2016

PRAXIS

BRIDGING THE GAPS

From SCI Research to Improved Outcomes

CONFERENCE REPORT

A SUMMARY REPORT ON THE INTERNATIONAL CONFERENCE HELD IN VANCOUVER, BC CANADA APRIL 25–27, 2016

NOVEMBER 2016

Prax-is/'praksəs/ n. ***The process by which a theory, lesson, or skill is enacted, embodied, or realized***

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Praxis 2016: Executive Summary

The Praxis 2016 conference was hosted by the Rick Hansen Institute (RHI) in Vancouver, British Columbia, Canada from April 25 to 27, 2016. This experientially structured event convened over 200 stakeholders from across Canada and around the world. In attendance were individuals with a spinal cord injury (SCI), researchers, clinicians, members of not-for-profit organizations, funders, industry representatives and investors, members of SCI healthcare consumer associations and advocacy groups, knowledge translation specialists and knowledge brokers, healthcare decision and policy makers, members of regulatory agencies, and others.

The primary goals of Praxis 2016 were to:

1. **Build a shared understanding** and synergy concerning terminology, knowledge translation and desired outcomes among a wide range of stakeholders.
2. **Foster the sharing of real world experience** between renowned healthcare innovators, leaders and champions, including unique perspectives from outside of the SCI community.
3. **Identify actions** necessary to overcome long-standing barriers and challenges to achieve translation of ideas, innovations, discoveries and knowledge into clinical practice and health policy.

Praxis 2016 is part of a process as well as a larger initiative to advance therapies for SCI, optimize SCI care, and improve the lives of all people who sustain a SCI.

This innovative conference was focused on the implications and application of information rather than on the presentation of information. Following a plenary session that described challenges and opportunities in SCI research and care, a facilitator guided four sessions over two days to begin to address obstacles in the translation from preclinical to clinical applications (bench to bedside) and from clinical research to clinical practice (bedside to worldwide). After listening to the experiences of subject matter experts and discussing the information and ideas presented, Praxis 2016 participants broke into small interdisciplinary groups, considered the translational barriers and challenges raised, and discussed further those that resonated most with their group. Conference participants focused on goals, desired outcomes, and necessary actions.

Refer to the Praxis 2016 conference program for details including the event schedule, session overviews, speaker bios, and poster listing:

http://www.rickhanseninstitute.org/images/stories/Praxis2016/PRAXIS_POE_Layout_v1.5.3_WEB.pdf

A preliminary independent review of participant reports indicates demand and desire from the SCI community for:

- Further **collaboration** and **communication** between SCI stakeholders
- Enhanced participation of **SCI consumers** across the translational research continuum
- Integration of **economics and implementation science** into preclinical and clinical research
- Greater attention to the **design and execution** of preclinical and clinical trials and the transition from preclinical to clinical applications
- Further consideration of **alternative business models** to secure funding for research, development, translation and commercialization of health technologies and practices with application in SCI

The following were also identified as necessary steps to optimize SCI research and care:

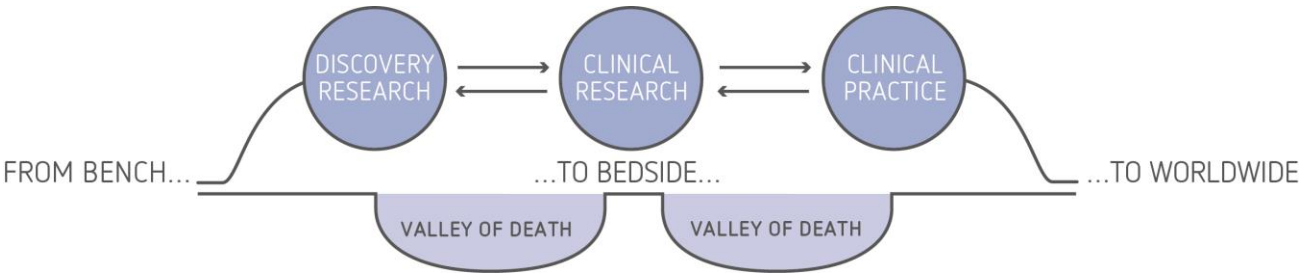
- Further education on **intellectual property, reimbursement**, and other commercialization considerations
- Further **knowledge translation and commercialization planning**
- Consistent application of **standards for evaluation** of health technologies and practices
- Further consideration of **regulatory incentives**

The Praxis 2016 Conference Report describes a process to achieve collective agreement on the next steps to overcome long-standing translational barriers and challenges in SCI research and care. A **Post-Praxis Executive Committee** has been established to develop an integrated multi-year action plan based on the information received from Praxis 2016 participants. The executive committee will serve as a bridge between the work of conference participants and the implementation of change by stakeholders in the SCI community.

Praxis 2016: Conference Overview

Prax-is/'praksas/n. ***The process by which a theory, lesson, or skill is enacted, embodied or realized***

In the field of SCI, few innovations and discoveries are successfully translated into products and services, and even years after transition from preclinical to clinical research, effective health technologies[1], evidence-based practices, and/or knowledge may remain underutilized in clinical practice. The translational process is so fraught with obstacles that these transitions are referred to as "Valleys of Death".



In order for ideas, innovations, discoveries, and knowledge to be successfully translated into clinical practice and health policy, two major valleys of death must be crossed:

- **Valley 1: Bench to Bedside**: Innovations, discoveries, and clinical knowledge create a potential for health benefits. These new approaches must be developed, validated, and translated into health technologies and/or practices (e.g., preventative and therapeutic interventions) that can be tested and evaluated in individuals with SCI.

- **Valley 2: Bedside to Worldwide**: Equitable access to evidence-based practices and innovative health technologies with application in SCI must be achieved.

[1] Health technology includes **devices** (preventative, therapeutic, diagnostic, and other), **pharmaceuticals**, **biologics**, **procedures**, **services**, **practices**, and **organizational systems** developed to solve health problems and improve quality of lives.

Praxis 2016, an international conference hosted by RHI in Vancouver, British Columbia, Canada from April 25-27, 2016, initiated a conversation about working together to identify and implement solutions to improve the lives of people with SCI. This experientially structured event convened multiple stakeholders from across the national and international SCI community and beyond.

