VON Grand Rounds

Evidence to Practice: Eat Sleep Console

May 14th, 2025

VON Vermont Oxford NETWORK

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2025 VON Grand Rounds Date: 05/14/2025

Planners: Danielle Ehret MD, MPH; Debra Sims PhD, RNC-NIC; Roger Soll MD; Denise Zayack RN, MPH

Speaker(s): Roger Soll MD; Danielle Ehret MD, MPH; Leslie Young, MD; Adrienne Pahl, MD

Purpose Statement/Goal of this Activity: Review of evidence, summary of current practice guidelines, synthesis of evidence in practice and interactive discussion with expert faculty – Opioid Withdrawal Assessment

The following have relevant financial relationships with ineligible companies (all have been mitigated):
None

All other speakers/planners/CMIE reviewers do not have any relevant financial relationships.

This activity did not receive any support from ineligible companies (grants or in-kind).

All recommendations involving clinical medicine made during this talk were based on evidence that is accepted within the profession of medicine as adequate justification for their indication and contradictions in the care of patients.

In support of improving patient care, this activity ahs been planned and implemented by The Robert Larner College of Medicine at the University of Vermont and Vermont Oxford Network. The University of Vermont is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialling Center (ANCC), to provide continuing education for the healthcare team.

The University of Vermont designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extend of their participation in the activity.

This program has been reviewed and is acceptable for up to 1.0 Nursing Contact Hours.

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit for learning and change.

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Moderators

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Evidence to Practice: Eat, Sleep, Console

Disclosures

Danielle Ehret MD, MPH is the Director of Global Health and Chief Medical Officer at Vermont Oxford Network (VON) and receives salary support to UVM for non-clinical time dedicated to her leadership roles.

Roger F. Soll, MD is the H. Wallace Professor of Neonatology at the Larner College of Medicine at the University of Vermont, Vice President of the Vermont Oxford Network, Director of the VON Institute for Evidence Based Practice, and Coordinating Editor of Cochrane Neonatal.

Leslie Young MD receives funding from the National Institutes of Health HEAL (Helping to End Addiction Long-term) Initiative for her research

Adrienne Pahl, MD has no disclosures.

No other relevant financial issues to disclose

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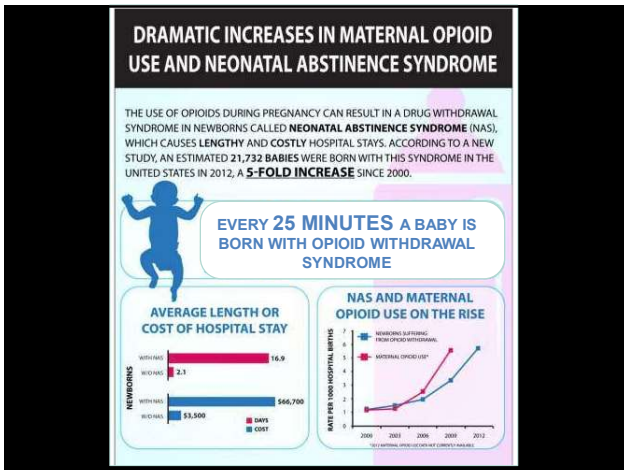

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How to Participate in Today's Webinar

- Chat questions and comments to "Everyone" during the presentations and discussion.
- Use Poll Everywhere to answer questions posed during the session. Please do not respond to polls in the Chat.

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Three ways to use Poll Everywhere

Option 1: Web
Go to "pollev.com/vtoxford"

Option 2: App
Poll Everywhere app: Enter username "vtoxford" and click "Join".

Option 3: Text
Text "vtoxford" to 22333, then send your response.

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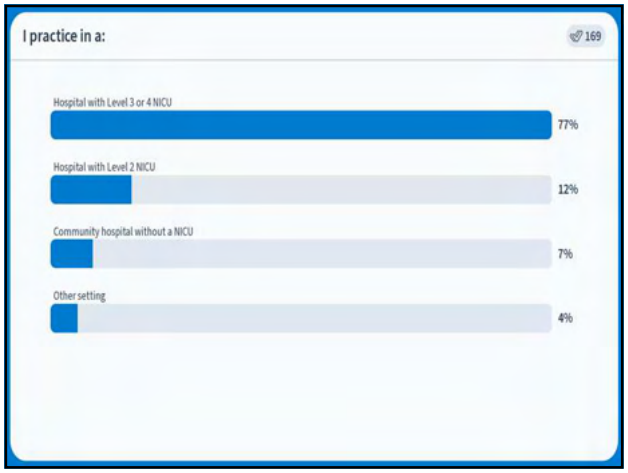

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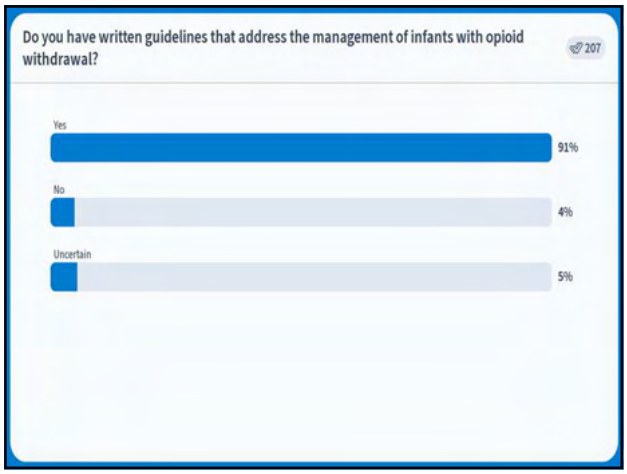

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Evidence to Practice: Care for newborns with opioid withdrawal

Roger F. Soll, MD
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A surge in opioid use

The United States has experienced a surge in opioid use and opioid-related complications.

From 1999 to 2009, there was a quadrupling of opioid pain reliever prescription sales nationwide

Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487–1492

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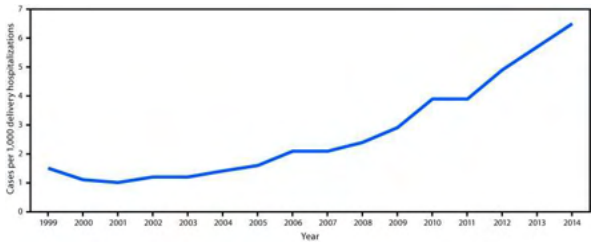
National prevalence of opioid use disorder per 1,000 delivery hospitalizations — National Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), United States, 1999–2014



Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid Use Disorder Documented at Delivery Hospitalization - United States, 1999-2014. MMWR Morb Mortal Wkly Rep. 2018 Aug 10;67(31):845-849.

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PEDIATRICS

Neonatal Opioid Withdrawal Syndrome

Assessment

In the 1970s, several scoring systems were developed to guide the diagnosis and treatment of neonatal abstinence syndrome/neonatal opioid withdrawal syndrome.

There is not one agreed-on scoring tool.

Patrick and colleagues. Neonatal Opioid Withdrawal Syndrome. Pediatrics November 2020; 146 (5): e2020029074. 10.1542/peds.2020-029074

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PEDIATRICS

Neonatal Opioid Withdrawal Syndrome

Assessment

The Finnegan Neonatal Abstinence Scoring System (FNASS), developed in the early 1970s by Dr Loretta Finnegan, is a widely used tool for assessing and managing neonatal opioid withdrawal syndrome (NOWS), helping healthcare professionals quantify the severity of withdrawal symptoms and guide treatment decisions.

