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NeuroMatters

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INSIDE THIS ISSUE

Focus of this Issue: **Investigator Initiated Research at Colorado Neurological Institute**

What is Investigator Initiated Research (IIR)?

Clinical trials that explore investigational drugs, devices and treatments are developed in different ways. Many clinical trials are sponsored by a private business entity such as a pharmaceutical or medical device company in order to advance their product toward regulatory approval for medical use. Alternately, smaller clinical trials are often developed by physicians and other medical professionals who routinely treat patients. Using clinical observations, investigators can generate hypotheses to develop novel therapies, diagnostic screening tools and increase medical/scientific knowledge that will lead to better patient care. In this instance, a non-profit such as Colorado Neurological Institute (CNI) can support initiatives to test these hypotheses through Investigator Initiated Research (IIR).

CNI passionately believes in clinical research as a means to advance care offered to patients and to provide the most cutting edge treatments available. By engaging in clinical research, we can offer investigational treatments to patients before they are available to the public. CNI encourages IIR in numerous ways. Direct financial support originates in the form of pilot awards for CNI affiliates, which is supported by CNI and Swedish Medical Center. The application process occurs biannually and all proposals are reviewed by a multi-disciplinary panel of neuroscientists. Applicants can request up to $50,000 over a period of two years to generate pilot data. These data are then used to apply for larger amounts of private and/or federal dollars, and to generate publications and presentations to be presented to the medical field. In the past three years, CNI has awarded over $145,000 to support these innovative research endeavors.

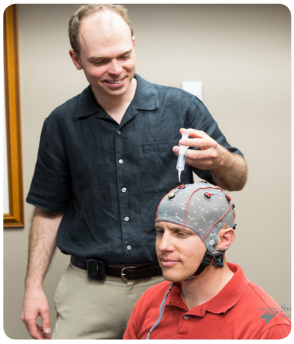
CNI logistical support is also available for all affiliated members to get IIR research projects up and running. This includes identifying possible grant funding sources, literature research, experimental design, statistical analysis, budgeting and more. Once funding is secured, CNI has experienced staff to assist in grant administration, contracting and trial coordination. A team of clinical research coordinators is available to ensure that all aspects of the clinical trial run smoothly, from site initiation to study closeout. Discussed in the rest of the issue are research projects that have received CNI support, either financially, logistically or both. Their diversity and insightfulness will amaze you.

For more information about CNI's research program, visit us at www.thecni.org/research or contact Alicia Novak, PhD, MBA Director of Research at research@thecni.org

For more information about CNI's pilot research awards, contact Larry Snell, PhD Research Development Manager at lsnell@thecni.org.

Investigator Initiated Research Projects

Development of a brain computer interface program for neuro-rehabilitation, Principal Investigator: Adam Hebb, MD



There are many neurological conditions in which there is a breakdown in the functioning of neural pathways in the brain or spinal cord, such as stroke and traumatic brain injury, to name a few. These conditions can lead to motor and sensory impairments that affect every aspect of a patient's life. Brain computer interface (BCI) is a generic term for technologies that tap into the intact neurological function that is upstream from a damaged area. This neurological activity can be collected using an EEG cap, which records surface brain activity at points on the scalp. With training, a BCI system may be able to mathematically interpret these signals and translate them into a computer signal or to drive an external device such as a robotic arm. These studies examine the development of a system using an EEG cap as a means to add function to patients with neurological injury. Dr. Hebb and his team of bio-engineers, including Joshua Nedrud, M.S., Sara Hanrahan, PhD and Ian Stemper, are designing this EEG system using healthy volunteers. Once functional, it will be used to implement a communication system or virtual limb control in patients with neurological injury at Craig Hospital. Future BCI applications include neuro-rehabilitation, communication, neuro-feedback and operation of robotic prosthetic limbs.

*Dr. Hebb is a functional neurosurgeon at Colorado Brain and Spine Institute and Swedish Medical Center who specializes in Deep Brain Stimulation (DBS), epilepsy, neuro-oncology and peripheral nerve surgeries.

» "With training, a BCI systerm may be able to mathematically interpret these signals and translate them into a computer signal or to drive an external device such as a robotic arm."

