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A Hospital-Level Intervention to Improve Outcomes of Opioid Exposed Newborns

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ABSTRACT

Purpose: The purpose of this quality improvement project was to determine if non-pharmacologic strategies such as a rooming-in approach to care for newborns at risk of developing neonatal abstinence syndrome (NAS) would reduce total length of stay (LOS) and reduce the need for pharmacologic treatment.
Design and methods: This was a quality improvement project utilizing a retrospective chart review. Records of newborns with in-utero methadone or buprenorphine exposure were reviewed who were born between January 2016–July 2017 and July 2017–August 2018 at Wellspan Health York Hospital. Starting in July 2017, newborns exposed to opioids who transitioned normally remained with their mothers for monitoring in the newborn nursery. Monitoring for withdrawal was continued on the pediatric floor after the mother's discharge from the postpartum floor.
Results: The primary outcome of total LOS was reduced from 14 days to 10.1 days ($p = 0.014$). The total length of pharmacologic treatment decreased from 15.68 days to 9.71 days ($p = 0.023$).
Conclusions: A rooming-in approach to care including management on a pediatric floor can reduce total length of stay and the duration of pharmacologic treatment in newborns with NAS. Newborns with NAS can be safely managed in an inpatient pediatric floor.
Practice implications: Implementing a rooming-in approach to care of newborns at risk of developing NAS can improve outcomes through a decreased length of hospital stay and decreased duration of pharmacologic treatment. This approach improves access to critical care services by safely monitoring newborns with NAS on an inpatient pediatric floor.

Background and problem description

The use of opioids among women of child bearing age is increasing in the United States and globally. Between 2000 and 2010, there was a 23% increase in opioid prescriptions filled among pregnant women enrolled in Medicaid (Ko et al., 2017). Opioid maintenance treatment programs that allow for control of withdrawal episodes and assist in reducing high risk drug seeking behaviors are available to pregnant mothers. The primary treatments for opioid addiction in pregnancy include methadone and buprenorphine therapy (Stover & Davis, 2015). Methadone and buprenorphine cross the placenta and put newborns at risk of developing neonatal abstinence syndrome (NAS) after birth.

With the increase in opioid use among pregnant mothers, there has been a substantial increase in NAS. The incidence of NAS in the United States has tripled from 1999 to 2013 (McCarthy, 2016; Tolia et al., 2015). More specifically, in Pennsylvania, the rate of NAS has increased 1096% from fiscal year 2000–2001 to fiscal years 2016–2017 (Pennsylvania Health Care Cost Containment Council, 2018). Due to the rise in NAS cases, healthcare costs associated with the treatment of NAS have risen as a result of increased lengths of stay (LOS), increased neonatal intensive care unit (NICU) admissions, and increased use of pharmacotherapy to treat NAS (Tolia et al., 2015).

NAS is a highly variable and complex disease process that can cause disturbances of the central and autonomic nervous systems, gastrointestinal system, and/or respiratory system (Kocherlakota, 2014). The clinical presentation of NAS can be variable depending on the opioid used during pregnancy, maternal drug history, timing of drug use before delivery, maternal metabolism, transfer across the placenta and placental metabolism, and newborn metabolism and excretion (Hudak, Tan, Committee on Drugs, Committee on Fetus and Newborn & American Academy of Pediatrics, 2012). When a fetus is chronically exposed to opioids followed by an abrupt cessation at birth, there is upregulation of cyclic adenosine monophosphate. Upregulation of cyclic adenosine monophosphate leads to increased production and release of several neurotransmitters such as noradrenaline, acetyl choline, and corticotrophin. Upregulation of cyclic adenosine causes decreased production of

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serotonin and dopamine. This pathway explains the clinical signs seen in NAS, such as hyperirritability, tremors, tachycardia, hyperthermia, hypertension, diarrhea, vomiting, yawning, sneezing, sweating, and disturbed sleep-wake patterns (Kocherlakota, 2014).