The Finnegan Neonatal Abstinence Scoring Tool is an assessment of 21 signs and symptoms related to opioid exposure used to determine an infant's need for pharmacologic treatment.

Infants are assessed on a point system where each sign and symptom are weighted with corresponding values. For many centers, the threshold to begin pharmalogic treatment is either three consecutive scores of 8 or more or two consecutive scores of 12 or more.

Patrick and colleagues. Neonatal Opioid Withdrawal Syndrome. Pediatrics November 2020; 146 (5): e2020029074. 10.1542/peds.2020-029074

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The Finnegan Neonatal Abstinence Scoring System (FNASS)

Benefits:
- Standardized assessment
- Guides treatment
- Facilitates communication
- Tracks progress
- Simple and widely used
- Helps identify infants who may need pharmacological treatment

Concerns:
- Complexity and length
- Subjectivity and poor inter-rater reliability
- Lack of validation for some items
- Uncertain clinical relevance
- Disruption to the infant
- Overestimation of withdrawal

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Evidence to Practice:
Care for newborns with opioid withdrawal

Approaches to management

- Non-pharmacological care for opioid withdrawal in newborns
- Pharmacological care for opioid withdrawal in newborns

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Non-pharmacological care for opioid withdrawal in newborns

Pahl A, Young L, Buus-Frank ME, Marcellus L, Soll R.

Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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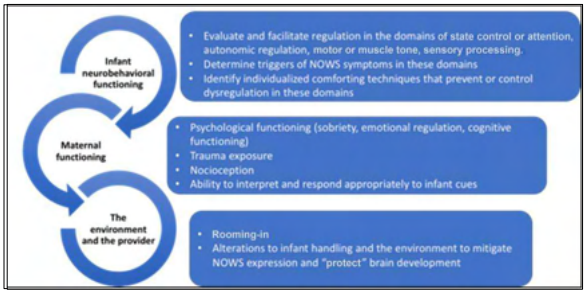
Non-pharmacological care for opioid withdrawal in newborns



Adapted from Velez M, Jansson LM. The opioid dependent mother and newborn dyad: non-pharmacologic care. J Addict Med. 2008;2(3):113–120.

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Non-pharmacological care for opioid withdrawal in newborns

Objectives

To evaluate the safety and efficacy of non-pharmacological treatment of infants at risk for, or having symptoms consistent with, opioid withdrawal.

Comparison 1: in infants at risk for, or having early symptoms consistent with, opioid withdrawal, does non-pharmacological treatment reduce the length of hospitalization and use of pharmacological treatment?

Comparison 2: in infants receiving pharmacological treatment for symptoms consistent with opioid withdrawal, does concurrent non-pharmacological treatment reduce duration of pharmacological treatment, maximum and cumulative doses of opioid medication, and length of hospitalization?

Pahl and colleagues. Non-pharmacological care for opioid withdrawal in newborns. Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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Non-pharmacological care for opioid withdrawal in newborns

Selection criteria

We included trials comparing single or bundled non-pharmacological interventions to no non-pharmacological treatment or different single or bundled non-pharmacological interventions.

We assessed non-pharmacological interventions independently and in combination based on sufficient similarity in population, intervention, and comparison groups studied.

We categorized non-pharmacological interventions as: modifying environmental stimulation, feeding practices, and support of the mother-infant dyad.

Pahl and colleagues. Non-pharmacological care for opioid withdrawal in newborns. Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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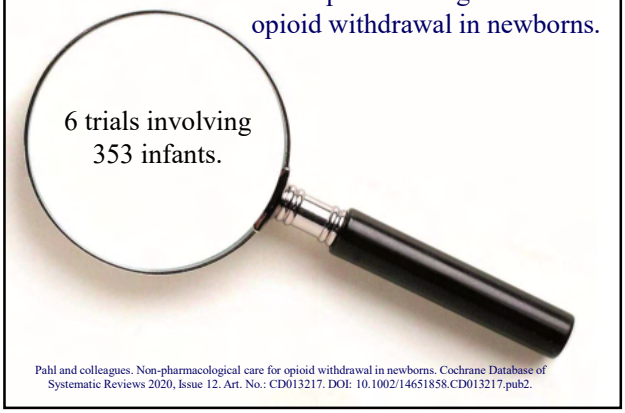
Non-pharmacological care for opioid withdrawal in newborns.



Pahl and colleagues. Non-pharmacological care for opioid withdrawal in newborns. Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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Non-pharmacological care for opioid withdrawal in newborns

Main results

We identified no RCTs in which infants receiving opioid treatment for symptoms consistent with opioid withdrawal participated.

The certainty of evidence for all outcomes was very low to low.

Of the six RCTs, four studies assessed modifying environmental stimulation in the form of a mechanical rocking bed, prone positioning, non-oscillating waterbed, or a low-stimulation nursery; one study assessed feeding practices (comparing 24 kcal/oz to 20 kcal/oz formula); and one study assessed support of the maternal-infant dyad (tailored breastfeeding support).

Pahl and colleagues. Non-pharmacological care for opioid withdrawal in newborns. Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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Non-pharmacological care for opioid withdrawal in newborns			
	Trials	Participants	Mean difference
Length of hospitalization (days)			
– *Modifying environmental stimulation*	1	30	MD 1 day lower (2.82 lower to 0.82 higher)
– *Feeding practices*			Not reported
– *Support of the mother-infant dyad*	1	14	MD 8.9 day lower (19.84 lower to 2.04 higher)
Pharmacological treatment with ≥ 1doses of opioid or sedative medication			
	Trials	Participants	Risk ratio
– *Modifying environmental stimulation*	3	92	RR 1.00 (0.86 to 1.16)
– *Feeding practices*	1	49	RR 0.92 (0.63 to 1.33)
– *Support of the mother-infant dyad*	1	14	RR 0.50 (0.13 to 1.90)

Pahl and colleagues. Non-pharmacological care for opioid withdrawal in newborns. Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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Non-pharmacological care for opioid withdrawal in newborns

Authors' conclusions

We are uncertain whether non-pharmacological care for opioid withdrawal in newborns affects important clinical outcomes including length of hospitalization and use of pharmacological treatment based on the six included studies.

Although caregivers are encouraged by experts to optimize non-pharmacological care for opioid withdrawal in newborns prior to initiating pharmacological care, we do not have sufficient evidence to inform specific clinical practices.

Larger well-designed studies are needed to determine the effect of non-pharmacological care for opioid withdrawal in newborns.

Pahl and colleagues. Non-pharmacological care for opioid withdrawal in newborns. Cochrane Database of Systematic Reviews 2020, Issue 12. Art. No.: CD013217. DOI: 10.1002/14651858.CD013217.pub2.

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Pharmacological care for opioid withdrawal in newborns

For infants with severe NOWS, use of a medication in addition to nonpharmacologic measures is necessary to improve clinical signs of withdrawal and minimize complications from withdrawal (e.g., severe weight loss).

Ideally, pharmacotherapy minimizes clinical signs of withdrawal, and then the infant is weaned off the medication using a standardized protocol to minimize total medication exposure.

Pharmacologic therapy should be considered for severe opioid withdrawal despite nonpharmacologic interventions.

