Protecting Our Infants Act: Report to Congress (SAMHSA Report)

Provides relevant background information of opioid use disorder, prenatal opioid exposure, and neonatal abstinence syndrome, reviews current activities of the HHS with relation to these issues, and recommends strategies to abate the gaps and obstacles identified in these activities.

Updated last **January 5, 2018**
for the 05/2017 report.

WHAT IT DOES

As directed by the Protecting Our Infants Act of 2015 (Public Law 114-91), the Substance Abuse and Mental Health Administration (SAMHSA) within the US Department of Health and Human Services (HHS) submitted a report to Congress on January 17, 2017 (noticed via 82 FR 6590). Included in this report are the findings of a review of existing HHS programs charged with combating prenatal opioid exposure and neonatal abstinence syndrome (NAS), a set of recommendations for prevention and treatment of intrauterine opioid exposure, and several strategies to resolve gaps and overlap in research and relevant federal programs.

Part 1 of the report provides background information on NAS and opioid use disorder (OUD), offering data on prenatal maternal opioid use and detailing the severity of consequences of opioid exposure to fetuses.

Part 2 of the report reviews HHS agencies' activities regarding the opioid crisis as they relate to fetuses, neonates, and women of reproductive age. In assessing those activities, the report cites gaps and offers recommendations for addressing those gaps in areas including:

- Data collection and surveillance;
- Research activities and publications;
- Programs and service delivery;
- Education; and
- Coordination across HHS agencies.

Part 3 posits recommendations for preventing prenatal opioid exposure, treating OUD, and diminishing NAS's impacts with bearing on all stages from pregnancy to parenting. These recommendations are largely derived from a 2016 Centers for Disease Control and Prevention policy called "Guideline for Prescribing Opioids for Chronic Pain" and a SAMHSA report called "Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance".

Finally, Part 4 of the report suggests a strategy to address the gaps and challenges in effective prevention of prenatal opioid exposure; likewise, the strategy offers methods for improving the clinical care of pregnant women, fetuses, and newborns who have or are at risk for OUD. Diminishing these weak points should effectively reduce the number of infants experiencing NAS and lessen the burdensome costs of opioid-exposed infants in neonatal care units. This strategy acknowledges that the various HHS agencies are collaborating well in caring for women and children with OUD, but that the agencies' efforts are hampered most notably by biases against OUD and other substance use disorders (SUDs) and against promoting public use of the most effective treatments.

The strategy includes but is not limited to the following elements:

- Prevention of intrauterine and postnatal opioid exposure by:
  - Standardizing medical terminology;
  - Improving screening and intervention processes;
  - Preventing and treating pain in preconception and pregnancy;

  - Increasing access to contraceptives to women at risk for substance-exposed pregnancies;
  - Providing a range of support and recovery systems for parents experiencing SUDs; and
  - Reducing barriers to seeking treatment for SUDs;
- Treatment of OUD-affected mothers and opioid-exposed infants through:
  - Collecting data about prenatal substance abuse in order to meet adequate treatment capacity;
  - Establishing protocols for identifying and managing NAS and neonatal opioid withdrawal syndrome (NOWS); and
  - Promoting breastfeeding among women receiving opioids for pain when appropriate and not contraindicated; and
- Improvement of services offered to mothers with OUD by:
  - Collecting data on insufficient care and treatment needs of mothers and children;
  - Developing protocols to guide treatment of infants with NOWS; and
  - Researching long-term developmental effects of intrauterine opioid exposure and developing mitigation services.

RELEVANT SCIENCE

Opioids are a class of drugs including those derived from opium, such as morphine, heroin, hydrocodone, and oxycodone, and those derived from synthetic processes, such as fentanyl. Opioids block pain by binding to receptors in the brain and other organ systems, mimicking natural neurotransmitters that limit the transmission of pain in the nervous system. In addition to pain relief, opioids can cause sleepiness and euphoria.

According to the report, fetal exposure to opioids can occur through a host of circumstances. Some women enduring acute or chronic pain may not realize they are pregnant and unwittingly introduce their fetuses to opioids as the mother seeks pain relief. Additionally, some healthcare providers encourage women who know they are pregnant to nonetheless continue opioid treatment for pain relief. And, some women struggling with OUD become pregnant and thus expose their fetuses to opioids. Of note, the number of women using opioids during pregnancy has increased from 1.2 to 5.6 per 1000 live births between 2000 and 2009.

According to the NIH, NAS occurs in newborns who are exposed to certain substances in utero (in the womb), potentially causing them to experience withdrawal symptoms after birth. The report mentions that other symptoms of NAS include hypersensitivity, hyperirritability, tremors, vomiting, respiratory difficulties, poor sleep, and low-grade fevers. When these symptoms are specifically due to opioid withdrawal, they are collectively termed neonatal opioid withdrawal syndrome (NOWS). Symptoms typically onset in the first few days after birth, though their duration and severity varies depending on a multitude of clinical factors. NAS occurs in 55 to 94% of infants whose mothers used opioids while pregnant, and was diagnosed in 21,732 newborns in 2012, a five-fold increase compared to the previous decade.

Medication-assisted treatment (MAT), a combination of FDA-approved medications (buprenorphine, naloxone, or methadone) and behavioral counseling so as to treat SUDs, has become a standard method for treatment of OUD. Research suggests that treating NAS with MAT can yield a 55% reduction in the average length of an infant's hospital stay as compared to those infants not receiving MAT, thus reducing overall healthcare costs.

ENDORSEMENTS & OPPOSITION

At present, there have not been any publicly reported endorsements of or opposition to this specific report.

However, the Protecting Our Infants Act of 2015, which mandated the creation of this report, received public endorsements:

- American Academy of Pediatrics, American Congress of Obstetricians and Gynecologists, and the March of Dimes, press release, November 17, 2015: "[We] applaud the passage of the bipartisan Protecting Our Infants Act of 2015 (S 799), which takes much-needed strides to reduce the number of newborns born exposed to drugs, such as opioids, and to improve their care.... [We] view today's action as a legislative victory for mothers and newborns across the country as the bill heads to the president for signature into law."

STATUS

SAMHSA released this report on January 17, 2017. SAMSHA opened a docket for public comment and incorporated those comments in its Final Strategy published on May 25, 2017.

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