Providing non-pharmacologic measures, such as non-separation and rooming-in, could help mitigate the signs of NAS as described above. Early skin-to skin care has been shown to reduce maternal and infant stressors, assist in regulating the autonomic nervous systems in newborns, improve bonding, and improve breastfeeding (Moore, Bergman, Anderson, & Medley, 2016). When there are no contraindications, breastfeeding has been shown to be an effective non-pharmacologic treatment approach to NAS (O'Connor, Collett, Alto, & O'Brien, 2013; Short, Gannon, & Abatemarco, 2016; Welle-Strand et al., 2013). Onset of NAS with methadone exposure is 48–72 h, and for buprenorphine exposure the onset is 30–60 h (Kocherlakota, 2014). These first 30–72 h are a critical period in which non-separation and non-pharmacologic measures could be beneficial to both the newborn and mother.

Available knowledge

Challenges in managing NAS

There is a lack of definitive evidence on the best treatment for NAS and lack of standardization among institutions (Wachman & Schiff, 2016). Approaches to managing newborns at risk for NAS are highly variable across institutions (Patrick, Kaplan, Passarella, Davis, & Lorch, 2014). In a prospective randomized double-blinded double-dummy clinical trial, known as the MOTHER study, considerable site differences were found in relation to NAS severity, duration, and treatment (Kirchner et al., 2014). Pharmacotherapy may be indicated for treatment of severe cases of NAS, however there may be approaches to management that could be utilized first to decrease the severity of NAS, shorten the LOS, and decrease costs associated with NAS. Research has shown rooming-in as a management approach to newborns at risk for NAS may reduce the need for pharmacotherapy and reduce the LOS (Grossman et al., 2017; Holmes et al., 2016; Howard et al., 2017; Hunseler, Bruckle, Roth, & Kribs, 2013; Kirchner et al., 2014; Lembeck et al., 2018; MacMillan et al., 2018; McKnight et al., 2016; Newman et al., 2015; Summey et al., 2018).

Rooming-in as a treatment modality for NAS

Several retrospective studies have shown that rooming-in as an initial management strategy for newborns at risk for NAS can decrease length of stay in the initial hospitalization. A retrospective analysis of maternal and perinatal data of newborns with NAS treated between 2004 and 2011 showed that newborns who roomed-in with their mothers had a shorter median length of hospital stay (Hunseler et al., 2013). In this analysis, median length of stay for the rooming-in group was 33 days compared to 41.5 days in the non-rooming in group (Hunseler et al., 2013). A retrospective cohort study to examine the association between rates of parental presence and NAS outcomes demonstrated that 100% parental presence was significantly associated with a 9 day decrease in length of stay with $p < 0.01$ (Howard et al., 2017). Another retrospective chart review examined differences in length of stay before implementing a rooming-in program and compared it to their previous standard of care of admitting all newborns at risk of developing NAS to the NICU. McKnight et al. (2016) found that there was a significant decrease in length of stay ($p < 0.001$) with the implementation of rooming-in, with the median length of stay decreasing from 24 days to 5 days.

Quality improvement projects have been published documenting improved length of stay with a rooming-in approach in the care of newborns at risk of developing NAS (Grossman et al., 2017; Holmes et al., 2016; Newman et al., 2015). Newman et al. (2015) implemented a rooming in program for newborns at risk for NAS at Kingston General Hospital in Ontario, Canada. Prior to this implementation, the standard of care was to admit directly to the NICU for observation and evaluation of NAS using the Finnegan scoring tool. The authors found that the mean LOS was significantly shorter after implementation of the rooming-in program, with a decrease in the mean LOS from 24.8 days to 7.9 days [$p < 0.001$] (Newman et al., 2015)

Programs have been implemented to provide comprehensive care to newborns at risk of developing NAS. The Children's Hospital at Dartmouth-Hitchcock implemented a quality improvement project aimed at reducing LOS and hospital costs through standardized treatment policies with a rooming-in approach outside of the NICU setting (Holmes et al., 2016). Through this initiative, newborns treated with morphine had a reduced length of stay from 16.9 days to 12.3 days. The length of stay for non-pharmacologically treated newborns remained the same at 4.2–4.4 days (Holmes et al., 2016).

