Quality Improvement Report

Feasibility and Acceptability of a Checklist and Learning Collaborative to Promote Quality and Safety in the Perinatal Care of Women with Opioid Use Disorders

Daisy Goodman, CNM, DNP, MPH, CARN-AP, Alexandra B. Zagaria, BS, Victoria Flanagan, MS, RN, Farrah Sheehan Deselle, MSN, RN, CLC, Amanda R. Hitchings, PsyD, Renee Maloney, RN, Themarge A. Small, MD, Autumn Versace Vergo, CNM, Martha L. Bruce, PhD, MPH

Introduction: Perinatal opioid use disorder (OUD) represents a maternal-child health crisis in the United States. Untreated, OUD is associated with maternal and neonatal morbidity due to infectious disease, polysubstance use, co-occurring mental health conditions, prematurity, neonatal opioid withdrawal, and maternal mortality from overdose. Although national guidelines exist to optimize perinatal care for women with OUD, wide variation persists in health care providers' experience caring for this population and in the quality of care delivered.

Process: We conducted a pilot study to determine whether the use of a checklist summarizing best practice could improve perinatal care for women with OUD. Implementation was supported by a learning collaborative of maternity care providers at 8 diverse sites across Vermont, New Hampshire, and Maine. Outcomes before and after implementation were compared to determine whether practice change occurred.

Outcomes: Data were collected from the records of 223 women with OUD who received prenatal care at pilot sites. All sites endorsed use of the checklist as a practice guide, and it was integrated in 78% of records reviewed. Across sites, significant improvement occurred in key elements of care, including increasing the proportion of women with access to the lifesaving drug naloxone (10.9% vs 36.3%, $P < .001$), receiving counseling about the benefits of breastfeeding (50.9% vs 72.0%, $P < .01$), and treating with nicotine replacement when indicated (9.1% vs 26.8%, $P = .01$). No significant change occurred in rates of prematurity, low birth weight, or breastfeeding at hospital discharge.

Discussion: Implementation of a checklist to facilitate best practice in the care of pregnant women with OUD is feasible, acceptable to maternity care providers, and represents a promising approach to improving quality of care for this vulnerable population. Additional research is needed to determine whether improvement in quality can transform perinatal outcomes.
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Keywords: antepartum care, public health, substance use disorders, vulnerable populations

INTRODUCTION

Perinatal opioid use is widely recognized as a maternal-child health crisis of increasing severity in the United States.[1,2] Untreated, opioid use disorders (OUDs) are associated with increased maternal and neonatal morbidity and mortality related to prematurity, infectious disease, neonatal opioid withdrawal, and overdose. Outcomes are worse in the context of polysubstance use, including tobacco, and improve with treatment, comprehensive services, and prenatal care attendance.[1-4]

Northern New England has seen a sharp rise in the prevalence of OUDs among pregnant women in the past decade. It is estimated that 3% to 8% of pregnant women regionally are affected by opioid use,[5-7] and maternity care systems struggle to respond. The problem of perinatal OUD is exacerbated by the scarcity of treatment programs that address the special needs of women, especially in rural communities.[8,9] As a result, prenatal care providers often face the double responsibility of helping women find treatment and subsequently coordinating care.[10]

Fortunately, pregnancy is a time of high motivation for treatment entry and a unique opportunity to engage women in comprehensive services.[11-14] Pregnant women with OUD often present with psychiatric and physical health comorbidities and high levels of unmet social needs, requiring a range of services and case management.[2,11] As a result, prenatal care providers frequently feel overwhelmed, under-resourced, and ill-prepared to provide optimal care.[15] Guidelines from national professional organizations and the World Health Organization have identified best practices in the perinatal care of women with substance use disorders generally, and OUD specifically, based on research over the past 5 decades.[14,16-19] However, significant challenges impede the implementation of these best practices.[20,21] This article describes the work of a regional perinatal improvement collaborative to address issues of quality in the maternity care received by women with OUD.

