'Eat, sleep, console' reduces hospital stay and need for medication among opioid-exposed infants

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Researchers have found the "Eat, Sleep, Console" (ESC) care approach to be more effective than using the Finnegan Neonatal Abstinence

Scoring Tool (FNAST) to assess and manage opioid-exposed newborns, according to a national, randomized controlled clinical trial.

Newborns cared for with ESC were medically ready for discharge approximately 6.7 days earlier and 63% less likely to receive medication as part of their treatment, compared to newborns cared for with FNAST. ESC prioritizes non-pharmacologic approaches to care, such as a low-stimulation environment, swaddling, skin-to-skin contact and breastfeeding.

ESC also encourages parental involvement in the care and assessment of their infants. These findings are based on the hospital outcomes of a large and geographically diverse group of opioid-exposed infants. A two-year follow-up study of a subset of infants is ongoing. The current findings are published in the *New England Journal of Medicine*.

"Medical care for newborns who were exposed to opioids during pregnancy varies widely across hospitals," said Diana W. Bianchi, M.D., director of NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), which co-led the study with the NIH Environmental Influences on Child Health Outcomes (ECHO) Program. "These findings are an important step toward standard, evidence-based guidance for the care of these infants."

Opioid-exposed newborns may develop symptoms of neonatal opioid withdrawal syndrome (NOWS), which includes tremors; excessive crying and irritability; and problems with sleeping and feeding. For the past 50 years, FNAST has been the traditional assessment tool for infants with NOWS. FNAST is an extensive scoring system that assesses signs of withdrawal in more than 20 areas. Concerns have been raised about its subjectivity and overestimation of the need for opioid medication.

The ESC care approach was developed about eight years ago and is growing in popularity in some nurseries but has not been rigorously tested in a large population. ESC assessments are centered on an infant's ability to eat, sleep and be consoled, and the approach keeps mother and baby together, enabling families to play a larger role in the care of their infants.

However, the widespread adoption of ESC without solid evidence of effectiveness and safety has raised concerns about potentially undertreating infants or discharging them prematurely.

The current study is part of the Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW) Collaborative.

"In the United States, at least one newborn with NOWS is diagnosed every 24 minutes," said Rebecca G. Baker, Ph.D., director of the NIH HEAL Initiative. "ACT NOW and similar studies reflect HEAL's urgent, all-hands-on-deck approach to offering scientific solutions to the many individuals, families and communities affected by the opioid crisis."

In the current study, researchers enrolled 1,305 infants across 26 U.S. hospitals. The hospitals were randomized to transition from usual care with FNAST to the ESC care approach at different times. On average, infants cared for with ESC were medically ready for discharge after an average of 8.2 days, whereas infants cared for with FNAST were medically ready for discharge after 14.9 days, with an average difference of 6.7 days between the two groups.

The study also evaluated whether newborns received opioid medication to manage their symptoms. Infants cared for with ESC were about 63% less likely to receive opioids (19.5% in the ESC group received opioid medication, compared to 52% in the FNAST group). Safety outcomes at three months of age were similar between both groups.

"The study included rural and medically underserved communities that have been hard hit by the opioid crisis," said Matthew W. Gillman, M.D., director of the NIH ECHO Program. "These findings promise to improve outcomes and address the long-term needs of opioid-exposed infants and their families."

ACT NOW is a collaborative effort between NICHD and ECHO to improve treatment and care of infants and children exposed to opioids during pregnancy. The program uses NICHD's Neonatal Research Network and ECHO's Institutional Development Award (IDeA) States Pediatric Clinical Trials Network to ensure a geographically and racially diverse group of participants.

More information: Young LW. *et al.*, Eat, sleep, console approach versus usual care for neonatal opioid withdrawal, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2214470

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