stem cells represent a very small population and are often buried deep within a given tissue, making them difficult to identify, isolate and grow in a laboratory setting.



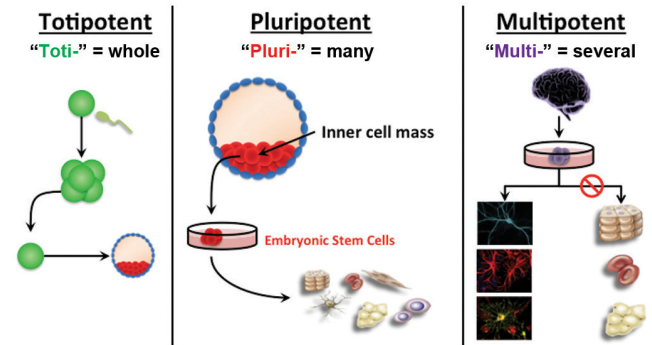
Neuron – Dr. Gerry Shaw, EnCor Biotechnology Inc.
Astrocyte – Abcam Inc.
Oligodendrocyte – Dhaunchak and Nave (2007).
Proc Natl Acad Sci USA 104:17813-8

EMBRYONIC STEM CELLS



Embryonic stem cells have been derived from a variety of species, including humans, and are described as “**pluripotent**,” meaning that they can generate all the different types of cells in the body. Embryonic stem cells can be obtained from the **blastocyst**, a very early stage of development that consists of a mostly hollow ball of approximately 150-200 cells and is barely visible to the naked eye. At this stage, there are no organs, not even blood, just an “inner cell mass” from which embryonic stem cells can be obtained. Human embryonic stem cells are derived primarily from blastocysts that were created by **in vitro fertilization (IVF)** for assisted reproduction but were no longer needed.

The fertilized egg and the cells that immediately arise in the first few divisions are “**totipotent.**” This means that, under the right conditions, they can generate a viable embryo (including support tissues such as the placenta). Within a matter of days, however, these cells transition to become pluripotent. None of the currently studied embryonic stem **cell lines** are alone capable of generating a viable embryo (i.e., they are pluripotent, not totipotent).



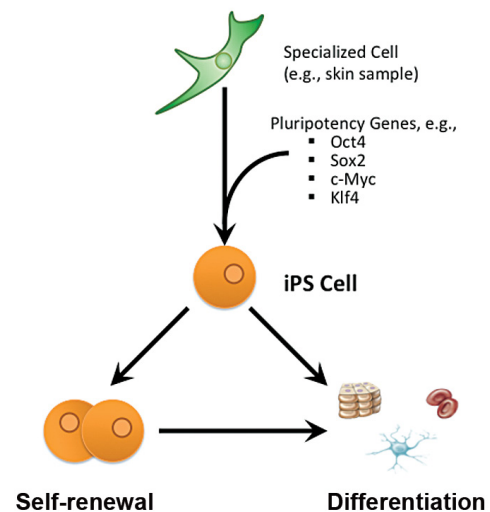
WHY ARE EMBRYONIC STEM CELLS SO VALUABLE?

Unlike tissue-specific (adult) stem cells, embryonic stem cells have the potential to generate every cell type found in the body. Just as importantly, these cells can, under the right conditions, be grown and expanded indefinitely in this unspecialized or “undifferentiated” state. These cells help researchers learn about early human developmental processes that are otherwise inaccessible, study diseases and establish strategies that could ultimately lead to therapies designed to replace or restore damaged tissues.

INDUCED PLURIPOTENT STEM CELLS

One of the hottest topics in stem cell research today is the study of induced pluripotent stem cells (iPS cells). These are adult cells (e.g., skin cells) that are engineered, or “reprogrammed,” to become pluripotent, i.e., behave like an embryonic stem cell. While these iPS cells share many of the same characteristics of embryonic stem cells, including the ability to give rise to all the cell types in the body, it is important to understand that they are not identical.

The original iPS cells were produced by using viruses to insert extra copies of three to four genes known to be important in embryonic stem cells into the specialized cell. It is not yet completely understood how these three to four “reprogramming” genes are able to induce pluripotency; this question is the focus of ongoing research. In addition, recent studies have focused on alternative ways of reprogramming cells using methods that are safer for use in clinical settings.



DISEASE-OR PATIENT-SPECIFIC PLURIPOTENT STEM CELLS

One of the major advantages of iPS cells, and one of the reasons that researchers are very interested in studying them, is that they are a very good way to make pluripotent stem cell lines that are specific to a disease or even to an individual patient. Disease-specific stem cells are powerful tools for studying the cause of a particular disease and then for testing drugs or discovering other approaches to treat or cure that disease. The development of patient-specific stem cells is also very attractive for cell therapy, as these cell lines are from the patient themselves and may minimize some of the serious complications of rejection and immunosuppression that can occur following

MOVING STEM CELLS INTO THE CLINIC

Clinical translation is the process used to turn scientific knowledge into real world medical treatments. Researchers take what they have learned about how a tissue usually works and what goes wrong in a particular disease or injury and use this information to develop new ways to diagnose, stop or fix what goes wrong. Before being marketed or adopted as standard of care, most treatments are tested through clinical trials. Sometimes, in attempting new surgical techniques or where the disease or condition is rare and does not have a large enough group of people to form a clinical trial, certain treatments might be tried on one or two people, a form of testing sometimes referred to as **innovative medicine**.

