# Mother & Baby Substance Exposure Toolkit

# Treatment

A part of the California Medication Assisted Treatment Expansion Project
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# Implement Trauma-Informed Care to optimize patient engagement

Best Practice No. 7

Outpatient, Labor and Delivery, Nursery/NICU, and Treatment

# Overview

Implement Trauma-Informed Care to optimize patient engagement in prenatal care.

# Why we are recommending this best practice

Many pregnant women with opioid use disorder (OUD) have experienced significant traumatic events, adversity, and toxic stress in their lives, including sexual abuse and other Adverse Childhood Experiences (ACEs). Trauma refers to intense and overwhelming experiences that involve serious loss, threat, or harm to a person's physical and/or emotional well-being. These experiences may occur at any time in a person's life; they may involve a single traumatic event or may be repeated over many years. These traumatic experiences often overwhelm a person's coping capacity. In many cases, prescription and/or illicit opioid use begins as a coping mechanism to manage the symptoms of post-traumatic stress disorder (PTSD).

Trauma-Informed Care is a strengths-based service delivery approach "that is grounded in an understanding of and responsiveness to the impact of trauma, that emphasizes physical, psychological, and emotional safety for both providers and survivors, and that creates opportunities for survivors to rebuild a sense of control and empowerment" (Hopper E, et al, 2009). Trauma-Informed Care acknowledges a patient's life experiences as key to improving engagement and outcomes while lowering unnecessary utilization. It changes the paradigm from one that asks, "What's wrong with you?" to one that asks, "What has happened to you?" Just as with "universal precautions" for infection control, Trauma-Informed Care necessarily assumes that every patient, and indeed every provider or staff person, has a history of traumatic stress.

In order to be successful, Trauma-Informed Care must be adopted at both the organizational and clinical levels and cannot be implemented as a singular, disconnected intervention that occurs between providers and a few patients who are seemingly appropriate for this kind of care based on their diagnosis and social history. Successful implementation requires a commitment from the agency, service line, or department for significant culture change at the organizational and clinical levels. Trauma-Informed Care is not a "one and done" training for staff and management. Rather, it is a comprehensive journey to implement systematic changes in how care is delivered for every person who enters care. It involves vigilance in anticipating and avoiding institutional processes and individual practices that are likely to retraumatize individuals, and it upholds the importance of consumer participation in the development, delivery, and evaluation of services. Furthermore, a trauma-informed organizational structure addresses the impact of trauma across the lifespan and the critical role of health care service delivery systems to interrupt the cycle of trauma by employing trauma-aware services, policies, and mindsets.

SAMHSA recognizes six principles that are fundamental to a Trauma-Informed Approach:

- Safety. Do we help promote a sense of safety for every person?
- Trustworthiness and Transparency. Do we conduct all patient care with complete transparency and with the goal of building and maintaining trust?
- Peer Support. Do we provide any peer support services or mutual help services that build upon the trauma-informed framework of safety, trust, and collaboration in care?
- Collaboration and Mutuality. Do we share power in decision making in a meaningful way and maximize the ability of patients to engage in care decisions?
- Empowerment, Voice, and Choice. How are we providing the resources necessary to both staff and patients in order to ensure skill building, goal-setting, and non-coercive treatment for every patient
- Recognition of cultural, historical, and gender issues. Are we actively working to move beyond cultural stereotypes based on gender-identity, race, sexual orientation, socioeconomic status, and more? Do we recognize historical trauma and impact on racebased disparities?

# **Strategies for Implementation**

- The Trauma-Informed Care Implementation Resource Center, developed by the Center for Health Care Strategies with support from the Robert Wood Johnson Foundation, offers a one-stop information hub for health care providers interested in implementing Trauma-Informed Care. It houses the following:
  - foundational content regarding the impact of trauma on health
  - o testimonials from providers who have adopted trauma-informed principles
  - in-the-field examples illustrating how to integrate Trauma-Informed Care into health care settings
  - o practical strategies and tools for implementing trauma-informed approaches
  - information for state and federal policymakers interested in supporting Trauma-Informed Care
- Review SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach (refer the Resources section of this Best Practice), which offers first steps to organizational assessment and development around the Trauma-Informed Care model of care. Identify how this model of care can be integrated into your current care model.
- Create a comprehensive organizational structure, whereby the entire workforce operates under a Trauma-Informed Care model. The San Francisco Department of Public Health Workforce Training Model and The Sanctuary Model examples can be found in the Resources section of this Best Practice.
- Start to adopt new organizational and clinical practices that address the impact of trauma on patients and staff, including but not limited to:
  - Lead and communicate about being trauma-informed
  - Engage patients in organizational planning and shared decision making about treatments
  - Train both clinical and non-clinical staff in trauma-specific approaches and build a trauma-informed workforce