Patrick and colleagues. Neonatal Opioid Withdrawal Syndrome. Pediatrics November 2020; 146 (5): e2020029074. 10.1542/peds.2020-029074

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Pharmacological care for opioid withdrawal in newborns

Multiple studies, including RCTs, have been conducted to find the optimal medication.

Pharmacologic management is associated with a longer overall length of stay (LOS) in the hospital,

Opioids remain the preferred mainstay pharmacological agent in the treatment of NAS, although there is no clear consensus on the choice of opioids.

Anbalagan and colleagues. Neonatal Abstinence Syndrome. In: StatPearls. Available from: https://www.ncbi.nlm.nih.gov/books/NBK551498/

Wachman EM, Schiff DM, Silverstein M. Neonatal Abstinence Syndrome: Advances in Diagnosis and Treatment. JAMA. 2018 Apr 03;319(13):1362-1374

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Pharmacological care for opioid withdrawal in newborns

A 2021 Cochrane review evaluating pharmacological treatments found that use of an opioid was associated with reduced treatment failure compared with phenobarbital, diazepam, or chlorpromazine.

Morphine and methadone remain the most common first-line medications and appear to be similarly safe and effective.

Morphine and methadone had similar rates of treatment failure, initiation of breast or expressed human milk feeding, and adverse events.

Zankl A, Martin J, Davey JG, Osborn DA. Opioid treatment for opioid withdrawal in newborn infants. Cochrane Database Syst Rev 2021;7(7):CD002059. doi: 10.1002/14651858.CD002059.pub4

Bagley SM, Wachman EM, Holland E, Brogly SB. Review of the assessment and management of neonatal abstinence syndrome. Addict Sci Clin Pract 2014;9(1):19. doi: 10.1186/1940-0640-9-19

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Seminars in Fetal and Neonatal Medicine
Volume 26, Issue 3, June 2021, 101218

Escaping the Finnegan – Is it time?

Rachana Singh, Jonathan M. Davis.

Seminars in Fetal and Neonatal Medicine, Volume 26, Issue 3, 2021, 101218, https://doi.org/10.1016/j.siny.2021.101218.

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The Finnegan Neonatal Abstinence Scoring System (FNASS)

Reliability

Some symptoms, which may not be exclusive to NOWS (e.g. hyperactive moro reflex, frequent yawning, nasal stuffiness, sneezing, etc.), can add up to 6 points on their own. This is concerning since the threshold for treatment in many facilities is a score of 8.

Further, an infant's score is based on 21 subjective items which commonly leads to a variability between scorers.

While the Finnegan Neonatal Abstinence Scoring Tool has been a catalyst in improving care, other newer methods may more accurately and effectively address the needs of infants with NOWS.

Shifting from a score-based assessment tool to a function-based tool, from medication management to primarily non-pharmacologic care, and from physician-led care to family-focused care management has been demonstrated to improve outcomes for infants with NOWS.

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Eat, Sleep, Console (ESC) Approach

ESC is an alternative approach to NOWS assessment that emphasizes non-pharmacologic care as the first line of treatment starting with the creation of a low stimulation environment.

ESC emphasizes parental involvement in determining care and treatment plans which result in increased support of the mother-infant dyad.

Compared to the 21-item list of the Finnegan tool which requires disturbing the infant, ESC focuses on 3 'observation only' items to guide management.

• Can the infant eat ≥ 1 oz per feed or breastfeed well? Can the infant sleep ≥ 1 hour? Can the infant be consoled within 10 minutes?

• If all three criteria are met, no further interventions are necessary. If not, increased nonpharmacologic interventions are prioritized before pharmacologic treatment is started.

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VON Vermont Oxford NETWORK

Discussants

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Associate Professor,
Larner College of Medicine
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Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW) Collaborative

- Designed to inform a standard approach to caring for infants with NOWS through large multicenter studies intentionally developed to address knowledge gaps in the field
  - Leveraging two established networks uniquely poised to address this crisis quickly and clinician scientists in highly affected areas who were motivated to develop evidence to improve care

IDeA States Pediatric Network ECHO A program supported by the NIH

NIH HEAL INITIATIVE

NICHD Neonatal Research Network

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Understanding the Clinical Landscape

ACT NOW: Current Experience Study

- Observational cross-sectional study
- 1377 infants born at or transferred to one of 30 participating sites
  - July 1, 2016 and June 30, 2017
- Designed to inform the ACT NOW clinical trials


PEDIATRICS

Site-Level Variation in the Characteristics and Care of Infants With Neonatal Opioid Withdrawal

Substantial site-level variation exists across all domains of care

NIH HEAL INITIATIVE

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Approach to Assessing Infants With NOWS

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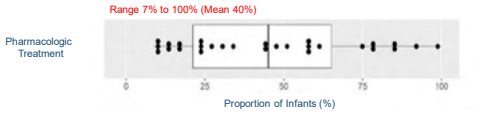
Answering the Right Question

Average hospital stay for infants with NOWS is ~12 days

- For infants who receive opioid treatment the average stay is approx. 3 weeks longer than for infants who do not (24 days vs. 4 days)



Is there a better way to assess NOWS severity and identify infants who should receive pharmacologic treatment?

NIH HEAL INITIATIVE

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Finnegan Neonatal Abstinence Scoring Tool

- Developed in the 1970s
- Includes 21 signs of withdrawal
- Scores dictate when opioid treatment is initiated, and how it is titrated
- Many clinicians believe that it overestimates the need for medication

"One nurse would score him for sneezing three times in a row, and the other wouldn't. One nurse would score him for a poopy diaper. The other one wouldn't."

Finnegan LP. Addictive Diseases. 1975

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Eat Sleep Console (ESC) Approach

Function based assessment of NOWS severity

- First proposed by Grossman and colleagues as a novel and simplified approach to the assessment of NOWS severity
- Emphasis on the functional components of withdrawal
  - Is the infant able to eat, sleep and be consoled?

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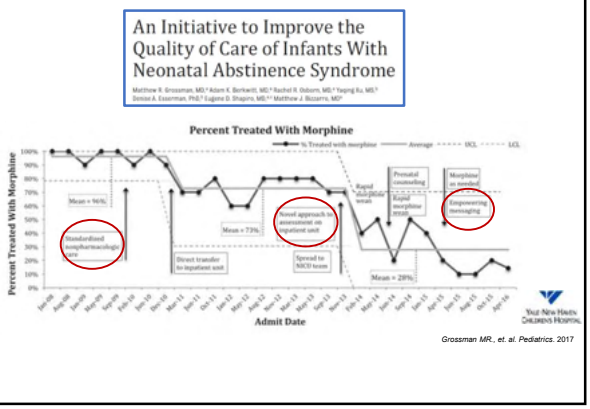
An Initiative to Improve the Quality of Care of Infants With Neonatal Abstinence Syndrome

Percent Treated With Morphine

Percent Treated With Morphine

Admit Date

Grossman MR., et. al. Pediatrics. 2017

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Eat Sleep Console (ESC) Approach

Function based assessment of NOWS severity
- First proposed by Grossman and colleagues as a novel and simplified approach to the assessment of NOWS severity
- Emphasis on the functional components of withdrawal
  - Is the infant able to eat, sleep and be consoled?