Background: Methods Used to Facilitate Best Practice

The care of individuals with OUD, similar to that of persons with other chronic health conditions, is best offered through an interprofessional team-based approach. Input from many disciplines, working together across system levels and care settings, is needed to address patients' complex needs. We

Address correspondence to Daisy Goodman, CNM, DNP, MPH, CARN-AP, Dartmouth Hitchcock Medical Center, 1 Medical Center Drive, Lebanon, NH 03756. Email: daisy.j.goodman@dartmouth.edu

Quick Points

◆ Perinatal opioid use disorder (OUD) has become a maternal-child health crisis in northern New England, contributing to severe morbidity and mortality for women of childbearing age.

◆ Although national guidelines exist to optimize the perinatal care of women with OUD, wide variation persists in the quality of care delivered in clinical settings. There is an urgent need for interventions to promote best practice in the care of this vulnerable population.

◆ Quality improvement methods have demonstrated success in improving care for a variety of chronic disease. These strategies can also be utilized to improve the care of women, newborns, and families affected by perinatal opioid use.

◆ The use of a simple checklist, supported by a learning collaborative, is feasible and acceptable to frontline clinicians and has demonstrated value in improving care for pregnant women with OUD.

sought to determine whether improvement methods such as practice facilitation and learning collaboratives, which are used to facilitate management of other health problems, might also be applied to perinatal substance use.

Practice facilitation is defined as a supportive service, incorporating quality and practice improvement methods, to build the internal capability of a practice to optimize care.[22] Two common facilitation approaches include providing just-in-time information to clinicians in the form of prompts, templates, or other reminders built into electronic health record (EHR) systems, intended to increase the likelihood that care will be consistent with accepted best practice, and providing ready access from the EHR to resources such as guidelines, educational materials, and other tools for clinicians.[23]

A popular example of a health care provider prompt is the use of checklists to help clinicians deliver key elements of care for complex health conditions or procedures.[24,25] This approach is widely used in surgical specialties,[25] and the World Health Organization's Safe Childbirth Checklist, defined as a "list of essential evidence based practices drawn from existing [World Health Organization] guidelines [that] should be performed at every birth to ensure the best outcome,"[25 (p.1)] has been disseminated extensively after testing by 38 implementation teams. Checklists enhance safety because they remind clinicians engaged in multiple tasks about essential details that might otherwise be omitted, and they can facilitate team communication.[24,25] However, the effectiveness of checklists depends upon whether they are clinically relevant, not burdensome, and perceived as capable of improving care.[24–29] Sustainability depends on easy integration into daily routines.[24,25] Therefore, any approach taken to implementation should ensure alignment with the local context.[24,29]

Learning collaboratives have been utilized to implement, adapt, and test integration of complex interventions across multiple sites since their introduction by the Institute for Healthcare Improvement. Learning collaboratives are frameworks through which organizations can learn from content experts and each another about a clinical area in which improvement is mutually perceived as necessary.[30] In the ambulatory setting, they have been effectively used to improve chronic disease management over the past 2 decades,[31,32] including through the integration of behavioral health services[33] and substance use treatment in primary care settings.[34,35]

Common elements of learning collaboratives that are associated with successful implementation of interventions and improved outcomes for patients include the development of a community of practice through synchronous meetings, either virtually or in person; an interprofessional approach; targeted educational programs to support programs of interventions; promotion of Plan, Do, Study, Act cycles for local adaptation of interventions; and using standard measures across sites with feedback and comparison of results.[23,35–38]

The aim of our project was to implement a program of similar interventions in the prenatal setting, to facilitate best practice for the perinatal care of women with OUD and improve key outcomes for women and newborns. This report describes the development and feasibility of a novel approach to implementation, piloted by a learning collaborative of regional prenatal care providers.

PROCESS

The Northern New England Perinatal Quality Improvement Network (NNEPQIN) is a consortium of more than 40 hospitals and affiliated ambulatory practices in Maine, New Hampshire, and Vermont. NNEPQIN provides infrastructure for disseminating clinical guidelines and facilitation of quality improvement initiatives in maternal-child health. Maternity care in this region is provided in a number of settings, including federally qualified health centers, community obstetric and gynecology practices, and 3 academic medical centers. Given the high prevalence and urgency associated with perinatal opioid use regionally, in 2016, NNEPQIN embarked on a multiyear project to improve quality and safety in the maternity care of women with OUD, based on feedback about gaps identified by members.

