Briefing Summary "Neonatal Opioid Withdrawal Syndrome" September 26, 2017

On September 26, 2017, the Women's Congressional Policy Institute (WCPI) sponsored a briefing, "Neonatal Opioid Withdrawal Syndrome," in cooperation with Reps. Susan Brooks (R-IN) and Lois Frankel (D-FL), Co-Chairs of the Congressional Caucus for Women's Issues (Women's Caucus), and Reps. Mimi Walters (R-CA) and Brenda Lawrence (D-MI), Vice-Chairs of the Women's Caucus. The briefing was the thirteenth in a women's health series sponsored by WCPI over several years, with support from the Robert Wood Johnson Foundation.

Members of Congress

Rep. Katherine Clark (D-MA) shared a story of a baby born with neonatal opioid withdrawal syndrome (NOWS) in her district. The syndrome caused seizures so severe that the infant's retina had detached. After multiple discussions with experts and advocates in the field, it was clear that a standardization of best practices and data collection nationwide was needed. Rep. Clark stressed that how we treat neonates born with NOWS cannot be separated from how we treat their mothers. In her closing statement, Rep. Clark mentioned a recent site visit to Boston Medical Center where a program focused on "Eat, Sleep, Console" has reduced an infant's stay in the neonatal intensive care unit (NICU) from an average of 23 days to 9 days. These results show the importance of maintaining and fostering the mother and infant bond and the inclusion of wrap-around services for these families.

Rep. Lois Frankel (D-FL) stated that there are many crises affecting the United States, but NOWS is at the top of the list.

Rep. Evan Jenkins (R-WV) introduced Dr. Sean Loudin, one of the speakers. Rep. Jenkins stated that Dr. Loudin is his hero and was honored to have the opportunity to introduce him. Five years ago as state senator, Rep. Jenkins received a call from two NICU nurses requesting him to come to Cabell Huntington Hospital to understand the severity of the cases the hospital was facing. After this visit, Rep. Jenkins worked with these two NICU nurses and Dr. Loudin to open Lily's Place, which recently celebrated its third anniversary.

Speakers

Uma M. Reddy, MD, MPH

The first speaker was Uma M. Reddy, MD, MPH, Project Scientist for the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network Pregnancy and Perinatology Branch, and the moderator for the briefing.

Dr. Reddy manages diverse research studies focused on clinical obstetrics, reproductive epidemiology, and prenatal diagnosis. In addition, her scientific responsibilities also include serving as the program scientist for the Maternal-Fetal Medicine Units Network and for large research studies focused on adverse pregnancy outcomes.

After receiving her undergraduate medical degrees from Brown University, Dr. Reddy completed her residency in OB/GYN at the Johns Hopkins Hospital. Dr. Reddy then obtained her master of public health in biostatistics at the Johns Hopkins Bloomberg School of Public Health and was a Robert Wood Johnson Clinical Scholar. She completed her maternal-fetal medicine fellowship at Thomas Jefferson University in Philadelphia.

Dr. Reddy reiterated Rep. Clark's statement that the impact of the opioid epidemic has not spared pregnant women and that one infant is born with NOWS every 25 minutes in the United States. The dearth of research surrounding pregnant women and neonates inspired a 2016 workshop at NIH cosponsored by the Centers for Disease Control and Prevention (CDC), American Congress of Obstetricians and Gynecologists (ACOG), American Academy of Pediatrics (AAP), Society for Maternal-Fetal Medicine (SMFM) and the March of Dimes.

In the workshop, experts from diverse disciplines convened to address key scientific opportunities to advance the understanding of opioid use disorders in pregnant women and their neonates to improve outcomes for these affected women, their babies, and their families.

Diana W. Bianchi, MD

The second speaker was Diana W. Bianchi, MD, Director, Eunice Kennedy Shriver NICHD at the National Institutes of Health (NIH). Dr. Bianchi oversees research on pediatric health and development, maternal and reproductive health, population dynamics, intellectual and developmental disabilities, and medical rehabilitation. A practicing medical geneticist with special expertise in reproductive genetics, she maintains her own lab at NIH.

A recipient of many awards in her field, Dr. Bianchi earned her medical degree from Stanford University School of Medicine. Following medical school, she completed her residency training in pediatrics at Boston Children's Hospital and her postdoctoral fellowship training in medical genetics and neonatal-perinatal medicine at Harvard Medical School.

Dr. Bianchi stated that the basic problem is that most people start using opioids as a prescription medication. Unfortunately, the euphoria associated with exposure to the opioids becomes harder and harder to achieve with the opioids alone. Individuals who become addicted move on to other drugs, such as heroin, fentanyl, and carfentanil, which is an elephant tranquilizer.

NOWS refers to signs and symptoms in newborns exposed to opioids. The infants are difficult to console and their symptoms can include irritability, tremors, feeding issues, vomiting, diarrhea, sweating, and seizures. Dr. Bianchi emphasized the enormity of this epidemic with the following statistics:

- Opioid use has quadrupled over the last decade
- 259 million prescriptions for opioids were written and filled in 2012
- Every three minutes a woman seeks emergency care for prescription opioid misuse
- Deaths involving synthetic opioids (mostly fentanyl) have increased from 3,000 to 20,000 in just three years

Dr. Bianchi is primarily concerned about pregnant women and their use of opioids. On average, women take between three and five prescription medications during pregnancy. The most recent statistics on record are from 2012: 22,000 infants were born with NOWS in the US. The cost of this epidemic is enormous; \$1.5 billion in hospital charges for treating infants with NOWS.