- Create a safe physical and emotional environment
- Prevent secondary traumatic stress in staff
- Hold each other accountable
- Screen all patients for trauma
- Engage referral sources and partner organizations that are also traumainformed

### Resources

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### **Holly Smith**

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Holly Smith is a certified nurse-midwife with 20 years' experience in diverse practice settings. She is the project manager for the CMQCC/CPQCC Mother and Baby Substance Exposure Initiative. Previous to this role, she was a the lead editor for the CMQCC Toolkit to Support Vaginal Birth and Reduce Primary Cesareans, and a clinical lead for the CMQCC Collaborative to Support Vaginal Birth and Reduce Primary Cesareans, a large-scale quality improvement project with over 90 California hospitals. Her primary role as clinical lead focused on assisting southern California hospitals with the implementation of evidence-based practices to reduce cesarean. She is a hospital coach and steering committee member for the American College of Nurse-Midwives' Reducing Primary Cesareans Project, and expert consultant on various national and state quality improvement and health policy initiatives. Additionally, she chairs the Health Policy Committee of the California affiliate of the American College of Nurse-Midwives and is a health policy consultant to the California Nurse-Midwives Foundation.

### **Margaret Yonekura**

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Margaret Lynn Yonekura, M.D., F.A.C.O.G. is a board certified obstetrician-gynecologist with subspecialty certification in Maternal-Fetal Medicine. She is a recognized expert in the fields of infectious diseases in Ob-Gyn and perinatal substance abuse. Throughout her career Dr Yonekura has established comprehensive care programs to address her patients' complex needs. She is currently a member of the Women's Health Policy Council of L.A. County's Office of Women's Health, L.A. County Perinatal & Early Childhood Home Visiting Consortium, Reproductive Health and the Environment Advisory Committee, and L.A. County Diabetes Prevention Program Community Advisory Committee.

# Understand and implement the principles of Motivational Interviewing

Best Practice No. 8

Outpatient, Labor and Delivery, Nursery/NICU, and Treatment

# Overview

Motivational Interviewing (MI) is a patient-centered counseling approach rooted in key theoretical principles—including decisional balance, self-perception theory, and the transtheoretical model of change—that uses directed techniques to enhance patients' intrinsic motivations for and reduce their ambivalence toward behavior change. Introduced in the early 1980s as a counseling strategy for encouraging behavior change among people with alcohol dependence, the principles, methods, and specific techniques employed in MI have been researched and analyzed for a variety of health conditions for which behavior change is a critical part of health-promoting interventions. MI has now been firmly established as an effective, evidence-based practice in the treatment of substance use disorders (SUDs) and other health conditions including diabetes, obesity, and smoking cessation.

MI uses principles of collaboration between the provider and client (rather than confrontation), the intent of which is to develop rapport and trust, along with evocation of the client's own thoughts and ideas (rather than imposing the provider's opinions), and autonomy and self-efficacy (rather than authority). MI recognizes that true motivation for behavioral change rests within the client. While the provider may have different opinions about the timing or approach to a particular condition, an understanding of the client's experience and beliefs and ultimately eliciting the client's own motivations for changing unhealthful behaviors is more likely to result in lasting change.

The optimal implementation of this best practice would be for hospital and office-based providers to organize MI trainings and regular practice opportunities for all of their staff, especially clinical staff involved in gathering patient information who might have the opportunity to motivate behavior change. In the absence of resources for MI training, this best practice includes several techniques that can be employed without significant training. Additionally, the curriculum included in the Resources section of this Best Practice incorporates links to several web-based videos demonstrating some of these techniques that may be helpful adjuncts to staff interested in further MI exposure and practice.