At the onset of the project, we conducted a survey of the primary contacts from each NNEPQIN member organization about the impact of perinatal substance use on their hospital units or ambulatory practices, inviting them to identify elements of care that they felt were lacking. Ninety-one health care professionals responded, representing nursing, midwifery, behavioral health, and medicine. The vast majority felt that substance use had a moderate to very large impact on their office-based or hospital practice. More than half indicated that communication about substance use was neutral to nonexistent between inpatient and outpatient

settings and between maternity care and substance treatment providers. In open-response questions, participants described lack of professional knowledge about evidence-based recommendations for the care of women with substance use disorders and identified a need for clinical algorithms and tools to enhance communication between prenatal and hospital-based health care providers. These data were used as a basis for developing project interventions.

The project was reviewed by the Dartmouth College Committee for the Protection of Human Subjects and determined to be a health care improvement program rather than human subjects research. The SQUIRE guidelines for publications describing system-level work to improve health care quality, safety, and value (version 2.0) were used in preparing this article.[39]

Planning the Intervention

Based on the findings of the NNEPQIN survey, an interprofessional Advisory Group was convened to review existing guidelines for managing perinatal OUD. Its focus was on OUD specifically because rising opioid overdose rates among women had made this as an urgent regional concern. Regional experts in obstetrics, pediatrics, addiction, and infectious disease, representing nursing, midwifery, and medicine, identified elements for inclusion in a document summarizing best practice. A checklist was developed with essential evidence-based practices that the group agreed should be provided to all women with OUD (see Table 1 for the checklist elements and Supporting Information: Appendix S1 for the full checklist template). The intent of the checklist was twofold: to facilitate guideline-concordant care and to serve as a documentation and communication tool as women transitioned to the hospital setting for labor and birth.

We designed a 3-part intervention, consisting of (1) the 26-item checklist, (2) a year-long learning collaborative including at least one representative from each practice (nurse, physician, advanced practice nurse, midwife, social worker, or behavioral health clinician), and (3) a toolkit for the perinatal care of women with substance use disorders, publicly available on the NNEPQIN website, that included the summary of best practice, links to printer-ready patient education materials, sample consent forms, and other useful resources.

Eight practices were recruited to implement the checklist and participate in a learning collaborative. We modeled our approach on that of collaboratives convened to improve care for other chronic disease conditions.[31,32,34,35,37] Representatives from participating sites met monthly during clinicians' lunchtime, using a digital platform (WebEx; Cisco Systems, Milpitas, CA). Learning sessions included participant discussion about implementation strategies and presentations by regional experts on topics identified as clinically challenging. These included harm reduction approaches and access to naloxone, smoking cessation, hepatitis C screening and diagnosis, prenatal and postpartum cannabis use, and treatment of co-occurring mental health conditions. The explicit goal of the collaborative was to facilitate learning about evidence-based practice. A secondary goal was to promote use of the

Table 1. Elements Included in the Checklist
Element
Federally compliant consent to share information with treatment provider[a]
HIV status[b]
HBsAg, HBcAb, HBsAb[b]
Hepatitis C antibody[b]
HCV viral load and genotype if indicated[b]
Liver function tests[b]
Serum creatinine[b]
Institutional drug testing policy reviewed
Plan of Safe Care introduced[c]
Behavioral health referral offered
Needs assessment, care management referral
Risks of nonprescribed drugs and alcohol discussed[d]
Marijuana counseling[d]
Tobacco cessation counseling or treatment[e]
Naloxone (Narcan) discussed, offered
Third trimester
Repeat HIV, HBsAg, HCVAb, GC, CT
Ultrasound (growth, fluid)
Urine toxicology with confirmation **(consent required)**
Urine ethyl glucuronide/ethyl sulfate (alcohol metabolites) if concern for alcohol use
Third trimester education
Review Plan of Safe Care[c]
Review institutional drug testing policy[e]
NAS and newborn care discussed
Breastfeeding discussed
Pain management discussed
Family planning discussed
Pediatrician identified
Other