Yale New Haven Children's Hospital examined how several key interventions in the management of NAS could reduce LOS (Grossman et al., 2017). A simplified approach to NAS assessment using the eat, sleep, and console model was implemented. This quality improvement project found that standardization of non-pharmacologic interventions such as low stimulus environments, encouraging rooming-in, and transfer of newborns directly to the pediatric inpatient unit versus the NICU resulted in a 74% decrease in average length of stay ($p < 0.001$) from 22.4 days to 5.9 days (Grossman et al., 2017).

Finally, recent research has investigated outcome differences in newborns at risk of developing NAS who are managed in the NICU versus the pediatric floor (Lembeck et al., 2018). A retrospective cohort study of 235 newborns greater than or equal to 34 weeks gestation showed those cared for in a NICU setting compared to a pediatric floor had longer LOS and longer length of pharmacological treatment (Lembeck et al., 2018). Upon multivariable analysis, newborns cared for in the NICU had 12.6 days longer pharmacologic treatment and 12.3 days longer LOS than those newborns cared for on the pediatric floor (Lembeck et al., 2018). This study demonstrated that caring for newborns at risk of developing NAS on a pediatric floor could potentially improve short term outcomes and reduce hospital costs associated with NAS (Lembeck et al., 2018).

There are variations among institutions in the approach to treatment of NAS (Kirchner et al., 2014). The evidence described above shows rooming-in as a management approach to NAS can significantly reduce LOS as well as the need for and duration of pharmacological treatment (Grossman et al., 2017; Holmes et al., 2016; Howard et al., 2017; Hunseler et al., 2013; Lembeck et al., 2018; MacMillan et al., 2018; McKnight et al., 2016; Newman et al., 2015; Summey et al., 2018). More recent research has demonstrated that newborns with NAS can be monitored on a pediatric floor versus an intensive care unit (Lembeck et al., 2018). This shift in care as evidenced by the literature can decrease LOS, reduce need for pharmacologic treatment, and improve access to critical care areas. These findings align with the specific aims for this project.

Specific aims

The primary aim of this project was to determine if non-pharmacologic strategies such as a rooming-in approach to care for newborns at risk of developing NAS would reduce total LOS. The secondary aim was to learn how rooming-in can aid in reducing the need for pharmacologic treatment of NAS. Lastly, this project aimed to show that newborns at risk of developing NAS can be effectively managed in an inpatient pediatric ward versus the NICU.

Methods

Context

The project site was at Wellspan Health York Hospital, a 580-bed community teaching hospital in south central Pennsylvania. The area of focus for this project was within the Women and Children's Service Line (WCSL). The WSCL includes a labor and delivery unit, a newborn nursery with private post-partum rooms, a 44 open bed Level 3 NICU, and a pediatric floor with private rooms. There are >3000 deliveries per year and an average of 500 NICU admissions per year. In fiscal years 2016 and 2017, there were an average of 70 babies born with NAS that were admitted to the NICU at York Hospital. Prior to July 2017, all newborns born exposed to maternal methadone or buprenorphine were directly admitted to the NICU for monitoring for NAS. This approach separated mothers and their newborns during a crucial time frame for mitigating signs of NAS and establishment of breastfeeding. Intensive care beds were occupied with these otherwise stable newborns, that could be reserved for more critically ill newborns. Newborns exposed to short acting opioids and/or whose mothers were not receiving buprenorphine or methadone were not previously admitted to NICU unless there was another clinical reason for NICU admission; thus, those newborns were not included in this quality improvement project.

Intervention

After July 2017, all newborns greater than or equal to 35 weeks gestation with in-utero methadone or buprenorphine exposure remained with their mother and received NAS scoring in the newborn nursery for the first 2–4 days, then transferred to the pediatric floor for continuation of monitoring and/or pharmacologic treatment for a minimum 5–7 days. There were no other changes to our management of newborns at risk for NAS. Nursing staff in the newborn nursery were well-versed in caring for newborns at risk for NAS due to them already managing newborns exposed to short-acting opioids. Nursing staff on pediatric floors were given education by unit educators on caring for newborns with NAS. Pediatric physicians and nurse practitioners were previously knowledgeable about managing newborns with NAS. There were no delays in data collection due to education and onboarding of nursing staff, physicians, and nurse practitioners.

