RESEARCH ARTICLE

A Quality Improvement Initiative to Improve the Care of Infants Born Exposed to Opioids by Implementing the Eat, Sleep, Console Assessment Tool

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ABSTRACT

OBJECTIVES: The incidence of infants born exposed to opioids continues to rise. Historically, newborns with neonatal abstinence syndrome have been treated with medication-weaning protocols, leading to costly and prolonged hospital stays. We aimed to reduce the proportion of newborns with neonatal abstinence syndrome who receive opioid medications for treatment of withdrawal symptoms through a quality improvement program.

METHODS: In 2016, we formed a multidisciplinary team and used quality improvement methodology to conduct plan-do-study-act cycles. Interventions included prenatal education, family engagement, nonpharmacologic treatments, morphine as needed, and the eat, sleep, console assessment tool. Primary metrics were the proportion of newborns exposed to opioids requiring pharmacologic treatment and the cumulative dose of opioids per exposed newborn requiring pharmacologic treatment.

RESULTS: There were 81 infants in the baseline period (January 2015–September 2016) and 100 infants in the postintervention group (October 2016–August 2018). For infants who required medication for treatment, the postintervention group had significantly lower total cumulative dose in methadone equivalents (1.3 mg vs 6.6 mg), shorter length of stay (10.9 days vs 18.7 days), and nonsignificant lower direct costs ($11 936 vs $15 039).

CONCLUSIONS: The described intervention effectively replaced the Finnegan Neonatal Abstinence Scoring System and had improved outcomes in more exposed infants receiving no opioid treatment, and when medication was required, the total cumulative dose of opioids was lower. The postintervention group had shorter average length of stay and lower costs.

www.hospitalpediatrics.org
DOI:https://doi.org/10.1542/hpeds.2019-0144

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HOSPITAL PEDIATRICS (ISSN Numbers: Print, 2154-1663; Online, 2154-1671).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Supported by CHRISTUS St. Vincent Regional Medical Center. Funding for this project came from the hospital budget allocated to the Clinician-Directed Performance Improvement department.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

Dr Achilles conceptualized and designed the project and drafted the initial manuscript; Ms Castaneda-Lovato oversaw project implementation, coordinated and supervised data collection, and critically reviewed the manuscript; and both authors approved the final manuscript as submitted.

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The burden of the current opioid crisis is well known, and the rate of pregnant women with opioid use disorder continues to increase. When fetuses are exposed to opioids in utero, they may develop withdrawal symptoms known as neonatal abstinence syndrome (NAS) or neonatal opioid withdrawal syndrome (NOWS). There was a greater than fivefold increase in the proportion of infants born with NAS and/or NOWS from 2004 to 2014. Nationally, rates of opioid use disorder at delivery hospitalization more than quadrupled during 1999–2014, to 6.5 per 1000 births in 2014. In 2014, $563 million was spent on costs for treatment of NAS and/or NOWS.[1–3] Our statewide rate of NAS has increased 324% between 2008 (3.3 per 1000 live births) and 2017 (14 per 1000 live births).[4]

On the basis of the local burden of NAS, we designed a quality improvement (QI) project with the global aim to improve the care of NAS at a community hospital in the Southwest. Our baseline rate of newborns born exposed to opioids was 3.9%. Thirty percent of exposed newborns required treatment with methadone, had an average length of stay (ALOS) of 19 days, and had an average total direct cost of $16 000. Historically, newborns with NAS are transferred to a NICU where rooming-in with a parent is not possible.[5–7] Infants are observed for withdrawal symptoms for a minimum of 96 hours while being scored every 3 hours with the Finnegan Neonatal Abstinence Scoring System (FNASS).[8] If newborns require treatment of withdrawal symptoms, then a medication-weaning protocol is initiated.[5–7] Nationally, newborns with NAS occupy up to 4% of NICU beds.[9]

Authors of recent studies have demonstrated that rooming-in, maximization of nonpharmacologic care, and a novel assessment tool can safely reduce pharmacologic therapy, decrease length of stay (LOS), and lower costs for newborns affected by NAS.[10–14] Our aims with this project were to reduce the proportion of newborns exposed to opioids who receive any opioid medications by 20% and reduce the total dose of opioid medications by 20% through interventions designed to implement these new treatment models for NAS.

