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QUALITY IMPROVEMENT ARTICLE

A quality improvement initiative to implement the eat, sleep, console neonatal opioid withdrawal syndrome care tool in Massachusetts' PNQIN collaborative

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Abstract

Objective To support hospitals in the Massachusetts PNQIN collaborative with adoption of the ESC Neonatal Opioid Withdrawal Syndrome (NOWS) Care Tool© and assess NOWS hospitalization outcomes.

Study design Statewide QI study where 11 hospitals adopted the ESC NOWS Care Tool©. Outcomes of pharmacotherapy and length of hospital stay (LOS) and were compared in Pre- and Post-ESC implementation cohorts. Statistical Process Control (SPC) charts were used to examine changes over time.

Results The Post-ESC group had lower rates of pharmacotherapy (OR 0.35, 95% CI 0.26, 0.46) with shorter LOS (RR 0.79, 95% CI 0.76, 0.82). The 30-day NOWS readmission rate was 1.2% in the Pre- and 0.4% in the Post-ESC cohort. SPC charts indicate a shift in pharmacotherapy from 54.8 to 35.0% and LOS from 14.2 to 10.9 days Post-ESC.

Conclusions The ESC NOWS Care Tool was successfully implemented across a state collaborative with improvement in NOWS outcomes without short-term adverse effects.

Introduction

Incidence of Neonatal Opioid Withdrawal Syndrome (NOWS), also referred to as Neonatal Abstinence Syndrome (NAS), increased 433% from 2004 to 2014, accounting for 2.9 billion dollars in hospitalization costs [1].

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Costs related to in-utero opioid exposure include prolonged hospital stays primarily related to initiation of pharmacologic treatment [2, 3]. Rates of pharmacotherapy range anywhere from 10–90% in varied care settings [2, 4, 5].

Since its introduction 45 years ago, the Finnegan Neonatal Abstinence Scoring Tool (FNAST) has been the most frequently used tool to assess and treat infants with NOWS [3, 6, 7]. The scale consists of 21 signs of withdrawal which are assigned a numeric score; typically three scores of ≥8 or two scores of ≥12 trigger initiation of pharmacotherapy [6, 8, 9]. However, many of the signs measured are not specific to NOWS and can be present in non-opioid-exposed infants, some are of uncertain clinical significance, and poor internal consistency has raised questions regarding the tool's validity [8, 10]. Despite its widespread use, the FNAST has never been validated to guide pharmacotherapy. Further, many shorter versions of the FNAST have been developed, but none are used frequently in clinical practice [8].

Developed in 2014 as a novel function-based assessment method for NOWS, the Eat, Sleep, Console (ESC) approach places focus on how withdrawal is impacting the infant's ability to function. The criteria for assessing and managing NOWS is based on whether the infant can eat well, sleep for at least 1 h, and be consoled [11, 12]. The ESC approach emphasizes implementing non-pharmacological care as first-line treatment for NOWS, including a low-stimulation environment, clustered care, and breastfeeding [11, 12]. This novel approach was associated with decreased rates of pharmacotherapy, and shorter length of stay and hospital costs in a single center when accompanied by other quality improvement (QI) interventions [11].

In 2016, a structured ESC NOWS Care Tool© was developed as an objective method to document use of the ESC approach, using age-based definitions for what defines adequate oral intake, sleep, and consolablity in an infant with NOWS, and was piloted in a single urban academic medical center [13]. In 2017, the tool was revised to include a formal non-pharmacologic intervention (NPI) checklist that includes evidence-based, baby- and family-centered NOWS best practices including rooming-in, parental presence, and breastfeeding, and was field tested in a Northern New England Perinatal Quality Improvement Network (NNEPQIN) QI learning collaborative. In 2018, the tool was further revised based on reliability data and provider feedback obtained through hospital QI implementation and standardized trainings [14, 15]. This revised tool has not yet been validated or further assessed for reliability between providers.

Compared to the Finnegan Scale, the ESC NOWS care approach, with or without use of the formal ESC NOWS Care Tool, has been associated with decreased rates of pharmacotherapy and shorter hospitalizations in single-center QI studies [11, 13, 16–19]. All prior studies implemented ESC in the context of a comprehensive QI bundle aimed at improving non-pharmacologic care, with many hospitals implementing established interventions such as parental engagement, rooming-in, and breastfeeding [20–22]. The success of centers first adopting the ESC model, combined with its ease of administration, its family-centered approach, and its incorporation of best practices including rooming-in and breastfeeding, has resulted in the wide spread of ESC to hospitals and perinatal networks throughout the country.