Pharmacologic treatment options included morphine, clonidine, and/or phenobarbital. Morphine was the first line pharmacologic treatment. Bolus dosing of morphine on an as needed basis was an additional pharmacologic treatment. A weaning protocol of morphine by 10% was initiated if NAS scores were stable for at least 24 h. Weaning of other medications was done by provider discretion.

Rooming-in for the purpose of this project was defined as keeping the newborn in the mother's hospital room during the initial course of the hospitalization and providing a private room on the pediatric floor for continued non-separation of mother and newborn while being monitored for NAS. Contraindications for rooming-in included newborns <35 weeks gestation and those newborns with comorbidities requiring NICU admission such as sepsis, respiratory distress, and hypoglycemia. Newborns born at outside hospitals and transferred to our hospital were excluded from the review.

Study of the intervention

A retrospective chart review was performed for the pre-implementation period of January 2016–June 2017. The implementation of the process change described previously occurred in July 2017. A retrospective chart review was performed for the post-implementation period of July 2017–August 2018. Inclusion criteria included gestational age of 35 weeks or greater and in-utero exposure to methadone or buprenorphine for at least one month prior to delivery. Newborns excluded from review included those born at 34 6/7 weeks gestation or less and comorbidities requiring NICU admission such as respiratory distress, sepsis, hypoglycemia, and/or congenital abnormalities. Subjects were identified through a secure hospital database identifying social work consults of mothers presenting to labor hall with known in-utero drug exposure.

Measures

Records were reviewed for demographic and birth characteristics including gestational age, birthweight, sex, and Apgar scores at one and 5 min of life. Maternal categorical data collected included prenatal use of methadone, buprenorphine, and/or polypharmacy. Polypharmacy for the purpose of this project was defined as the use of psychiatric medications, such as selective serotonin reuptake inhibitors and benzodiazepines, in addition to methadone or buprenorphine. Tobacco, cocaine, and other illicit drugs were not included in polypharmacy due to inconsistency with maternal reporting and/or inability to determine from chart review. Total LOS was measured as the total number of hospital days from the day of birth until discharge to home. Total NICU LOS was measured as the total number of hospital days spent in the NICU. The need for pharmacologic treatment was recorded for both pre and post implementation. If pharmacologic treatment was necessary, the day of life the newborn began pharmacologic treatment was noted. Medications used to treat NAS were recorded as morphine, clonidine and/or phenobarbital. The total length of pharmacologic treatment in days for both time periods was recorded. Feeding method was recorded as formula, breastmilk, or a combination of formula and breastmilk.

Data analysis

Data analysis was conducted using IBM SPSS statistics version 24 (IBM Corp. Released, 2016). Results were considered significant at the 0.05 level. Data were analyzed using independent samples *t*-test, Mann-Whitney test, Fishers Exact test, and Pearson's chi-square test.

Ethical considerations

The University of Alabama Institutional Review Board and Wellspan Health York Hospital Institutional Review Board approved this project. There was no prospectively collected data, and thus no access to newborns and their parent or opportunities to seek informed consent. A partial waiver of patient authorization to use protected health information for recruitment or screening was obtained. This project posed no greater than minimal risk and had no direct impact on newborns' rights, welfare, or clinical care. Every measure was taken to ensure confidentiality of records with data collection completed on a secure and encrypted hospital computer. Each newborn received a unique project number to replace the medical record number. Data was analyzed in a de-identified manner.

Results

Ninety-three charts were reviewed of newborns with in-utero opioid who were born prior to the initiation of our rooming-in model of care between June 1, 2016-June 30, 2017. Forty-eight infants met eligibility requirements for inclusion in the review. Seventy-three charts were reviewed of newborns with in-utero opioid exposure born after the implementation of rooming-in between July 1, 2017-August 30, 2018. Forty newborns met eligibility requirements for inclusion in the review. There were no statistically significant variances in demographic characteristics between the two groups other than the 5-minute Apgar score. There were no significant differences in feeding method between the two groups. Infant, maternal, and feeding characteristics are displayed in Tables 1 and 2.