METHODS

In 2016, as part of a hospital sponsored Clinician-Directed Performance Improvement project, we formed a multidisciplinary team that included physicians, nurses, nurse managers, social workers, and pharmacy, IT, and data specialists. Project dates were from October 2016 to August 2018 at a community hospital with ∼1200 deliveries per year and ∼50 newborns exposed to opioids per year. We used QI methodology to identify potential causes for overuse of opioid treatment in our NAS population. We then identified 6 leverage points, from which we developed interventions for plan-do-study-act (PDSA) cycles.[15] Table 1 reveals leverage points, interventions, PDSA cycles, and implementation dates. Direct cost figures were obtained from hospital accounting and were determined by a relative value unit–based costing methodology to assign cost to various chargeable activities.

Baseline

The baseline period was from January 2015 to September 2016. During this time, we scored newborns exposed to opioids every 3 hours with FNASS and used a methadone-weaning protocol on the basis of those scores.[8] Newborns were discharged at 96 hours if no methadone was required to control symptoms of withdrawal or 48 hours after the last dose of methadone was given. No newborns were discharged on methadone or any medication.

Interventions

PDSA Cycle 1: Prenatal Education

To address lack of prenatal education, our intervention was to create a pamphlet called "Newborns Exposed to Drugs During Pregnancy: A Guide for Families." This was distributed to all obstetricians and gynecologists, family practices, and

TABLE 1 Leverage Points, Interventions, and PDSA Cycles

Leverage Point	Intervention	PDSA Cycle	Date
Prenatal maternal education	Prenatal pamphlet given to obstetrician and Subutex clinics RN visit to Subutex clinics	1	September 2016
Improving maternal drug screening and infant testing	Universal screening questions on admission to L&D Umbilical cord testing	1	September 2016 December 2016
Improving infant assessments	Training sessions for pediatric and L&D nurses on FNASS on newborns schedule	1	September 2016
Improving family engagement, understanding, education, and involvement in infant's care	Admission packet for families with clear expectations and agreement letter	1	October 2016
Nonpharmacologic treatments for infants	Low-stimulation environment, donor breast milk, and cuddler program	1	October 2016
Provider education for pediatric hospitalists, FP resident or attending physician	Group meetings and 1-on-1 sessions	1	October 2016–May 2017
Medication and protocol change	Transition from methadone-weaning protocol to morphine as needed	2	March 2017
Infant assessment change	Transition from FNASS to ESC	3	August 2017
Infant weight loss	Maximize feeding and calories with nasogastric feeds Infant-based feeding readiness and quality score NEWT in EMR DHM	4	Ongoing from April 2018

FP, family practice; NEWT, Newborn Weight Loss Tool; RN, registered nurse.

buprenorphine and methadone clinics in the area. Families learn what to expect during their hospitalization and receive the message that they will be the most important treatment for their newborn during their hospitalization.

PDSA Cycle 1: Maternal Drug Screening and Newborn Drug Testing

Admit screening questions and orders on admission to labor and delivery (L&D) were implemented into the electronic medical record (EMR). If concerns of exposure exist, then newborns are tested with both a urine drug screen and umbilical cord tissue testing from United States Drug Testing Laboratories.[16]

PDSA Cycle 1: Improving Infant Assessments

Before knowledge of the eat, sleep, console (ESC) assessment tool, we had conducted training sessions for all L&D and pediatric nurses on FNASS scoring to increase interrater reliability.[8] We changed scoring from a fixed schedule of every 3 hours to every 3 to 4 hours to be on the newborn's schedule and not wake newborns if they were sleeping.[10]

Improving Family Engagement

Families with confirmed opioid exposure were given a booklet on admission that provides detailed information regarding how to help console their infant and tools to maximize nonpharmacologic treatment. Parents sign an agreement letter stating they understand how important their care is to the infant and commit to participate in the plan of care.