Since 2016, the Perinatal-Neonatal Quality Improvement Network of Massachusetts (PNQIN) has led a statewide improvement initiative to improve care for opioid-exposed mother-infant dyads, representing approximately 2% of births statewide [23]. Goals of the initiative have included promotion of established best practices in non-pharmacologic care, such as increasing family engagement, rooming-in, and appropriate use of breastmilk. Although not a primary goal of the collaborative, many participating centers expressed interest in adopting the ESC approach as part of their non-pharmacologic interventions after the ESC approach was first published [11]. To support this growing interest and to standardize practices, PNQIN instituted a formal QI initiative in 2017 to implement the ESC NOWS Care Tool in centers pursuing ESC. We sought to describe our implementation process, and assess its impact on two main NOWS hospital outcomes, pharmacotherapy and length of hospital stay (LOS), and balancing measures of emergency room (ER) visits and hospital readmissions in eight community and three tertiary care academic PNQIN hospitals fully implementing the tool and formally collecting data.

Subjects and methods

Context

The PNQIN collaborative includes 37 birthing hospitals as well as numerous state agencies including the Department of Public Health, Department of Children and Families, and Health Policy Commission [23]. Twenty-nine of 37 PNQIN hospitals participated in an ESC NOWS Care Tool roll-out program between 2017 and 2019, with participation defined as attendance at least one of several ESC Care Tool training workshops and webinars offered over this period. A total of 11 hospitals had fully implemented the ESC NOWS Care Tool with complete data collection by December 2019 at the time of analysis. Hospital team participation was voluntary with in-kind effort. Hospital teams were multidisciplinary, including nursing, physicians, social work, peer recovery coaches, and lactation specialists. Before the QI initiative, all hospitals utilized the FNAST for NOWS

assessments and a standard morphine taper as first-line pharmacotherapy.

QI approach

We used the Institute for Healthcare Improvement Breakthrough Series framework - a collaborative improvement model that adapts and applies existing knowledge to multiple similar sites to accomplish common aims [24]. This approach included large statewide summits, smaller ESC-focused workshops, webinars, team sharing, standardized training materials, implementation checklists, and a shared de-identified database with quarterly reports to the hospitals outlining progress for each outcome measure relative to other participating hospitals.

Interventions

A timeline of our statewide implementation of ESC is included as Supplemental Fig. 1.

Teams involved in the work

The PNQIN perinatal opioid project leadership team consists of 38 members, including individuals from pediatrics, obstetrics, and state agencies. The ESC core leadership team consisted of three individuals including co-creators of the ESC NOWS Care Tool. Hospital care teams consisted of at least one physician and one nursing leader from each hospital. Teams were encouraged to be multidisciplinary and to meet monthly.

ESC NOWS care tool description

Infants are assessed every 3–4 h for their ability to eat effectively for expected gestational and postnatal age, sleep for at least 1 h after feeding, and to console within 10 min with level of consoling support required. Individual ESC items are assessed for association with NOWS. If the infant is not doing well in one of the three ESC domains, then a bedside huddle is recommended involving the parent and care team. First-line therapy for NOWS is optimized through systematic use of the NPI checklist. If NPIs are optimized and NOWS-related ESC difficulties persist, then pharmacotherapy is initiated per hospital guidelines. Infants are weaned from medication when they are eating, sleeping, and consoling well. During the pilot phase at the first hospital, the pilot ESC Care Tool was used. The ESC Care Tool was then further developed into the first edition ESC Care Tool in 2017 and into the second edition in 2018. The second edition of the ESC Care Tool was then adapted by all 11 centers, and was used in either paper or electronic version based on hospital preference.

Statewide summits

During the intervention period, biannual statewide PNQIN summits were held with an average attendance of 350–450 participants and 25–30 hospitals at each summit [23]. Topics related to non-pharmacologic care and/or ESC were presented at each summit. Smaller 45-minute ESC NOWS Care Tool implementation workshops were also offered. Hospital QI teams presented local improvement projects during poster sessions and oral presentations.

