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

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BACKGROUND AND OBJECTIVES: The incidence of neonatal abstinence syndrome (NAS), a constellation of neurologic, gastrointestinal, and musculoskeletal disturbances associated with opioid withdrawal, has increased dramatically and is associated with long hospital stays. At our institution, the average length of stay (ALOS) for infants exposed to methadone in utero was 22.4 days before the start of our project. We aimed to reduce ALOS for infants with NAS by 50%.

METHODS: In 2010, a multidisciplinary team began several plan-do-study-act cycles at Yale New Haven Children's Hospital. Key interventions included standardization of nonpharmacologic care coupled with an empowering message to parents, development of a novel approach to assessment, administration of morphine on an as-needed basis, and transfer of infants directly to the inpatient unit, bypassing the NICU. The outcome measures included ALOS, morphine use, and hospital costs using statistical process control charts.

RESULTS: There were 287 infants in our project, including 55 from the baseline period (January 2008 to February 2010) and 44 from the postimplementation period (May 2015 to June 2016). ALOS decreased from 22.4 to 5.9 days. Proportions of methadone-exposed infants treated with morphine decreased from 98% to 14%; costs decreased from \$44824 to \$10 289. No infants were readmitted for treatment of NAS and no adverse events were reported.

CONCLUSIONS: Interventions focused on nonpharmacologic therapies and a simplified approach to assessment for infants exposed to methadone in utero led to both substantial and sustained decreases in ALOS, the proportion of infants treated with morphine, and hospital costs with no adverse events.

Infants exposed to opioids in utero may develop neonatal abstinence syndrome (NAS), a constellation of neurologic, gastrointestinal, and musculoskeletal disturbances associated with opioid withdrawal.¹ At our institution, infants exposed to methadone in utero who developed signs of withdrawal were given a diagnosis of NAS. The number of infants at Yale New Haven Children's Hospital (YNHCH) exposed to methadone in utero increased by 74% from 2003 to 2009, and the average length of stay (ALOS) in 2008 to 2009 was 22.4 days, longer than almost all other primary inpatient diagnoses at our institution. In addition, these

abstract

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Dr Grossman conceptualized and designed the project, drafted the initial manuscript, and coordinated data collection; Drs Berkwitt and Osborn helped design the project, collected data, and critically reviewed the manuscript; Ms Xu and Dr Esserman carried out the statistical analysis and critically reviewed the manuscript; Dr Shapiro helped analyze data and critically reviewed the manuscript; Dr Bizzarro helped design the project and critically reviewed the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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infants were occupying an increasing percentage of NICU beds and had an average cost of hospitalization of \$44 800. From 2003 to 2009 at YNHCH, 98% of infants exposed to methadone in utero were treated with morphine, a higher percentage than in any published report.¹

Previous initiatives at other institutions have successfully reduced ALOS for NAS. Holmes et al² reported a reduction in ALOS from 17 to 12 days after adopting a rooming-in model focused on optimizing nonpharmacologic interventions. Asti et al^{3–5} reported a reduction in ALOS in a NICU of 36 to 18 days for infants with NAS after implementing a stringent weaning protocol and standardizing the scoring of the Finnegan Neonatal Abstinence Scoring System (FNASS), a tool that assigns a numerical score to 21 subjective clinical signs of NAS and is commonly used to guide pharmacologic management of NAS.

Despite the wide acceptance of the FNASS, its utility in improving outcomes for infants with NAS has not been formally evaluated.⁶ There is also no evidence that most infants with NAS require management in a NICU.⁶ In fact, the environment in some NICUs may impose barriers to implementing nonpharmacologic interventions, such as rooming-in. We set out to change the paradigm of how we approached the management of infants with NAS. We aimed to decrease our ALOS by 50% by focusing interventions on nonpharmacologic care. We also measured morphine use and hospital costs for infants with NAS born at our institution.

METHODS

Context

From March 2010 to June 2016, we conducted a quality improvement project at YNHCH, an academic medical center with ~4500 births



FIGURE 1

Key driver diagram for NAS quality improvement project.

and 850 NICU admissions annually. We applied our interventions to all infants with NAS (infants exposed in utero to opioids who developed signs of withdrawal), but we analyzed only those born at \geq 35 weeks' gestation whose mothers took methadone daily for at least 1 month before delivery. We considered this population to be the most likely to develop signs of withdrawal.⁶ We excluded infants with significant comorbidities, including sepsis and the need for either surgery or respiratory support (supplemental oxygen, noninvasive ventilation, and/or intubation for ≥ 2 days).

