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Into practice

Managing Abstinence in Newborns (MAiN): Redesigning NAS care for the mother/baby unit

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ABSTRACT

- Multiple system components can be engaged to provide improved patient care for infants with NAS and their caregivers.
- Prenatal consultation between mothers taking long-acting opioids and newborn care providers improves communication and care plan development for the newborn.
- A multidisciplinary team and standardized processes allow NAS care and treatment to be safely provided on Mother/Baby units.
- Outpatient weaning under the supervision of a medical home is a feasible alternative to a prolonged hospital stay for newborns on pharmacotherapy.

1. Background

As the opioid epidemic has grown in the United States (US), the incidence of opioid-exposed newborns experiencing postnatal withdrawal, or neonatal abstinence syndrome (NAS), has sharply increased. Current estimates for infants with NAS range from 2.6 per 1,000 births to 16.2 per 1,000 births, depending on US geographic region. The South Atlantic region, which contains the state of South Carolina (SC), has the third highest rate of NAS in the US. SC state data show that the NAS rate in 2018 was 28 per 1,000 births compared to three per 1,000 births in 2010.

In 2003, an alternative model of care for infants at risk of developing NAS was established at a large academic medical center in upstate SC. This case report describes the multidisciplinary, coordinated-care model, titled Managing Abstinence in Newborns (MAiN), and lessons learned from 15 years of MAiN development and implementation efforts.

2. Organizational context

The MAiN model was initiated at Greenville Health System in Greenville County, SC (recently renamed PrismaHealth-Upstate), which

experienced the second highest NAS incidence rate in SC between 2000-2014 (8.22 per 1,000 births) (Fig. 1.) Designated as an academic medical center in 2013, Prisma Health-Upstate partners with universities on health-related research and education programs and engages with local entities, such as Health Sciences South Carolina and the SC Hospital Association, to influence and develop health policy throughout the state.

Annually, the Prisma Health Children's Hospital-Upstate provides primary and specialty care for more than 400,000 adolescents, children, and infants.³ The principal hospital in the system, Greenville Memorial Hospital (GMH), currently delivers around 4,000 babies each year and is the regional referral center for mothers with high-risk medical conditions. Care for the well newborn is delivered in the maternal room, and the facility has been designated as Baby-Friendly since 2014.⁴ The normal newborn nursery space is used for infants who require continuous monitoring, urgent evaluation, or separation from the mother for specified indications (e.g. procedures, surgery, adoption). The neonatal intensive care unit (NICU), which is upstate SC's leading perinatal teaching center, provides specialty care for premature and critically-ill infants.

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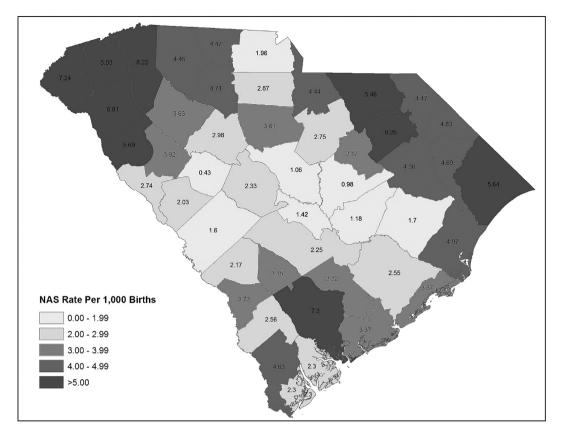


Fig. 1. Neonatal abstinence syndrome rate per 1000 births by county in South Carolina, 2006-2014 *Source*: Developed by authors.

3. Problem

There is no unified, standardized approach for evaluating or treating infants with NAS. Existing strategies have involved quantifying the severity of neonatal withdrawal symptoms using an abstinence scoring method and initiating pharmacotherapy in intensive care settings once sufficient NAS signs and symptoms are displayed. 5-8 The conventional approach to managing NAS has several limitations. Abstinence scoring tools are used inconsistently across settings and results are subjective, which has led to substantial variability in NAS diagnosis rates. 9 Treatment delivered in higher-level care settings often requires separation of mother and infant, thus inhibiting beneficial mother-baby bonding experiences during a critical period of newborn development. Suggested thresholds for treatment are typically based on abstinence scores rather than a comprehensive clinical assessment that takes into account caregiver and staff input and objective measures such as intake, output, and weight loss level. Institutional pressures to reduce length of stay, NICU days, and costs may support care strategies that stigmatize pharmacotherapy, leading to a withholding of medication for symptomatic infants. Choice of pharmacotherapy (methadone vs morphine) is also disputed, and no medications are yet FDA-approved specifically for the treatment of NAS. 10