Approach emphasizes
1) Use of function-based assessments of NOWS severity
2) Optimization of non-pharmacologic care
3) Focus on educating, supporting, encouraging and empowering families in the care of their infants

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ESC Care Tool

Assessment and management tool that guides care provided under the ESC care approach

Developed by
- Children's Hospital at Dartmouth-Hitchcock - Bonny Whalen, MD & Kathryn MacMillan, MD
- Boston Medical Center - Elisha Wachman, MD & Susan Minear, MD
- Yale-New Haven Children's Hospital - Matthew Grossman, MD

- Developed to streamline implementation and support consistent application of ESC

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ESC Care Tool

Assessment

EATING
Takes > 10 min to coordinate feeding *or* **breastfeeds < 10 min** *or* **feeds < 10 mL** *(or other age-appropriate duration/volume)* **due to NOWS?** Yes / No
SLEEPING
Sleeps < 1 hr due to NOWS? Yes / No
CONSOLING
Takes > 10 min to console *(or* **cannot stay consoled for** *at least* **10 min) due to NOWS?** Yes / No
Consoling Support Needed *(assessed independent of NOWS)*
1: Able to console on own
2: Able to console within (and stay consoled for) 10 min with caregiver support
3: Takes > 10 min to console *(or* cannot stay consoled for *at least* 10 min) despite caregiver's best efforts

Management

CARE PLAN
Formal Parent Caregiver Huddle Indicated to formally review NPIs to be increased further? Yes / No / NA (choose NA if Full Care Team Huddle indicated as this includes Parent/Caregiver)
Full Care Team Huddle Indicated to formally discuss ESC difficulties and/or other significant concerns present, consider all possible etiologies for symptoms, re-assess if NPIs are maximized, and determine if NOWS pharmacologic treatment or other changes in management are needed? Yes / No
Management Decision
a: **Continue Optimize NPIs**
b: **Initiate NOWS Pharmacologic Treatment** (please list medication initiated)
c: **Continue NOWS Pharmacologic Treatment**
d: **Other** (please describe - e.g., LC & /or OT/PT Consult, Start 2nd Pharm Agent [indicate name], Increase, Wean or Stop Medications)

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ESC Care Tool

Non-Pharmacologic Care Interventions

NON-PHARM CARE INTERVENTIONS (I = Increase Now, R = Reinforce, E = Educate for Future, NA = Not Applicable/Available)	
Rooming-in (i.e., caring for infant in their own room with earliest caregiver response to infant stress or hunger cues)	
Parent-caregiver presence to help calm and care for infant	
Skin-to-skin contact when caregiver fully awake/alert to help organize infant feeding behaviours, calming & sleep	
Holding by parent/caregiver/cuddler to help calm infant & aid in sleep (with caregiver fully awake/alert)	
Safe & effective swaddling (e.g., extremities swaddled in flexed position, blanket snug, no extra blanket around baby's face)	
Optimal feeding (e.g., baby offered feedings when showing hunger cues & fed till content)	
Non-nutritive sucking with infant's hand, pacifier, adult caregiver's washed or gloved finger	
Quiet, low light environment to help limit overstimulation of infant (e.g., tv volume down, quiet "white noise" machine or phone app)	
Rhythmic movement provided by parent/caregiver or infant calming device (e.g., "jiggling" or infant swing in presence of alert adult)	
Additional help/support in room (e.g., other parent, family member, friend, cuddler, staff member, recovery coach, DCYF worker)	
Limiting # of visitors & duration of visit(s) to maximize disruptions in infant's care environment & sleep	
Clustering care & assessments with infant's awake times (e.g., RN & infant provider perform assessment together after infant feedings)	
Safe sleep fall prevention (e.g., infant sleeps on back, safely swaddled, in own sleep space)	
Parent-caregiver self-care & rest (e.g., identifying another adult to care for infant so parent can rest or take a walk/break)	
Optional Comments: (e.g., staff caring for baby as parents not available or able to safely care for baby; other NPIs [please describe])	

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Eating, Sleeping, Consoling Care Approach

- Function based assessment of NOWS severity
  - Emphasis on the functional components of withdrawal
    - Is the infant able to eat, sleep and be consoled?
- Optimization of supportive interventions as first line treatment
- Emphasis on education, support, and empowerment of families in the care of their infants

Guided by use of the ESC Care Tool

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Eating, Sleeping, Consoling Care Approach

Initial quality improvement initiatives showed promise with improvement in hospital outcomes
- Reduction in receipt of pharmacologic therapy
- Reduction in length of stay
- Increased parental presence
- No reported increase in adverse events

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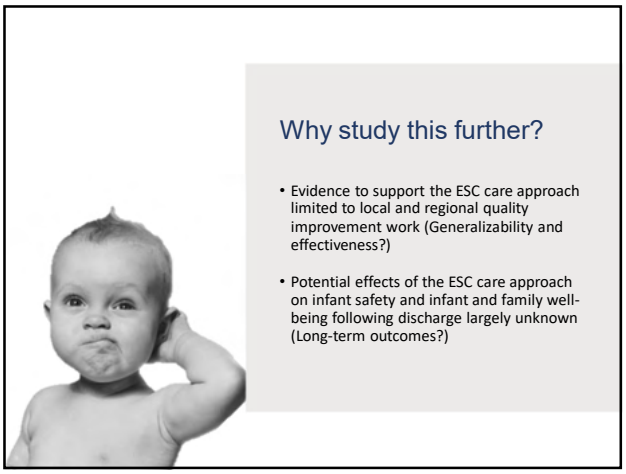

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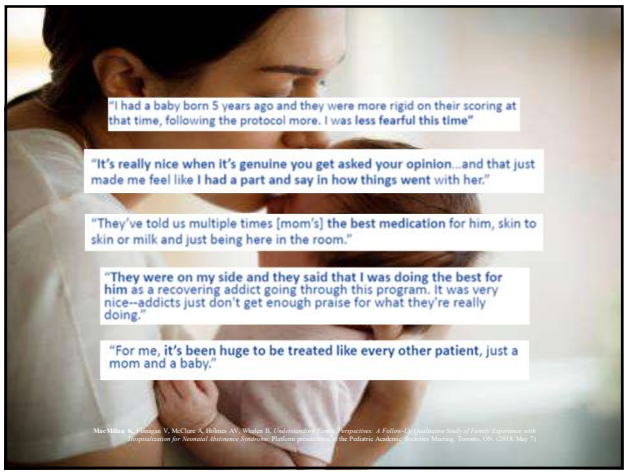

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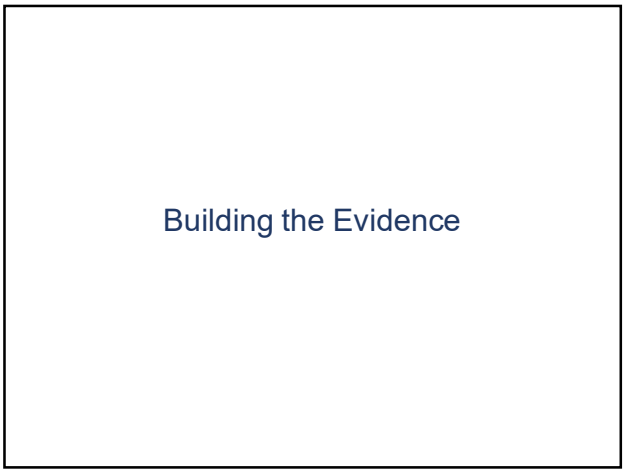