During the preintervention period (January 2008 to February 2010), all infants at risk for NAS were admitted directly to our NICU after birth, where signs of NAS were monitored by using the FNASS. Infants with either 3 FNASS scores ≥ 8 or 2 scores \geq 12 in a 24-hour period were given morphine (starting at 0.05 mg/kg per dose every 3 hours and adjusted based on subsequent FNASS scores). Infants were initially managed in the NICU and then, at the discretion of the attending neonatologist, were either discharged from the NICU or transferred to the inpatient unit. In either unit, infants were discharged at day 5 of life (if no morphine was

given) or 1 day after morphine was stopped.

Interventions

In 2009, we noted an increase in the number of infants with NAS and formed a multidisciplinary team that included attending physicians, residents, staff nurses, nursing leadership, child life specialists, and social workers to develop interventions aimed at improving care of these infants and reducing ALOS. We identified 4 key drivers of ALOS: nonpharmacologic interventions, simplified assessment of infants, decreased use of morphine, and communication between units (Fig 1). During the next 5 years, using plan-do-study-act cycle methodology, we developed and implemented 8 interventions (listed below their respective key driver) aimed at reducing the ALOS of infants with NAS. The chronology of the interventions is listed in Table 1.

Nonpharmacologic Interventions

Standardized Nonpharmacologic Care on the Inpatient Unit

We standardized 4

nonpharmacologic interventions. (1) Infants were placed in a lowstimulation environment with dimmed lights, muted televisions, and reduced noise. (2) Staff engaged parents continuously in the care of their infants (volunteers were used if a family member was not available); parents were strongly encouraged to room-in, to feed their infants on demand, and to tend to their infant if crying. (3) Staff were trained to view nonpharmacologic interventions as equivalent to medications; when increased intervention was warranted, the approach was to increase the involvement of the parents before using pharmacologic treatment. Finally, in conjunction with the well-baby nursery (WBN), we encouraged breast-milk feeding of all infants for whom there were no contraindications (ie, illicit drug use or HIV).

Prenatal Counseling of Parents

Several weeks before delivery, our outpatient care coordinator provided parents with informational handouts, told them that they would be expected to stay with their infant throughout the hospitalization, and answered questions.

Empowering Messaging to Parents

On the inpatient unit, we explained that our first-line and most important treatment would center around measures to comfort the infant and that these should be performed by a family member. Parents were told that they were the treatment of their infants and must be present as much as possible. Nurses and physicians focused on supporting and coaching parents on the care of their infants.

Simplified Assessment of Infants

We discontinued use of FNASS scores to guide pharmacologic management on the inpatient unit (FNASS was still used in the WBN and NICU). Instead, we developed and used our own functional assessment focused on 3 simple parameters: the infant's ability to eat, to sleep, and to be consoled. If the infant was able to

TABLE 1 Summary of Interventions

Interventions	Completion Date
Standardized nonpharmacologic care on the inpatient unit	February 2010
Transfer from WBN to the inpatient unit	February 2011
Development of a novel approach to assessment	January 2014
Spread of change concepts to NICU	January 2014
Rapid morphine weans	June 2014
Prenatal counseling of parents	June 2014
Morphine given as needed	May 2015
Empowering messaging to parents	May 2015

breastfeed effectively or to take ≥ 1 oz from a bottle per feed, to sleep undisturbed for ≥ 1 hour, and, if crying, to be consoled within 10 minutes, then morphine was neither started nor increased regardless of other signs of withdrawal. If the infant did not meet these criteria, staff first attempted to maximize nonpharmacologic interventions; if these attempts were unsuccessful, morphine was initiated or increased.

Decreased Use of Morphine

Rapid Morphine Weans

Our previous approach for infants with NAS had been to reduce the initial dose of morphine by not >10% every 24 to 48 hours. With the increase in nonpharmacologic management, we modified our approach to allow for decreases in the peak dose of morphine by 10% as often as 3 times a day.

Morphine Given as Needed

We noticed that signs of withdrawal were not always consistent throughout the day. In addition, sometimes we were unable to provide optimal nonpharmacologic care, such as when no parent, family member, or volunteer could be present. If maximal nonpharmacologic interventions were unsuccessful, we would give 1 dose of morphine (0.05 mg/kg per dose) and reassess the infant in 3 hours. If the infant was sleeping well, eating well, and consolable within 10 minutes, additional doses of morphine were not administered.