Several alternative models of care for managing infants with NAS have been described in recent literature. For many opioid-exposed infants, non-pharmacologic treatment measures, such as breastfeeding, swaddling, acupressure, and rooming-in, can decrease NAS severity, need for pharmacologic treatment, total treatment duration, and hospital length of stay (LOS). 11,12 For infants that require pharmacotherapy, standardized treatment and weaning protocols can reduce pharmacologic treatment duration and hospital LOS. 13–15 Combined inpatient/outpatient weaning protocols have documented hospital charge savings and LOS reductions. 16–19 Despite these advances, there is still no national consensus on which care strategy or combination of

strategies is superior for improving overall infant health and short and long-term outcomes. As such, care for infants with NAS is often fragmented and lacks coordination within and across healthcare delivery settings.

A physician champion and a multidisciplinary team of GMH staff, including partners from pediatric and developmental medicine, pediatric pharmacy, nursing administration, social work, physical and occupational therapies, and child advocacy, developed the MAiN model. Motivation for addressing this challenge stemmed from the need for a standardized NAS care protocol at GMH. In 2003, the clinical team believed that improvements in organizational efforts and treatment standards could improve outcomes for affected neonates. The team initiated an informal quality improvement project with goals to define an appropriate length of stay for medical monitoring based on exposure, develop a standardized plan of care for all substance-exposed newborns, and create a specialized care map for neonates at high risk for developing neonatal abstinence syndrome after fetal opioid exposure. Secondary goals were to reduce NICU transfers, promote maternal care for the infant, expand services provided for NAS care, and ensure a robust handoff to a medical home for the infant at discharge.

The physician champion and her team also considered the perceived ethical dilemma that infant populations at high risk for opioid dependency were being treated differently based on their source of exposure. After extended opioid treatment in a critical care setting, infants are often weaned from opioids to prevent a withdrawal syndrome. However, after continuous exposure to opioids during gestation, neonates are never treated prophylactically. The medical team hypothesized that prophylactic treatment may prevent opioid withdrawal and its complications in the population of exposed newborns who are at high risk for dependency. As a result, methods for anticipatory weaning were investigated.

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4. Solution

4.1. Developing MAiN

In the early 2000s, there were no clinical practice guidelines describing appropriate care for opioid-exposed newborns at GMH, which had adopted a general approach to treating NAS based on the best evidence at the time. Substance-exposed newborns were monitored in the well nursery for 10 days, regardless of exposure, in order to allow adequate identification of drug effects and withdrawal, investigation by child protective services (CPS), and the development of a plan of safe care after discharge. With mandated prolonged stays, symptom patterns among exposed newborns were easily identified during clinical care. It was observed that newborns exposed to maternal methadone therapy during late gestation had very high rates of NAS requiring treatment, while those exposed to other prescription medications, including shortacting opioids and illicit substances, had very low rates of NAS requiring treatment. Over time, clinicians expressed frustration about being able to "predict" when NAS was likely to occur but having no clear plan for its prevention or treatment. A desire to explore such options and to improve overall care was the driver for innovation.

To identify and implement organizational change, a multidisciplinary team was engaged. Various options were considered to improve care standards. Options included alternative models for managing NAS that have been described in the literature, such as nonpharmacologic interventions, standardizing pharmacologic treatment and weaning protocols, and combined inpatient/outpatient weaning.

The first course of action involved defining standardized care and length of stay for substance-exposed neonates based on maternal history and maternal and/or infant toxicology screenings. After literature review and clinician consensus, a policy was developed as a resource for providers and staff. Neonates exposed to prescription, short-acting controlled substances or illicit drugs would require a minimum stay of three days for monitoring. Those exposed to long-acting controlled substances would require a minimum five-day stay, based on the known elimination half-life of medications such as methadone, buprenorphine, and clonazepam. If significant symptoms of withdrawal had not been identified by the end of the prescribed monitoring period, and all other discharge criteria were met, the infant could be medically cleared for ongoing care at home.