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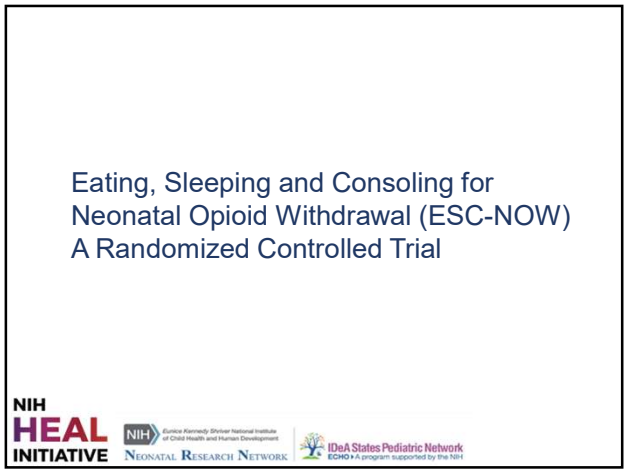

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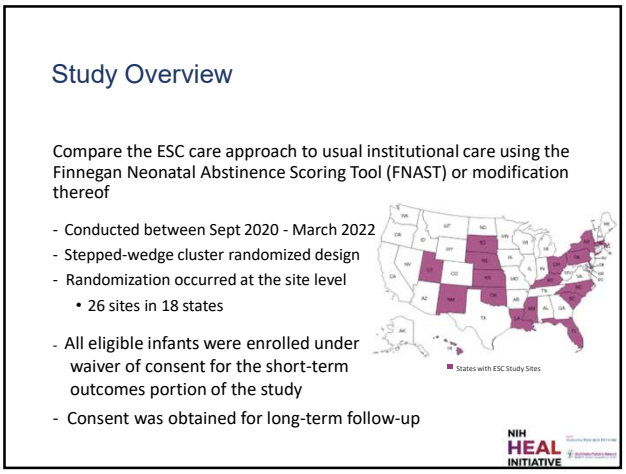

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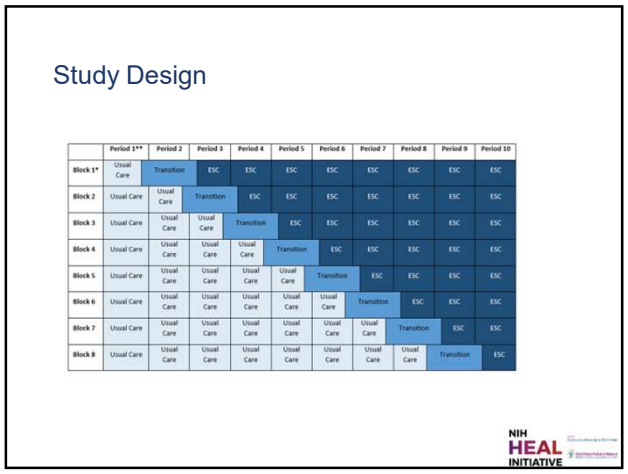

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Intervention - Usual Care

Sites provided care to infants using the usual institutional care practices for all domains of care including assessment of withdrawal severity using FNAST, use of non-pharmacologic interventions, pharmacologic treatment, and discharge

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Intervention - ESC

Sites provided care for infants using the ESC Care Tool for the assessment of withdrawal severity and to guide management. Non-pharmacologic interventions were optimized to the extent possible at each site. Approach to pharmacologic treatment and discharge was per the sites usual care practices.

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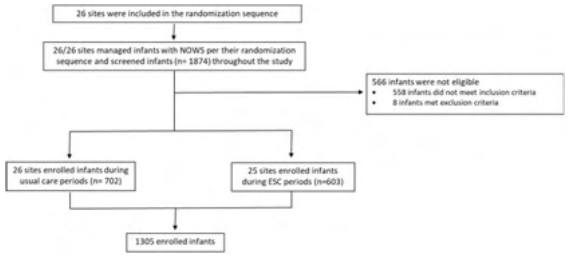
Study Enrollment



Young and colleagues for the ACT NOW Collaborative. Eat, Sleep, Console Approach or Usual Care for Neonatal Opioid Withdrawal. N Engl J Med. 2023 Jun 22;388(25):2326-2337. doi: 10.1056/NEJMoa2214470.

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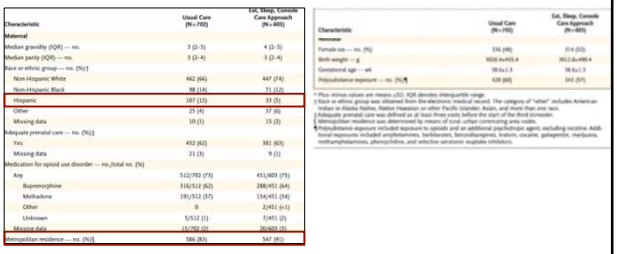
Maternal and Infant Characteristics



Characteristic	Usual Care (N = 702)	Eat, Sleep, Console Care Approach (N = 603)
Maternal		
Median gravidity (IQR) — no.	3 (2-5)	4 (2-5)
Median parity (IQR) — no.	3 (2-4)	3 (2-4)
Race or ethnic group — no. (%)†		
Non-Hispanic White	462 (66)	447 (74)
Non-Hispanic Black	98 (14)	71 (12)
Hispanic	107 (15)	33 (5)
Other	25 (4)	37 (6)
Missing data	10 (1)	15 (2)
Adequate prenatal care — no. (%)‡		
Yes	432 (62)	381 (63)
Missing data	21 (3)	9 (1)
Medication for opioid use disorder — no./total no. (%)		
Any	512/702 (73)	451/603 (75)
Buprenorphine	316/512 (62)	288/451 (64)
Methadone	191/512 (37)	154/451 (34)
Other	0	2/451 (<1)
Unknown	5/512 (1)	7/451 (2)
Missing data	15/702 (2)	20/603 (3)
Metropolitan residence — no. (%)§	586 (83)	547 (91)

Characteristic	Usual Care (N = 702)	Eat, Sleep, Console Care Approach (N = 603)
Neonate		
Female sex — no. (%)	336 (48)	314 (52)
Birth weight — g	3026.4±455.4	3012.8±490.4
Gestational age — wk	38.6±1.3	38.6±1.3
Polysubstance exposure — no. (%)¶	429 (60)	343 (57)

* Plus-minus values are means ±SD. IQR denotes interquartile range.
† Race or ethnic group was obtained from the electronic medical record. The category of "other" includes American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, Asian, and more than one race.
‡ Adequate prenatal care was defined as at least three visits before the start of the third trimester.
§ Metropolitan residence was determined by means of rural–urban commuting area codes.
¶ Polysubstance exposure included exposure to opioids and an additional psychotropic agent, excluding nicotine. Additional exposures included amphetamines, barbiturates, benzodiazepines, kratom, cocaine, gabapentin, marijuana, methamphetamines, phencyclidine, and selective serotonin reuptake inhibitors.