Refer to the Praxis 2016 conference program for details including the event schedule, session overviews, speaker bios, and poster listing:

http://www.rickhanseninstitute.org/images/stories/Praxis2016/PRAXIS_POE_Layout_v1.5.3_WEB.pdf

PRAXIS 2016 AT A GLANCE

200 PARTICIPANTS
104 ORGANIZATIONS
7 COUNTRIES
21 SPEAKERS
3 WORKING SESSIONS
48 POSTERS

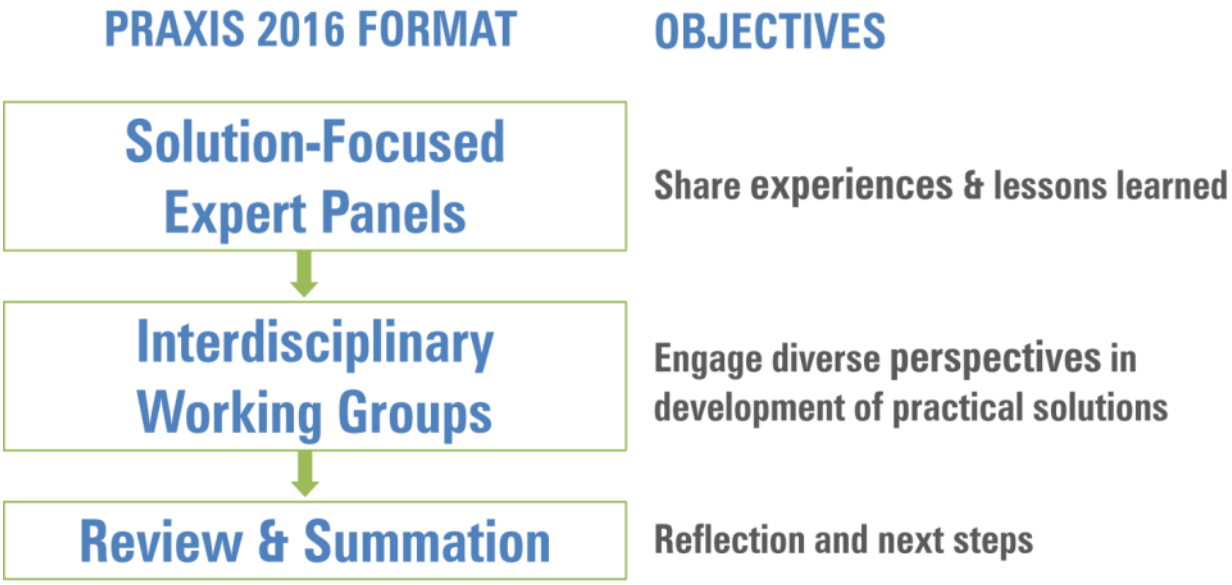
PRAXIS 2016: BREAKDOWN OF THE 200 PARTICIPANTS*

*Of these 200 participants, 16 are individuals with SCI.

The primary goals of Praxis 2016 were to:

1. **Build a shared understanding** and synergy concerning terminology, knowledge translation and desired outcomes among a wide range of stakeholders.
2. **Foster the sharing of real world experience** between renowned healthcare innovators, leaders and champions, including unique perspectives from outside of the SCI community.
3. **Identify actions** necessary to overcome long-standing barriers and challenges to achieve translation of ideas, innovations, discoveries and knowledge into clinical practice and health policy.

A distinguishing feature of Praxis 2016 was the interactive format, intended to maximize participant collaboration. In each of the four solution-focused sessions, experts opened the discussion with a brief introduction of particular translational research obstacles, and then offered solutions based on their experience or contribution in working to overcome barriers and challenges. Following interactive discussions between panel members and other conference participants, all participants broke into small groups and, guided by work sheets including questions posed by the panel, discussed solutions to identified translational research obstacles. Table assignments enabled representation from across sectors, thereby ensuring a variety of perspectives were shared.



Highlights drawn from the four sessions are presented below to provide additional context:

Valley 1	**Session 1:** **Product Development and Delivery – Challenges and Solutions in Device, Drug, and Cellular Therapies:** • Common outcome goals and terminology among stakeholders including key decision makers are necessary to improve the traversal of the valleys of death and increase the prospect of market success. • Consideration of "lessons learned" in previous clinical trials regarding problematic areas such as funding and regulatory requirements are required to optimize trial design and execution. • Consideration of new business models (e.g., non-profit/ for-profit hybrid) is required to accelerate the regulatory approval process, allowing ideas, innovations, and discoveries to get to market faster.
Valley 1	**Session 2:** **Preclinical and Clinical Trials of Regeneration and Repair in SCI:** • Research design and execution should consider the fact that sponsors assess trials in a similar way to gambling: what is the expected/desired outcome, what is the chance of it occurring, and what is the reward if it does occur? • The lack of success in translation thus far may suggest that the strength of evidence required to justify clinical testing has not been determined. • Addressing the need for predictive models at the pre-clinical phase will help to overcome challenges in transitioning from pre-clinical to clinical applications. • Strategies are needed to increase SCI consumer participation in clinical trials.
Valley 2	**Session 3:** **Bringing Knowledge into Clinical Practices:** • Behavioural change is important in translating health technologies and knowledge into clinical practice. • The uptake of evidence-based clinical practices can be facilitated through readily available guidelines and protocols, implementation-specific funding, milestone-based funding, and clinical consortia and networks' collective efforts.

Valley 2	**Session 4:** **Financial Viability - Uncertain Markets, Investors, Industry, Intellectual Property, Product Development, and Reimbursement:** • Advocacy is needed to achieve regulatory reforms that may encourage pharmaceutical investment. • It is important to consider patent processes and filing strategies early. • Reimbursement strategies are a critical aspect of commercialization.

The strategies and recommended actions presented and discussed at Praxis 2016 will be used by the **Post-Praxis 2016 Executive Committee** to develop an integrated multi-year action plan and to guide the development, communication, and dissemination of outputs (including peer reviewed publications) arising from Praxis 2016. RHI is committed to coordinating the development of the multi-year action plan informed by Praxis 2016, and will support the executive committee. An independent multi-year evaluation is also underway to determine the impact of Praxis 2016 and inform future events hosted by RHI.

To learn more and become involved:

Visit www.rickhanseninstitute.org/work/model/praxis2016
Email praxis@rickhanseninstitute.org

Opening Plenary Session

Opening Remarks

BILL BARRABLE, CEO, RICK HANSEN INSTITUTE

> *"We hope that you look back on this meeting as a milestone on our journey toward a world without SCI and secondary complications. We have a lot of work to do, and the true value of this meeting will be apparent many months down the line."*
> ***Bill Barrable***

Bill Barrable welcomed participants, highlighting RHI's commitment to bringing stakeholders together and facilitating international collaboration. Praxis 2016 was designed to be action-oriented and to maximize participant interaction to develop potential solutions to the recognized translational valleys. He reminded attendees that the most substantial work begins after Praxis 2016's conclusion. Everyone involved in the spectrum of translating SCI research into improved outcomes for individuals with SCI will need to work together to bring these identified solutions into reality.

The Praxis Conference Challenge

DR. GRAHAM CREASEY**,** PARALYZED VETERANS OF AMERICA PROFESSOR OF SPINAL CORD INJURY MEDICINE, DEPARTMENT OF NEUROSURGERY, STANFORD UNIVERSITY

Dr. Graham Creasey elaborated on the Praxis 2016 theme of bridging gaps by describing the critical need to establish effective communication among all stakeholders across the SCI research and care continuum. Our community needs to define the needs, timeframes, realistic goals and priorities required to drive the translation of research into improved outcomes. While achieving commercial viability is a complex and demanding task, with vision, resources, collaboration, and good intent it is possible to find success. SCI consumers, in particular, have an essential leadership role to play in identifying needs, shaping priorities, and advancing strategies.