Much of Dr. Bianchi's daily work focuses on prevention, which starts with prenatal care. Many women using opioids receive little or no prenatal care. Many women are reluctant to disclose their substance use in fear that their baby will be taken away from them. Ideally, screening of pregnant women with opioid use disorder at intervals throughout their pregnancy is optimal. Medication-assisted therapy with methadone or buprenorphine is the standard of care.

- Methadone treatment: Improved compliance with obstetric care, higher birth weights, and lower preterm birth and infant mortality rates
- Buprenorphine treatment: Decreased risk of overdose and improved neonatal outcomes

Dr. Bianchi stated that it is critical we think about babies differently from adults with opioid exposure. Generally, babies do not die as a result of NOWS because they are born in a hospital setting where they are closely monitored. Some newborns prenatally exposed to methadone do not exhibit signs of NOWS until three to five days after birth and may already have been discharged from the hospital. These situations present another set of dangerous circumstances for the infant and mother.

There are multiple approaches to address the issues surrounding infants with NOWS. The most immediate question is where to treat the newborn. Some babies can be released to their home and others need to be admitted to an intensive care unit. Up to 80 percent of infants need pharmacologic interventions and evaluation by social services. Additionally, breastfeeding should be encouraged as it is associated with decreased severity of NOWS and enhances the maternal-child bond. Breastfed infants are less likely to need pharmacologic treatment compared to formula-fed infants.

The NIH is collaborating on a number of activities in response to this public health crisis including:

- Funding two grants via NICHD that began in July 2012 and July 2015
- Hosting a scientific workshop to identify research gaps for screening and management of opioid misuse and NOWS, which was published in *Obstetrics and Gynecology* in July 2017
- A research effort led by NIH/NIDA to reduce the time to improve or develop medication to treat pain, addiction, and reverse overdoses
- Advancing Clinical Trials in NOWS (ACT NOW), a partnership between NICHD, the Environmental Influences on Child Health Outcomes (ECHO), and National Institute on Drug Abuse (NIDA), to pilot a common protocol to generate evidence to inform best practice
- Leading the Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) to develop recommendations regarding therapies used by pregnant and lactating women

Sean Loudin, MD, FAAP

The last speaker was Sean Loudin, MD, FAAP, Associate Professor, Department of Pediatrics, Joan C. Edwards School of Medicine, Marshall University; Medical Director, Lily's Place, Huntington, WV. Dr. Loudin joined the faculty at Marshall University School of Medicine in 2011, where he is an Associate Professor in the Department of Pediatrics. He serves as the medical director for both the Neonatal Therapeutic Unit at Hoops Family Children's Hospital and Lily's Place, where they provide specialized care for drug exposed infants.

A native of West Virginia, Dr. Loudin attended medical school and completed his pediatric residency at Marshall University Joan C. Edwards School of Medicine. He continued his training and completed a Neonatal-Perinatal fellowship at the Medical University of South Carolina.

Dr. Loudin began his presentation stating that we need to look at NOWS as just the tip of a very large iceberg. There are so many considerations to take into account before a baby is even born with NOWS. Early fetal development is when the nerves and receptors of the brain are formed. Having an understanding of the importance of this early wiring is critical when addressing a course of treatment for the infant.

According to Dr. Loudin, 10-14 percent of babies are born with NOWS at Cabell Huntington Hospital (CHH). What makes his work unique is that about half of the babies born with NOWS are usually exposed to more than one drug, which substantially impacts the care they receive. The openings of the Neonatal Therapeutic Unit at Hoops Family Children's Hospital and Lily's Place have allowed CHH to house only 20 percent of babies born with NOWS in their NICU decreasing the numbers of families we had to turn away for other medical emergencies that occur during delivery and birth. These specialized treatment units have saved West Virginia \$11 million in hospital charges since 2011.

Dr. Loudin also stated the importance of focusing attention on the mothers because her health impacts the infant's health. It takes about 12 weeks of intensive outpatient therapy for recovery and stabilization for pregnant and early post-partum women. Further, when a mother and baby are enrolled in a program together, it saves about \$1,000 per dyad in one year.

Discussion

The first question was directed to Dr. Bianchi regarding her support for breastfeeding infants with NOWS; do the benefits outweigh the risks of breastfeeding when a woman is still using opioids. Dr. Bianchi stated that the amount of drugs delivered via breast milk is a smaller fraction of what the baby received in utero. Studies have examined the risk/benefit, which show that the benefits of breastfeeding outweigh the risks of exposure to the drug through breast milk.

Another question was asked to determine the age at which babies "outgrow" the need to be consoled or have as much attention as required at birth. Dr. Loudin answered that the American Academy of Pediatrics has shown it can take as long as six months for full withdrawal.

There was discussion related to how providers can be trained to ignore their own racial biases about drug users to ensure that every patient is properly diagnosed and treated. Dr. Reddy pointed to the universal screening recommendation by the American College of Obstetricians and Gynecologists that seeks to address the unconscious bias present in medical practice.

Another question related to access to birth control as a preventive measure. Such access has been encouraged at facilities treating mothers and infants with NOWS, as well as at substance misuse treatment programs.

The webcast of the briefing can be viewed by clicking here.