PDSA Cycle 1: Nonpharmacologic Treatments

We emphasize a low-stimulation environment by encouraging a dark, quiet room, swaddling, swaying, rocking, and skin-to-skin contact and providing adequate feeds of breast milk, donor human milk (DHM), or formula to minimize excessive weight loss and allow for adequate growth.[17] As per the American Academy of Pediatrics Committee on the Fetus and the Newborn clinical report on neonatal drug withdrawal, the goals of therapy are to involve the family as the primary treatment of the newborn and ensure that the newborn has adequate sleep and nutrition.[17] We use a cuddler program when family members are not available. We encourage breastfeeding unless there is current active illicit drug use or infectious risk.

PDSA Cycle 1: Provider Education

Pediatric hospitalists, family practice attending physicians, and resident education occurred in meetings and in 1-on-1 sessions. Education included grand rounds from a national speaker who is well versed in ESC.

PDSA Cycle 2: Pharmacologic Treatments

In March of 2017, we switched from a methadone-weaning protocol to morphine as needed.[12,13] A medical doctor (MD) evaluates if medication is necessary to help control withdrawal symptoms, and if so, a 1-time dose of morphine 0.05 mg/kg orally is given and the newborn is placed on monitors. In our protocol, morphine can be given every 3 hours as needed but an MD must write an order for each dose. We did not titrate morphine or use adjuvant therapies.

PDSA Cycle 3: ESC

In August of 2017, after learning about ESC, we retrained L&D and pediatric nurses as well as all MDs who care for newborns on this novel assessment tool.[12,13] We had the ESC assessment tool built into our EMR. Nurses assess infants every 3 to 4 hours on the newborn's schedule so as not to wake them, and simply document yes or no answers for each assessment:

- eat: goal feeds or 1 oz per feed or breastfeeds well;
- sleep: 1 hour undisturbed; and
- consoled within 10 minutes.

If an infant is not consolable within 10 minutes, the protocol then calls for maximizing nonpharmacologic measures such as swaddling and low-stimulation environment. If after a total of 30 minutes a newborn is still inconsolable, the MD is called to evaluate the newborn to determine if a 1-time dose of morphine is appropriate.[12,13]

Study of the Intervention

We compared outcomes from the baseline time period January 2015 to September 2016 and postintervention period from October 2016 to August 2018. Although subsequent modifications were made, we considered this time frame to be postintervention because the majority of interventions occurred during PDSA cycle 1. PDSA cycles 2 and 3 began in 2017. We compared maternal and newborn characteristics to ensure there were no significant differences between the 2 groups. We compared NAS outcomes using statistical process control charts over time.

Metrics

The project's primary metrics were (1) proportion of newborns exposed to opioids requiring treatment with opioids and (2) cumulative dose of opioids per exposed newborn requiring treatment. Because the transition to morphine from methadone occurred during the postintervention phase, newborns receiving morphine had an equianalgesic conversion of 3.5/1.[18] Secondary metrics were LOS for exposed newborns, LOS for exposed newborns requiring opioids, direct cost per exposed newborn, and direct cost per exposed newborn requiring opioids. Balance metrics included rate of 30-day all-cause readmission, rate of 30-day readmission related to NAS, and death or NICU transfer within 30 days.

To ensure completeness of data, a Midas report that identifies all patients with administrative codes for NAS (*International Classification of Diseases, 9th* and *10th Revisions*) were reviewed for inclusion criteria. We then involved the informatics department to create and cross-reference 2 additional reports. The first was a pharmacologic report that captured all newborns that received methadone or morphine treatment. The second report was built to capture any newborns that had an order for Finnegan scoring or ESC as of August 2017. All reports were run on a monthly basis. We now cross-reference our Midas reports with all umbilical cord samples that are sent for toxicology testing. Direct cost data were only available from January 1, 2015, through June 30, 2018,

because of a change in EMR systems. There is no direct cost data from July to August of 2018 ($N = 9$ patients).