Welcome Address

DR. ERIC MARCOTTE**,** INSTITUTE OF NEUROSCIENCES, MENTAL HEALTH AND ADDICTION (INMHA), CANADIAN INSTITUTES OF HEALTH RESEARCH

The Canadian Institutes of Health Research (CIHR) have a strong commitment to patient-oriented research in moving healthcare knowledge in Canada from basic research to clinical trials and into practice. Dr. Marcotte explained that CIHR accomplishes this mission through a variety of programs and in collaboration with the Canadian federal government's other research granting agencies (National Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council), and various foundations. Marcotte concluded by highlighting the role that collaboration can play in overcoming the challenges of moving basic research into reality.

Overcoming Barriers: Making a Difference through Innovation and Collaboration

RICK HANSEN, CEO, RICK HANSEN FOUNDATION

After participants viewed a brief video pointing to the importance of accessibility for all, Rick Hansen congratulated those present on working together to help people with SCI live their lives to full potential. Significant progress has been made in the field of SCI in the last 30 years, and the idea of finding a cure or cures for SCI is becoming more plausible every day. However, despite recent advances in the field, substantial barriers must be overcome to give people with SCI restored function and improved quality of life. Hansen concluded, "I hope we can look back at this moment of time and say we really turned the dial and elevated the trajectory towards the cure for SCI."

Why Not Now? Lessons Learned from a Consumer Perspective

JENNIFER FRENCH, EXECUTIVE DIRECTOR AND CO-FOUNDER, NEUROTECH NETWORK

Focusing on the repercussions that the two translational valleys of death have on the everyday lives of people with SCI, Jennifer French urged participants to consider two questions with respect to bringing much needed change: "If not now, when? And if not me, who?" Recounting the story of a snowboard accident in 1998 that left her tetraplegic, French described how these questions led to her becoming the first woman to receive the Implantable Stand and Transfer System, a functional electrical stimulation device. Almost 20

years later, this technology is still not available to the wider SCI population, a clear example of a working product not making it through the second valley of death. While the SCI field invests heavily in basic research, very little of that basic research is translated into commercial products. In closing, French emphasized that "doing things differently" is needed to get innovations to the people who need them. French's network is an advocate for the combination of neuromodulative technology to specific impairments and methods to increase third party support for their availability.

Influence and Advocacy to Overcome Translation Barriers: The Role of the SCI Consumer

DR. KIM ANDERSON-ERISMAN, DIRECTOR OF EDUCATION, MIAMI PROJECT TO CURE PARALYSIS

Dr. Kim Anderson-Erisman began by underscoring the importance of SCI stakeholders coming together as equals to address current barriers to knowledge translation and commercialization. Drawing from her unique perspective as a researcher and educator living with SCI, she commented on the need for consumer input and leadership in areas to be discussed during the four solution-focused sessions including product development, clinical trial design and recruitment, knowledge translation, and financial viability consideration. All of which have been shown to be effective in addressing current translational barriers and challenges. Anderson-Erisman concluded with, "We need to value each other and treat each other as equals in order to develop practical solutions to our barriers."

KEYNOTE PRESENTATION: Translational Research – An Implementation Promise

DR. FRANCESCO MARINCOLA, CHIEF RESEARCH OFFICER, SIDRA MEDICAL AND RESEARCH CENTRE; PROFESSOR OF MEDICINE, WEILL CORNELL MEDICAL COLLEGE

> *"We need translational medicine because there are very cost effective solutions to the chronic medical conditions which represent two-thirds of healthcare spending."*
> ***Dr. Francesco Marincola***

Quoting Jonas Salk, and sharing his experience guiding basic science research to clinical applications in cancer immunology, Dr. Francesco Marincola urged participants to consider several problems in translational research: that basic research is not always applicable to humans; that there is not enough effort put into learning from previous mistakes; and that translational medicine too often does not involve SCI consumers.

Dr. Marincola commented that the current cycle of discovery and development is based on an incomplete understanding of human pathophysiology, beginning with poorly predictive preclinical models that lack appropriate markers. The result is drug development by approximation, massive costs for drug testing in humans, and a lack of surrogate biomarkers. However, strategies like drug screening and long-term clinical benefit assessments are generating improvements.

He described an additional area of complexity in translational medicine: it is defined differently by various stakeholders (e.g. patients/physicians/clinical laboratory professionals versus academia versus the

commercial sector). Stakeholders need to come together to realize these definitions are not mutually exclusive so that everyone can collaborate rather than compete.

Suggesting examples of recent advances in cancer immunology that might also work in SCI, Dr. Marincola urged SCI stakeholders to dare themselves to push beyond the traditional "no entry" signs in scientific research. This approach encourages diverse opinions and new ways of thinking that can drive innovation in research and its application.

Valley 1: Bench to Bedside

SESSION 1: Product Development and Delivery – Challenges and Solutions in Device, Drug and Cellular Therapies

CHAIR AND SESSION OUTPUT LEAD: DR. GRAHAM CREASEY

Session 1 focused on developing solutions to the obstacles facing the development and delivery of innovations and scientific discoveries with application in SCI. Significant resources are required to move innovations and discoveries from the preclinical to the clinical phase of development, to acquire sufficient clinical data, and then to implement a successful commercialization strategy.

LESSONS LEARNED PANEL

> *"We learn more from the challenges than we do from the triumphs, and if you ignore history, you are bound to repeat it."*
> ***Dr. P. Hunter Peckham***

LESSONS LEARNED FROM A MEDICAL DEVICE PERSPECTIVE IN SCI
DR. P. HUNTER PECKHAM, DONNELL INSTITUTE PROFESSOR OF BIOMEDICAL ENGINEERING, CASE WESTERN RESERVE UNIVERSITY

As the lead inventor of the Freehand System, which had its first in-human trial in 1986, Dr. Peckham highlighted the need for the SCI field to consider new business models to bring breakthrough research to SCI consumers. The company NeuroControl was founded in 1994 to commercialize the Freehand technology, but despite the clinical success of the System, (the 312 people implanted had almost complete functional use of one hand) NeuroControl took the technology off the market in 2001.

Challenges included a slow, complex regulatory pathway and insufficient reimbursement. When commercial uptake of this novel technology turned out to take longer than anticipated, NeuroControl's investors began to press for more immediate returns on their financing. An independent business analysis found that the

barriers imposed by the U.S. Food and Drug Administration (FDA) and Medicaid were the primary reasons for the commercial failure of the Freehand System.

Today many of the challenges faced by NeuroControl remain. Approximately 19% of potential users are averse to invasive surgical procedures, and the regulatory climate has become even more challenging. Despite these issues, reasons for optimism remain. The effect size for a neuro-prosthesis is potentially large and the Freehand technology has now demonstrated decades of safe and reliable performance in users. A novel technology platform, the Networked Neuroprosthetic System, can be scaled to include multiple functions, with recent improvements allowing customization for individual users. An increased familiarity with regulatory and reimbursement agencies, a new healthcare system in the United States, and better awareness of new technologies among SCI consumers should permit the sustainable commercialization of the product.