The second course of action involved creating order sets to specify abstinence scoring frequency, supportive care measures, family education, cardiorespiratory monitoring, consultations (social work, physical and occupational therapy), and barrier cream use for the prevention of perianal skin breakdown. Standing orders also specified indications for neonatal urine and meconium toxicology and HIV testing. Prior to implementation, unit administration was engaged to ensure the availability of equipment and to provide staff training on accurate abstinence scoring, supportive care, and special education for families. Discussions with consulting services were held to ensure that an increase in demand could be met, based on an expected increase in referrals.

Third, consultations were held between pediatric pharmacists and neonatal providers to investigate the optimal method for treating opioid withdrawal in opioid-exposed newborns. A majority of pregnant women (82% between 2006-2014) receiving opioid replacement therapy in our community are maintained on methadone, and existing institutional protocols for opioid weaning (in critical care settings) had been established using methadone as the medication of choice. As a result, methadone was selected as the optimal pharmacotherapy for our population. Next, a review of existing national approaches was performed. Pharmacokinetics of methadone dosing and steady state for adults and children were reviewed. Neonatal providers suspected that newborns exposed to higher maternal methadone doses may have a higher risk for and severity of NAS based on clinical experience. With no clear dose-response relationship between maternal methadone dose

and NAS severity demonstrated in the medical literature at that time, two dosing regimens (provided in the supplementary materials) were selected based on maternal opioid dose cutoff, and dosing guidelines were incorporated into the medication orders, along with automatic consultation by the pediatric pharmacist and medication teaching for caregivers.

Finally, a plan for outpatient weaning was established for all infants who received inpatient treatment. Outpatient weaning was a strategy that had been previously utilized by inpatient pediatric hospitalists within our institution, with low rates of readmission. The pediatric pharmacist developed the weaning calendar prior to infant discharge, and the hospital's outpatient pharmacy had the appropriate medication stocked for discharge prescriptions with instructions for use. Further, a single community medical home was identified to manage medication weans.

4.2. Adapting MAiN

Input from multi-disciplinary team members to improve the MAiN model was provided over the course of more than 10 years. Venues for individual feedback occurred during shared patient care, formal meetings around specific deliverables, and meetings with key providers, such as the Pediatric Pharmacy and Therapeutics Committee, unit dyad leadership meetings, and fetal care and departmental meetings.

Key changes occurred after a meeting was held between the inpatient team and outpatient pharmacy to discuss medication dispensing for outpatient weaning. At that time, the exact amount of liquid medication required was dispensed in a medication bottle. Family interviews revealed that in order to measure the small amounts needed for weaning, medication was often poured into a bowl or cup, pulled into the provided oral syringe, and then the leftover medication returned to the bottle using a funnel. It was suspected that small amounts of medication were lost in each transfer, with additional loss from the dead space in the hub of the oral syringe. After the team meeting, the outpatient pharmacy agreed to dispense all medication doses in prefilled oral syringes, at no extra charge to the patient. Although some reports of suspected mishandling existed before this change, they became rare thereafter.

Issues with the outpatient wean were also addressed. Over the preceding years, variability among weaning calendars developed by different pediatric pharmacists had been noted. Some weans were three weeks long, while others were 10 weeks. Outpatient pediatric providers complained about having to write a new prescription for medication after 30 days of weaning. As a solution, all weaning calendars were standardized. After reviewing published reports of successful wean rates, the team decided upon twice-weekly weans of 10–15% of the discharge dose, with a total wean length not to exceed 30 days.

Another key change occurred in response to mothers on opioid replacement therapy expressing frustration over receiving mixed messages about the impact of long-acting opioids on the baby. Mothers were often given conflicting information by their treatment and obstetric providers, friends, family, and the media. Their expectations varied: some anticipated a normal two-day hospital stay, while others expected immediate and prolonged NICU care. All voiced similar concerns regarding their questions being inadequately addressed prior to delivery. To address these concerns, the clinical champion began offering prenatal consultations to mothers taking opioid replacement therapy in late gestation. A MAiN case manager, which was funded by the SC Department of Alcohol and Other Drug Abuse Services, was hired to work with a primary social worker to identify and schedule eligible women for prenatal consults. Mothers who qualified received a 30-minute in-person consult late in the third trimester. Phone consultations were offered for women with transportation barriers. In addition, access to neurodevelopmental screening and more medical homes in the community were added to the program over time.

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Table 1 Core beliefs of Managing Abstinence in Newborns program. Source: Developed by authors.