ESC training workshops

Statewide one-day ESC NOWS Care Tool training workshops were offered three times during the intervention period, with an average of 100 participants and 14 hospital teams at each, including the 11 hospital teams included in this analysis. Workshops were run by the ESC NOWS Care Tool creators and consisted of background education on the ESC care approach including non-pharmacologic care, formal training in use of the ESC NOWS Care Tool using standardized interactive written and video cases, provider panel discussions, and presentations by local hospitals successfully implementing ESC.

ESC training materials

A standardized ESC NOWS Care Tool training package was provided to all hospitals and loaded onto a password-protected PNQIN website. The ESC training website contained (1) background presentations on the rationale behind ESC, (2) published manuscripts on ESC, (3) the 2nd edition ESC NOWS Care Tool© and (4) its training manual, (5) an ESC inter-rater reliability tool, (6) ESC training video, (7) standardized case examples and quizzes, (8) sample staff training presentations, (9) an electronic health record tip sheet, and (10) sample ESC NOWS hospital protocols.

ESC webinar series

Between 2018 and 2019, nine webinars were hosted and available to all participating hospitals. Topics included hospital sharing of successes and challenges in implementing ESC, rooming-in, breastfeeding, review of ESC publications and state data, and ESC challenging case discussions.

Hospital presentations

Three of 11 hospitals had an onsite grand rounds presentation, provided by a PNQIN ESC training team, for their larger hospital staff to assist with ESC NOWS Care

Tool "buy in" and dissemination of information. These site visits were arranged upon request by the hospital teams.

Contextual elements

Hospitals were surveyed on contextual elements including changes made in NOWS care over the study period, and on their primary location of NOWS care after maternal discharge and/or when the infant required pharmacologic treatment. These elements included changes in breastfeeding eligibility guidelines, implementation of rooming-in programs, establishment of hospital Baby-Friendly designation for the promotion of breastfeeding and maternal-infant bonding, implementation of non-pharmacologic care bundles, changes in medication protocols, changes in prenatal education, the addition of peer recovery coaches, and establishment of a trauma-informed care curriculum for staff.

Data collection

Hospitals in the PNQIN collaborative were asked to participate in voluntary data entry into a statewide de-identified database. Data points collected included maternal demographics, prenatal exposures, NOWS pharmacologic treatment details, non-pharmacologic care received (e.g., breastfeeding, rooming-in, skin-to-skin), and discharge disposition. Beginning in 2017, hospitals were asked to complete a supplemental data form focused on balancing measures including ER visits and hospital readmissions within 30 days of discharge and other perceived adverse events related to NOWS care. All data were hand abstracted by the hospital teams. The database was launched in 2016 with pre-ESC NOWS Care Tool implementation data serving as baseline.

Study of the interventions

We included infants who were ≥35 weeks' gestation, had known prenatal opioid exposure, and were monitored for NOWS. Exclusion criteria included exposure to naltrexone or to illicit substances without a known opioid exposure. Hospitals were asked to document the NOWS assessment method used for each infant in the database, and from this the ESC Care Tool start date for each hospital was determined. We then combined cohort data from all 11 hospitals implementing the ESC NOWS Care Tool, with complete data through December 2019, and compared NOWS outcomes Pre- and Post-ESC implementation. Hospitals that implemented other changes in their care model without full adaption of ESC were not included in this analysis. To establish whether observed outcomes were related to the intervention, we used statistical process control (SPC) charts and regression model analyses.

Outcome measures

Outcome measures were chosen based on the NOWS literature [21]. The primary outcome measure was proportion of infants who received pharmacotherapy. The secondary outcome measure was LOS, which includes pharmacologically treated infants and those treated with non-pharmacologic care interventions alone. No infants were sent home on opioid medications. Other outcome measures included opioid treatment days (pharmacologically treated infants), hospital NOWS-related readmissions and ER visits within 30 days of discharge, and any perceived adverse events associated with NOWS (e.g., seizures, transfers to higher levels of care). Process measures included rooming-in (defined as at least one night prior to maternal discharge), Neonatal Intensive Care Unit (NICU) admission, initiation of breastmilk feedings, any breastmilk intake on day of hospital discharge, skin-to-skin within the first 24 h of life, and discharge disposition (maternal custody vs. other). Data were reviewed for completion by two study authors; sites were notified to fill in missing data prior to final analysis.