Analysis

We used proportions for categorical variables and means or medians for continuous variables. We compared categorical variables using χ^2 or Fisher's exact tests that were based on cell sample size and compared continuous variables using t tests or Wilcoxon rank tests that were based on the underlying distribution. We considered a 2-tailed value of $P \leq .05$ as statistically significant and present 95% confidence intervals. Statistical analysis was performed by using JMP 11.0 software (SAS Institute Inc, Cary, NC). Control charts were created by using statistical process control software for Excel, and X-bar or XmR charts were selected on the basis of the underlying distribution with control limits defined at 3 SDs.

Ethical Considerations

This project was determined to be exempt by the institutional review board.

RESULTS

Eighty-five of 2207 infants born in the baseline period were exposed to opioids in utero ("exposed"; 3.9%). Four infants from this group required early transfer to another facility NICU for non–NAS-related causes and were excluded from analysis, leaving a total of 81 in the baseline group. For the postintervention period, 104 of 2444 infants were exposed (4.3%). Four were excluded from the postintervention group also transferred to a NICU for non-NAS causes, leaving a total of 100 exposed newborns in the final analysis. Reasons for NICU transfers included pneumothorax, respiratory failure, and prematurity.

Table 2 demonstrates characteristics of exposed newborns from the baseline and postintervention groups. Newborns did not significantly differ by sex or race. Postintervention exposed newborns were of slightly lower gestational age (38.4 weeks vs 38.9 weeks; $P = .04$) and birth weight (2.78 kg vs 2.89 kg; $P = .11$). History of maternal drug use and newborn feeding decisions did not differ significantly between the groups. Ten percent of the postintervention exposed newborns received DHM (alone or in combination with maternal milk or formula). DHM was not available in the baseline period. The postintervention group did experience slightly higher mean maximum weight loss during their admission (8.1% vs 6.8%; $P = .07$).

Opioid treatment of exposed newborns did significantly differ between the 2 groups, with more of the postintervention group receiving morphine rather than methadone. In the postintervention group, more exposed infants received no opioid treatment at all (76% vs 69%; $P < .0001$). The total cumulative dose of opioids (in methadone equivalents) was also much lower in the postintervention group (0.2 mg vs 2.0 mg; $P < .0001$). Hospital LOS was lower in the postintervention group (6.5 days vs 9.0 days; $P = .008$). Total direct costs were also lower in the postintervention group, although this was not statistically significant ($5657 vs $7359; $P = .48$). All-cause readmission rates within 30 days did not significantly differ comparing the baseline and postintervention groups (2% vs 3%; $P = 1.0$). The 2 readmissions in the baseline group were for a brief resolved unexplained event and hyperbilirubinemia requiring phototherapy. In the postintervention group, there were 3 all-cause readmissions: 1 for fever, 1 for hyperbilirubinemia, and 1 readmitted for reasons related to NAS in the postintervention group. This infant was admitted for feeding difficulties and excess crying.

Differences between groups were most pronounced in the subset of 49 exposed infants who required pharmacologic treatment of NAS. Figures 1 and 2 are control charts demonstrating cumulative opioid dose and hospital LOS for sequential newborns requiring pharmacologic treatment of NAS. Compared with the baseline group, the postintervention group had lower total cumulative dose in methadone equivalents (1.3 mg vs 6.6 mg; $P < .0001$) and shorter LOS (10.9 days vs 18.7 days; $P = .0005$). Although not statistically significant, total direct costs were lower in the postintervention group ($11 936 vs $15 039; $P = .18$).

DISCUSSION

In recent years, there has been a shift in treatment models for NAS. In 2016, Holmes et al[10] published an article in which rooming-in in lieu of a NICU stay as part of a standardized treatment program was found to safely reduce pharmacologic therapy, LOS, and hospital costs. MacMillan et al[11] performed a systematic review and meta-analysis, concluding that rooming-in was beneficial in decreasing pharmacologic treatments and decreasing LOS. In 2017, Grossman et al[12] published the first account of a novel simplified approach to assessment of infants exposed to methadone that was focused on an infant's ability to eat, sleep, and be consoled. This new ESC approach led to decreased ALOS, proportion of infants treated with morphine, and hospital costs, with no adverse events.[12] Additional descriptions of the ESC assessment approach have been described.[13,14]

Our findings are consistent with those of researchers that emphasized nonpharmacologic treatment,[10–14] rooming-in,[10,11] ESC,[12–14] and morphine as needed[12,13] in improving NAS outcomes. Since morphine as needed was first introduced, no other infant was treated with the methadone-weaning protocol, although it was still available in the EMR. No provider has used the FNASS since ESC was introduced.