For more information on how science becomes medicine, please visit www.closerlookatstemcells.org.

CURRENT THERAPIES

Blood stem cells are currently the most frequently used stem cells for therapy. For more than 50 years, doctors have been using bone marrow transplants to transfer blood stem cells to patients, and more advanced techniques for collecting blood stem cells are now being used to treat leukemia, lymphoma and several inherited blood disorders. Umbilical cord blood, like bone marrow, is often collected as a source of blood stem cells and in certain cases is being used as an alternative to bone marrow transplantation.

Additionally, some bone, skin and corneal diseases or injuries can be treated by grafting tissues that are derived from or maintained by stem cells. These therapies have also been shown to be safe and effective.

POTENTIAL THERAPIES

Other stem cell treatments, while promising, are still at very early experimental stages. For example, the **mesenchymal stem cell**, found throughout the body including in the bone marrow, can be directed to become bone, cartilage, fat and possibly even muscle. In certain experimental models, these cells also have some ability to modify immune functions. These abilities have created considerable interest in developing ways of using mesenchymal stem cells to treat a range of musculoskeletal abnormalities, cardiac disease and some immune abnormalities such as graft-versus-host disease following bone marrow transplant.

REMAINING CHALLENGES

Despite the successes we have seen so far, there are several major challenges that must be addressed before stem cells can be used as cell therapies to treat a wider range of diseases.

First, we need to identify an abundant source of stem cells. Identifying, isolating and growing the right kind of stem cell, particularly in the case of rare adult stem cells, are painstaking and difficult processes. Pluripotent stem cells, such as embryonic stem cells, can be grown indefinitely in the lab and have the advantage of having the potential to become any cell in the body, but these processes are again very complex and must be tightly controlled. iPS cells, while promising, are also limited by these concerns. In both cases, considerable work remains to be done to ensure that these cells can be isolated and used safely and routinely.

Second, as with organ transplants, it is very important to have a close match between the donor tissue and the recipient; the more closely the tissue matches the recipient, the lower the risk of rejection. Being able to avoid the life-long use of immunosuppressants would also be preferable. The discovery of iPS cells has opened the door to developing patient-specific pluripotent stem **cell lines** that can later be developed into a needed cell type without the problems of rejection and immunosuppression that occur from transplants from unrelated donors.

Third, a system for delivering the cells to the right part of the body must be developed. Once in the right location, the new cells must then be encouraged to integrate and function together with the body's other cells.

GLOSSARY

Blastocyst

A very early embryo that has the shape of a ball and consists of approximately 150-200 cells. It contains the inner cell mass, from which embryonic stem cells are derived, and an outer layer of cells called the trophoblast that forms the placenta.

Cell line

Cells that can be maintained and grown in a dish outside of the body.

Clinical translation

The process of using scientific knowledge to design, develop and apply new ways to diagnose, stop or fix what goes wrong in a particular disease or injury.

Differentiation

The process of development with an increase in the level of organization or complexity of a cell or tissue, accompanied by a more specialized function.

Embryo

The early developing organism; this term denotes the period of development between the fertilized egg and the fetal stage.

Embryonic stem cell

Cells derived from very early in development, usually the inner cell mass of a developing blastocyst. These cells are self-renewing (can replicate themselves) and pluripotent (can form all cell types found in the body).

Induced pluripotent stem (iPS) cell

Induced pluripotent cells (iPS cells) are stem cells that were engineered ("induced") from non-pluripotent cells to become pluripotent. In other words, a cell with a specialized function (for example, a skin cell) that has been "reprogrammed" to an unspecialized state similar to that of an embryonic stem cell.

Innovative medicine

Treatments that are performed on a small number of people and are designed to test a novel technique or treat a rare disease. These are done outside of a typical clinical trial framework.

In vitro fertilization

A procedure in which an egg cell and sperm cells are brought together in a dish to fertilize the egg. The fertilized egg will start dividing and, after several divisions, forms the embryo that can be implanted into the womb of a woman and give rise to pregnancy.

Mesenchymal stem cells

Mesenchymal stem cells were originally discovered in the bone marrow, but have since been found throughout the body and can give rise to a large number of connective tissue types such as bone, cartilage and fat.

Multipotent stem cells

Stem cells that can give rise to several different types of specialized cells, but in contrast to a pluripotent stem cell, are restricted to a certain organ or tissue types. For example, blood stem cells are multipotent cells that can produce all the different cell types that make up the blood but not the cells of other organs such as the liver or brain.