# Why we are recommending this best practice

- Motivation is a key to behavior change. It is multidimensional, dynamic, and fluctuating; influenced by social interactions; and can be modified and influenced by the provider's style. The provider's task is to elicit and enhance motivation.
- MI is effective as an adjunct to enhancing entry into and engagement and retention in interventions that support various kinds of behavior change, including but not limited to substance abuse treatment. It has also been used to encourage rapid return to

treatment following relapse.

• MI is increasingly used as a stand-alone brief intervention during routine encounters with patients.

- MI is an approach that has been empirically shown to be more effective than giving advice, which tends to occur frequently in health care delivery.
- "Readiness to change bad habits is generally a developmental process, and the
  precepts of MI, including patience, listening, empathy, and change talk, can be useful
  tools." (Prochaska J, et al, 1995).

# **Strategies for Implementation**

Ideally, providers can use MI curricula to become more proficient in these techniques, and all levels of staff can participate in these curricula and employ these techniques. One such curriculum is included in the Resources section for this Best Practice. In the absence of formal training, several specific MI strategies and techniques are described below.

Incorporate the foundational principles of MI into communication with pregnant and parenting women with opioid use disorder (OUD). These foundational principles of MI should be employed continuously over time and include:

- Express empathy through reflective listening
- Develop discrepancy between patient's goals or values and their current behavior
- Avoid argument and direct confrontation
- Adjust to patient resistance rather than opposing it directly
- Support self-efficacy and optimism

Employ the following general style of MI in all patient communication:

- Asking Permission Permission is a deeply respectful foundation of mutual dialogue
- **Engaging** Engagement is the establishment of trust and a mutually respectful relationship
- **Focusing** Focus is the ongoing process of seeking and maintaining a direction for the exploration conversation
- **Evoking** Evoking refers to eliciting the patient's own motivation for change.
- **Planning** Planning is the process of deciding on a specific plan for change that the patient agrees is important and is willing to undertake.
- **Linear and Iterative Processes** Change talk within MI is both a linear and iterative process.

The following are specific motivational skills and strategies that can be practiced and incorporated into all patient engagements, especially those that involve behavior change and compliance with treatment plans. Each of these strategies is described in more detail in the MI Curriculum included in the Resources section of this Best Practice.

Employ the OARS+ model as one set of specific MI skills.

• Open ended questions elicit crucial information that may not be gathered from close ended questions.

- Instead of asking "Have you used any drugs during your pregnancy?", one might say
  "I treat a number of women who have used prescription medications and other drugs
  during their pregnancy. Please share with me which kinds of prescription meds or
  other drugs, if any, you have used during or before this pregnancy."
- Instead of asking "Have you ever been in treatment?", one could request "Tell me about your recovery journey."
- Affirmations are statements of appreciation
  - "I'm impressed that you followed up with the MAT referral"
  - "You've stayed off drugs for 2 months. That's great!"
- **R**eflections establish understanding of what the patient is thinking and feeling by saying it back to the patient as statements, not questions.
  - Patient: "I've been this way for so long."
  - Provider reflection: "So this seems normal to you" or "So this seems like a hard cycle to break."
- **S**ummaries are highlights of the patient's ambivalence that are slightly longer than brief reflections and serve to ensure understanding and transition from one topic to another.
  - For a patient wanting to stop using drugs during pregnancy: "You have several reasons for quitting drugs: You want to get your life back, you want to give your baby the best chance at a healthy life, and you want to be able to manage life's issues without relying on drugs as a crutch. On the other hand, you're worried about what kind of recovery path would work for you; you're worried that you won't have the motivation and strength to stick with a recovery path. Would that sum it up?"

**Rolling with resistance** requires the listener/provider to pause and shift conversations when signs of an argument or confrontation begin to appear. Resistance behavior occurs when points of view differ, generally when the provider is moving the patient ahead too quickly, or the provider fails to understand something of importance to the patient. When resistance appears, the listener/provider should change strategies and utilize OARS techniques.

**Developing discrepancy** involves the listener/provider guiding the conversation so the patient can articulate their personal beliefs and future goals (listen especially for statements about life, family, health, financial status, living situation, and other personal considerations). Developing discrepancy between the patient's behaviors and their broader life goals is essential because patients are more often motivated to change when they arrive at that conclusion themselves rather than hearing it from someone else.