DRUG DEVELOPMENT IN SCI

DR. ANDREW BLIGHT, CHIEF SCIENTIFIC OFFICER, ACORDA THERAPEUTICS

Using his experience at Acorda Therapeutics, Dr. Blight shared the example of developing a drug for SCI that was ultimately a success for multiple sclerosis patients. He said that translating a treatment from laboratory idea through clinical trials to regulatory approval, was necessarily a difficult journey, like crossing Death Valley in a wagon train and that we should not expect there to be bridges over or shortcuts through it. Extending that analogy, he pointed to several necessities for a successful crossing of this valley of death, including a clear sense of the destination (a realistic clinical goal), sufficient supplies (in the form of funding), robust equipment (a treatment that has the desired effect), the ability to reach the goal, useful tools (outcome measures that will show the effect), and a team of people able to navigate the challenges to be met along the way.

Part of the problem we have in SCI research is that there are few previously successful trails to follow, and as yet no clarity on the right tools to use. Once a trail has been blazed for a particular therapy or drug that can be taken through to approval, others should have an easier time following, as they have in other conditions. Appropriate clinical endpoints are necessary for success. Among the key requirements for SCI research to cross the valleys of death and achieve commercial success is agreement on the measurement of outcomes relevant to the treatment itself (what is it expected to do?) among regulatory decision makers, practicing clinicians and ultimately health care providers and payers who ask whether the benefit justifies the cost.

Dr. Blight's work at Acorda focused initially on efforts to improve neurological function in SCI. There were and remain challenges with raising enough money to support a full clinical development program in SCI, but the ultimate problem was that the drug did not show sufficient efficacy to justify carrying on. The company was able to rescue its efforts in developing the drug by redirecting its use to multiple sclerosis, where the drug showed promising efficacy and this path was eventually successful. This emphasizes the primary importance of choosing interventions that are capable of successful translation, a message that can be derived from a number of past failures in the field.

> *"A number of trails in SCI have now been blazed, and the equipment we have is gradually improving. The key element is getting to the goal. We need to be more organized to keep our wagons together and get us across the desert."*
> ***Dr. Andrew Blight***

THE GERON STORY: LESSONS LEARNED FROM A COMMERCIAL STEM CELL STUDY
DR. EDWARD WIRTH, CHIEF MEDICAL OFFICER, ASTERIAS BIOTHERAPEUTICS

Dr. Wirth shared his experience with the first clinical trial for a human embryonic stem cell treatment for SCI, as well as difficult lessons learned regarding the funding and regulatory requirements for human research.

The pharmaceutical company Geron began working in the 1990s on using stem cells that might be used to regenerate nerve fibres damaged by SCI. Dr. Wirth oversaw the regulatory approval process at Geron, including preclinical safety studies and development of an Investigational New Drug (IND) application. After overcoming concerns about cell purity, Geron enrolled the first trial subject in 2010 and another four the following year. Despite great hopes for using stem cells to improve outcomes for SCI patients, the company halted all stem cell clinical trials in 2011. Faced with funding constraints, Geron decided to invest instead in their oncology research portfolio, which was further along in the clinical trial process.

Two years later, after initially trying to sell the stem cell program, former Geron executives acquired the rights to the product through the company BioTime and its subsidiary Asterias Biotherapeutics. The trial program is now supported by a US $14.3 million grant from the California Institute for Regenerative Medicine. Safety studies and FDA approval of a new trial protocol are complete, and a thoracic SCI clinical trial was resumed in 2014. Asterias is also moving into a clinical trial with cervical SCI, which is now in the dose escalation study phase.

Even with these successes, Wirth underscored that Asterias is still in learning mode, especially with respect to regulatory and business processes. Issues around ethical controversies and economies of scale for stem cell research also remain.

NEW COMMERCIALIZATION STRATEGIES FOR SCI
MEGAN MOYNAHAN, EXECUTIVE DIRECTOR, INSTITUTE FOR FUNCTIONAL RESTORATION

Expanding on business lessons from NeuroControl's Freehand System, Ms. Moynahan outlined the non-profit/ for-profit hybrid business model developed by the Institute for Functional Restoration (IFR) to usher neuro-prosthetics through regulatory approval in Valley 2 and into the marketplace. IFR, a novel non-profit organization created to act as a corporate partner to Case Western Research University, is looking to partner with for-profit companies. IFR currently has a product in its pipeline, and expects to have it ready for commercialization once clinical trials are complete in a few years. Moreover, since neuro-prostheses are a modular scalable platform, IFR anticipates having a pipeline of products for hand, trunk, bladder, bowel and sexual function.

Although IFR's current activities are similar to a small start-up, IFR is a non-profit organization funded through grants and philanthropy. Once IFR forms a partnership with a for-profit company, the non-profit/profit entity begins seeking investments. IFR then returns to a more traditional non-profit role, focusing on efficacy in SCI and facilitating patient access to the technology.

> *"We need to learn directly from the lessons of the past so we can tackle issues head on in the future."*
> ***Ms. Megan Moynahan***

In a traditional investor model, a company must become successful before revenues offset costs. However, IFR can use funding from grants and philanthropy to avoid being pressured to seek investment until after the research and development phase is complete. This model can help avoid the premature termination of promising research. Philanthropy may also assist with advocacy during the regulatory approval process, as well as with reimbursement decisions.

PARTICIPANT REPORTS

After hearing the experiences of the Lessons Learned Panel and discussing the information and ideas presented, Praxis 2016 participants broke into small interdisciplinary groups. They were provided with a discussion guide and were asked to record answers to questions posed by the Lessons Learned Panel. In doing so they considered the barriers and challenges identified by the Panel and/or listed in a handout, and then further discussed those that resonated most with the group.

A preliminary review of participant reports from session 1 indicated demand for:

- Further collaboration and communication between SCI stakeholders
- Greater involvement of SCI consumers across the translational research continuum
- Better integration of economics and implementation science into preclinical and clinical research
- Greater attention to the design and execution of preclinical and clinical trials
- Further consideration of alternative business models to secure research and development funding and achieve translation
- Further information regarding requirements and processes to increase the likelihood of sustainability and financial viability

This list of participant recommendations or suggestions is not exhaustive, nor is it limited to the translational research barriers and challenges identified in session 1.

A complete synthesis of this group work from session 1 as well as the suggested next steps and actions offered by participants in sessions 2 through 4 will be conducted by RHI, and provided to the Post-Praxis

Executive Committee for review. The executive committee will lead the development of a comprehensive multi-year action plan.