Communication Between Units

Transfer From WBN to the Inpatient Unit

Our level IV NICU housed infants with NAS in rooms with as many as 12 infants. Parents were not able to room-in and the ability to provide a low stimulation environment was extremely limited. We discontinued the practice of directly admitting infants at risk for NAS to the NICU after birth in an effort to keep the mother-infant dyad intact. Instead, these infants were brought to the WBN where FNASS scores were measured. If any score was >8. the neonates were preferentially transferred to the inpatient unit where the mothers could room-in. Neonates were admitted to the NICU only if an unforeseen medical problem arose or if there was no bed available on the inpatient unit. On the inpatient unit, nonpharmacologic interventions were initiated as soon as possible for all opioid-exposed infants, whether they had clinical signs of withdrawal or not.

Spread of Change Concepts to NICU

A focused educational session about our new approach to the management of infants with NAS was provided to NICU staff who were encouraged to transfer infants with NAS to the inpatient unit as soon as possible and, ideally, before starting morphine.

Study of the Intervention

We compared demographic features, including rates of polypharmacy (defined as methadone use in addition to mother's use of cocaine, selective serotonin reuptake inhibitors, benzodiazepines, or opioids other than methadone) and outcomes of infants in the baseline and postimplementation periods. *P* values (2-tailed) are reported from pairwise *t* tests for continuous variables and from either χ^2 tests or Fisher's exact tests (if cell count <5) for categorical variables. Analyses were performed by using SAS version 9.3 (SAS Institute, Inc, Cary, NC).

Measures and Analysis

Our primary outcome measure was ALOS, calculated from date of birth, measured as day of life 0, until date of discharge. Secondary measures included the proportion of infants treated with morphine and the average total cost of hospitalization, including direct and indirect costs. Cost information was obtained from the YNHCH analytics department and adjusted for inflation (2016 dollars).⁷ Process measurements included the proportion of infants who were taking \geq 50% of their feeds as breast milk at time of discharge and the proportion of infants initially admitted to the NICU for management of NAS. As balancing measures, we tabulated the number of infants transferred to an ICU from the inpatient unit, the number of infants with seizures, and readmissions within 30 days of discharge related to withdrawal. We compared measures after the interventions were fully implemented (May 2015 to June 2016) with the same measures during the baseline period (January 2008 to February 2010). There were no additional hospitalwide interventions to reduce ALOS in newborns ≥35 weeks' gestational age during the study period. To ensure completeness of data, records of all patients with administrative codes for NAS (International Classification of Diseases, Ninth Revision: 779.5 and 760.72; International Classification of Diseases. 10th Revision: P04.49 and

P96.1) were reviewed for inclusion criteria. We used statistical process control (SPC) charts to evaluate the impact of our interventions. SPC charts were developed by using Microsoft Excel QIMacros. SPC uses statistical methods to analyze common cause variability, to produce control limits to assess the process capability, and to identify special cause variation, or incidences of statistically significant (P < .01) variability.⁸

Ethical Considerations

The Yale University Human Investigation Committee determined that this project was exempt from review. No interventions involved comparison of therapies and subjects were not randomized. All charts were accessed by quality team members and no personal health information was shared outside of the organization.

RESULTS

Of the 421 infants \geq 35 weeks' gestational age diagnosed with NAS from January 2008 to June 2016, 287 met inclusion criteria, including 55 in the baseline period, 188 during the intervention period, and 44 in the postimplementation period. Those excluded included 132 infants not exposed to methadone and 2 infants who had serious comorbid conditions. The characteristics and outcomes of the infants during the different time periods are presented in Table 2. The ALOS decreased from 22.4 days in the preimplementation period (January 2008 to February 2010) to 5.9 days (74% reduction) in the postimplementation period (May 2015 to June 2016) (P < .001). Special cause variation (8 consecutive points below the centerline) first occurred in March 2010, after standardization of nonpharmacologic interventions; it next occurred in December 2011, after implementation of direct transfer to the inpatient unit; it next

occurred in January 2014, after implementation of novel approach to assess infants on the inpatient unit and spread of change concepts to the NICU; it next occurred in June 2014, after implementation of prenatal counseling and rapid morphine weaning; and it next occurred in June 2015, after implementation of as-needed morphine dosing and empowering messaging to parents. There was narrowing of the control limits after each special cause variation (Figs 2 and 3).