Change Talk is defined as statements made by the patient that indicate motivation for,

consideration of, or commitment to change behavior. There are clear correlations between patients' change talk and outcomes. Once the listener/provider and patient have established a trusting relationship and have open communication about the patient's substance use, the listener/provider can guide the patient to expressions of change talk using some of the techniques listed below. Each of these strategies is described in more detail in the Motivational Interviewing Curriculum included in the Resources section of this Best Practice, along with additional strategies for eliciting change talk.

- Preparing change talk employs the DARN model as one set of specific MI skills
  - Desire to change (Ask "Why do you want to make this change?")
  - **A**bility to change (*Ask "How might you be able to do it?"*)
  - **R**easons to change (*Request "Share one good reason for making this change."*)
  - **N**eed to change (Ask "On a scale of 0-10, with 10 being the highest, how important is it for you to make this change?")
- Implementing change talk employs the CAT model as one set of specific MI skills.
  - **C**ommitment (*Ask "What do you intend to do?"*)
  - **A**ctivation (*Ask "What are you ready (or willing) to do"?*)
  - Taking steps (Ask "What steps have you already taken?")

**Coding and Reimbursement** – MI focused on increasing the patient's understanding of the impact of their substance use and motivating behavior change can be coded for reimbursement whenever a positive screen (through interview, formal screening tool, or toxicology) is identified and documented in the medical records. Evaluation and Management (E/M) service codes for both assessment and intervention are listed below (and can be coded with modifier 25 when they are performed during the same clinical visit as other E/M services):

- 99408 Alcohol and/or substance abuse (other than tobacco) structured assessment and brief intervention services 15-30 minutes (the comparable Medicare code is G0396)
- 99409 Alcohol and/or substance abuse (other than tobacco) structured assessment and brief intervention services greater than 30 minutes (the comparable Medicare code is G0397)

# **Deep Dive**

Decisional Balance is a Motivational Interviewing tool that encourages change talk by eliciting the client's own ideas and motivations for change. The grid below is an easy way of remembering the questions asked in Decisional Balance, which are most effective when asked in sequence.

- 1. **What are some of the good things about using** *fill in the substance*? This will not elicit much change talk, but will get the client talking in a non-defensive way.
- 2. **What are some of the bad things about using** *fill in the substance*? This question begins to elicit a client's ambivalence about their behavior and will start the change talk.

# 3. What are some of the downsides of getting into a treatment/recovery program?

Clients will often start talking about their fears.

# 4. What are some of the good things about getting into a treatment/recovery program?

This question will likely elicit the most change talk, as the client discusses their own ideas and motivations for change. When this comes from the client instead of the provider, it comes without resistance and may include some motivations that the provider would not have considered.

	Good	Not so Good
Not Changing	What are the advantages of the status quo?	What are the disadvantages of the status quo?
Changing	What are the advantages of changing	What are the downsides of changing?

Decisional Balance Grid

# Resources

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Dr. Helen DuPlessis is a Physician Principal at Health Management Associates.

She has a rich history of involvement in healthcare administration for a variety of organizations, expertise in program and policy development, practice transformation, public health, maternal, and child health policy, community systems development, performance improvement, and managed care. Prior to joining HMA, Dr. DuPlessis served as the chief medical officer with St. John's Well Child and Family Center. Other notable professional experiences include her work as senior advisor to the UCLA Center for Healthier Children, Families and Communities where she provided leadership, research, program development support, counsel and representation to local, state and national efforts, and community level systems transformation. She also trained and mentored students in various disciplines and educational levels.

# Encourage breastfeeding for women with opioid use disorder

Best Practice No. 9

Outpatient, Labor and Delivery, Nursery/NICU, and Treatment

# Overview

Women should feel empowered to make an informed decision about newborn feeding. Women should be given information about the benefits of breastfeeding, as well as information that addresses concerns specific to opioid use disorder (OUD) and breastfeeding.

# Why we are recommending this best practice

The first few hours and days of a newborn's life constitute a critical window for establishing lactation. Breastfeeding confers many advantages on both mother and infant. The United States Surgeon General, World Health Organization (WHO), and American Academy of Pediatrics (AAP) recommend exclusive breastfeeding for the first six months unless contraindicated.