The use of morphine as needed was first described by Grossman et al[12] in 2017 as part of a large QI project to improve the quality of care of infants with NAS. Interventions included but were not limited to standardizing nonpharmacologic care, replacing FNASS with ESC, and initiating a rapid morphine wean by as much as 10% as often as 3 times a day. However, they noticed signs of withdrawal were not always consistent throughout the day. The authors then decided that if maximal nonpharmacologic measures were unsuccessful, they would give a 1-time dose of morphine at 0.05 mg/kg per dose and reassess the infant in 3 hours. If the infant was sleeping well, eating well, and could be consoled within 10 minutes, additional doses of morphine were not given. Although this is a novel approach, no infants were

TABLE 2 Characteristics of Newborns With In Utero Exposure to Opioids

Characteristic	Baseline Group ($N = 81$)	Postintervention Group ($N = 100$)	*P*
Demographics and birth characteristics			
Female sex, *n* (%)	34 (42)	52 (52)	.18
Race, *n* (%)			.50
White	35 (44)	35 (35)	
Hispanic	43 (54)	63 (63)	
Native American	0 (0)	1 (1)	
African American	0 (0)	0 (0)	
Other	1 (1)	1 (1)	
Gestational age, wk, mean (CI)	38.9 (38.5–39.2)	38.4 (38.1–38.7)	.04
Birth weight, kg, mean (CI)	2.89 (2.79–3.00)	2.78 (2.69–2.87)	.11
Maternal history of drug use, *n* (%)			
Opioids			.47
No treatment program	23 (28)	25 (25)	
Methadone	11 (14)	9 (9)	
Subutex	47 (58)	66 (66)	
Alcohol	4 (5)	6 (6)	1.0
Benzodiazepine	3 (4)	8 (8)	.35
Smoking	3 (4)	11 (11)	.09
Multiple	33 (41)	42 (42)	.86
Feeding			
Feeding type, *n* (%)			.92
Exclusive breast milk, maternal or donor	26 (32)	37 (37)	
Exclusive formula	36 (44)	41 (41)	
Combination of breast milk and formula	18 (22)	21 (21)	
Received donor breast milk, *n* (%)	0 (0)	10 (10)	.002
Maximum wt loss, % of birth wt (CI)	6.8 (5.8–7.9)	8.1 (7.2–9.1)	.07
Hospital course			
Opioid treatment during admission, *n* (%)			<.0001
None	56 (69)	76 (76)	
Methadone	25 (31)	6 (6)	
Morphine	0 (0)	18 (18)	
Newborns receiving opioid treatment during admission			
Cumulative dose of opioid treatment (methadone equivalents), mg, mean (CI)	6.6 (5.4–7.8)	1.3 (0.1–2.7)	<.0001
LOS, d, mean (CI)	18.7 (16.1–21.4)	10.9 (8.2–13.7)	.0005
Total direct costs, $, mean (CI)	15 039 (12 182–17 897)	11 936 (8309–15 563)	.18
Readmission within 30 d, *n* (%)	2 (2)	3 (3)	1.0

CI, confidence interval.

readmitted for treatment of NAS and no adverse events were reported.

Many newborns exposed to opioids experience excess weight loss because of feeding difficulties. It is well known that newborns affected by NAS lose more weight compared with healthy newborns.[19–21] Bogen et al[21] suggest early initiation of a high-calorie formula is beneficial to newborns exposed to opioids by increasing percent weight gained per day compared with a standard calorie group.