Adapted with permission from the Northern New England Perinatal Quality Improvement Network.
Abbreviations: CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrheae*; HBcAB, hepatitis B core antibody; HBsAG, hepatitis B surface antigen; HCV, hepatitis C; HCVAb, hepatitis C antibody; NAS, neonatal abstinence syndrome; NRT, nicotine replacement therapy.
[a]Consent form compliant with 42 Code of Federal Regulations, part 2, regarding disclosure of substance use treatment status.
[b]Refers both to date that blood was drawn and date that laboratory test results were available.
[c]The development of a Plan of Safe Care at the time of newborn discharge is mandated by federal law for each newborn affected by prenatal substance exposure. Each state is required to pass rules determining how this mandate is to be carried out by hospital staff, and variation exists between the 3 states represented in this pilot.
[d]Counseling provided about risks of cannabis and other nonprescribed substances.
[e]Refers to any form of tobacco intervention: counseling, NRT, or referral.

checklist in a context-sensitive manner, without sacrificing essential elements identified by the Advisory Group.

To be sensitive to natural practice conditions, we did not impose standard implementation guidelines. Instead, each site was assisted by project team members to create a process map illustrating their local practice workflow, to determine how and where to best introduce the checklist.

Women receiving prenatal care at participating sites were considered eligible to have the checklist included in their care at the time that OUD was identified. The checklist itself was designed as a fillable form to allow documentation when a specific item was addressed (Table 1). Pilot practices were instructed to use it in the following 2 ways: (1) to guide the care provided to each woman with OUD and (2) where possible, to incorporate it in her health record as a communication tool for health care providers caring for the woman and newborn at the time of birth.

Study of the Intervention

To evaluate the effectiveness of this novel implementation approach, we tracked checklist utilization by clinicians by calculating the proportion of eligible records in which the checklist was deployed, as well as the proportion of eligible records that included a substance-related diagnosis in the problem list. Changes in care processes were measured through reviewing health records. We tracked rates of hepatitis C screening, pharmacotherapy for co-occurring mental health disorders, smoking cessation counseling and treatment, access to naloxone, and patient education about breastfeeding and risks of non-prescribed substances. We also tracked clinical outcome measures, including birth weight, gestational age at birth, urine toxicology, and use of tobacco products at time of birth, using hospital discharge summaries.

To protect patient privacy, deidentified data for women with OUD who received prenatal care at pilot sites were abstracted from health records by a member of that site's clinical team at 8 weeks after birth. Data were uploaded to a secure Research Electronic Data Capture (REDCap) database designed for the project. REDCap reports were reviewed by the project team, and discrepancies were reconciled through discussion with sites.

Analysis

Data were transferred from REDCap to Stata (StataCorp LLC, College Station, TX) to calculate descriptive and simple statistical comparisons. Process measures and clinical outcomes for women receiving care prior to implementation of the checklist were compared with those of women receiving care after implementation. Chi-square tests were used for categorical data, and two-sample t tests (unpaired) were used for continuous variables. To avoid introducing bias in favor of the intervention, missing values were assumed to be unchanged from baseline (before checklist implementation) for the purpose of analysis.

OUTCOMES

Eight NNEPQIN-affiliated sites that provided maternity care to women with OUD volunteered to implement the checklist, give feedback on the usability and contents of the toolkit, and participate in the learning collaborative. Pilot testing occurred over 13 months in 2017 and 2018. Data were collected from the records of 223 women with OUD, 55 of whom were cared for prior to implementation of the checklist and 168 afterwards. In the combined sample (N = 223), 42 (19%)

of women with OUD were treated with methadone (Methadose), 167 (75%) with buprenorphine (Subutex/Suboxone), and 14 (6%) did not receive any medication-assisted treatment. There was a nonsignificant increase in the proportion of women receiving treatment with buprenorphine from 65.5% to 78.0% over the course of the 13 months. In the cohort before checklist implementation, 25.5% received care in an integrated program in which they received medication-assisted treatment and maternity care; this number increased to 35.7% after implementation ($P > .05$; Table 2). No sites dropped out of the learning collaborative, although one stopped collecting data midyear after a key staff person left the practice.