Treatment of oculo-motor dysfunction in individuals with traumatic brain injury, Principal Investigator: Thomas Politzer, OD

Visual disturbances and related perceptual impairments are common after traumatic brain injury (TBI), but have traditionally been one of the least understood areas in brain injury rehabilitation. These impairments can cause devastating symptoms such as blurry vision, dizziness, headaches, incoordination, imbalance, inattention and fatigue. Currently, there is not an established paradigm for vision rehabilitation nor is there a reliable rating scale for the recording and communication of ocular-motor deficits. With the help of CNI's pilot award, Dr. Politzer and Co-Investigators, Don Gerber, PsyD, ABPP and Karen Rasavage, OTR, have begun to develop a quantitative measure for assessment of the visual deficits associated with TBI. This funding is also allowing the team to assess the effectiveness of their home-grown visual treatment program that was developed at Craig Hospital that is used for many TBI patients. The team hopes these tools will aid in the diagnosis and treatment of TBI oculo-motor deficits and enhance positive functional outcomes.

*Dr. Politzer is a Neuro-Optometrist in private practice and at Craig Hospital who specializes in vision rehabilitation for patients with neurological diseases.

» "With the help of CNI's pilot award, Dr. Politzer and Co-Investigators, Don Gerber, PsyD, ABPP and Karen Rasavage, OTR, have begun to develop a quantitative measure for assessment of the visual deficits associated with TBI."

Current CNI Principal Investigators

Richard Bellon, MD

Allen Bowling, MD, PhD

Ira Chang, MD

Christopher Fanale, MD

James Fenton, MD

Donald Frei, MD

Adam Hebb, MD

Daniel Huddle, DO

David Kelsall, MD

Rajeev Kumar, MD

Charles Livsey, MD, PhD

David Loy, MD, PhD

Cori Millen, DO

Robert Pratt, MD

G. Alexander West, MD, PhD

Current Areas of Research

Stroke

Neurointerventional Radiology

Neurosurgery/Brain and Spinal Injury

Multiple Sclerosis

Epilepsy

Huntington's Disease

Hearing

Head Pain

Parkinson's Disease

Other Movement Disorders

Humanitarian Use Devices (HUDs)

CNI is always seeking new research oppotunities...

Investigator Initiated Research Projects Cont.

Treatment of refractory Status Epilepticus, Principal Investigator: Charles Livsey, MD, PhD

Status Epilepticus (SE) is a severe form of continuous or repetitive epileptic seizures in which the morbidity and mortality statistics have remained largely unchanged for decades. While traditional SE treatments have largely targeted the receptors of a neurotransmitter, GABA, as well as sodium channels, new findings in basic and clinical research have revealed that glutamate receptors are also regulated in SE. Thus, a new paradigm to treat SE may involve the use of drugs to target glutamate receptors. Ketamine, an anesthetic that inhibits NMDA glutamate receptors, has yet to be proven as an effective treatment in SE. Prospective studies of the effectiveness of ketamine are needed to substantiate the anecdotal and retrospective evidence that ketamine is effective in the treatment of SE. Dr. Livsey and CNI have teamed up to develop a prospective clinical research protocol to examine the use of ketamine as an add-on agent in the treatment of SE.

*Dr. Livsey is an Epileptologist at Specialty Neurology PC and Swedish Medical Center who specializes in pediatric and adult seizures.

» **"Prospective studies of the effectiveness of ketamine are needed to substantiate the anecdotal and retrospective evidence that ketamine is effective in the treatment of SE."**

Levetiracetam outcomes in acute stroke patients, Principal Investigator: Ira Chang, MD

Patients with acute ischemic stroke, intracerebral hemorrhage and subarachnoid hemorrhage are at risk for developing seizures during the days following initial insult. It is common practice to prescribe an antiepileptic drug for seizure prophylaxis for a short period of time during the acute phase of patient's illness. However, there is little or no data regarding the efficacy of prophylactic administration of anticonvulsant medications and the resulting outcomes. Dr. Chang received a CNI pilot award to look at the 90 day outcomes of stroke patients who were given antiepileptic drugs, including Levetiracetam. Outcomes include seizure frequency, functional independence and adverse events. These data are collected in Swedish Medical Center's Stroke Database which is being used for data aggregation. These studies will provide additional information about the safety of using Levetiracetam as a prophylactic drug after stroke and hemorrhage.

*Dr. Chang is a Neurologist at Blue Sky Neurology and Swedish Medical Center who specializes in stroke and neurocritical care.

» "These studies will provide additional information about the safety of using Levetiracetam as a prophylactic drug after stroke and hemorrhage."