SESSION 2: Preclinical and Clinical Trials of Regeneration and Repair in SCI

CHAIR: DR. NAOMI KLEITMAN

SESSION OUTPUT LEAD: DR. JAMES GUEST AND DR. JOHN STEEVES

Session 2 continued to address Valley 1 challenges: those impeding the implementation of promising treatments to restore or improve function of the spinal cord itself. Although several SCI clinical trials (e.g. neuroprotection or the promotion of regeneration/restoration of spinal nerve circuitry) are either ongoing or complete, only a few have proceeded past early safety and efficacy studies. Progress has been hindered by a lack of financial backing, recruitment difficulties, selection of over optimistic endpoints, and insufficient evidence of clinically meaningful effectiveness. Implementation has been affected by controversy regarding risk-benefit balance.

CASE STUDY EXPERIENCES PANEL

A FUNDER'S PERSPECTIVE: WEIGHTING OF CONSIDERATION, CHANCE AND PRIZE
DR. LYN JAKEMAN, PROGRAM DIRECTOR, NATIONAL INSTITUTES OF HEALTH/NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NIH/NINDS)

Dr. Lyn Jakeman opened with a comparison between gambling and the process for choosing which advances to fund: they both involve consideration, chance, and a prize. Considerations include the amount of money, time, and research team participation required. Funding agencies have limited resources, and it is difficult to predict which trials will be successful. Funders want to invest in the best evidence-informed opportunities, but most trials move forward before they have all the information required to make an informed decision.

Dr. Jakeman described one of the projects supported by NINDS: ProTECT III. This was a promising Phase III clinical trial designed to examine the effects of early progesterone on traumatic brain injury. Potential challenges to success were addressed during the review process and trial execution. The evidence was strong, with 46 published preclinical efficacy studies in animal models and four Phase II human trials showing benefit. The primary outcome measure was selected only after careful analysis. Despite this, ProTECT III was halted because there was no evidence of benefit compared to placebo. A second trial conducted at the same time with a slightly different progesterone formula similarly found no benefit.

Halting the trial led to several repercussions: disbelief that a treatment would ever be found, expiration of intellectual property and patents, loss of motivation for drug companies, and therapy fatigue, i.e. the thinking that progesterone will not work as a neuroprotective treatment because it did not work in traumatic brain injury.

> *"This case study shows that we are not finished developing guidelines. If we keep doing things the way we have always done them, we are never going to get a treatment."*
> ***Dr. Lyn Jakeman***

Dr. Jakeman put forward six recommendations for action to overcome these challenges in the future:

1. Define the disease to stratify participants and mechanisms
2. Improve preclinical data quality and reporting
3. Validate translatable outcome measures
4. Incorporate preclinical results into trial design
5. Develop physiological/functional clinical markers
6. Expand Phase I and II trials with larger, adaptive designs

A CLINICIAN/RESEARCHER PERSPECTIVE: CAN PRECLINICAL DATA PREDICT SUCCESS OF CLINICAL STUDIES? RETROSPECTIVE REVIEW OF PAST AND CURRENT NEUROPROTECTION STUDIES

DR. BRIAN KWON, CANADA RESEARCH CHAIR IN SPINAL CORD INJURY, UNIVERSITY OF BRITISH COLUMBIA

Based on lessons learned from his work on a magnesium formulation for SCI treatment, Dr. Brian Kwon discussed the difficulties involved in translating therapies from preclinical to clinical trials and suggested areas for action. This SCI treatment work began in 2004 under Medtronic, and significant effort was put into completing safety and efficacy studies. The project was later picked up by Acorda Therapeutics, which initiated a preclinical trial to test the treatment in pigs. Despite the large amount of prior work done, the study results – which have still not been published – showed no improvement in outcomes.

Dr. Kwon described "a tug of war" in SCI research regarding the timing of moving treatments into the clinical stage. Those who push therapies forward early need to be mindful of how inherent biases and conflicts of interest might influence their approach to scientific robustness. Sensible, reasonable, and independent preclinical testing should be encouraged as a way to promote new therapies as well as to facilitate translation. He suggested five considerations for improving the preclinical phase:

1. Objective pooling/aggregating of preclinical studies
2. Systematic preclinical randomization trials
3. Judicious use of large animal or primate models
4. Acknowledgement that preclinical and clinical models might not be the same and the need to look for biological commonalities
5. Deciding what to do with negative data

> *"Half of the art is knowing when to stop. Deciding what to do with negative data is challenging, but it is possible that the wagon we are on is just not engineered well enough to get through the valley."*
> ***Dr. Brian Kwon***

Dr. Kwon concluded by emphasizing that improving the translation from preclinical testing to clinical trials will take the courage to ask tough questions about robustness. It will also take collaboration and continued efforts to improve how studies are evaluated. Finally, it will require the SCI field to challenge its assumptions about the clinical applicability of animal models.

A TRIALIST/RESEARCHER PERSPECTIVE: CHALLENGES IN RECRUITMENT IN SCI CLINICAL TRIALS – A VIEW FROM THE TRENCHES

MICHELE (SHELLY) TOWLE, ASSISTANT DIRECTOR, SCI PROGRAM, DP CLINICAL, INC.

Shelly Towle shared with attendees some of the factors leading to the low recruitment numbers for SCI clinical trials, and recommended areas of action to encourage higher participation. She presented the example of DP Clinical's recent examination of five clinical trials which determined there were three main contributing factors for low recruitment: low site participation, delay in start-up, and weaknesses in protocol design.

Ms. Towle explained that patients are only offered the opportunity to participate in a trial if the site at which they are treated is part of that trial. DP Clinical found that only approximately 35% of sites contacted agreed to participate in a clinical trial. Those that did not participate were either not interested, did not have sufficient staffing with research experience, or did not have enough time to take on an SCI study. As a result, DP Clinical has reached out to SCI organizations, model healthcare systems, university department chairs, and current investigators to encourage newly qualified physicians to become more systematically involved in clinical research. DP Clinical is also developing internal clinical research teams dedicated to managing the rigorous demands of these trials, as well as engaging new sites.

> *"We need the advocacy of the SCI patient at every step in designing these clinical trials. My hope is that the future Implementation Team includes an SCI patient who can contribute his/her experience about what they need and the outcomes that can help someone live through an injury."*
> ***Shelly Towle***

A delay in site start-up also impacts recruitment numbers. On average it takes a site six months to activate enrollment in a clinical trial. Protocol designs also need to be revisited and the entry criteria carefully evaluated as to not unduly restrict enrollment. When the entry criteria are numerous and stringent many participants that are screened are deemed to be ineligible to participate in the study, and so are not randomized into the trial groups. Hence, researchers should be prepared to pre-screen a large number of participants in order to complete enrollment in a study.

Ms. Towle suggested seven areas of focus:

1. Increasing the participation of sites and their effectiveness at recruiting participants
2. Establishing effective action plans for identifying and screening participants who present at trauma centers
3. Reconsidering protocol design, planning and implementation based on probable recruitment
4. Enlisting the expertise of steering committees
5. Being realistic with the number of required study assessments
6. Minimizing protocol amendments in early phase of study start-up
7. Streamlining site start-up processes

PARTICIPANT REPORTS

Following presentations from members of the Case Study Experiences Panel and an interactive discussion, participants returned to the small interdisciplinary groups established in session 1 to discuss questions posed. With the barriers and challenges identified by the Case Study Experiences Panel in mind, including the heterogeneity of SCI, participants proceeded to formulate next steps and actions to ensure implementation of solutions to long-standing barriers and challenges pertaining to preclinical and clinical trials of regeneration and repair in SCI.