Table 1
Infant and maternal characteristics.

		Group				Significance
		Pre		Post		
		Count	Column N %	Count	Column N %	
Sex (newborn)	Female	23	47.9%	23	57.5%	0.399
	Male	25	52.1%	17	42.5%	
Maternal Buprenorphine	No	26	54.2%	15	37.5%	0.137
	Yes	22	45.8%	25	62.5%	
Maternal methadone	No	21	43.8%	25	62.5%	0.091
	Yes	27	56.3%	15	37.5%	
Polypharmacy	No	33	68.8%	33	82.5%	0.216
	Yes	15	31.3%	7	17.5%	
Feeding method	Breastfeeding	8	16.7%	6	15.0%	0.709[a]
	Breastfeeding & formula	21	43.8%	21	52.5%	
	Formula only	19	39.6%	13	32.5%	

Note: Fisher's exact test.
[a] Pearson's Chi Square.

There were 100% NICU admissions in the pre-implementation group versus 7.5% in the post -implementation group ($p < 0.001$). Total NICU LOS decreased from an average of 8.2 days in the pre-implementation group to 0.2 days in the post-implementation group ($p < 0.001$). The total LOS decreased from 14 hospital days in the pre-implementation group to 10.1 days in the post-implementation group ($p = 0.032$). Table 3 shows primary and secondary outcomes.

There were no statistically significant reductions in pharmacologic treatment and DOL pharmacologic treatment was initiated, however there were significant findings with the length of treatment between the two groups. Pharmacologic treatment was started on 25 newborns (52.1%) in the pre-implementation group versus 17 newborns (42.5%) in the post-implementation group ($p = 0.399$). Of the newborns started on pharmacologic treatment, medication was started on average at day of life 2.52 in the pre-implementation group versus average day of life 3.29 in the post-implementation group ($p = 0.107$). Length of treatment significantly decreased from an average of 15.68 days to 9.71 days in newborns requiring pharmacological treatment between the two groups ($p = 0.023$).

Discussion

The primary aim of this project was to determine if a rooming-in approach to care of newborns at risk of developing NAS could reduce the total LOS. This quality improvement initiative demonstrated a statistically significant reduction in total length of stay for newborns with in-utero exposure to methadone or buprenorphine with a rooming-in approach to care without any adverse outcomes or increase in readmission rates. These findings align with several research and quality improvement studies that previously showed rooming-in as a management approach to newborns at risk of developing NAS may reduce the total LOS (Grossman et al., 2017; Holmes et al., 2016; Howard et al., 2017; Hunseler et al., 2013; Kirchner et al., 2014; Lembeck et al., 2018; MacMillan et al., 2018; McKnight et al., 2016; Newman et al., 2015; Summey et al., 2018).

Length of pharmacologic treatment significantly decreased from an average of 15.68 days to 9.71 days in newborns requiring pharmacologic treatment between the two groups. These findings have clinical significance in management of this patient population and align with previous quality improvement projects showing an overall reduction in the need for pharmacologic treatment and length of treatment with a rooming-in management strategy (Holmes et al., 2016). Of note, one newborn in the post-implementation group only received a one-time dose of morphine. Bolus versus scheduled morphine could potentially be a consideration for future management of this population.

The reduction in NICU admissions and total LOS in the NICU were significant in this project and have important clinical implications. In the pre-implementation group, 100% of newborns at risk of developing NAS were admitted to the NICU for evaluation and treatment of NAS. This decreased to 7.5% in the post-implementation group. The 7.5% accounted for newborns who were admitted to the NICU from newborn nursery due to elevated scores within the first day of life and later transferred to the pediatric floor for continued monitoring. Admission to the NICU during this time was due mostly to physical layout to allow the mother easier access to her newborn while she was still on the postpartum floor. This significant finding demonstrated that newborns at risk for NAS without coexisting comorbidities can be adequately monitored in the well newborn nursery and the pediatric floor, which has been shown to reduce the LOS and need for pharmacologic treatment (Lembeck et al., 2018). This allows for improved access to intensive care beds that would otherwise be occupied by these newborns.