Core Beliefs

- All women deserve a positive birth experience
- Mothers and newborns belong together, with rare exception
- Sudden opioid withdrawal is painful, potentially harmful, and should be prevented
- Health care providers should advocate for the well-being of vulnerable populations
- · All patients deserve a primary care medical home

4.3. Fully-adapted MAiN

After years of MAiN adaptation, a set of core beliefs were developed to guide future program efforts (Table 1). Fig. 2 depicts an organizational and treatment flow chart of the mature MAiN model.

4.3.1. Prenatal pathway

Women taking daily opioids during pregnancy are referred to MAiN prenatally or identified at delivery after the birth of a healthy newborn. In the prenatal pathway, obstetric providers in the GMH referral region identify a pregnant woman taking daily opioids for a medical condition or supervised opioid-replacement therapy and make a referral to the MAiN case manager. If a woman intends to deliver at GMH, and the infant is expected to be otherwise healthy at delivery, the MAiN case manager contacts the mother by phone at 34-35 weeks gestation to schedule a prenatal consultation with the medical director. The phone or in-person prenatal consult covers similar information on a variety of topics, such as risk for NAS and a recommended care plan, preparation for extended stay in the hospital, breastfeeding, partnering with the family to provide treatment on the mother/baby unit, and medical home plans. Sensitive topics, such as risk for needing NICU care, criteria for CPS involvement, co-morbid medical conditions (such as hepatitis C infection), mental health needs and privacy concerns are also addressed. The MAiN case manager provides additional support by answering questions that may arise during gestation or the birth hospitalization and by providing education about safe sleep, developmental screening and community resources to caregivers.

4.3.2. Inpatient pathway

Whether identified prenatally or at delivery, if an otherwise healthy newborn admitted to the Mother/Baby Unit is at high risk for opioid withdrawal, they are referred to MAiN to be managed by the medical director or her partners. Infants experience a normal admission process to the Mom/Baby unit, with early skin-to-skin and breastfeeding support. Specialized orders are initiated, and mothers receive social work assessment, education about recognizing withdrawal, and techniques for providing comfort care. Evaluation and treatments by physical and occupational therapists are completed. All neonates have barrier skin cream ordered to prevent diaper rash. Because risk of seizures in infants with NAS is elevated, apnea/bradycardia monitoring is initiated in the mother's room and connected to the patient call system. A collaborative care plan and discharge criteria are discussed with the mother.

Newborns with fetal exposure to maternal buprenorphine (12mg or more) or methadone (20mg or more) are identified as high risk for developing NAS. For these infants the physician will offer early pharmacotherapy, which is initiated within 24 hours of birth if approved by the mother. Newborns who are not treated early but who develop significant signs and symptoms of opioid withdrawal may be treated with pharmacotherapy after the first 24 hours. Additional instruction and practice administering medication as well as education about recognizing over-sedation are provided. Medication dosing is spaced from every six to every 12 hours over approximately one week in the hospital. For all infants, targeted education about homecare of the newborn during the weaning period, such as signs of worsening or increased withdrawal symptoms, preventable ED visits and readmissions, abusive head trauma, and safe sleep, is also provided. Before discharge, the case manager schedules outpatient appointments for weekly wean visits with the designated medical home and a three-to six-month formal developmental screen. Additional referrals to outpatient therapies, or state or community agencies may be made.

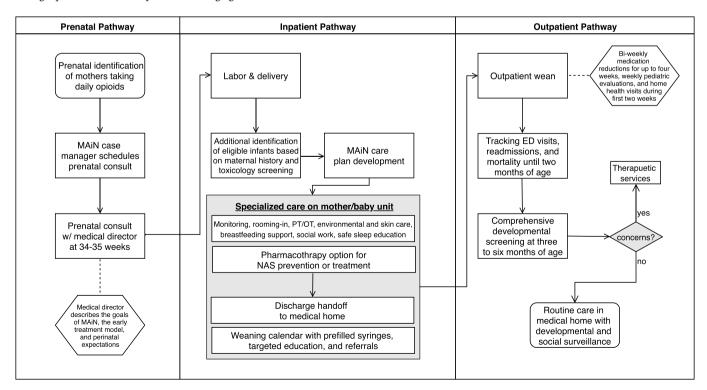


Fig. 2. Flow process through the prenatal, inpatient, and outpatient pathways for the Managing Abstinence in Newborns program.

Abbreviations: MAiN, Managing Abstinence in Newborns; PT/OT, physical therapy/occupational therapy Source: Developed by authors.