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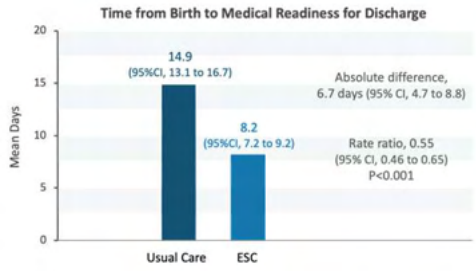
Primary Outcome



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Secondary and Safety Outcomes

- Length of hospital stay: Absolute difference 6.2 (95% CI, 4.6-7.7) days
  Usual Care 14.0 (95% CI, 12.7-15.3) vs. ESC 7.8 (95% CI, 7.1-8.5)
- Pharmacologic treatment reduced by 32.5 percentage points
  Usual care 52% (95% CI, 45.4-58.7) vs. ESC 19.5% (95% CI, 14.9-24.2)

Variable	Usual Care (N = 702)	Eat, Sleep, Console Care Approach (N = 603)
	number of patients (percent)	
Inpatient outcome		
Composite safety outcome†	1 (<1)	2 (<1)
Seizures	1 (<1)	0
Accidental trauma	0	2 (<1)
Outcome at 3 mo		
Composite safety outcome‡	113 (16)	86 (14)
Acute or urgent care visit	40 (6)	13 (2)
Emergency department visit	66 (9)	47 (8)
Hospitalization§	24 (3)	35 (6)
Composite critical safety outcome	5 (1)	1 (<1)
Nonaccidental trauma	4 (1)	1 (<1)
Death	2 (<1)	0

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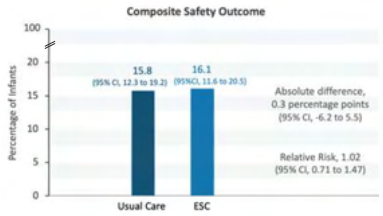

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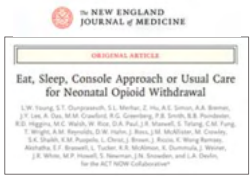
Summary

When compared to usual care, the ESC care approach

- Decreased the time until infants were medically ready for discharge
- Reduced the receipt of pharmacologic treatment



The ESC care approach appears to be safe for the assessment and management of infants with NOWS through early infancy

Young and colleagues for the ACT NOW Collaborative. Eat, Sleep, Console Approach or Usual Care for Neonatal Opioid Withdrawal. N Engl J Med. 2023 Jun 22;388(25):2326-2337. doi: 10.1056/NEJMoa2214470.

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Building the Evidence

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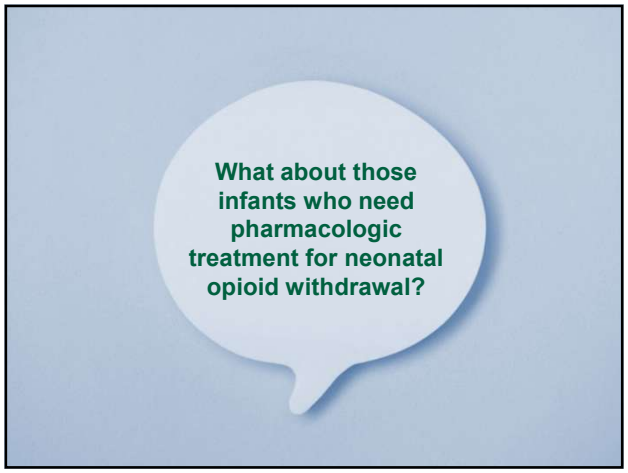

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JAMA Pediatrics

Influence of Eat, Sleep, and Console on Infants Pharmacologically Treated for Opioid Withdrawal: A Post Hoc Subgroup Analysis of the ESC-NOW Randomized Clinical Trial.

Devlin LA, Hu Z, Merhar SL, and colleagues for the for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network National Institutes of Health Environmental Influences on Child Health Outcomes Program Institutional Development Award States Pediatric Clinical Trials Network

JAMA Pediatr. 2024;178(6):525–532. doi:10.1001/jamapediatrics.2024.0544

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Infants Treated Pharmacologically

463 infants were pharmacologically treated
- 320 managed with usual care
- 143 managed with ESC care approach

Outcome	Adjusted analysis[b]			
	Usual care	ESC care approach	Absolute effect, difference (95% CI)	Estimated effect (95% CI)
Time until opioid treatment initiated, h[c]	53.0 (48.5 to 57.4)	75.4 (62.1 to 88.7)	22.4 (7.1 to 37.7)	1.42 (1.14 to 1.77)[d]
Peak opioid dose, MME/kg[e]	0.147 (0.127 to 0.168)	0.126 (0.105 to 0.146)	0.022 (−0.001 to 0.044)	0.85 (0.72 to 1.01)[d]
Receipt of adjuvant therapy, %[f]	20.0 (6.3 to 33.7)	14.9 (7.3 to 22.6)	5.1 (−8.8 to 19.0)	0.74 (0.35 to 1.56)[d]

Devlin and colleagues Influence of Eat, Sleep, and Console on Infants Pharmacologically Treated for Opioid Withdrawal: A Post Hoc Subgroup Analysis of the ESC-NOW Randomized Clinical Trial. JAMA Pediatr. 2024;178(6):525–532. doi:10.1001/jamapediatrics.2024.0544

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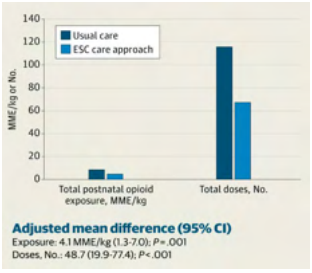
Infants Treated Pharmacologically



Adjusted mean difference (95% CI)

Duration of treatment: 6.3 days (3-9.6)

Length of stay: 6.2 days (3-9.2)

Devlin and colleagues Influence of Eat, Sleep, and Console on Infants Pharmacologically Treated for Opioid Withdrawal: A Post Hoc Subgroup Analysis of the ESC-NOW Randomized Clinical Trial. JAMA Pediatr. 2024;178(6):525–532. doi:10.1001/jamapediatrics.2024.0544

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What about the growth and feeding outcomes for infants cared for using the ESC care approach?

68

JAMA Pediatrics

Infant Feeding and Weight Trajectories in the Eat, Sleep, Console Trial: A Secondary Analysis of a Randomized Clinical Trial.

Merhar SL, Hu Z, Devlin LA and colleagues for the for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network National Institutes of Health Environmental Influences on Child Health Outcomes Program Institutional Development Award States Pediatric Clinical Trials Network

JAMA Pediatr. 2024;178(10):976–984. doi:10.1001/jamapediatrics.2024.2578

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Infant Growth and Feeding Outcomes

All 1305 infants were included in this secondary analysis
- 702 managed with usual care
- 603 managed with ESC care approach

Outcome	Adjusted analysis, % (95% CI)[a] Usual care	ESC	Absolute effect difference (95% CI)
Weight loss >10%[e]	20.6 (17.6 to 23.7)	23.0 (18.4 to 27.5)	2.3 (−4.1 to 8.8)
Maximum percentage weight loss, mean (95% CI), %[e]	7.61 (7.21 to 8.01)	7.98 (7.53 to 8.42)	0.37 (−0.25 to 0.99)
Discharge weight (z score), mean (95% CI), g[c,d]	−1.24 (−1.28 to −1.20)	−1.27 (−1.31 to −1.22)	0.03 (−0.04 to 0.10)
Weight on DOL 3 (z score), mean (95% CI), g[c,d]	−1.01 (−1.05 to −0.98)	−1.08 (−1.12 to −1.05)	0.07 (0.02 to 0.12)

Merhar and colleagues. Infant Feeding and Weight Trajectories in the Eat, Sleep, Console Trial: A Secondary Analysis of a Randomized Clinical Trial. JAMA Pediatr. 2024;178(10):976–984. doi:10.1001/jamapediatrics.2024.2578