California State Bill (SB) 402, signed into law in 2013, states "This bill would require all general acute care hospitals and special hospitals that have a perinatal unit to adopt, by January 1, 2025, the 'Ten Steps to Successful Breastfeeding,' as adopted by Baby-Friendly USA, per the Baby-Friendly Hospital Initiative, or an alternate process adopted by a health care service plan that includes evidenced-based policies and practices and targeted outcomes, or the Model Hospital Policy Recommendations as defined."

Although a stable mother being treated for OUD with pharmacotherapy is encouraged to breastfeed her infant, there are some situations where breastfeeding is not recommended, including if the mother is HIV-positive, has active tuberculosis, has active herpes simplex lesions, is Hepatitis B or C-positive and has cracked or bleeding nipple(s), or has returned to illicit or inappropriate drug use.

**HIV:** In resource rich areas such as the United States, the CDC recommends AGAINST breastfeeding in mothers with HIV regardless of the viral load or treatment history.

**Hepatitis B, Hepatitis C, Herpes Simplex:** The CDC recommends breastfeeding for women with Hepatitis B infection when infants have been appropriately immunized with Hepatitis B Immunoglobulin and vaccine; and for women with Hepatitis C infection, as long as nipples are not cracked or bleeding. If the mother with Herpes Simplex Virus has lesions on the breast, or who has Hepatitis B or C and has cracked or bleeding nipples, the CDC recommends to temporarily stop nursing and to express and discard the breastmilk. When the nipple(s) are well-healed and no longer bleeding, the mother may return to breastfeeding. If only one side is affected, the mother may continue to breastfeed on the unaffected side.

**Active (untreated) tuberculosis:** The AAP recommends against breastfeeding in the setting

of active, infectious tuberculosis. In this situation, expressed milk can still be given to the newborn. Breastfeeding can resume after a minimum of 2 weeks of treatment for tuberculosis, and when the mother is documented to no longer be infectious.

Illicit or Inappropriate Drug Use: According to the AAP "maternal substance abuse is not a categorical contraindication to breastfeeding" and therefore well-nourished narcotic dependent mothers being treated for OUD with pharmacotherapy are encouraged to breastfeed in the absence of illicit drug use. Breastfeeding is contraindicated if "relapse" occurs, or a return to any illicit drug use or frequent legal substance misuse, especially if relapse has occurred in the 30-day period prior to delivery. Infrequent substance use, especially if outside of the 30-day window before delivery, may not necessarily be a contraindication to breastfeeding, but each woman must be carefully and individually evaluated for type of substance used, length of time since last use, and other risk factors. Refer to ABM Clinical Protocol #21 in the References section of this Best Practice for more detailed guidelines.

# **Strategies for Implementation**

- **Develop breastfeeding protocol for women with OUD.** Create a multidisciplinary team ideally including obstetricians, midwives, family physicians, pediatricians, nurses, lactation specialists, pain/addiction specialists, pharmacists, and social workers to create a facility-specific protocol addressing the following topic areas:
  - Information for women with OUD and clinicians caring for them: Create userfriendly resources on the benefits of breastfeeding for women with OUD and their newborns and include important contraindications.
  - Develop a protocol for identification of women with OUD and mobilization of required resources to support breastfeeding, emphasizing best practices such as early skin-to-skin care.
  - Develop a plan for outpatient breastfeeding and newborn nutritional support.
     Develop a workflow to ensure pregnant patients with OUD are discharged with a plan to support breastfeeding and the overall nutrition for their newborns; this plan should include appropriate short interval pediatric follow-up, access to advice on lactation continuation, and access to local or online breastfeeding support resources.
- Train the workforce on breastfeeding for women with OUD. Educate physicians, nurses, and other care team members on the benefits of breastfeeding for women with OUD and institute multimodal strategies for implementation of developed protocols.
  - Educate clinical staff on the strength of evidence and criteria for safety of breastfeeding for women with OUD. Determine appropriate avenues through which to educate hospital staff (e.g., emails, physical bulletin boards, staff meetings) and mitigate discrimination and bias toward patients with OUD.
  - Train providers on OUD treatment protocols. Create standards for providers caring for pregnant patients to provide information relevant to breastfeeding decisions and ask questions about the mother's concerns and barriers surrounding breastfeeding.
- Implement quality improvement strategies to improve breastfeeding in women

**with OUD:** Create process metrics that allow for regular evaluation of facility-based breastfeeding support protocols.