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4.3.3. Outpatient pathway

For any infant who receives inpatient methadone therapy, weaning begins after discharge and takes place outpatient over two to four weeks. At discharge, the outpatient pharmacy provides caregivers with pre-filled syringes for the entire wean. The average discharge dose for treated neonates is 0.5mg every 12 hours. The cost of the pre-filled syringes for the average 30-day outpatient wean is approximately \$5 to \$15. During the outpatient wean, dosage reductions occur twice weekly, always on Sundays and Wednesdays. The medical home provides weekly pediatric evaluations (on Mondays or Thursdays) to assess weaning tolerance and make adjustments, if needed, SC Department of Health and Environmental Control (DHEC) postpartum home health nurses visit caregivers once per week for the first two weeks of weaning. The first DHEC visit (within a week of discharge) is automatically offered for any Medicaid-eligible infant, and a second visit (one week later) is provided by DHEC through a special agreement with the MAiN program. The MAiN case manager is responsible for postnatal tracking of emergency department visits, readmissions and mortality for weaning babies until two months of age and following-up with caregivers to provide a developmental appointment reminder for all substance-exposed infants. For recurrent noncompliance with appointments or concerns about child welfare, a referral to CPS may be made. If concerns are founded and depending on the events that led to CPS involvement, CPS develops a safety plan for ongoing care of the affected neonate, as well as a structured monitoring and treatment plan for caregivers, or the infant's custody may be reassigned to a protector, kinship caregiver, or foster caregiver. Comprehensive developmental screening takes place starting at three to six months and continues until age three. If any developmental concerns are noted, infants are referred for therapeutic services. After age three, routine developmental and social surveillance continues within the medical home.

4.4. MAiN program evaluation

Since 2003, a majority of mothers (90%) whose newborns qualified for early treatment have chosen to proceed with the MAiN treatment protocol. Mothers often describe personal adverse experiences with opioid withdrawal and express a strong desire to prevent similar suffering for their babies. For the 13 mothers who declined early treatment, only two of their infants did not ultimately need methadone therapy to control symptoms of opioid withdrawal. As a result, the original risk stratification to determine which neonates qualify for early treatment has remained the same since the MAiN model was initiated. While there is still not enough evidence in medical literature to support greater initiation dosing by maternal medication dose, the efficacy of our approach has been monitored internally by tracking frequency of dose adjustment during the hospital stay for either poor symptom control or over sedation. A need for dose increases or decreases are infrequent in both groups (those started on 0.05mg/kg/dose vs. 0.1mg/ kg/dose), and given that the initial dose selected by the physician for early treatment is within the recommended range for symptom-based treatment for NAS,⁵ adjustments to our original dosing stratification have not been warranted.

In 2015, Greenville Health System partnered with Clemson University to complete a retrospective evaluation of the MAiN model. This evaluation showed that infants managed with the MAiN model experience similar medical and safety outcomes but reduced LOS and NICU use compared to infants treated with standard NAS care. We estimate that GMH eliminates approximately 500 NICU days annually using this model. While not a primary rationale for implementing MAiN, lower costs achieved through reduced LOS and NICU use is an important benefit, as are increased opportunities for mother/baby bonding and supportive care.

During the hospital stay, all MAiN mothers who completed prenatal consultation are asked about their experience and how it might have been improved. They are offered an opportunity to provide written

feedback (anonymous or identifiable) as well. Enrolled mothers report being satisfied overall with the quality of prenatal consultations and information provided before delivery. Moreover, they have been pleased with how well early treatment limits the development of signs and symptoms of opioid withdrawal in their neonates, promoting normal bonding, sleep, and feeding experiences during extended rooming-in. Mothers have overwhelmingly expressed gratitude that their greatest fears - separation from the baby and feeling stigmatized were never realized. Negative feedback has included a desire for earlier discharge, since early treated newborns are often perceived by their mothers as "doing well" and "acting normally." Mothers have also stated that sometimes staff are not empathetic during interactions or are inconsistent in their messaging about breastfeeding. In addition to feedback from mothers, we have solicited provider and staff feedback during clinical work and at group faculty and staff meetings. Positive feedback from providers and staff who use the MAiN model include satisfaction with its consistency of care, immediate results and positive impact on families. Negative feedback has related to staffing issues, since it takes more time to care for MAiN couplets than low-risk couplets. A monthly meeting of core MAiN staff (medical director, program manager, case managers) includes new feedback, case reviews, and identification of opportunities for improvement.