Checklist Utilization

The checklist was successfully incorporated into the health record in 131 (78.0%) of the records reviewed after implementation. Two sites were unable to accomplish integration in an EHR and utilized the checklist in paper format. Both reported sharing a copy with patients as a working document. One site used the checklist only as a practice guideline, rather than including it in women's records. Learning collaborative participants from all sites reported that they found the checklist helpful in improving the quality of care they provided.

Process Change

Significant improvement also occurred in several key care processes included on the checklist (Table 3). There was a statistically significant increase in the proportion of records in which a diagnosis related to substance use appeared on the problem list, from 90.9% before implementation to 98.2% after ($P = .01$). The proportion of women who were offered access to naloxone (Narcan) increased from 10.9% to 36.3% ($P < .001$), along with the proportion of smokers for whom nicotine replacement therapy was prescribed (9.1% to 26.8%; $P = .01$). More women were counseled about the benefits of breastfeeding (50.9% vs 72.0%; $P < .01$), and the proportion of women testing positive for hepatitis C antibody who had follow-up testing to determine hepatitis C chronicity also increased (66.7% vs 88.9%; $P = .04$). There were nonsignificant increases in the proportion of women diagnosed with a co-occurring psychiatric illness (63.6% vs 72.0%) and the proportion of women with diagnosed psychiatric illness who were prescribed a psychiatric medication (25.7% vs 40.0%; $P > .05$ for both).

No changes in clinical outcomes reached statistical significance (Table 4). Excluding twin births, the preterm birth rate before checklist implementation was 11.1%, decreasing to 10.4% after implementation, and the rate of singleton low-birth-weight newborns decreased from 16.7% to 12.2% ($P > .05$ for both). The rate of breastfeeding at hospital discharge remained stable (69.1% vs 70.2%; $P = .87$), despite improvement in antenatal counseling. Similarly, the rate of tobacco use did not change significantly before and after implementation (80% vs 84.5%; $P = .43$), despite significant increases in the proportion of smokers who were prescribed nicotine replacement therapy (Tables 3 and 4).

Table 2. Demographic Characteristics, Before and After Checklist Implementation (N = 223)

Demographic Characteristics	Before Implementation (n = 55)	After Implementation (n = 168)	P Value
Age at birth, n (%), y			.31
≤17	0	1 (0.6)	
18-24	17 (30.9)	36 (21.4)	
25-44	38 (69.1)	131 (78)	
Race and ethnicity, n (%)			
White	53 (96.4)	168 (100)	.01
Black	1 (1.8)	0	.08
Other	1 (1.8)	0	.08
Hispanic or Latino	2 (3.6)	3 (1.8)	.51
Parity, n (%)			.24
Multiparous	44 (80)	121 (72.0)	
Nulliparous	11 (20)	47 (28.0)	
Treatment type, n (%)			.18
Methadone	14 (25.5)	28 (16.7)	
Buprenorphine products	36 (65.5)	131 (78.0)	
No MAT	5 (9.1)	9 (5.4)	
Treatment integration[a], n (%)			.32
Referral-based MAT	36 (65.5)	98 (58.3)	
Colocated MAT	14 (25.5)	60 (35.7)	
Number of prenatal visits, mean (SD)	10.2 (5)	11.1 (5.2)	
Weeks' gestation at prenatal care entry at site[b], n (%)	–	13.4 (7.7)	–
≤13	–	108 (64.3)	
14-28	–	48 (28.6)	
≥29	–	12 (7.1)	

Abbreviation: MAT, medication-assisted treatment.
[a]Treatment integration refers to whether a woman received MAT and maternity care within the same practice (colocated) or is referred to an external provider for MAT (referral-based).
[b]Gestational age at entry to prenatal care was added for records after implementation of the checklist to track length of exposure time to checklist interventions.