Data analysis

We compared outcomes during Pre- and Post-ESC study periods, defined as prior to and after the ESC NOWS Care Tool start date. Each hospital's data were converted to quarters pre- and post- their ESC implementation start date. We evaluated nine quarters pre- and seven quarters post-ESC. SPC charts were used to analyze quarterly performance over time for the main outcome measures of pharmacotherapy and LOS. Control charts were created and analyzed using established rules for special cause variation including eight or more points in a row above or below the center line, or six consecutive points increasing or decreasing (trend) [25].

Multivariable mixed-effect logistic regression models were used to measure the association of ESC implementation on pharmacotherapy, including secondary agent use, after adjusting for maternal opioid, breastfeeding, and psychiatric medications. Covariates known to be associated with NOWS outcome measures were examined. Those with $p < 0.05$ were included in final models. We used a multivariable mixed-effects Poisson regression model for LOS and opioid days to account for the non-normally distributed continuous outcomes. All models included random intercepts for clustering by delivery hospitals.

Ethical considerations

This statewide QI project was determined to be not-human-subjects research by the institutional review boards at the PNQIN leadership team hospitals. All participating centers

Table 1 Hospitals participating in ESC NOWS care tool roll-out.

Hospital	Pre-ESC ($N = 753$) N (%)	Post-ESC ($N = 475$) N (%)	Type of hospital	Primary location of NOWS care
1	91 (12.1%)	147 (30.9%)	Tertiary	Inpatient Pediatrics
2	47 (6.2%)	21 (4.4%)	Community	Postpartum Unit
3	19 (2.5%)	20 (4.2%)	Community	Inpatient Pediatrics
4	93 (12.4%)	65 (13.7%)	Community	Inpatient Pediatrics
5	11 (1.5%)	57 (12.0%)	Tertiary	Inpatient Pediatrics
6	222 (29.5%)	71 (14.9%)	Tertiary	Postpartum Unit/NICU
7	23 (3.1%)	6 (1.3%)	Community	Postpartum Unit
8	94 (12.5%)	29 (6.1%)	Community	Postpartum Unit/SCN
9	4 (0.5%)	9 (1.9%)	Community	Postpartum Unit
10	53 (7.0%)	18 (3.8%)	Community	Inpatient Pediatrics
11	96 (12.7%)	32 (6.7%)	Community	Postpartum Unit/SCN

NICU Newborn Intensive Care Unit, *SCN* Special Care Nursery.

completed a data use agreement with PNQIN to submit de-identified data through the secure statewide database.

Results

There were 753 infants in the Pre- and 475 in the Post-ESC cohorts. Table 1 shows each hospital with information about the type of center and number of infants. The primary location of NOWS care after maternal discharge and/or when infants received pharmacologic treatment included Postpartum and Inpatient Pediatrics Units; only three hospitals utilized NICUs or Special Care Nurseries.

Other NOWS improvement actions implemented by hospitals during the study time period included: (1) changes in breastfeeding guidelines or establishment of hospital Baby-Friendly designation [26] ($n = 3$), (2) implementation of rooming-in ($n = 2$), (3) revised non-pharmacologic care bundles ($n = 5$), (4) changes in medication protocols ($n = 3$), (5) improved prenatal education ($n = 4$), (6) peer recovery coach programs ($n = 3$), and (7) staff trauma-informed care curriculum ($n = 2$).

Pre- and Post-ESC cohort demographics are shown in Table 2. Post-ESC, fewer infants were cared for in a NICU (OR 0.51, 95% CI 0.38, 0.69), and more infants received skin-to-skin (OR 2.20, 95% CI 1.54, 3.14) and their mother's milk at discharge (OR 1.34, 95% CI 1.03, 1.73). There were more polypharmacy and illicit drug-exposed infants in the Post-ESC cohort. Comparison of NOWS outcome measures are shown in Table 3. In multivariable mixed-effects regression models, the Post-ESC group had lower rates of pharmacotherapy (OR 0.35, 95% CI 0.26, 0.46) and secondary agent use (OR 0.23, 95% CI 0.12, 0.44), with shorter LOS (RR 0.79, 95% CI 0.76, 0.82) and opioid treatment days (RR 0.80, 95% CI 0.75, 0.86). The 30-day NOWS readmission rate was 1.2% in the Pre- and 0.4% in the Post-ESC cohort ($p > 0.3$), and 30-day ER visit rate was 1.6% Pre- versus 0.8% Post-ESC ($p > 0.3$). There were no reported additional adverse events. Stratified analyses by hospital are shown in Supplemental Table 1; nine of the 11 hospitals had notable decreases in need for pharmacotherapy or LOS following ESC adoption, with significant improvements seen in the larger centers with sufficient sample size.