A preliminary review of participant reports indicated demand for:

- Further collaboration and communication between SCI stakeholders
- Greater involvement as well as consideration of consumers (not limited to individuals with SCI);
- Development of a comprehensive patient recruitment strategy
- Greater attention to the design of clinical trials as well as the transition from preclinical to clinical applications
- Development of methods and standards to better assess health outcomes and address the heterogeneity of SCI
- Greater attention to the feasibility of clinical trials and resource requirements
- Greater access to comprehensive data
- Further consideration of relative opportunities to achieve translation of ideas, innovations, discoveries, and knowledge in SCI acute, rehabilitation, and community care

Valley 2: Bedside to Worldwide

SESSION 3: Bringing Knowledge into Clinical Practices

CHAIR: DR. CATHERINE TRUCHON

SESSION OUTPUT CO-LEADS: DRS. CATHERINE TRUCHON AND CATHY CRAVEN

Session 3 focused on the challenges in translating leading practices and standardizing care in a range of areas, including SCI care. Although effective health technologies and expert-informed clinical guidelines for SCI exist, they are often not implemented as intended or to the extent desired. Resulting disparities in care across healthcare jurisdictions may lead to inefficiencies or unrealized health benefits. In the area of rehabilitation care, proposed factors contributing to the gap between evidence-informed practice and actual practice include resource constraints, policies, culture, and other impediments to behavioural change.

> *"Although Canada is doing well in terms of rehabilitation services, we have a long way to go in providing the best and most up-to-date practices and technology."*
> ***Dr. Catherine Truchon***

PERSPECTIVES PANEL – USING WHAT WE KNOW

REHABILITATION RESEARCH: CHALLENGES ASSOCIATED WITH TRANSLATION & IMPLEMENTATION
DR. ANTHONY BURNS, PHYSIATRIST, UHN-TORONTO REHABILITATION INSTITUTE; ASSOCIATE PROFESSOR, DEPARTMENT OF MEDICINE, UNIVERSITY OF TORONTO

Dr. Anthony Burns put forward solutions to rehabilitation challenges. Rehabilitation is very complex compared to drugs and procedures, since it requires the simultaneous application of multiple treatments by many team members. There have been significant efforts made in recent years to develop a classification system or taxonomy for rehabilitation treatments.

Through his comparison of researchers and clinicians by using the phrase "researchers are from Mars and clinicians are from Venus", Dr. Burns made the point that researchers work in controlled environments whereas clinicians work in unpredictable environments. Similarly, large cultural differences exist between private industry and public or non-profit healthcare organizations.

Dr. Burns outlined several suggestions to support knowledge translation:

1. Explore alternate models to reduce the funding requirements of new interventions, e.g., separating implementation funding from clinical operations, and incorporating quality and innovation metrics into funding incentives
2. Use benchmarking and clinical decision making tools

3. Apply frameworks such as the Ottawa Decision Support Framework and the National Implementation Research Network for implementation of best practices
4. Use the SCI Knowledge Mobilization Network to support best practices implementation initiatives across rehabilitation programs

> *"The valley of death sounds and is intimidating, and it is going to take a team effort to lead ourselves out of this valley."*
> ***Dr. Anthony Burns***

BEHAVIOUR CHANGE PERSPECTIVE: IMPLEMENTATION OF LEADING PRACTICES IN STROKE
DR. MARK BAYLEY, MEDICAL DIRECTOR, BRAIN & SPINAL CORD REHAB PROGRAM, UHN-TORONTO REHABILITATION INSTITUTE

Speaking from experience with stroke rehabilitation, Dr. Mark Bayley showed how behaviour change techniques could be employed in SCI. People change what they do, not as a result of an analysis that shifts their thinking, but because they are shown a truth that influences their feelings. Understanding the components of the knowledge-to-action cycle is critical in effectively changing behaviour.

> *"A key element that we all have to work on is tailoring everything to patients."*
> ***Dr. Mark Bayley***

He commented that in knowledge translation, elements of the capacity to implement change tend to be emphasized instead of the most effective mechanisms to shift behavior. Attention should be given instead to training, enabling individuals, and restructuring the environment. An implementation strategy must also be tailored to the environment and the behaviours of those in it. Additionally, interventions can be combined for greater effect.

Dr. Bayley described a behaviour change intervention from the Stroke Strategy in Ontario that used a report card for every health authority to capture the attention of health funders and leaders. The report card led to the development of a policy where pay was partly based on whether a key leading practice was implemented and resulted in a decrease in mortality. His example underpinned the importance of tailoring strategies for individuals, with consideration given to patients and targeted behaviours, care providers and their environment, and funders/policy makers, and population level data.

FRONT-LINE CARE PERSPECTIVE: MAKING REAL CHANGES
DR. CATHY CRAVEN, MEDICAL LEAD, BRAIN & SPINAL CORD REHAB PROGRAM, TORONTO REHABILITATION INSTITUTE; ASSOCIATE PROFESSOR, DEPARTMENT OF MEDICINE, UNIVERSITY OF TORONTO

Dr. Cathy Craven discussed challenges in implementing best practices through the specific example of "exercise is medicine" (EIM). During development of the Rehabilitation Environmental Scan Atlas: Capturing Capacity in Canadian SCI Rehabilitation, Dr. Craven and colleagues observed that clinicians in 37

domains of rehabilitation delivery across Canada were not implementing leading practices because of barriers related to leadership, policy and funding formulae. One challenge relates to the EIM movement, where any activity is deemed good, whereas with Activity-Based Therapy SCI patients need to participate in specific exercise activities. In general, healthcare decisions makers and funders also do not understand that exercise is used in three distinct ways: neuro-recovery, neuro-muscular repair, and long-term health and wellness. To overcome this, leaders and decision makers at local, regional, provincial/state, and national levels need to be educated, using consistent language, about the benefits of evidence-based rehabilitation.

Another challenge is the time frame when patients are discharged from treatment centres. The potential for recovery is expected to be greatest in the first 3 months after injury. However, patients are often discharged from rehabilitation care before they have had full opportunity to garner the benefits of rehabilitation during this critical period of time. In addition, there is a lack of consensus regarding the measurement of incremental changes in function to support the evaluation of health technologies and knowledge translation in rehabilitation care.

Dr. Craven suggested several Valley 1 actions:

1. Develop a large natural history study to better understand the factors that contribute to patient outcomes
2. Calculate the Minimally Clinically Importance Difference (MCID)
3. Use the Life Satisfaction Checklist (LSC) for optimal rehab outcomes
4. Position neuroprotection and cellular therapy as a value-added proposition

For Valley 2 Dr. Craven recommended the following actions:

1. Undertake an evaluation framework of adequate duration to measure the social impact of Activity Based Therapy
2. Build in economic arguments such as return on investment (ROI)
3. Target policy changes at vital points along the continuum of care
5. View change in function as a math equation with both fixed and non-fixed constraints

Using data from the Spinal Cord Injury Research Evidence Project (SCIRE), Dr. Craven argued that the SCI field is not ready for guidelines about activity-based therapy. Instead she suggested evidence-based informed protocols (EIP) – which have been used successfully in screening for osteoporosis – until the literature advances.