Table 3. Change in Care Processes (N = 223)

Care Processes	Before Checklist (n = 55), n (%)	After Checklist (n = 168), n (%)	P Value
Substance-related diagnosis on problem list	50 (90.9)	165 (98.2)	.01
Naloxone prescription discussed/offered	6 (10.9)	61 (36.3)	<.001
Psychiatric diagnosis other than SUD in problem list	35 (63.6)	121 (72.0)	.24
Treated with psychiatric medication if diagnosed with psychiatric illness[a]	9 (25.7)	48 (40.0)	.12
Nicotine replacement prescribed[b]	4 (9.1)	40 (26.8)	.01
Screened for hepatitis C antibody	49 (89.1)	160 (95.2)	.10
Tested for chronic hepatitis C if antibody positive[c]	10 (66.7)	48 (88.9)	.04
Breastfeeding education documented	28 (50.9)	121 (72.0)	<.01

Abbreviation: SUD, substance use disorder.
[a]Denominator for this variable limited to patients who had a diagnosed psychiatric illness.
[b]Denominator for this variable limited to patients who smoked.
[c]Denominator for this variable limited to patients testing positive for the hepatitis C antibody (n = 15 [27.3%] before checklist implementation; n = 54 [32.1%] after checklist implementation). Total population rate of chronic hepatitis C was 15.2% (30/198) among those tested.

DISCUSSION

This implementation pilot demonstrates the feasibility of using a checklist and learning collaborative to improve delivery of evidence-based care to pregnant women with OUD. Learning collaborative participation enabled practices to share strategies for incorporating guideline-concordant care into daily practice. The acceptability of the checklist was demonstrated by the extent to which it was utilized, either through integration into an EHR system or in paper format, and through endorsement by clinicians during learning

Table 4. Clinical Outcomes (N = 223)

Clinical Outcomes	Before Checklist (n = 55), n (%)	After Checklist (n = 168), n (%)	P Value
Drug screen positive in third trimester or at admission	21 (38.2)	49 (29.9)	.25
Preterm birth[a,b]	6 (11.1)	17 (10.4)	.88
Low birth weight[a,c]	9 (16.7)	20 (12.2)	.40
Attended postpartum visit	32 (58.2)	104 (62.7)	.56
Breastfeeding at time of hospital discharge	38 (69.1)	118 (70.2)	.87
Tobacco use at time of birth	44 (80)	142 (84.5)	.43

[a]Singleton births only (n = 54 before checklist implementation; n = 164 after checklist implementation).
[b]Preterm: <37 weeks' gestation.
[c]Low birth weight: ≤2500 grams.

collaborative sessions. Significant improvement in care processes were achieved in several measures, including substance-related diagnosis being entered into the problem list, providing access to the lifesaving medication naloxone, increased breastfeeding education, diagnostic testing for hepatitis C, and nicotine replacement for tobacco use disorder. This pilot was not sufficiently powered to demonstrate improvement in clinical outcomes for women and newborns.

Lessons Learned

This project demonstrated that regional perinatal quality collaboratives can play a central role in addressing the complex problem of perinatal OUDs. Engaging with NNEPQIN members to elicit input about their needs informed an approach which proved to be relevant and useful. Implementation across diverse EHR systems proved challenging, underscoring the need to include expertise in information technology on improvement teams.

Over the 2 years of this project, perinatal opioid use has become a focus of national policy, advocacy, and related initiatives by professional organizations. During the same period, national guidance documents were released on the same topic.[14,17] The community of practice developed through our learning collaborative facilitated awareness of these resources among participants and may have further contributed to observed improvements in care. Three of our pilot sites also received funding to enhance their programs, in part because of their ability to report site-specific outcomes.

Internal and external pressures for change are critical to the success or failure of implementation programs. Equally essential is the presence of mechanisms through which change can occur, in the form of innovations relevant to a specific context and capable of adaptation and pilot testing.[21] This project confirmed the need for adaptation of interventions by sites while maintaining fidelity to evidence-based guidelines through participation in the learning collaborative and access to toolkit resources.

