VA's Dr. John McGeary receives $200K for study on Synchronized Transcranial Magnetic Stimulation for Substance Use Disorder

PROVIDENCE – **DR. JOHN McGEARY**, a research scientist and staff psychologist at the VA RR&D Center for Neurorestoration and Neurotechnology at the Providence VA Medical Center, received an award July 1 for a two-year research study from the VA Office of Rehabilitation Research and Development.

Photo demonstrating the use of a Synchronized Transcranial Magnetic Stimulation device in a home setting.
[COURTESY OF WAVE NEUROSCIENCE INC.]

Dr. McGeary's project, titled "Synchronized Transcranial Magnetic Stimulation for Substance Use-Disordered Veterans," will evaluate the acceptability, tolerability and safety of synchronized TMS as a potential treatment for substance use disorders.

The nearly $200,000 study will allow McGeary and his team at the Providence VA Medical Center, which includes leaders in neurostimulation – **DR. NOAH PHILIP**, Chief of Psychiatric Neuromodulation and Addiction Treatment and **DR. ROBERT SWIFT**, Chief of Mental Health and Behavioral Science Services – to take key first steps to developing a potential new treatment for opiate use disorder, cocaine use disorder, and alcohol use disorder.

"As the response to the COVID-19 pandemic created challenges for traditional forms of addiction treatment, it is more important than ever to develop new treatments, particularly ones that could be used in a home setting," said Dr. McGeary. "There are currently no FDA-approved treatments for cocaine use disorder, so this technology could be a critically important tool for treatment in these cases as well, if the research supports its use." ❖

FDA issues Emergency Use Authorization to Yale School of Public Health for SalivaDirect, which uses a new method of saliva sample processing

On August 15 the U.S. Food and Drug Administration issued an emergency use authorization (EUA) to Yale School of Public Health for its SalivaDirect COVID-19 diagnostic test, which uses a new method of processing saliva samples when testing for COVID-19 infection.

"Providing this type of flexibility for processing saliva samples to test for COVID-19 infection is groundbreaking in terms of efficiency and avoiding shortages of crucial test components like reagents," said FDA Commissioner **STEPHEN M. HAHN, MD**.

SalivaDirect does not require any special type of swab or collection device; a saliva sample can be collected in any sterile container. This test is also unique because it does not require a separate nucleic acid extraction step. This is significant because the extraction kits used for this step in other tests have been prone to shortages in the past. Being able to perform a test without these kits enhances the capacity for increased testing, while reducing the strain on available resources. Additionally, the SalivaDirect methodology has been validated and authorized for use with different combinations of commonly used reagents and instruments, meaning the test could be used broadly in most high-complexity labs.

Yale intends to provide the SalivaDirect protocol to interested laboratories as an "open source" protocol, meaning that designated laboratories could follow the protocol to obtain the required components and perform the test in their lab according to Yale's instructions for use. Because this test does not rely on any proprietary equipment from Yale and can use a variety of commercially available testing components, it can be assembled and used in high-complexity labs throughout the country, provided they comply with the conditions of authorization in the EUA.

This is the fifth test that the FDA has authorized that uses saliva as a sample for testing. Testing saliva eliminates the need for nasopharyngeal swabs, which have also been prone to shortages, and alleviates the patient discomfort associated with these swabs. Since the saliva sample is self-collected under the observation of a healthcare professional, it could also potentially lower the risk posed to healthcare workers responsible for sample collection. While FDA has seen variable performance in tests using saliva, Yale School of Public Health submitted data with its EUA request from which the FDA determined that Yale's test meets the criteria for emergency authorization when used to test saliva samples for SARS-CoV-2, the virus that causes COVID-19 infection. ❖

RIH Alzheimer's researchers present at virtual international meeting

PROVIDENCE – Researchers from the Alzheimer's Disease and Memory Disorders Center at Rhode Island Hospital presented five abstracts at the annual Alzheimer's Association International Conference held virtually recently.

JONATHAN DRAKE, MD, associate director of the center, presented an abstract which assessed whether molecular blood biomarkers of vascular inflammation could be a useful tool in assessing risk for Alzheimer's disease. Results showed that a blood-based protein called Vascular Cell Adhesion Molecule–1 (VCAM–1), an indicator of active inflammation of the body's blood vessels, was higher in people who were further along in the Alzheimer's disease spectrum than those who are less affected. Alzheimer's disease detected early in life may be altered over time with effective interventions. "Developing blood-based biomarkers for Alzheimer's disease is an important milestone that needs to be achieved," said Drake. "This is especially important in the current era given recent advances in the field identifying midlife vascular risk factors as representing between 30 to 60% of one's risk for later-life Alzheimer's disease. Importantly, vascular risk factors are theoretically modifiable, meaning that important steps toward optimal health taken early in life may decrease your risk for succumbing to this devastating disease as you get older."

BRIAN OTT, MD, center director, presented results from a study to determine if in-car video technology can effectively detect unsafe driving events in cognitively impaired older adults, and if providing feedback about these events to drivers and their family members can lead to a reduction in the frequency and severity of unsafe driving behaviors. Unsafe driving events were captured from in-car video recorders and later analyzed, categorized and scored. Half of the participants in the study were monitored but received no feedback. The other half of the participants and their family members were sent a weekly report by mail along with a DVD of recorded unsafe driving events with recommendations. Those in the group who received feedback had 21% fewer unsafe driving events (UDE) compared to the group who receive no feedback. The feedback group also saw a 48% decrease in severity of UDE while the non-feedback group saw a 37% increase. "Results of the study suggest that it may be possible to improve driving safety among older drivers with cognitive impairment using video technology and a behavior modification approach aimed directly at problem behaviors that cause unsafe driving events," said Ott.

LAURA KORTHAUER, PhD, and Ott presented findings on the value of primary care providers (PCPs) screening for early detection of cognitive impairment. The study examined the case histories of 100 local patients referred by their PCPs for genotyping and telephone screening. "Primary care is an important gateway for screening patients for risk for cognitive decline," said Korthauer. "This study shows that implementing a cognitive and genetic screening program for AD risk in a primary care setting is feasible and well-received by patients. The program may provide added value to PCPs in advising patients about risk factor modification."

LORI DAIELLO, PharmD, ScM, presented information on the protocol for an upcoming study of older adults undergoing elective surgery and the role of impaired blood-brain barrier (BBB) function as a pre-surgery indicator of cognitive problems in those with and without risk factors for Alzheimer's disease. "BBB dysfunction is an indicator of brain vulnerability and neurodegeneration in Alzheimer's disease that may also be an important risk factor for postoperative delirium and delayed or incomplete cognitive recovery," said Daiello. "CREATES is the first study of perioperative cognitive outcomes to investigate BBB function with this brain imaging approach. The results will provide important insights into the underlying mechanism(s) of memory impairments that may follow major surgery."

GEOFFREY TREMONT, PhD, presented evidence that yoga may improve some aspects of brain health in individuals living with Mild Cognitive Impairment, a condition often seen as a precursor to Alzheimer's disease. His study included 12 weeks of twice weekly yoga classes, while his colleague, Dr. Jennifer Davis conducted classes involving interactive discussion and presentations addressing healthy living topics relevant to aging and cognitive impairment. "The results of this study showed no statistical differences in specific areas of thinking between the yoga classes and the healthy living classes," said Tremont. "However, we did see signs that yoga participation was associated with improvements in participants' ability to process visual information and engage in planning, organization and holding information in short-term memory." The study also found that the yoga group had a greater decline in perceived stress, whereas the healthy living classes showed a greater reduction in depressive symptoms when compared to the other group. ❖