70

Infant Growth and Feeding Outcomes

All 1305 infants were included in this secondary analysis
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- 603 managed with ESC care approach

Outcome	Adjusted analysis, % (95% CI)[a] Usual care	ESC	Absolute effect difference (95% CI)
High-calorie formula during hospital stay (maximum caloric density >20 kcal/oz)[e]	41.4 (30.9 to 51.8)	35.5 (26.1 to 45.0)	5.8 (−4.9 to 16.6)
Required NG/OG/gavage feed[e]	19.4 (15.0 to 23.8)	13.7 (8.6 to 18.8)	5.6 (−0.7 to 12.0)
Fortified formula at discharge[e]	4.4 (1.9 to 6.8)	4.0 (1.3 to 6.7)	0.3 (−3.9 to 4.5)

Merhar and colleagues. Infant Feeding and Weight Trajectories in the Eat, Sleep, Console Trial: A Secondary Analysis of a Randomized Clinical Trial. JAMA Pediatr. 2024;178(10):976–984. doi:10.1001/jamapediatrics.2024.2578

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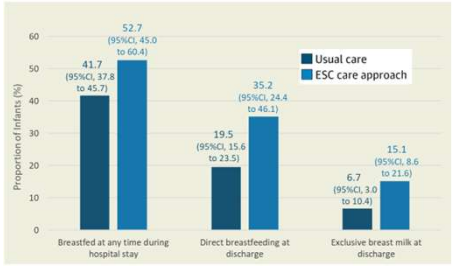
Infant Growth and Feeding Outcomes



	Breastfed at any time during hospital stay	Direct breastfeeding at discharge	Exclusive breast milk at discharge
Absolute Effect Difference	11.0 percentage points (95%CI, 1.0 to 20.9)	15.7 percentage points (95%CI, 4.1 to 27.3)	8.4 percentage points (95%CI, 0.9 to 15.8)

Merhar and colleagues. Infant Feeding and Weight Trajectories in the Eat, Sleep, Console Trial: A Secondary Analysis of a Randomized Clinical Trial. JAMA Pediatr. 2024;178(10):976–984. doi:10.1001/jamapediatrics.2024.2578

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What about PRN/symptom-based/ just-in-time/as needed dosing of pharmacologic treatment?

73

Ongoing Research

Optimizing Pharmacologic Treatment for Neonatal Opioid Withdrawal (**OPTimize NOW**): A Symptom-Based Dosing Approach

- Comparative effectiveness multicenter randomized controlled trial being conducted at 23 sites across 13 states
- Two-period cluster crossover design
- **Primary Objective**: To compare the length of time from birth until medically ready for discharge between infants with NOWS who are ≥ 36 weeks' gestation, at risk for pharmacologic treatment, and managed for NOWS with either a symptom-based dosing approach or a scheduled opioid taper approach
- Anticipate completion of enrollment in Spring 2025

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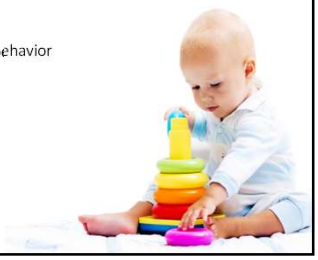
What about the longer-term outcomes for these infants and families?

75

ESC-NOW Study follow-up

- Follow-up through 2 years of age for the consented subpopulation of infants has been completed and will further inform application of this care approach
- Includes outcomes in three prospectively identified domains
  - Infant wellbeing
  - Family/caregiver wellbeing
  - Infant neurodevelopment and behavior

Stay tuned…



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Discussants

Adrienne Pahl, MD
Assistant Professor,
Larner College of Medicine
University of Vermont

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Implementation & Training Options:

Translating Evidence to Practice

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ESC Care Tool Training

Sites trained in different settings:

- Large and small
- Academic and community
- Level 3 and 2 NICU, Level 1 Nursery
- Varied resources and hospital level policies
- Multi-site perinatal quality improvement networks and individual sites

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26 sites

25 sites

NNEPQIN
24 sites

80

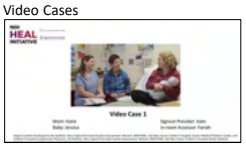
Successful Training Approaches Vary

Train-the-Trainer Approach:

- Duration has varied from half-day to 3-day formats
- In Person and/or Virtual
- Varying degrees of collaborative vs. individual work
- May include asynchronous components to accommodate scheduling needs

In Person Simulation

Video Cases



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Common Training Elements

Pre-Training

- Assess site strengths and needs
- Background education on NOWS
- Review of ESC Care Tool and Guide
- Independent Completion of Written Case

Post-Training

- Discuss Challenging Cases and System Challenges in collaborative setting
- Rotating Supplementary Education Modules for Care of this Population

Resources

- Foundational NOWS and ESC Care Tool educational model recordings
- Written Cases for practice with answer key
- Written Cases for interrater reliability

Interrater Reliability

- 100% IRR for Gold Star Rater status
- 80% IRR for bedside staff

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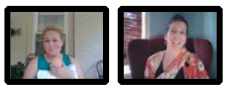
ACT NOW ESC Trial Train-the-Trainer Session

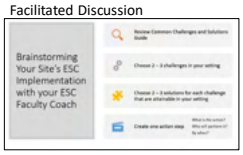
2-day intensive training:

- Review use of the ESC Care Tool
- Pre-recorded faculty simulation case
- Live virtual case simulations
- Complete written cases and review Interrater Reliability
- Brainstorm anticipated challenges and solutions
- Interactive Trauma Informed Care Modules

Virtual Simulation



Facilitated Discussion



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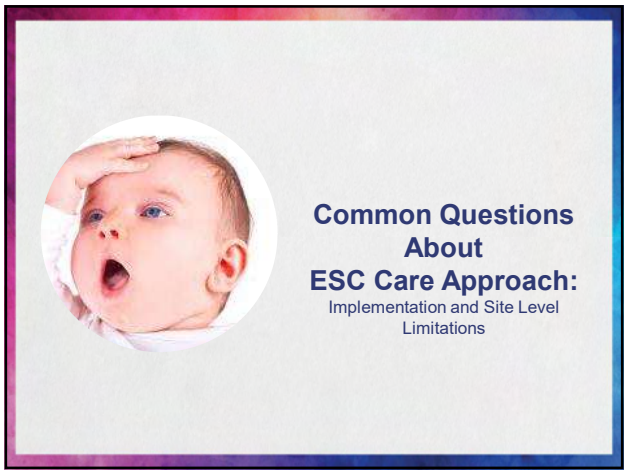

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How do we approach ESC training and maintain competence?

- **Initial training** – Case based training customized to site with a goal of 80% interrater reliability for bedside use
- **Just-in-Time training** - resources for nurses/team members who have not recently cared for an infant with NOWS and desire/need a refresher
- **Bedside Practice** - perform ESC Care Tool assessment with any infant (opioid *OR* non-opioid exposed) every few months to maintain comfort/confidence
- **Annual Online Competency** - education & IRR testing using written cases and / or videos
- **Forum for Case Discussion**- discuss common problems and scenarios in caring for opioid-exposed newborns and their families, brainstorming barriers/challenges and facilitators/possible solutions in Q&A fashion
- **Attend Education** – local/regional/offsite/virtual opportunities

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How do we prepare families before hospitalization?