- Define target metrics for breastfeeding in OUD. Develop facility-specific metrics for tracking implementation and effectiveness of the breastfeeding program for women with OUD, including measurement of initiation and continuation of breastfeeding.
- Delineate role(s) for OUD treatment assessment and improvement. Designate either an individual or a team to take accountability for ongoing facility-level assessment and improvement of metrics for breastfeeding in women with OUD.



# **Baby M**

As soon as Baby M is born, the maternity nurse asks if she can place him on Kayla skinto-skin. Although Kayla had been unsure about breastfeeding, with encouragement from the nurse with whom she has begun to establish a trusting relationship, she decides to place Baby M on the breast. This makes Kayla feel happy and helps her bond with Baby M. She feels that she can soothe his cries by breastfeeding.

Breastfeeding is beneficial for the health of both the mother and newborn. It reduces the risk of infection, immune mediated disorders, and obesity in the newborn; and it reduces the risk of postpartum hemorrhage, hypertension, diabetes, and breast and ovarian cancer in the mother. In newborns at risk for NAS, breastfeeding reduces the need for pharmacologic treatment. The process of breastfeeding stimulates the release of oxytocin. Oxytocin induces the dopaminergic pathway of the reward system, which mediates a mother's behavioral response to her newborn's cues, promoting bonding and attachment between mother and newborn. Supporting breastfeeding in a woman with OUD empowers her to provide the best care for her newborn. The reward and stress response pathways may be altered in women with OUD, making it especially important that providers promote breastfeeding in this vulnerable population to optimize emotional and behavioral outcomes for both mother and newborn.

While promoting breastfeeding and skin-to-skin care, it is important to emphasize safe sleep methods. If a mother is fatigued or too sleepy to safely hold her newborn, she should lay the newborn on its back on a firm sleeping surface to decrease the risk of sudden infant death syndrome.

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Mimi Leza is the Perinatal Services Coordinator for Ventura County Public Health and currently the co-chair of the Perinatal Substance Use Taskforce of Ventura County. Her background is in Pediatric nursing with extensive experience in caring for NICU babies with NAS and children with prenatal substance use exposure. As a Public Health Nurse, she specialized in providing case management for pregnant and parenting women with SUD and recruiting and training perinatal providers in the SBIRT process.

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Dr. Pamela Flood is Professor of Anesthesiology, Perioperative, and Pain Medicine at Stanford University. Her research interests include prevention and reduction of pain and opioid use in women after delivery. She divides her clinical time between labor and delivery and her outpatient pain management clinic. She clinical work is directed toward compassionate weaning of high dose opioids and management of pelvic pain syndromes.

# Initiate medication assisted treatment in the prenatal setting

Best Practice No. 10

**Outpatient and Treatment** 

# Overview

Implement an outpatient protocol for evidence-based evaluation, treatment, and continuity of care for pregnant patients with opioid use disorder (OUD). Arranging for the provision of medication assisted treatment (MAT) on site is an optimal way to deliver the standard of care for pregnant women with OUD.

# Why we are recommending this best practice

The pregnant woman with OUD who presents for prenatal care has a unique opportunity to initiate treatment for OUD. While the care team may initially find such a patient challenging, they have a chance to introduce life-changing therapy. Along with the screening and brief intervention portions of SBIRT, obstetric providers can offer MAT treatment. Few obstetric providers have received training in OUD management and understandably feel reluctant to begin this practice. Obstetric providers often feel more comfortable referring patients with OUD to a stand-alone outpatient opioid treatment clinic or other office-based outpatient treatment (OBOT) program for induction and management of OUD with MAT. However, the desired future state in opioid treatment is for patients with OUD to be able to begin treatment wherever they receive medical or prenatal care. Providers who can initiate treatment for OUD will have a significant impact on the unmet treatment gap in their county.