Investigator Initiated Research Projects Cont.

Self-efficacy program for recently diagnosed Parkinson's patients, Principal Investigators: Rajeev Kumar, MD and Diane Cook

Support groups for patients with neurological diseases have shown to be effective in helping patients cope with medical and psychological issues as well as building a network of peers. The introduction of self-efficacy or the belief in one's ability to reach goals, into a support group is a new concept. Newly diagnosed Parkinson's disease (PD) patients face many challenges in learning to adapt to a chronic and progressive disease. The integration of self-efficacy training into a support group for newly diagnosed PD patients is designed to promote behaviors that have an influence on how patients experience and manage their disease as well as their perceived quality of life. With the aid of CNI pilot monies, Dr. Kumar and Diane Cook are examining neurological and psychological differences in patients receiving immediate versus delayed self-efficacy training. Dr. Cynthia McRae, Professor of Counseling Psychology at the University of Denver is also a collaborator who is providing measurement expertise. The team hopes to develop PD patient run self-efficacy support groups as community resources from these studies.

*Dr. Kumar is a Neurologist at Rocky Mountain Movement Disorders Center and specializes in Movement Disorders including Parkinson's and Huntington's Diseases. Diane Cook is a Parkinson's patient, community advocate for Parkinson's disease, a CNI Board Member and a business owner.

» "The integration of self-efficacy training into a support group for newly diagnosed PD patients is designed to promote behaviors that have an influence on how patients experience and manage their disease as well as their perceived quality of life."

New Faces in CNI Research

Jeanne Swanson, RN

Research Coodinator

Jeanne Swanson joined CNI in the fall of 2013 as a Clinical Research Coordinator. She has been a nurse since 1997 and previously worked for Radiology Imaging Associates as an Interventional Radiology Nurse with a special emphasis in Interventional Oncology.

Sara Hanrahan, PhD

Investigator Scientist

Sara Hanrahan completed her PhD in Biomedical Engineering at the University of Utah. She studied the effects of anesthesia on neural activity and examined neural activity during hand and arm movements for the development of a neural prosthesis. At the CNI, Sara analyzes patients neural activity and behavioral data to gain knowledge of disorder pathology, treatment and rehabilitation.At the CNI, Sara analyzes neural activity and behavioral data obtained from patients with movement disorders, epilepsy, spinal cord injury and traumatic brain injury to gain knowledge of disorder pathology, treatment and rehabilitation.

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New clinical research trials to improve the care of your patients:

Ictus - Phase 2/3 study of intravenous thrombolysis and hypothermia for acute treatment of ischemic stroke

Prisms - A phase IIIb, double-blind, multi-center study to evaluate the efficacy and safety of Alteplase in patients with mild stroke: rapidly improving symptoms and minor neurological deficits

Socrates – A randomized, double-blind, multinational study to prevent major vascular events with Ticagrelor compared to aspirin (ASA) in patients with acute ischaemic stroke or TIA

Scent - The Surpass IntraCranial Aneurysm EmbolizatioN System Pivotal Trial to treat large OR giant wide neck aneurysms

Scaffold - GORE Carotid Stent Clinical Study for the treatment of carotid artery stenosis in patients at increased risk for adverse events from carotid endarterectomy

Respond - A Multicenter, Open-Label, 12-Month Observational Study Evaluating the Clinical Effectiveness and Impact on Patient-Reported Outcomes of Oral Tecfidera™ (dimethyl fumarate) Delayed-Release Capsules in Patients With Relapsing Forms of Multiple Sclerosis After Suboptimal Response to Glatiramer Acetate

Teri-Pro - A Prospective, Single-Arm, Clinical-Setting Study to Describe Efficacy, Tolerability and Convenience of Teriflunomide Treatment Using Patient Reported Outcomes (PRSO)in Relapsing Multiple Sclerosis (RMS) Patients

with appreciation to

Health ONE Swedish Medical Center

CNI COLORADO NEUROLOGICAL INSTITUTE

Providing enhanced care, research and resources to patients with neurological conditions

- Founded in 1988
- 501(c)(3) not-for-profit organization
- More than 50 affiliate medical professionals specializing in the neurosciences
- Largest, most comprehensive neuroscience center in the Rocky Mountain region
- Programs in nearly every neurological specialty
- Clinical research studies
- Affiliated with Swedish Medical Center and Craig Hospital

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