SPC charts indicate a significant shift in pharmacotherapy from 54.8 to 35.0% and LOS from 14.2 to 10.9 days Post-ESC, with the start of improvement occurring two quarters prior to the ESC start date (Figs. 1 and 2). Results were sustained for the seven quarters post-ESC implementation.

Complete data on readmission and ER visits post-discharge were missing from six of the 11 hospitals without access to this data in the Pre-ESC cohort. These six hospitals reported no readmissions related to NOWS in their Post-ESC cohorts. Otherwise, the data were assessed for missingness with <5% missingness for all variables.

Discussion

The ESC NOWS Care Tool was successfully implemented across a state perinatal QI collaborative with notable sustained improvement in NOWS hospitalization outcomes, specifically a decrease in pharmacotherapy and LOS without an increase in short-term adverse events. Results were seen in the context of hospitals receiving ESC NOWS Care Tool standardized training and QI implementation support, with infants receiving standardized ESC assessments and a comprehensive non-pharmacologic care bundle.

An important finding of this study is that decreases in pharmacotherapy and LOS were seen on average six months prior to the implementation of ESC, a finding that

Table 2 Demographics of the Pre- and Post-ESC implementation cohorts.

Demographic	Pre-ESC ($N = 753$) N (%) or mean (SD)	Post-ESC ($N = 475$) N (%) or mean (SD)	Post- vs Pre-OR/RR (95% CI)	P value
Maternal age (years)	30.5 (4.6)	30.6 (4.4)	1.01 (0.97,1.05)	0.73
Maternal race/ethnicity				
- Hispanic	65 (8.6%)	44 (9.3%)	1.76 (1.14, 2.69)	0.05
- Black, Non-Hispanic	23 (3.1%)	21 (4.4%)	1.64 (0.85, 3.17)	
- White, Non-Hispanic	630 (83.7%)	381 (80.2%)	Reference	
- Other, Non-Hispanic	21 (2.8%)	18 (3.8%)	1.36 (0.68, 2.72)	
Maternal opioid				
- Methadone[a]	237 (31.5%)	142 (29.9%)	0.85 (0.62, 1.17)	0.76
- Buprenorphine[a]	252 (33.5%)	174 (36.6%)	0.92 (0.68, 1.25)	
- Other prescribed	33 (4.4%)	12 (2.5%)	0.79 (0.39, 1.62)	
- Illicit	231 (30.7%)	147 (30.9%)	Reference	
Other maternal exposure				
- Cocaine	114 (15.1%)	95 (20.0%)	1.45 (1.06, 1.96)	**0.02**
- Marijuana	205 (27.2%)	120 (25.3%)	1.30 (0.97, 1.73)	0.08
- Alcohol	23 (3.1%)	10 (2.1%)	0.68 (0.32, 1.45)	0.32
- SSRI, Gabapentin, Benzodiazepines	141 (18.7%)	132 (27.8%)	1.70 (1.28, 2.25)	**<0.001**
- Amphetamine	51 (6.8%)	35 (7.4%)	1.12 (0.70, 1.79)	0.65
- Nicotine	367 (48.7%)	258 (54.3%)	2.33 (1.77, 3.08)	**<0.001**
Gestational age (weeks)	38.5 (1.6)	38.3 (1.5)	0.99 (0.98, 1.01)	0.55
Birth weight (grams)	3045 (539)	3027 (492)	0.99 (0.99, 1.00)	**<0.001**
Infant gender				
- Male	387 (51.4%)	249 (53.0%)	1.04 (0.81, 1.33)	0.76
- Female	366 (48.6%)	266 (48.1%)	Reference	
Breastmilk initiation	374 (49.7%)	261 (54.9%)	1.32 (1.02, 1.70)	**0.04**
Any breastmilk at discharge	314 (41.7%)	221 (46.5%)	1.34 (1.03, 1.73)	**0.03**
Rooming-in	628 (83.4%)	427 (89.9%)	1.43 (0.98, 2.09)	0.06
Skin-to-skin	585 (77.7%)	424 (89.3%)	2.20 (1.54, 3.14)	**<0.001**
Location of care				
- Level 1 Nursery	585 (77.7%)	439 (92.4%)	8.06 (5.01, 12.96)	**<0.001**
- SCN or NICU	331 (44.0%)	110 (23.2%)	0.51 (0.38, 0.69)	**<0.001**
- Pediatrics	147 (19.5%)	247 (52.0%)	4.75 (3.10, 7.28)	**<0.001**
First NOWS medication				
- Morphine	396/413 (95.7%)	90/165 (54.6%)	Reference	**<0.001**
- Methadone	17/413 (4.1%)	72/165 (43.6%)	18.64 (10.46, 33.19)	
Secondary agent				
- Clonidine	110/199 (59.1%)	29/53 (54.7%)	Reference	0.45
- Phenobarbital	76/199 (40.9%)	19/53 (35.9%)	1.42 (0.57, 3.59)	
Discharged home with parent	492 (73.1%)	355 (76.2%)	1.24 (0.92, 1.67)	0.16