The proportion of infants treated with morphine decreased from 98% to 14% (*P* < .001) and the average cost of hospitalization decreased from \$44824 to \$10289 (*P* < .001). For the infants transferred from the WBN to the inpatient unit without a NICU stay, only 6% (2/35) received treatment with morphine. The proportion of infants that took the majority of their feeds from breast milk increased from 20% to 45% (P = .01), and the proportion of infants admitted directly to the NICU decreased from 100% to 20% (P < .001).

No patient admitted to the inpatient unit required transfer to an ICU. There were no seizures reported in any patient. There were no readmissions within 30 days of discharge related to signs of withdrawal in either the baseline or the postimplementation periods.

DISCUSSION

The use of quality improvement methodology to improve the care of infants with NAS led to both substantial and sustainable decreases in ALOS, far beyond our goal of a 50% reduction. The use of morphine and the average cost of hospitalizations also were substantially reduced. Our 8 plan-do-study-act cycles led to an improvement in ALOS, well below that reported in any other published studies. There were no statistically significant differences in One of our study's strengths was the inclusion of all methadoneexposed infants, which allowed us to fully measure the impact of our interventions. Many studies define infants with NAS as only those who receive pharmacologic treatment.9-12 However, requiring pharmacologic treatment for a diagnosis of NAS limits the ability to draw conclusions about the efficacy of nonpharmacologic interventions. The use of medication to treat clinical signs should not be the sole factor used to define the syndrome. Although we applied our interventions to all opioid-exposed infants, we focused our evaluation on the subset of opioid-exposed infants most likely to develop withdrawal, regardless of the eventual treatment received. Infants exposed to methadone are more likely to manifest signs of withdrawal than those exposed to short-acting opioids or buprenorphine.^{6,13} By initiating intensive nonpharmacologic interventions for all methadoneexposed infants from the time of birth and before the presentation of clinical signs of withdrawal, we were able to intervene earlier and to prepare parents for their critical role in treatment. We believe this strategy contributed greatly to our success.

Another strength of our project was the development of novel criteria for the clinical assessment of infants with NAS. Criteria for either starting or altering treatment with opioids based on FNASS scores have never been validated.⁶ An FNASS score cannot be obtained without disturbing and unswaddling the baby, which increases the likelihood of high scores in many categories (eg, tremors, tone, and cry). Our approach encouraged providers to focus on a small number of clinically TABLE 2 Characteristics and Outcomes of the Newborns and Their Mothers

Characteristics of the Newborns	Baseline ($N = 55$)	Postimplementation ($N = 44$)	Р
Girl, no. (%)	31 (56)	25 (56)	.96
Race, no. (%)			.19
White	45 (85)	42 (95)	
African American	2 (4)	0 (0)	
Hispanic	6 (11)	2 (5)	
Birth weight, kg ^a	3.1 ± 0.6	3.1 ± 0.6	.72
Apgar score at 5 min ^a	8.7 ± 0.8	8.8 ± 0.8	.92
Head circumference, cm ^a	33.1 ± 1.8	32.8 ± 1.4	.44
Characteristics of the mothers			
Polypharmacy, no. (%) ^b	18 (33)	16 (36)	.70
Cesarean delivery, no. (%)	24 (44)	13 (30)	.15
Cigarette smoking, no. (%)	30 (58)	26 (59)	.53
Alcohol, no. (%)	1 (2)	0 (0)	.36
Public insurance, no. (%)	48 (96)	42 (95)	.90
Mother's age, y ^a	27.5 ± 5.8	29.1 ± 5.1	.16
Gestational age, wk ^a	38.9 ± 1.6	38.4 ± 1.4	.09
Methadone dose, mg/d ^a	85.6 ± 34.3	94.5 ± 37.8	.23
Gravidaª	3.2 ± 1.8	3.2 ± 1.9	.94
Outcomes			
Hospital length of stay, d ^a	22.4 ± 10.8	5.9 ± 1.9	<.001
Treated with morphine, no. (%)	54 (98)	6 (14)	<.001
Cost, US dollars ^{a,c}	44824 <u>+</u> 23726	10289 ± 5068	<.001
Breast-milk fed at discharge, no. (%)	11 (20)	20 (45)	.01
NICU stay, no. (%) ^d	55 (100)	9 (20)	<.001

In the baseline period, data were unavailable for 5 patients for insurance, 3 patients for cigarette smoking, and 2 patients for ethnicity.