We did find an increase in weight loss in the postintervention group. We are currently in PDSA cycle 4 with interventions to decrease excess weight loss by introducing an infant feeding readiness score and early increase in higher-calorie formula and instituting early nasogastric feedings. Approximately 25% and 46% of baseline and postintervention newborns received nasogastric feeds in our project. The infant-based feeding readiness and quality score will be built into our EMR, in which, for

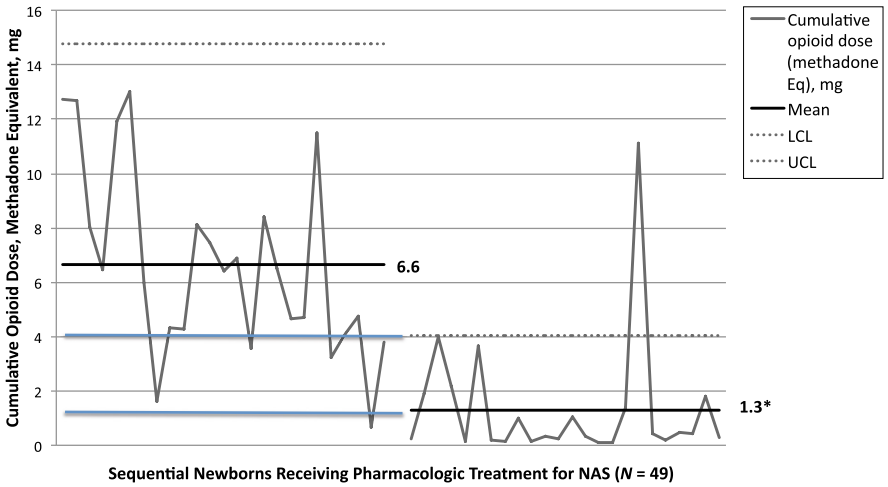

FIGURE 1 Opioid dose for newborns receiving pharmacologic treatment for NAS before and after intervention. XmR chart with control limits set at 3 SDs. Means and control limits are shifted between baseline and postintervention data to clarify the change. The baseline period was from January 2015 to September 2016. The postintervention period was from October 2016 to August 2018. Special cause is suggested in this control chart by >7 consecutive baseline points below average, 4 out of 5 consecutive points in zone B (1–2 SDs) or beyond, and 2 out of 3 consecutive points in zone A (2–3 SDs) or beyond. LCL, lower control limit; UCL, upper control limit. *$P < .0001$ for difference in means (Wilcoxon rank test).

example, 75% of goal feeds over 30 minutes would be considered good feed.[22] We will also be integrating the Newborn Weight Loss Tool into our EMR to better identify excess weight loss earlier in these at-risk newborns.[23] Our intention is to optimize nutrition through supplementation and fortification, lactation support, DHM, and speech and language pathology evaluation before starting medication.[17] Breastfeeding is known to decrease symptoms of NAS.[24,25] We have made the assumption that DHM will have some additional benefits over formula, although there are no known proven benefits in this population. Breastfeeding and donor milk must be balanced with the increased need for higher calories, which can be accomplished by adding human milk fortifier. Using DHM without the additional calories may have played a role in excess weight loss in the postintervention group.