Strengths and Limitations

Strengths of this project include the simplicity of the checklist approach, relevance of the intervention to the needs described by regional clinicians, the community of practice provided by the learning collaborative, and the avoidance of standardized implementation protocols that would have required altering the conditions in which the checklist was deployed.

Limitations to the generalizability of this approach include the lack of diversity in the population served, reflecting the demographics of pregnant persons with OUD in northern New England. Thus, adaptations may be needed for other contexts or communities. Additional limitations include the pre-post design, lack of a control group, and data quality risks inherent in relying on health records as a source. These factors preclude the ability to attribute observed improvements to project interventions per se.

CONCLUSION

The success or failure of an intervention to meet and sustain improvement targets has been attributed to a "subtle interplay between the content (the what) of change, the context (the where) of change, and the process (the how) of change."[40] Therefore, effective implementation across diverse settings requires an approach that balances adaptation to context while holding true to the core elements essential to evidence-based care.[20,21]

The urgency of the current opioid epidemic and its impact on maternal and child health underscore the need for simple and effective mechanisms to improve the maternity care of women with OUDs. Our project was able to demonstrate the success of one such approach, with promising implications for practice change. The recent release of national practice guidelines and safety initiatives for the care of this vulnerable population provides a rich opportunity to take this work forward on a larger scale.[17,19]

AUTHORS

Daisy Goodman, CNM, DNP, MPH, CARN-AP, is an assistant professor of obstetrics and gynecology at the Geisel School of Medicine and teaches health care quality improvement at the Dartmouth Institute. She is a member of the treatment team at Dartmouth-Hitchcock's Moms in Recovery program, an multidisciplinary substance use treatment program for pregnant and parenting women.

Alexandra B. Zagaria, BS, is a project manager and implementation specialist in the department of psychiatry addiction

treatment programs at Dartmouth-Hitchcock Medical Center. She is also earning her MPH from the Dartmouth Institute within the Geisel School of Medicine at Dartmouth.

Victoria Flanagan, MS, RN, is a perinatal nurse educator and Operations Director for the Northern New England Perinatal Quality Improvement Network.

Farrah Sheehan Deselle, MSN, RN, CLC, is the Childbirth & Parenting Preparation, Education & Support Program Coordinator at Catholic Medical Center in Manchester, NH.

Amanda R. Hitchings, PsyD, is a clinical psychologist practicing integrated medicine in a variety of specialty medicine practices, including women's health, panic management, and weight and wellness at Dartmouth-Hitchcock. She is an associate professor at Antioch University's clinical psychology program.

Renee Maloney, RN, is the clinical nurse manager at the Pregnancy Care Center at Catholic Medical Center in Manchester, NH. She is the coordinator of Roots for Recovery, a comprehensive recovery program at the Pregnancy Care Center for pregnant and postpartum women with substance use disorder.

Themarge A. Small, MD, is a clinical assistant professor of obstetrics and gynecology and a generalist obstetrician-gynecologist in practice at Southwestern Vermont Medical Center. She is part of the team of maternity nurses, pediatricians, and midwives who established the hospital's SafeArms program, a program to support pregnant and postpartum women with histories of substance use.

Autumn Versace Vergo, CNM, is a certified nurse-midwife in clinical practice at Cheshire Medical Center, an affiliate of the Dartmouth-Hitchcock Health System in Keene, NH. She is part of the care team at Cheshire's Mothers in Recovery, an multidisciplinary substance use treatment program for pregnant and parenting women and their families.

Martha L. Bruce, PhD, MPH, is a professor in the Department of Psychiatry, Department of Community and Family Medicine, and the Dartmouth Institute for Health Policy and Clinical Practice at the Geisel School of Medicine at Dartmouth and Principal Scientist at Dartmouth-Hitchcock Medical Center.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Template for health record to facilitate best practice in the care of pregnant women with opioid use disorders.

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