PARTICIPANT REPORTS

Once again, Praxis 2016 participants broke into small interdisciplinary groups and proceeded to formulate next steps and actions to address the main barriers and challenges discussed by the Perspectives Panel and/or listed in the barriers and challenges at-a-glance document provided at each table. Participants were provided a discussion guide and were asked to record answers to questions posed by the Perspectives Panel.

Groups discussed tools and strategies to facilitate the implementation of leading practice in SCI and the applications of suggested tools and strategies.

An initial review of participant reports indicates support for:

- Further collaboration and communication between SCI stakeholders
- Integration and development of infrastructure
- More consistent approaches to stakeholder education
- Greater involvement and consideration of the needs of consumers (not limited to individuals with SCI) in SCI research and care
- Better integration of economics and implementation science into research
- Development of capacity in SCI research and knowledge translation

Praxis 2016 participants also identified key stakeholders that need to be engaged in order to achieve progress in the implementation of leading practices in SCI.

This list of general suggestions is not exhaustive nor is it limited to the translational research barriers and challenges identified in session 3.

SESSION 4: Financial Viability – Uncertain Markets: Investors, Industry, IP and Insurance-Product Development and Reimbursement

CHAIR: DR. LISA MCKERRACHER

SESSION OUTPUT CO-LEADS: DR. DENNIS CHOI AND DR. LISA MCKERRACHER

Session 4 brought together experts from industry to discuss SCI from a healthcare industry perspective and to address the challenge of limited financial resources for first-in-man and placebo-controlled studies for novel drugs or cell-based therapies. Testing new products in patients requires the financial resources to support patent applications, products manufactured using good manufacturing practices, and non-clinical safety studies in at least two species. Successful commercialization requires clinical studies that demonstrate robust functional improvement as well as value for patients to ensure reimbursement from insurance companies and government payers. An understanding of regulatory and commercial aspects of product development, and what happens after a clinical trial success, shows the importance of determining potential product value on patient care and also for planning of preclinical studies and clinical trials that are in line with commercial goals.

OPENING COMMENTS

LISA MCKERRACHER, SESSION CHAIR

Dr. McKerracher drew attention to the fact that in order to be better prepared for financial viability, all stakeholders need to understand what happens after a successful clinical trial and drug/device launch. Several critical milestones are involved in drug and device development, with increasing complexity and cost when an innovation moves from Phase II to Phase III and into a launch. The requirements of regulatory acceptance should inform clinical design, prescription labels, and the commercial launch strategy.

> *"It is hard to be a trail blazer but once there is a trail other people will follow."*
> ***Dr. Lisa McKerracher***

In the absence of Phil Tinmouth of Vertex Pharmaceuticals Inc., Dr. McKerracher went on to describe an innovative and successful partnership between not-for-profit foundations and industry that has led to sustainability for the foundation, product development success for the industry partner and more importantly, a successful drug for the patients.

Over the years, the Cystic Fibrosis Foundation (CFF) has invested in Aurora Biosciences (now Vertex Pharmaceuticals) to help support discovery and development activities for the treatment of people suffering from cystic fibrosis (CF); in exchange for this support CFF now receives royalties. In 2012, the U.S. FDA approved the use of the drug Kalydeco for the treatment of a specific form of CF. The discovery and development of Kalydeco was partially supported by the CFF funding.

In 2014, CFF sold its economic rights to Kalydeco and certain other CF drugs developed by Vertex to a royalty buyer for US$3.3 billion. It is assumed that with these funds, the CFF will fund other CF drug discovery efforts.

EXPERIENCE-IN-ACTION PANEL

INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

DR. KATHLEEN MARSMAN, PATENT AGENT, BORDEN LADNER GERVAIS LLP

> *"Clinicians, consumers, service providers and basic researchers all have inspired ideas. We should come together to invent as a village rather than working in isolation."*
> ***Dr. Kathleen Marsman***

Given that the patent filing process is lengthy and expensive, Dr. Kathleen Marsman pointed to the importance of companies having a patent strategy. The correct timing to file is also important – while there may be pressure to publish results, the sharing of data can impact the chances of receiving a patent. Some jurisdictions (like Canada and the U.S.) have a one-year grace period for those who disclose an invention as

long as the inventor files a provisional patent application within one year of the first public disclosure. In the United States, the Bayh-Dole Act mandates that inventions supported by public funding should be protected and owned by the public, typically overseen by university technology transfer offices. In Canada the policy varies from institution to institution.

Dr. Marsman drew on three examples to describe how non-exclusive licensing and open data can be used to overcome some of the challenges with patenting. Non-exclusive licensing was used successfully by the Hospital for Sick Children (Toronto) and the University of Michigan following the discovery of a genetic mutation in people with cystic fibrosis. This strategy kept the information public so research could continue, with the Cystic Fibrosis Foundation responsible for sublicensing under reasonable terms for those wishing to conduct laboratory testing. More recently, in Canada a non-exclusive licensing arrangement was established for genome testing of Long QT syndrome so that a not-for-profit entity could license gene-related patents royalty-free. Finally, she described open data as a possible useful approach, with 70 researchers at the Montreal Neurological Institute agreeing not to take proprietary positions on items like brain scans, clinical data, and access to tissue banks to encourage others to freely access the information.

BUSINESS AND REGULATORY CHALLENGES: A SOLUTIONS PERSPECTIVE

DR. DENNIS CHOI, PROFESSOR AND CHAIR, DEPARTMENT OF NEUROLOGY, STONY BROOK MEDICINE

Dr. Dennis Choi argued that more attention needs to be paid to pharmaceutical disinvestment. He drew attention to the fact that six out of the ten largest companies have recently downsized their investments in central nervous system (CNS) research. The CNS fields are very complicated, with lower success rates and higher costs compared to other fields. This disinvestment is unfortunate, given that knowledge of CNS biology is thriving.

More effort needs to be put into building ROI arguments, including economic analyses that demonstrate the costs and benefits of breakthroughs, and the ways in which expensive, high-impact drugs are counter-balanced by healthcare savings. Advocacy on policy changes is also needed to improve ROI, although care must be taken so that the goal is for societal benefit and not exclusively industry profits.

> *"We should base change on the need to remove the disincentives to innovation and develop a flexible mechanism for encouraging therapeutic development in needed areas. The larger village has to get together to make this a priority."*
> ***Dr. Dennis Choi***

Dr. Choi recommended three areas for advocacy:

1. Improving market protection for innovative drugs so that these therapies are not disadvantaged by long development times
2. Developing market protection extensions for breakthrough, high-impact drugs [a similar approach taken by GAIN (Generating Antibiotic Incentives Now) which resulted in five years of additional data exclusivity for antibiotics]

3. Implementing a more graded regulatory approach, such as adaptive licensing, rather than the current binary approved/not approved system

COMMERCIALIZATION

RON PODRAZA, CO-FOUNDER AND CEO, REIMBURSEMENT PRINCIPLES, INC.