Lastly, feeding methods were examined between the two groups. Although not a direct measurement of the severity of NAS, Short et al. (2016) showed a statistically significant inverse relationship between breastfeeding and LOS. Exclusive breastfeeding, a combination of breastfeeding and formula feeding, and formula feeding were compared between the pre-implementation and post-implementation groups. There were no significant differences between the two groups, however

Table 2
Infant characteristics.

Group		N	Mean	Std. deviation	Significance
Gestation	Pre	48	39.0	1.4	0.760
	Post	40	38.9	1.4	
Birthweight	Pre	48	3092.3	454.0	0.711
	Post	40	3050.4	600.8	
Apgars 1 min	Pre	48	8.1	0.5	0.308
	Post	40	8.3	0.9	
Apgars 5 min	Pre	48	8.9	0.3	0.020
	Post	40	9.0	0.0	

Note: Independent Samples t-test.

Table 3
Primary and secondary outcomes.

Outcome	Group	N	Mean	Std. deviation	Significance
Total LOS	Pre	48	14.0	9.3	0.014
	Post	40	10.1	4.3	
NICU	Pre	48	8.2	6.4	<0.001
LOS	Post	40	0.2	0.6	
Length of treatment	Pre	25	15.68	10.181	0.023
	Post	17	9.71	2.592	

Note. Independent Samples t-test; Length of treatment showed same significance with independent samples *t*-test and Mann-Whitney test.

it is interesting to note that in our study exclusive breastfeeding was slightly higher in the pre-implementation group, although breast and formula feeding were higher in the post- implementation group. Exclusive breastfeeding poses a challenge due to an increase in corticotrophin and acetylcholine in infants experiencing neonatal abstinence syndrome, which can lead to hyperphagia, vomiting, and diarrhea (Kocherlakota, 2014). For this reason, supplementation with formula, and sometimes high caloric formulas are necessary. Feeding approaches for newborns at risk of developing NAS could potentially indicate an area for improvement at our facility in supporting breastfeeding in this population if there are no other contraindications.

This project had several strengths. One strength was the process of identification of newborns who may be eligible for chart review. Diagnosis codes can be inaccurate and identifying newborns through social work consults ensured that all potential newborns exposed to buprenorphine or methadone were included for initial screening. The electronic health record provided an accurate way to perform the chart review with easy navigation to data points needed for the project. Another strength was the level of commitment among newborn nursery and pediatrics to change practice and manage NAS infants.

Limitations

There were several limitations to this quality improvement project. Single center study and small sample size were major limitations of the study. The small sample size may have led to non-significant data analysis. Maternal tobacco and other illicit drug use were not included in this project, which may be an area to consider for future projects. Provider variability for starting and weaning pharmacologic treatment may have been a limitation in the study, as interpretation of NAS scores may differ among providers. Bolus and/or as needed dosing was not standardized among providers. Finally, the physical layout of newborn nursery, the NICU, and the pediatric floor may have limited this project. The pediatric floor is in another area of the hospital which made it challenging for mothers who were still inpatients on the maternity ward to room-in 100% of the time with their newborns if pharmacologic treatment was indicated prior to the mother's discharge from the maternity ward.

Conclusions

Rooming-in as an approach to management of newborns at risk of developing NAS can reduce the total LOS, reduce the need for pharmacologic treatment, and reduce the duration of pharmacologic treatment. Newborns with NAS can be safely managed on an inpatient pediatric floor. This management approach can enhance utilization of NICU beds and improve access to critical care services. Future research should focus on developing standardized treatment protocols for both non-pharmacologic and pharmacologic management of NAS.

CRediT authorship contribution statement

Melinda Cree: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Visualization, Writing - original draft, Writing - review & editing. **Puneet Jairath:**Conceptualization, Data curation, Methodology, Supervision, Writing - review & editing. **Olivia May:**Supervision, Writing - review & editing.

Declaration of Competing Interest

None.

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