Pluripotent stem cells

Stem cells that can become all the cell types that are found in an implanted embryo, fetus or developed organism. Embryonic stem cells are pluripotent stem cells.

Self-renewal

The process by which a cell divides to generate another cell that has the same potential.

Stem cells

Cells that have both the capacity to self-renew (make more stem cells by cell division) and to differentiate into mature, specialized cells.

Tissue-specific stem cells

(also known as adult or somatic stem cells)

Stem cells found in different tissues of the body that can give rise to some or all of the mature cell types found within the particular tissue or organ from which they came, i.e., blood stem cells can give rise to all the cells that make up the blood, but not the cells of organs such as the liver or brain.

Totipotent stem cells

Stem cells that, under the right conditions, are wholly capable of generating a viable embryo (including the placenta) and, for humans, exist until about four days after fertilization, prior to the blastocyst stage from which embryonic stem cells are derived.



The Craig H. Nielsen Foundation is proud to support

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The Nielsen Foundation is dedicated to supporting both programs and scientific research to improve the quality of life for those affected by and living with spinal cord injury.

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2020

A Year of Milestone Anniversaries!

30 years ago, on the 26th of July 1990, President George H.W. Bush signed the Americans with Disabilities Act ("ADA") into U.S. law.

The purpose of the law is to make sure that people with disabilities have the same rights and opportunities as everyone else in the United States.

Global Technology Services Group remains, as ever, a strong supporter of the ADA as well as the Unite to Fight Paralysis (www.u2fp.org) vision that every person has equal access to treatments that will restore health and independence after spinal cord injury.

2020 is also the 15th anniversary of the Annual Working 2 Walk Science and Advocacy Symposium, which in this Covid-19 year is being live-streamed in Salt Lake City.

Our Global Technology family is honored to support all families coping with disability and congratulates Working 2 Walk on its 15th anniversary of leadership in promoting research into rehabilitation and a wide range of medical discoveries.

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CONVENING THE COMMUNITY

Working 2 Walk Science & Advocacy Symposium

Our conference is a collaborative gathering that prioritizes the voice of the Spinal Cord Injury (SCI) Community. We bring together research scientists, clinicians, and community advocates, along with investors and industry leaders to exchange information and strategies for achieving recovery from SCI.

RACE FOR CURATIVE INTERVENTIONS

Team U2FP

When you join Team U2FP you're helping us accelerate cures for the Spinal Cord Injury (SCI) Community! Your fundraising efforts help fuel all of our initiatives, pushing us closer to our goal: to achieve functional recovery for those living with an SCI.

RAISING OUR VOICE

Cure Advocacy Network (CAN)

With almost \$12M in legislative funding passed by CAN Activists from the SCI Community - the tide is turning. We're making our voices heard. We've passed Spinal Cord Injury Research Bills in Pennsylvania, Minnesota, Ohio and Washington states with new initiatives started in Wisconsin, Texas and Colorado.

Learn more at **U2FP.org!**

FUND THE BEST SCIENCE

Scientific Advisory Board (SAB)

Our elite panel of SCI scientists critically evaluates research proposals and creates the necessary feedback so that funders are assured their investment has the best chance of success.

CONVERSATIONS FOR CURES

CureCast Podcast

Co-hosts Jason Stoffer & Matthew Rodreick conduct interviews with SCI Scientists and Advocates to help unpack cure research and deepen the dialogue with the SCI Community

FOSTER COLLABORATION

Think Tanks - Work Groups

U2FP facilitates 3 separate groups of experts to foster collaboration and innovation in the following areas:

- Neuromodulation
- Activity Based Therapy Centers
- Translational

SUBMERGED.

WHO ARE WE WHEN WE LOSE WHAT DEFINES US?

SUBMERGED is a documentary film that follows one woman's quest to find a cure for spinal cord injury — and the journey that unfolds as a result. SUBMERGED is grateful to have U2FP as both a fiscal sponsor and a friend throughout this filmmaking process. We are very excited to share this film project with you all in 2021!

On the eve of Independence Day, 2012, Kelsey Peterson dove into Lake Superior, off the shores of Wisconsin; she hit the lake bottom head first, sustaining a life-changing injury that would rob her of her ability to move her limbs and strip her of her self-identities as an athlete and dancer.

Now she has to redefine who she is as she seeks answers regarding a cure — of body and spirit.

Within the spinal cord injury (SCI) community, Kelsey found peers and allies in her quest to answer the question: Who am I now?

As she grapples with the ebb and flow of hope and acceptance, she talks with some of the top SCI cure researchers in the field and meets with new friends who help give her strength and the will to return to dance. And when a cutting-edge clinical trial surfaces, it tests her expectations and her faith in the possibility of a cure.

Follow the development of Submerged.

- submergedfilm.com/
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Photo credit: Tyler Croat

Working 2 Walk

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