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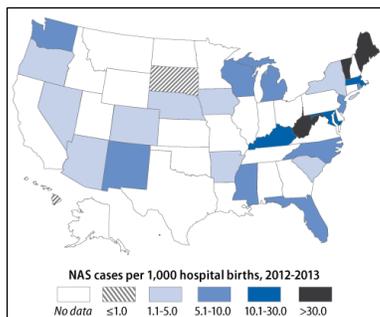
Opioid Use and Neonatal Abstinence Syndrome

The prevalence of opioid use disorder (OUD)—problematic opioid use leading to clinically significant impairment or distress—among pregnant women has gradually increased as the nation’s opioid epidemic has unfolded. This has led to increases in several adverse outcomes for infants, including neonatal abstinence syndrome (NAS). Recent efforts by both Congress and the U.S. Department of Health and Human Services (HHS) have focused on addressing the rising rate of NAS.

NAS is a withdrawal syndrome that often occurs when newborns no longer receive a substance, such as an opioid, that was administered in utero. According to a 2014 *Pediatrics* article focusing on opioid use and NAS, NAS symptoms can occur within 24 to 72 hours of birth and may last up to several months, depending on the type of opioid exposure (e.g., heroin, methadone, or buprenorphine). Such symptoms can include tremors, feeding and sleeping difficulties, temperature instability, and hyperirritability. While other substances (e.g., alcohol) have been associated with NAS, opioids are one of the most common substances associated with this syndrome.

According to a 2018 Centers for Disease Control and Prevention (CDC) analysis, the national prevalence (new and existing cases) of OUD during pregnancy increased from 1.5 OUD cases per 1,000 hospital births in 1999 to 6.5 OUD cases per 1,000 hospital births in 2014. New cases (incidence) of NAS have also increased over a similar time period. From a national perspective, a 2012 *JAMA* study found that the incidence rate of NAS has increased significantly, from 1.2 cases per 1,000 hospital births per year in 2000 to 3.4 cases per 1,000 hospital births per year in 2009. However, the incidence rate of NAS has varied by state (see **Figure 1**). These select data are among the most recent national and state-level estimates available.

Figure 1. Incidence Rate of NAS per 1,000 Hospital Births in 25 States, 2012 and 2013



Source: Ko et al., 2016, “Incidence of Neonatal Abstinence Syndrome – 28 States, 1999–2013,” *MMWR*.

Note: 2013 incidence rates are reported, except 2012 data reported for four states (Maine, Maryland, Massachusetts, and Rhode Island) without 2013 data.

NAS Screening and Treatment

No specific NAS screening guideline has been uniformly endorsed or adopted in clinical practice. Health care providers typically diagnose NAS using statistically validated scoring tools (e.g., Finnegan Neonatal Abstinence Scoring Tool) that score severity based on observed symptoms in the infant. Medical literature points to the importance of hospitals and nurseries adopting standard screening protocols, as well as properly training staff on the correct use of validated scoring tools.

NAS is a treatable condition that may require both pharmacologic (e.g., methadone) and non-pharmacologic care (e.g., gentle handling and feeding on demand). According to a 2017 Government Accountability Office (GAO) report, there is no national standard of care for NAS treatment. However, the American Academy of Pediatrics (AAP), a professional organization of pediatricians, recommends that infants with NAS should initially be treated with non-pharmacologic care, as pharmacologic treatment may be necessary only for severe cases. In addition, multiple research studies highlight the importance of involving mothers during treatment. The AAP further recommends that case management services (which assist the infant and caregiver in obtaining necessary medical, educational, and other services) can ensure that quality care is provided within each treatment stage.

Gaps in Research on Screening and Treatment

Several recent reports have identified a lack of research on standardized, uniform screening tools and treatment protocols. In 2016, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH) held a workshop with invited experts to review research gaps on opioid use in pregnancy, NAS, and childhood outcomes. The workshop proceedings cited gaps specific to NAS, including the need for more objective screening tools and the most effective types of non-pharmacologic and pharmacologic therapies to use in different clinical scenarios. In 2017, HHS highlighted similar research gaps in screening tools and treatment protocols, including the need for further development of objective screening tools and how exposure to different opioid types and/or other substances during pregnancy may affect the severity and treatment of NAS.

According to a 2015 GAO report that examined federally funded research on prenatal drug use, executive agency officials and experts also cited NAS screening and treatment research gaps. Reasons for these gaps included difficulties conducting research among pregnant women with substance use disorders, as well as other research areas beyond prenatal drug use receiving funding priority (the report did not specify these other areas).

