

UC San Diego to Lead Personalized Medicine Project on Mood-Stabilizer

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An international team, led by University of California, San Diego School of Medicine researchers, has been awarded a \$6.5 million grant from the National Institutes of Health (NIH) to study the pharmacogenomics of a key mood-stabilizing drug used to treat bipolar disorder.

The grant expands the NIH's Pharmacogenomics Research Network (PGRN), a long-term, multi-million dollar effort to investigate and fulfill the potential of personalized medicine.



John R. Kelsoe, MD

John R. Kelsoe, MD, professor of psychiatry in UC San Diego's School of Medicine, will oversee the 5-year project to better understand the genetic bases of bipolar disorder and one of major drugs used to treat it: lithium.

"In every area of medicine, patients respond differently to medicines and some not at all," said Kelsoe. "In treating psychiatric illnesses, this is particularly problematic because it can take years before a correct diagnosis is made. During that time, a patient might see three or four doctors and go through a series of wrong treatments or no treatment at all."

"The promise of personalized medicine in general and pharmacogenomics specifically is the idea that one day we might be able to, say, take a saliva sample and examine it for genetic markers that indicate how a patient will likely respond to different drugs. Doctors could then prescribe an individualized treatment that had the best chance of working quickly and effectively."

Bipolar disorder is a poorly understood mental illness characterized by alternating episodes of extreme mania and depression. It is thought to have multiple, but still unidentified, causes, including a strong genetic component. The National Institute of Mental Health estimates 5.7

million American adults are affected, with the median age of onset at 25. Extreme cases may feature delusions, hallucinations or suicidal thoughts.

Lithium is the oldest and best known of drugs used to treat bipolar disorder, also known as manic-depressive disorder. In some diagnosed cases, lithium can dramatically improve patients' conditions. "It's effective for as long as it's taken. It helps prevent subsequent episodes. Patients can essentially return to normal lives," said Kelsoe.

The challenge has been to identify early those bipolar disorder patients who will benefit from being treated with lithium – about 20 percent of all diagnosed cases, said Kelsoe. The UC San Diego-led study is a step in that direction. The study involves ten research partners, with UC San Diego acting as the coordinating center. The other participating institutions are Indiana University, University of Chicago, University of Iowa, University of Pennsylvania, Johns Hopkins University, University of Michigan, the Translational Genomics Institute in Phoenix, Case Western Reserve University, University of Bergen in Norway, and Dalhousie University in Canada.

Research plans call for diagnosing and treating with lithium a total of 700 patients at the ten sites, following the patients' progress for two years, with a particular emphasis on noting the occurrence of any relapses and the period of time it takes to recover. At the same time, researchers will examine patients' genomes for DNA markers that could ultimately be used to predict how and why some people respond to lithium treatment and others do not.

"If we can identify key genetic markers, then patients can receive the appropriate treatment sooner, and get better faster," said Kelsoe.

Another aspect of the project is to develop a better, deeper understanding of how lithium actually works. "The reality is that we just don't understand a lot of the biology involved," said Kelsoe. "Lithium works, but we don't really know why."

Collaborating with scientists at the Salk Institute for Biological Studies, Kelsoe and colleagues will study stem cells derived from patients' skin biopsies that have been reprogrammed to become neurons. They will look to see how lithium and other drugs interact with the neurons at a cellular level.

"The discoveries we make could help us improve lithium as an effective drug, or even provide new insights for the development of other drugs and therapies," said Kelsoe.

About the PGRN

Spearheaded by the NIH's National Institute of General Medical Sciences (NIGMS) and launched in 2000, the Pharmacogenomics Research Network consists of 14 research groups and five resource development groups. The former investigate genetic questions related to diseases and disorders as varied as mental illness, cancer, asthma, nicotine addiction, heart disease and

rheumatoid arthritis. The latter provide DNA sequencing capacity, statistical analysis expertise, and standardized terminology for pharmacogenomics research.

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