Mixed-effects logistic regression models for binary outcomes, and mixed-effects Poisson regression models for continuous outcomes. All models include random intercepts to control for clustering by delivery hospital. Rooming-in was defined as at least 24 h of rooming-in prior to maternal discharge; breastfeeding was defined as any mother's milk consumption.

SSRI Selective Serotonin Reuptake Inhibitors, *SCN* Special Care Nursery, *NICU* Newborn Intensive Care Unit, *NOWS* Neonatal Opioid Withdrawal Syndrome.

[a]All women were on prescribed methadone or buprenorphine for the treatment of Opioid Use Disorder (OUD).

has also been seen in prior single-center QI studies that implemented the ESC care approach in the context of larger NOWS QI efforts [11, 13, 16–19]. Hospitals in our study reported making changes in prenatal education, rooming-in, breastfeeding, and non-pharmacologic care bundles in those months leading up to ESC NOWS Care Tool transition, demonstrating the importance of this comprehensive care approach. The ESC Care Tool approach, by involving the caregiver as a key component of the assessment and inclusion of the NPI checklist at every assessment, inherently triggers culture change focused on maternal-infant bonding and a patient-centered approach.

This study has several strengths; it is the largest study to examine implementation of ESC to date, and the first multi-

Table 3 NOWS outcomes Pre- and Post-ESC implementation cohorts.

NOWS outcome	Pre-ESC $N = 753$ N (%) or mean (SD)	Post-ESC $N = 475$ N (%) or mean (SD)	Post- vs pre-unadjusted OR/RR (95% CI)	P value	Post- vs pre-adjusted OR/RR (95%CI)[a]	P value
Any pharmacotherapy	413 (54.8%)	165 (34.7%)	0.39 (0.30, 0.51)	**<0.001**	0.35 (0.26, 0.46)	**<0.001**
Any secondary agent	199 (26.4%)	53 (11.2%)	0.28 (0.15, 0.52)	**<0.001**	0.23 (0.12, 0.44)	**<0.001**
Length of stay (days)	14.2 (9.5)	11.1 (7.9)	0.79 (0.76, 0.82)	**<0.001**	0.78 (0.75, 0.81)	**<0.001**
Opioid treatment days	16.3 (8.5)	12.6 (8.4)	0.85 (0.79, 0.91)	**<0.001**	0.80 (0.75, 0.86)	**<0.001**
Subset analysis of balancing measures						
30-day readmission[b]	8/252 (3.2%)	13/241 (5.4%)	0.65 (0.21, 2.00)	0.45		
30-day readmission due to NOWS[b]	3/252 (1.2%)	1/241 (0.4%)	0.35 (0.04, 3.35)	0.36		
30-day ER visit[b]	13/252 (5.2%)	17/241 (7.1%)	1.40 (0.66, 2.94)	0.38		
30-day ER visit due to NOWS[b]	4/252 (1.6%)	2/241 (0.8%)	0.52 (0.09, 2.86)	0.45		

[a]Mixed-effects multivariate (adjusted) logistic regression models for binary outcomes, and mixed-effect multivariate (adjusted) Poisson regression models for continuous outcomes adjusted for site, maternal opioid, breastfeeding, and psychiatric medication co-exposure. All models include random intercepts to control for clustering by delivery hospital.

[b]Indicates analysis done on a subset of the cohort ($N = 252$ in the Pre- and $N = 241$ in the Post-ESC) from five hospitals with complete data.