Select Health Outcomes Among Infants with NAS

At a joint 2016 workshop with invited experts in the field, NIH found a lack of evidence about the long-term health effects of prenatal opioid exposure and NAS.

Since that time, a few academic research articles have examined short- and long-term health outcomes among infants with and without NAS, respectively. These articles suggest that infants with NAS are susceptible to

- hospital readmission within the first five years of life,
- delayed developmental milestones and higher rates of strabismus (crossed eyes) by the age of two, and
- poor academic performance in secondary schooling.

HHS's Role in Addressing NAS

HHS is addressing NAS through data and surveillance, research and evaluation, programs and services, and education activities in its respective agencies. These agencies include CDC, the Administration for Children and Families (ACF), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), and the Substance Abuse and Mental Health Services Administration (SAMHSA). CDC generally conducts surveillance of OUD among pregnant women and NAS. SAMHSA largely focuses on addressing prenatal substance use among pregnant women and recovery services for mothers, as evidenced by a recently released clinical guidance for treating pregnant and parenting women with OUD. ACF and HRSA largely focus on services for infants and children affected by prenatal substance use, including NAS.

CMS oversees Medicaid, a federal-state health care program that finances health care coverage for diverse groups of low-income populations, including children, pregnant women, adults, individuals with disabilities, and people aged 65 and older. As reported to Congress by the Medicaid and CHIP Payment and Access Commission (MACPAC), Medicaid covered almost half of all births in the United States in 2014, and according to 2018 *Pediatrics* article, Medicaid covered 82% of NAS-related births in 2014. In light of Medicaid's importance in addressing NAS, CMS released an informational bulletin for states in June 2018 that discusses Medicaid's role and limitations in NAS diagnosis and treatment, as well as Medicaid reimbursable treatment design approaches states may wish to pursue.

HHS's Strategy to Address NAS

The Protecting Our Infants Act (P.L. 114-91) was enacted in November 2015. It required HHS, among other things, to conduct a review of its planning and coordination activities related to prenatal opioid use (including NAS), develop a strategy to address gaps in research and federal programs, and submit a report to Congress on the findings of the review and the related strategy. After seeking public comment about its initial strategy, HHS released a final report in June 2017, *Protecting Our Infants Act: Final Strategy (Final Strategy)*. This *Final Strategy* report provides HHS's recommendations to address and expand on NAS prevention, treatment, and services activities administered by the department.

As required by the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198), a 2017 GAO report examined NAS in the United States and related treatment services under Medicaid. According to GAO, the strategy HHS outlined in its *Final Strategy* report does not have a comprehensive, organized method to address the demands of treating NAS. Specifically, GAO stated that the strategy lacks priorities, timeframes, and responsibilities for implementing HHS's proposed recommendations for addressing NAS. While HHS agreed with GAO's assessment, it noted that implementation of the strategy was contingent upon funding.

Provisions in the SUPPORT for Patients and Communities Act of 2018 Addressing NAS

In October 2018, Congress enacted the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 (P.L. 115-271). The SUPPORT Act is intended to address extensive overprescribing and misuse of opioids in the United States, building upon previous legislative efforts that were also intended to help address, in part, the opioid epidemic (e.g., CARA and the 21st Century Cures Act [P.L. 114-255]). Provisions in the SUPPORT Act relevant to NAS took a variety of approaches to address the issue, and are broadly summarized below.

- **Section 1005** requires HHS to issue guidance to improve care for infants with NAS and their families, and requires GAO to conduct a study addressing gaps in Medicaid coverage for pregnant and postpartum women with a substance use disorder.
- **Section 1007** adds a state option to make Medicaid inpatient or outpatient services available to infants with NAS at a residential pediatric recovery center.
- **Sections 7061-7064** require HHS, among other things, to conduct and disseminate research on NAS, provide an update on the implementation of and funding or additional authorities needed for its strategy to address NAS, and develop and promote educational materials about pain management and prevention of substance use disorders during pregnancy.
- **Section 7151** allows SAMHSA-funded Building Communities of Recovery grants to focus outreach activities on NAS.

Select Issues for Congress

Congress may consider prioritizing research on the standardization of screening and treatment, as well as long-term health outcomes associated with NAS. Congress may also consider expanding availability and coverage of different NAS treatments through Medicaid or other programs. Finally, Congress may consider monitoring HHS's efforts to address NAS, including potential costs associated with these efforts.

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