- **Reach out** to prenatal clinics/treatment programs about ESC care
- **Provide materials** (e.g. ESC Care Tool and Newborn Care Diary)
- **Educate** providers/programs on available community resources
- **Promote consistent messaging** by providers, nurses, staff

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We don't have a rooming-in setting or a parent is not present - Can we still use ESC?

- **Advocate** for the benefits of providing a rooming in environment for families
- **Provide a welcoming environment** for parents during the time they are there
  - Comfortable seating that is conducive to breastfeeding and skin-to-skin
  - Privacy screens or curtains in open spaces
  - Consider short term use of other private spaces when possible- ex. family room, staff pumping room
  - Seek out a place for families to stay overnight
- **Identify other supports** if parent is unable to be present - utilize cuddlers/volunteers, strategic staff assignments, or identified support persons when available

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Can we use the ESC Care Approach in the ICU?

- Optimize non-pharmacologic care *for your setting*
  - Adjust staffing and volunteers to support infant
  - Move location within the NICU to minimize stimuli
  - Reinforce the fundamental non-pharmacologic care interventions on the ESC Care Tool, especially the importance of parent/caregiver presence
- Broader considerations for the ICU setting:
  - Does the infant need ICU level of care?
  - Are symptoms "due to NOWS" or are they related to another etiology? Infants may be in the ICU for another reason (ie prematurity, concern for HIE, hypoglycemia, bilious emesis).

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Implementation Take Aways

- The ESC Care Tool can be successfully implemented in a variety of settings
- Staff trainings may take a variety of forms to suit your settings resources and needs
- Development of local expertise is an important first step to facilitate hospital training and implementation activities
- Focus on optimizing non-pharmacologic care for your setting

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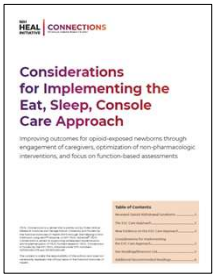
Opportunities: Training and Implementation

- Multiple pathways forward for training
- Training materials from the trial will be made publicly available following the close of the ESC-NOW study
- In partnership with the Vermont Oxford Network, ESC faculty will work to support training for individual hospitals, hospital networks, and perinatal quality collaboratives
- View and download the Eat, Sleep, Console (ESC) Implementation Planning Resource:



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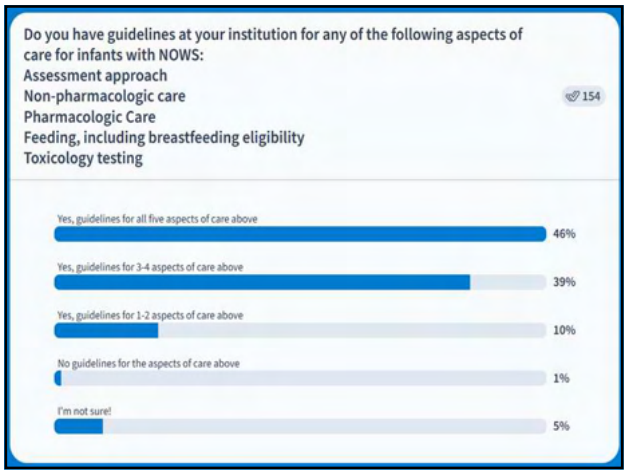

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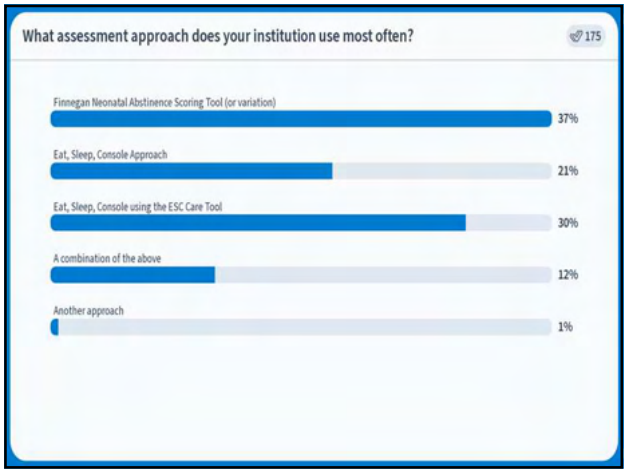

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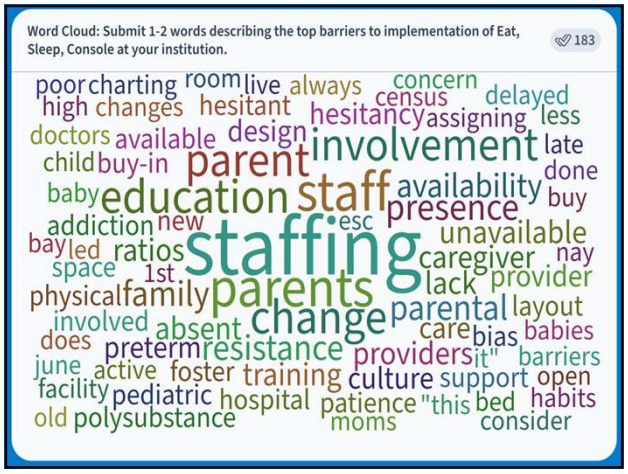

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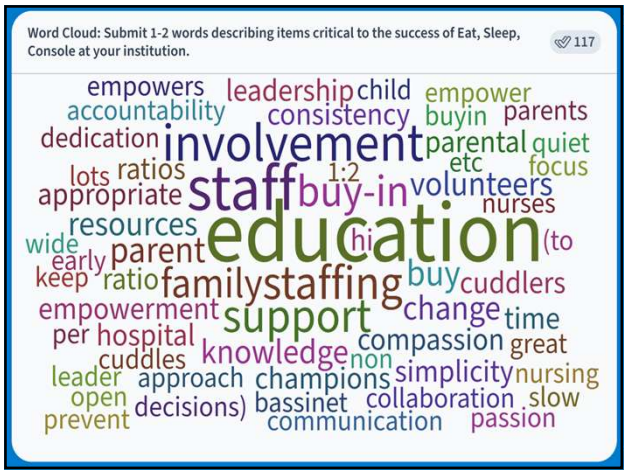

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Future sessions

August 6th 2025 – Evidence to Practice:
Oxygen in the NICU

November 12th 2025 – Evidence to Practice:
NICU Environment

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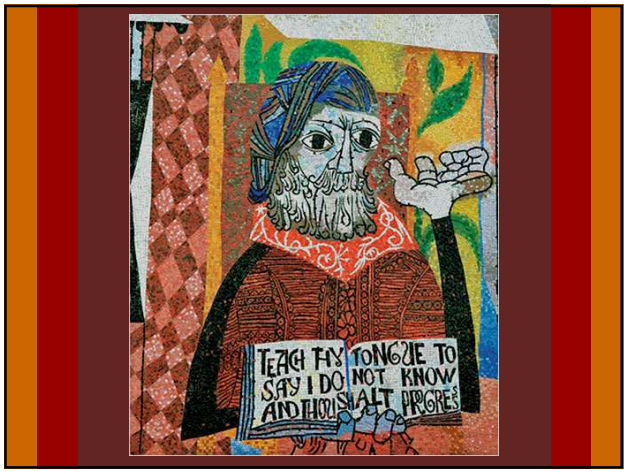

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