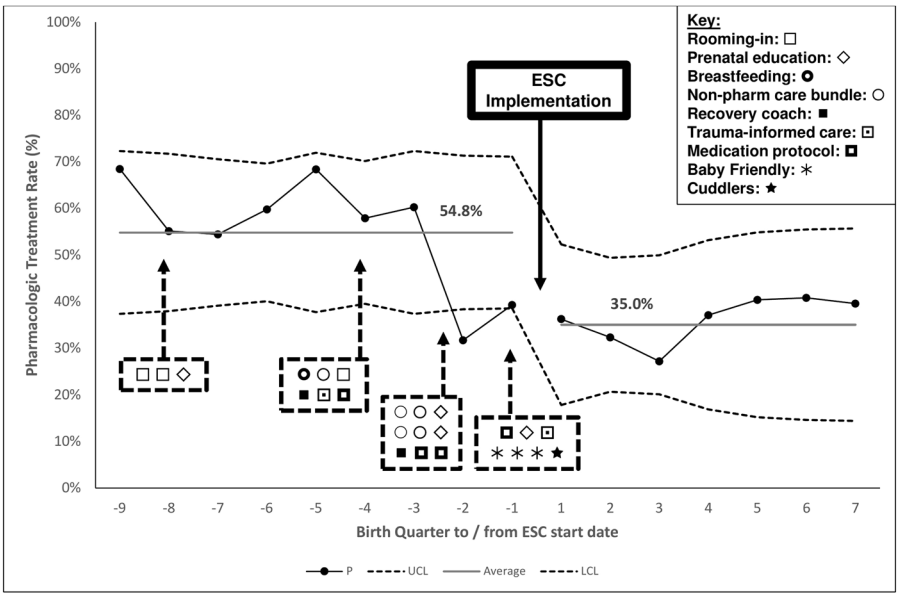

Fig. 1 Percent of opioid-exposed newborns ≥35 weeks receiving pharmacotherapy, Pre- and Post-ESC implementation. SPC chart (p-chart) of rate of pharmacotherapy for NOWS by quarter relative to ESC start date; process change is shown at ESC start date, reflecting special cause variation between the Pre- and Post-ESC implementation periods. Hospital contextual elements implemented prior to ESC are indicated by the symbols.

centered study of ESC implementation with 475 infants evaluated. It is also the first published multi-centered study evaluating use of the ESC Care Tool with assessment of post-discharge balancing measures. This project is likely to influence other individual hospitals and state collaboratives looking to implement changes to their NOWS care practices. Sustained changes were seen in both tertiary and community hospital settings, with no increase in readmissions or ER visits. Additional strengths include the demonstration of improved outcomes in the Post-ESC cohort despite an increase in the percentage of infants who were polypharmacy- and illicit drug-exposed [27]. Lastly, in addition to the benefits seen in our primary outcome measures, improvements were seen in breastfeeding, skin-to-skin, and decreased NICU utilization, consistent with current NOWS best practice recommendations [20, 22]. This adds to the robust evidence supporting these types of interventions even for hospitals not formally pursuing ESC adoption.

Limitations of our study include a lack of detailed information on all of the interventions implemented at each of the hospitals that could have contributed to our study's outcomes as well as lack of important process measures for non-pharmacologic care and parental engagement. As such,