> *"Even though budgets are limited there is a lot of ongoing creativity. People who specialize are typically very efficient and can incorporate innovations rapidly."*
> ***Mr. Ron Podraza***

Ron Podraza outlined the role of reimbursement strategies as a critical aspect of commercialization. In many reimbursement systems evidence derived from administrative data is used in decision making. Companies must be prepared to demonstrate that their innovation is medically necessary as well as clinically- and cost-effective. In some cases innovations are able to follow the reimbursement pathway of a previous innovation, which may take less time but has other challenges.

To ensure hospitals do not lose money, Mr. Podraza highlighted that decisions must also be made regarding the amount to be reimbursed, or the price. Other considerations include convincing payers of the importance of paying for a new health technology over the best currently available alternative, something that can be done through comparative effectiveness studies. Deciding on the type of study to inform pricing and reimbursement decisions is also important, as randomized control trials may not provide the information required by all decision makers.

Mr. Podraza concluded on an optimistic note, as hopeful developments are emerging in the reimbursement arena. For example, accountable care organizations are being assembled in the United States, whereby groups of hospitals are coordinating care to drive down costs. The bundled payment model, which originated in the private sector, has also been successfully deployed in North Carolina, e.g. with Blue Cross Blue Shield on knee joint replacement patients, and in Pennsylvania with the Geisinger Health System and open-heart surgery. The reemergence of centres of excellence with broader service offerings also provide promise with respect to the reimbursement process.

PARTICIPANT REPORTS

The Experience-in-Action Panel introduced fundamental considerations for health technologies in SCI and others areas to succeed or achieve financial viability. Following the presentations, Praxis 2016 participants discussed resource limitations in SCI research and health technology development, regulatory requirements, intellectual property, reimbursement, and commercialization considerations.

Although participants did not break into small groups, the larger interactive discussion highlighted the need for further stakeholder education regarding intellectual property, reimbursement, commercialization, and other sustainability and financial viability considerations, as well as the resources available and established processes to help increase the likelihood of successful commercialization. Overall, participants agreed that

further collaboration and consumer (not limited to individuals with SCI) engagement and participation are necessary to overcome the identified barriers and challenges. The discussion also revealed a need for further commercialization planning, integration of economic theory and methodology, application of standards for health technology assessment, and consideration of regulatory incentives.

Research into Action

The final session of the conference provided a transition between Praxis 2016 and the development of a strategy-based report that will guide action after the conference. The Session Chairs summarized conference learnings, conclusions and recommendations, and provided a summary of their perspectives.

> *"We've paused in our journey, discussed experiences, shared stories, and come to recommendations for how we can do better. Now it is time for us to strike out again together, with an adventurous and collaborative spirit, to press forward in improving the lives of people living with SCI."*
> ***Dr. Graham Creasey***

Session 1 Chair and Program Advisory Chair Dr. Graham Creasey spoke of the importance of informed, educated action. There is a gamble heading into risky areas, and the SCI community needs to work to manage that risk. If the risk/benefit ratio is too high, "You risk not just your career but the whole field; if there is a history of too many people heading out to a valley of death and never coming back, it deters exploration." He also spoke about the importance of collaboration, particularly with SCI consumers and commercial colleagues. By working as a team, priorities for action can be more clearly defined.

Session 2 Chair Dr. Naomi Kleitman mentioned how unusual it is to have the rich diversity of viewpoints represented at Praxis 2016. She spotlighted that the time is ripe for the SCI community to speak with a unified voice, especially in terms of priorities. Dr. Kleitman will share the insights of Praxis 2016 in future planning discussions at the Craig H. Neilsen Foundation.

Session 3 Chair Dr. Catherine Truchon highlighted that many of the solutions put forward at Praxis 2016 will not require significant resources to implement, as they are focused on optimizing processes, improving available data, increasing collaboration, and prioritizing input from people living with SCI. She committed to volunteer her time to help build the resulting action plan, in partnership with Graham Creasey and others and the Rick Hansen Institute.

Session 4 Chair Dr. Lisa McKerracher outlined some of the discussion topics that struck her during Praxis 2016, including the uncertain relationships with the FDA and Health Canada and the current era of pharmaceutical disinvestment. She stressed that regulatory change is needed to help translate research into improved outcomes for people living with SCI, and committed to bringing the identified issues to the Society for Neurotrauma to explore the creation of a lobby group.

IN HIS CONCLUDING REMARKS, RHI CEO Bill Barrable spoke about the courage to confront hard facts and embrace the inconvenient truth that the current SCI research trajectory is not what everyone would like it to be. The SCI community needs to identify priorities and work collectively to support innovation, including having SCI consumers involved from the beginning and providing more leadership. He closed the conference saying, "I am optimistic that the best is yet to come."

Next Steps

One of the stated goals of Praxis 2016 was to identify actions necessary to overcome long-standing barriers and challenges to achieve translation of ideas, innovations, discoveries and knowledge into clinical practice and health policy. Arguably, the other two goals (i.e., build a shared understanding and foster the sharing of real world experience) were necessary mechanisms to help achieve the larger goal.

Praxis 2016 reinforced the complexity of translational barriers and challenges in SCI, and so it is no surprise that the scope of solutions presented and discussed at Praxis 2016 was broad. The current conference report is descriptive in nature, and in terms of next steps, only goes as far as introducing the solutions or action areas that appeared to resonate, based on participant reports, with Praxis participants.

Participants described Praxis 2016 as stimulating, collaborative, informative, interactive, and solution based; however, the consensus was that informed action is required to achieve change. Based on close review of this report and information collected through the aforementioned participant working sessions, the invaluable information gained at Praxis 2016 will be clarified and distilled. An executive committee has been established to develop an integrated multi-year action plan based on the information received from conference participants. Supported by the Rick Hansen Institute, the Post-Praxis Executive Committee will in effect serve as the bridge between the work of Praxis 2016 participants and the implementation of change by stakeholders in SCI.

An independent multi-year evaluation is also underway to determine the impact of Praxis 2016 and inform future events hosted by the Rick Hansen Institute. We thank all of those who attended Praxis 2016 and shared their vision, thoughts, and experience.

To learn more and become involved:

Visit www.rickhanseninstitute.org/work/model/praxis2016
Email praxis@rickhanseninstitute.org

The Rick Hansen Institute is a Canadian-based not-for-profit organization committed to accelerating the translation of discoveries and best practices into improved treatments for people with spinal cord injuries. It does this by leading the collaboration of researchers, health care professionals, individuals with SCI and like-minded organizations across Canada and internationally. RHI has matched leadership and research collaboration with government funding to facilitate one of the largest interdisciplinary spinal cord injury research programs in the world.

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