The practice of outpatient weaning may be considered a novel approach, and few studies have reported outcomes associated with outpatient weaning. In our previous evaluation of the MAiN program, we found that ED visits for symptoms possibly or likely related to NAS during outpatient weaning were very low (4.6%) and were lower than ED visit rates for similar symptoms in SC newborns who were discharged after receiving standard NAS care without home weaning (7.9%). ²⁰ Readmission rates in both groups were similar. ²⁰ While outpatient weaning has been found to reduce hospital length of stay, data show that it is associated with a longer duration of opioid therapy. ²³

Despite these benefits, and years of refinements, the MAiN model has room for improvement; there are still unresolved questions that will need addressing. Further evaluation is needed to determine the long-term outcomes of infants treated with the MAiN model. We have recently partnered with the Prisma Health-Upstate Center for Developmental Services to evaluate the developmental outcomes of infants treated with MAiN and to compare these outcomes to those of infants treated with standard NAS care in SC. Additionally, we are actively working to implement new strategies to track MAiN infants through childhood, with special attention given to health services utilization, adverse childhood experiences, and school readiness.

5. Unsolved questions and lessons from the field

The MAiN model uses a comprehensive strategy to manage infants with fetal opioid exposure and is one of several newly-described NAS care innovations with the potential to improve care for this vulnerable population. Fifteen years of MAiN implementation highlights organizational and systems challenges to implementing the program. The model recommends hospital cardiorespiratory monitoring for newborns at risk for NAS, and many maternity rooms are not wired for central monitoring. While many hospitals have recently implemented "couplet care" with one nurse caring for both mother and baby in the same room, nursing staff may be more comfortable with caring for mom or baby but not both. Staffing by newborn providers also varies widely. Some facilities have newborn hospitalists responsible for well-baby care, while others are staffed by local providers who are more difficult to access during office hours. Most facilities without a NICU have limited or no access to pediatric therapies, pharmacists, social workers, case managers, and developmental specialists. Advocating for the addition of specialty pediatric services may be warranted for facilities interested in implementing the model. Moreover, the program recommends different starting methadone doses for infants based on maternal methadone or buprenorphine dose at delivery. Since the J. Hudson, et al. Healthcare xxxx (xxxxx) xxxxx

program started in 2003, a dose-response relationship between maternal methadone dose and NAS severity has not been clearly demonstrated, nor have recommendations been given about an optimal starting dose of methadone (other than a suggested range). Finally, controlled studies have not been conducted to measure the impact of early treatment on neonatal medical outcomes or long-term child health outcomes.

The clinical and scientific research community argues that caution should be used when initiating pharmacologic treatment for infants with NAS. Indeed, national trends are shifting toward using first-line non-pharmacologic therapies with the goal of reducing the use of pharmacologic treatment, when possible. Yet, a majority of infants (from 55% to 94%) with in-utero opioid exposure will develop withdrawal signs and symptoms.⁵ These symptoms may be mild but may also progress to morbidities such as seizures, feeding problems, weight loss, and sleep disturbance. For other conditions with high rates of morbidity, prevention is standard medical practice. For example, empiric IV antibiotic therapy is often provided to asymptomatic neonates with an increased risk for sepsis, intramuscular vitamin K is universally administered to prevent vitamin-K deficiency bleeding, and topical eye prophylaxis helps to prevent gonococcal ophthalmia, despite the fact that these conditions are rare. While every neonate exposed to opioids may not require pharmacologic treatment, prevention and management of pain is a responsibility of neonatal care providers and concerns about using pharmacotherapy for NAS should be balanced with this important goal in mind.²⁴ Therefore, new approaches to NAS care should consider strategies that help to avoid suffering and preventable morbidities for a majority of at-risk patients, specifically infants with significant prenatal opioid exposure.

MAiN was developed to address a variety of needs related to NAS care, including standardization, risk stratification, addressing perceived ethical conflicts associated with traditional approaches, and overall promoting multidisciplinary and family-centered care. Financial pressures related to NAS care are a concern to facilities, payers, and policymakers nationwide. As systems and payers move to population health management reimbursement models, a comprehensive, standardized model of care, such as MAIN, may offer cost-effective NAS care that promotes education, engagement, and empowerment of families during the course of treatment, without compromising medical and safety outcomes.

Contibutors statement

Dr. Hudson drafted the initial manuscript and revised it for critically important intellectual content. Ms. Charron and Drs. Bedi, Dickes, Mayo, and Sherrill drafted portions of the manuscript and revised it for critically important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Declaration of competing interest

None of the authors have any conflicts of interest to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hjdsi.2019.100404.

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