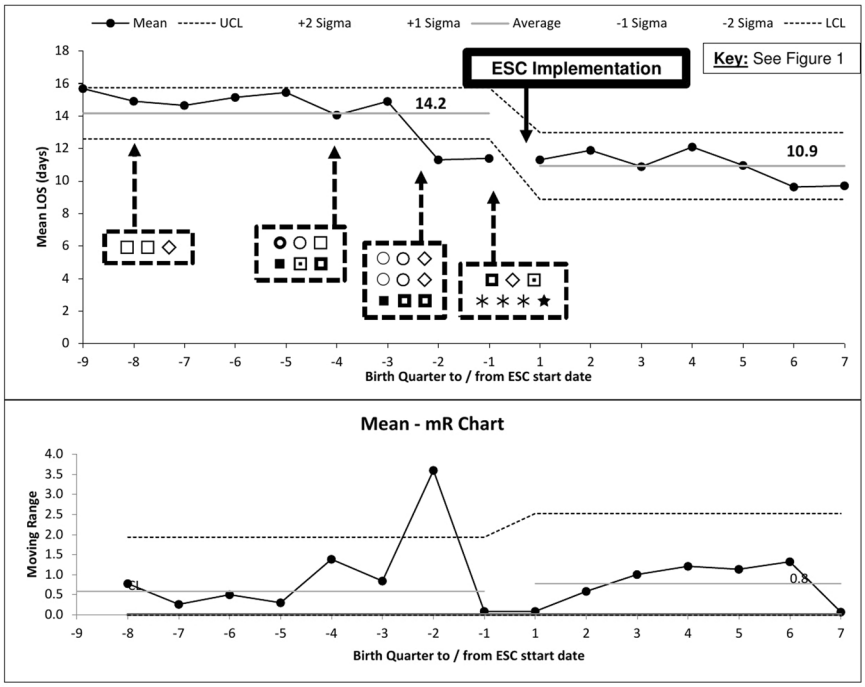

Fig. 2 Length of hospital stay (LOS) for opioid-exposed newborns ≥35 weeks, Pre- and Post-ESC implementation. SPC chart (XmR-chart) of length of stay (LOS) by quarter relative to ESC start date; top graph shows average LOS and bottom graph shows moving range. Process change is shown at ESC start date reflecting special cause variation in average LOS between the Pre- and Post-ESC implementation periods. Hospital contextual elements implemented prior to ESC are indicated by the symbols.

changes seen in outcomes in the Pre- vs Post-ESC cohorts may not be solely due to the ESC NOWS Care Tool intervention alone. More infants were cared for in less intensive care settings, which may have been secondary to the hospital's decision to change the overall location of care (in recognition of the benefits of rooming-in and parent-led care for opioid-exposed infants) [20, 22] or due to the decrease in use of pharmacotherapy. While we accounted for some site-specific differences by adjusting for covariates including study site and breastfeeding in the regression models, it is likely other site-specific differences were not measured. It is also possible that infants were seen in ERs or readmitted to hospitals not affiliated with the main reporting hospital. We are limited in that these balancing measures were missing from some of the hospitals due to the timing of data collection and inability to obtain this retrospective data from some centers. We are also limited in that no long-term follow-up was obtained; there may be adverse events further out than 30 days not identified in this study. Lastly, the validity and inter-rater reliability of the revised ESC NOWS Care Tool are yet to be published, limiting best practice recommendation of the tool for larger-scale use. Once validated and fully tested, a widely available training package including the ESC Care Tool and manual, training videos, and case examples would be helpful for institutions looking to implement the ESC NOWS Care Tool.

Despite this, this work is likely generalizable given the demonstration of feasibility in both tertiary care and smaller community hospital settings. It is noted that a significant amount of QI support and training were provided for participating hospitals. Hospitals without such support, and/or the capacity for rooming-in or parental engagement in care, may have more challenges with implementing the ESC care approach. However, this should not be an exclusion factor for implementing changes to NOWS care practices as demonstrated by the benefits seen before formal ESC Care Tool implementation in participating hospitals. With the ESC care approach now being implemented rapidly across the country [11–13, 16–19], there is dire need to additionally demonstrate safety and generalizability as well as to assess impact on longer-term outcomes. Importantly, adoption of ESC was not a primary improvement strategy of our statewide collaborative; rather, this initiative was undertaken to standardize practices among centers that had already decided to adopt ESC based on their own interpretation of the available evidence. As with all currently available assessment tools for NOWS, the ESC Care Tool is not yet validated; however, it embodies current best practice recommendations for NOWS including rooming-in, breastfeeding, and parental engagement [7, 8, 20–22]. Establishing safety and efficacy in a wide variety of clinical settings with varied maternal exposures is a key next step in examining the validity of the ESC Care Tool. A national NIH-funded multi-center step-wedge cluster randomized clinical trial is now underway with aims of assessing the short- and long-term outcomes of the ESC NOWS Care Tool for care of opioid-exposed newborns (NCT04057820).

In conclusion, the ESC NOWS Care Tool was successfully implemented as part of a state perinatal QI collaborative with sustained improvements in short-term NOWS

outcomes without adverse effects. Though benefits were seen without any immediate adverse effects, rigorous comparison studies examining the range of maternal and infant outcomes including long-term neurodevelopmental outcomes are needed before formal best practice recommendation can be made.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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