UAMS Receives $1M Grant for Two Clinical Trials on Opioid Withdrawal in Infants

LITTLE ROCK — The University of Arkansas for Medical Sciences (UAMS), in collaboration with the Duke Clinical Research Institute, has received a $1 million federal grant for two clinical trials involving infants with neonatal opioid withdrawal syndrome (NOWS).

The increase in maternal opioid use has resulted in a rise in the number of infants born with NOWS. The $1,066,433 in funding comes from the National Institutes of Health (NIH) Helping to End Addiction Long-term (HEAL) Initiative SM, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis.

At UAMS, Jeannette Lee, Ph.D., professor of biostatistics, and Jessica Snowden, M.D., associate professor of pediatrics, are leaders of the Data Coordinating and Operations Center for the Environmental influences on Child Health Outcomes (ECHO) IDeA States Pediatric Clinical Trials Network, which will conduct the trials in conjunction with the Neonatal Research Network, which is funded by the Eunice Shriver Kennedy National Institute for Child Health and Human Development. Both trials aim to address management of infants exposed in utero to opioids.

“The two clinical protocols that we will be testing were developed over a two-year period through collaboration among the clinical sites and coordinating centers that are a part of this united effort,” Lee said. “In both instances, we are looking for new, improved tools for treating these infants, who are born with the physical symptoms of opioid withdrawal.”

One study will evaluate an innovative approach called “Eating, Sleeping and Consoling” for its effectiveness in caring for NOWS infants, as measured by decreased length of hospital stay compared to usual care. The other study will examine a rapid schedule of weaning NOWS infants from opioid replacement therapy to determine if it shortens the weaning period compared to usual care.

Both trials are scheduled to launch this year.
Symptoms of NOWS, which was previously known as neonatal abstinence syndrome, can include high-pitched crying, irritability, exaggerated reflexes, altered sleep-wake cycles, tremors, seizures, vomiting, loose stools, poor feeding, sweating, sneezing and temperature instability. Treatments often include kangaroo care skin-to-skin contact with caregivers; calm, dark, protective environments; and medication-assisted treatment like the drug methadone for opioid withdrawal.

The NIH HEAL Initiative\textsuperscript{SM} is funding hundreds of projects nationwide and includes research that is tackling the opioid crisis from all angles, including projects to understand, manage and treat pain and improve treatment for opioid misuse and addiction.

In 2016, UAMS was able to establish the Data Coordinating and Operations Center (DCOC) thanks to a $40 million, four-year grant from the NIH Office of the Director/ECHO Program. All participating sites are part of the IDeA (Institutional Development Award) Program, which aims to increase federal funding to states like Arkansas that have historically seen low level of NIH support.

The network, one of the components of ECHO, includes 17 awardee clinical sites in Alaska, Arkansas, Delaware, Hawaii, Kansas, Kentucky, Louisiana, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, Oklahoma, Rhode Island, South Carolina, Vermont and West Virginia. The role of the DCOC is to provide communications, administration, logistics, informatics and statistical support to the development and implementation of clinical trials to be conducted by the network.

In addition, because the network is located in states that have varying levels of experience with participating in pediatric clinical trials, the network is engaged in capacity building and professional development at the sites.

Launched in 2016, ECHO aims to enhance the health of children for generations to come. Research conducted through ECHO focuses on five key pediatric outcomes that have a high public health impact: pre-, peri- and postnatal outcomes; upper and lower airway health; obesity; neurodevelopment; and positive health. The Coordinating Center for ECHO is at the Duke Clinical Research Institute (DCRI).

UAMS is the state’s only health sciences university, with colleges of Medicine, Nursing, Pharmacy, Health Professions and Public Health; a graduate school; hospital; a main campus in Little Rock; a Northwest Arkansas regional campus in Fayetteville; a statewide network of regional campuses; and seven institutes: the Winthrop P. Rockefeller Cancer Institute, Jackson T. Stephens Spine & Neurosciences Institute, Harvey & Bernice Jones Eye Institute, Psychiatric Research Institute, Donald W. Reynolds Institute on Aging, Translational Research Institute and Institute for Digital Health & Innovation. UAMS includes UAMS Health, a statewide health system that encompasses all of UAMS’ clinical enterprise including its hospital, regional clinics and clinics it operates or staffs in cooperation with other providers. UAMS is the only adult Level 1 trauma center in the state. \textit{U.S. News \\& World Report} named UAMS Medical Center the state’s Best Hospital; ranked its ear, nose and throat program among the top 50 nationwide; and named six areas as high performing — cancer, colon cancer surgery, heart failure, hip replacement, knee replacement and lung cancer surgery. UAMS has 2,727 students, 870 medical residents and five dental residents. It is the state’s largest public employer with more than 10,000 employees, including 1,200 physicians who
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