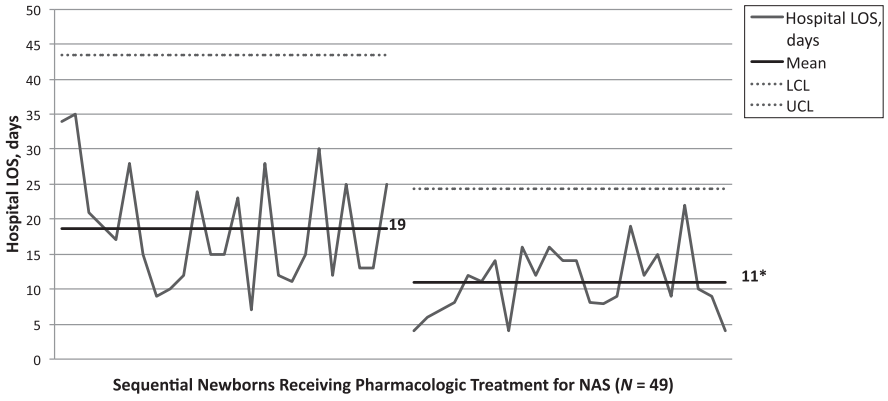

FIGURE 2 Hospital LOS for newborns receiving pharmacologic treatment for NAS, before and after intervention. XmR chart with control limits set at 3 SDs. Means and control limits are shifted between baseline and postintervention data to clarify the change. The baseline period was from January 2015 to September 2016. The postintervention period was from October 2016 to August 2018. The majority of interventions (PDSA cycle 1; see Table 1) were put in place between September and October 2016. Special cause is suggested in this control chart by >7 consecutive baseline points below average and 4 out of 5 consecutive points in zone B (1–2 SDs) or beyond. LCL, lower control limit; UCL, upper control limit. *$P < .0005$ for difference in means (Wilcoxon rank test).

Our hospital QI project successfully integrated a new treatment of NAS by replacing the FNASS and methadone-weaning protocol with nonpharmacologic management as first-line treatment, a simplified ESC assessment tool, and the introduction of morphine as needed. Additional interventions included prenatal education, better screening of mothers on admission to L&D, improved drug testing of newborns, and increased emphasis on family engagement in the hospital. Our results reveal more exposed infants received no opioid treatment at all, and when medication was required, the total cumulative dose of opioids was much lower. The findings between baseline and postintervention groups were particularly pronounced in the subset of exposed infants who required pharmacologic treatment of NAS. Compared with the baseline group, the postintervention group had significant shorter LOS and nonsignificant lower total direct costs.

This project has several strengths. When we first started this QI project, we did not know about ESC and morphine as needed. We had already begun by retraining all nurses in improved FNASS scoring to increase interrater reliability and introduced the notation of scoring infants on their schedule.[10] We were able to shift course dramatically within a few months from FNASS to the ESC assessment tool and discontinue a methadone-weaning protocol while introducing morphine as needed. This took a significant amount of education and required buy-in from all nurses and medical staff. We showed success with not just a methadone-exposed population but also mothers on buprenorphine or other opioids, polysubstance abuse, and current illicit use. In addition, we used a simplified approach

to morphine of 0.05 mg/kg orally × 1 without increase or weaning the dose, and no adjuvant therapy was used. We were also able to offer the postintervention group DHM when breast milk was insufficient or contraindicated. This was not yet available in the baseline group.

There are several limitations to the study. We do not have a NICU on-site, so all families roomed-in throughout their hospital stay. This limits generalizability because having space and staff to room-in may be a challenge in some settings. Changing from methadone to morphine during the project may be a confounder, although we used an equianalgesic dosing conversion of 3.5/1. We did not quantify family presence or nurse satisfaction with the project. We frequently employ nasogastric feeds to maximize caloric intake in newborns, which may not be possible in other settings. In addition, we cannot say which of our interventions had the most significant impact between the ESC assessment tool, morphine as needed, emphasis on nonpharmacologic treatment, and/or improved family involvement.

This project replicated previous findings of improved care for NAS from other tertiary institutions but enhances generalizability to the community hospital setting. We safely decreased opioid use, LOS, and cost among all infants exposed to a variety of opioids, including buprenorphine, methadone, polysubstance abuse, and current maternal illicit drug use. This was achieved through a QI project that was focused on rooming-in, nonpharmacologic treatments, and better family engagement in the setting of a simplified ESC assessment tool and use of medication as needed for treatment of withdrawal symptoms.

Additional studies may include universal maternal toxicology testing in a noncriminalized setting, the addition of DHM for all families, and a standardized feeding protocol to address significant weight loss issues in newborns with withdrawal symptoms.

ACKNOWLEDGMENTS

We thank Dr Lara Goitein who helped design the data collection instruments, conducted the initial analyses, and assisted with the manuscript, Ms Catalina Roybal, data specialist, for her contribution in data collection, and Ms Amy Thatcher, SLP, for her guidance in infant feeding. We also thank the nursing staff at CHRISTUS St Vincent Regional Medical Center. We appreciate assistance given from the pharmacy department.

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DOI: 10.1542/hpeds.2019-0144 originally published online July 29, 2019;

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