^b Methadone use in addition to mother's use of cocaine, selective serotonin reuptake inhibitors, benzodiazepines, or opioids other than methadone (determined either via history and/or urine testing of mother).

^c Adjusted for inflation.

^d Patients with any time spent in the NICU.

relevant factors to assess the need for treatment with morphine. Ideally, all infants should feed well, sleep well, and be easily consoled. We determined that if infants with NAS met these goals, then treatment was successful irrespective of the FNASS score.

When we began our initiative, all infants with NAS were admitted directly to the NICU, an environment that did not permit rooming-in and rarely provided consistent, nonpharmacologic interventions other than swaddling. In this setting, 98% of infants exposed to methadone developed signs of withdrawal severe enough to receive pharmacologic treatment. Our intervention changed the milieu in which these infants were managed from one with limited ability to optimize nonpharmacologic interventions to a low-stimulation environment with an intense focus on the involvement of parents and

continuous assessment of the infant's comfort. In the process, we were able to change a system in which parents were merely allowed to visit their infant to one in which they were empowered to be the most important part of their infant's care. This approach employed the power of the maternal-infant bond to treat NAS.^{14,15} After the implementation of these interventions, the use of morphine to treat NAS decreased to 14%.

In the United States from 2009 to 2012, the ALOS for all infants with NAS was 17 days; infants requiring pharmacologic interventions had an ALOS of 23 days.¹⁶ By changing the paradigm of how infants with NAS are treated and evaluated, we reduced our ALOS to 5.9 days. The potential savings in hospital costs from this approach is considerable. Based on the average cost of a hospital day for an infant with NAS at our institution in 2015 to 2016

^a Mean ± SD.





FIGURE 2

A (length of stay) and B (cost), XmR SPCs where each dot represents a patient exposed to methadone prenatally. C (treated with morphine), p-chart where each dot represents 10 patients exposed to methadone prenatally. The centerline for A and B shifted downward (8 consecutive points below the mean) in March 2010, January 2012, and May 2015. The centerline in A also shifted downward in June 2014. The centerline in C shifted in March 2011 and January 2014. LCL, lower control limit; LOS, length of stay; UCL, upper control limit.



В

Percent Transferred to NICU



FIGURE 3

A (% breast-milk fed) and B (% transferred to the NICU), SPC p-charts where each point represents 10 infants exposed to methadone prenatally. The centerline for A shifted upward in February 2010 and January 2014. The centerline for B shifted downward in January 2010 and June 2014. LCL, lower control limit; UCL, upper control limit.

(\$1750), we estimate a savings of \$1.52 million in total hospital costs if the ALOS of infants with NAS had remained at baseline level (22.4 days). Applying this approach nationally could lead to substantial savings.

There are some limitations to our study. Implementation of our intervention bundle evolved over a 5-year period. Several of our

interventions involved changes in the culture of how infants with NAS were managed, a process that takes time to implement, particularly when existing models of care have been ingrained for many years. During implementation of the intervention bundle, there were changes in both staffing models and hospital policies that may have affected our results. However, the proportional decrease in ALOS for all hospital

patients during this period (9%) was far smaller than the proportional decrease in ALOS for infants with NAS (74%). Second, although rooming-in was an important component of the intervention, we do not have an estimate of the amount of time that a parent was with his/ her child, so we could not assess whether there was a "dose-response" effect. Lastly, we do not know if any infants were readmitted to a different hospital. However, that is unlikely because most hospitals in the area transfer infants with NAS to YNHCH.

CONCLUSIONS

We demonstrated that supportive, nonpharmacologic interventions combined with assessments that focused on the functional well-being of infants with NAS, rather than on FNASS scores, dramatically and sustainably reduced ALOS below previously published levels. We reduced resource use, including less use of morphine and fewer NICU stays. Additional studies that assess effects on growth, development, and behavioral outcomes are needed as are studies that quantify the effect of the involvement of parents in the care of children with NAS.

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ABBREVIATIONS

ALOS: average length of stay FNASS: Finnegan neonatal abstinence scoring system NAS: neonatal abstinence syndrome SPC: statistical process control WBN: well-baby nursery YNHCH: Yale New Haven Children's Hospital

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