# **Strategies for Implementation**

- Engage the whole team. Successful integration of a new service will require front office, back office, and providers all educated about the successful outcomes in pregnant women with OUD who are on MAT.
- Providers must receive a Drug Addiction Treatment Act of 2000 (DATA 2000) X waiver to be able to prescribe MAT. Federal legislation (SUPPORT Act, 2018) and previous legislation includes CNMs, NPs, and CRNAs in addition to physicians as eligible to complete this training. Online training programs are readily available. Physicians require 8 hours of training, and non-physician providers require 24 hours of training.
- Build policies/procedures for MAT to allow for a uniform care delivery system.
- Use a toolkit. Numerous toolkits exist that provide clinics with the education and resources needed to offer MAT. One such is example is the Providers Clinical Support System (PCSS). <a href="https://pcssnow.org/resources/clinical-tools/">https://pcssnow.org/resources/clinical-tools/</a>

• Identify who to call for help. Know how to refer patients who fail buprenorphine to methadone treatment programs when necessary. Consider using a consultation service such as the FREE Clinician Consultation Center at UCSF which has a Substance Use Warmline at 855-300-9595 and is available Monday through Friday during daytime business hours, and a specific Consultation line for licensed practitioners in California that is available 24/7. This line is staffed by physicians, pharmacists, and nurses with special expertise in pharmacotherapy options.

• Explore emerging therapies. Aside from traditional in-office induction, consider other modalities that best suit your patients. These include home and hospital induction, micro-dosing transition, and Buprenorphine Quick Start.

# Resources

- 1. SAMHSA Waiver Application and Training.
- 2. Providers Clinical Support System (PCSS). Clinical Tools.
- 3. Guidelines for Physicians Working in California Opioid Treatment Programs. Chapter 4.
- 4. ED Bridge. Buprenorphine Quick Start in Pregnancy Algorithm.
- 5. California Health Care Foundation Webinar: "Expanding Access to Buprenorphine in Primary Care Settings".
- 6. California Health Care Foundation. Everything You Need to Know About Buprenorphine.
- 7. Urban Institute: California County Fact Sheets: Treatment Gaps in Opioid-Agonist Medication Assisted Therapy (OA-MAT) and Estimates of How Many Additional Prescribers Are Needed.
- 8. UCSF Substance Use Warmline

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### **Holly Smith**

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Holly Smith is a certified nurse-midwife with 20 years' experience in diverse practice settings. She is the project manager for the CMQCC/CPQCC Mother and Baby Substance Exposure Initiative. Previous to this role, she was a the lead editor for the CMQCC Toolkit to Support Vaginal Birth and Reduce Primary Cesareans, and a clinical lead for the CMQCC Collaborative to Support Vaginal Birth and Reduce Primary Cesareans, a large-scale quality improvement project with over 90 California hospitals. Her primary role as clinical lead focused on assisting southern California hospitals with the implementation of evidence-based practices to reduce cesarean. She is a hospital coach and steering committee member for the American College of Nurse-Midwives' Reducing Primary Cesareans Project, and expert consultant on various national and state quality improvement and health policy initiatives. Additionally, she chairs the Health Policy Committee of the California affiliate of the American College of Nurse-Midwives and is a health policy consultant to the California Nurse-Midwives Foundation.

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Dr. Khan is an Addiction Medicine specialist and Chief of Addiction Medicine consult-liaison service and outpatient specialty clinic at Ventura County Medical Center. He is the medical director of Prototypes Southern California which has hundreds of residential treatment beds as well as medical-withdrawal (detox) beds throughout Southern California. Dr. Khan is the Medical Director of the Ventura County Backpack medicine group, and Primary Care Hepatitis C Eradication Project. His niche is managing SUD in pregnancy and is a national speaker on this topic.

# Implement an inpatient treatment protocol for pregnant women with opioid use disorder

Best Practice No. 11

Labor and Delivery and Treatment

### Overview

While the ideal timing for initiation of medication assisted treatment (MAT) would be early in the pregnancy, implementation of an inpatient protocol for evidence-based evaluation, treatment, and discharge of pregnant patients with opioid use disorder (OUD) is the next best opportunity to address the chronic disease of OUD and improve long term outcomes for the pregnant woman and her affected infant.

# Why we are recommending this best practice

The patient with OUD who presents to labor and delivery in labor also presents with a unique opportunity to initiate treatment for opioid use. While the provider and nursing staff may initially find such a patient challenging, they can introduce life-changing therapy at this distinct moment. Providers often feel uncomfortable prescribing MAT for various reasons, many of which are common misperceptions, including:

- Myth: Inpatient providers believe they cannot treat OUD because they do not have a waiver to prescribe MAT ("X waiver").
  - Fact: federal law allows providers without an X waiver to administer or dispense (but not prescribe) buprenorphine on an inpatient basis for up to 72 hours. This law is known as the "three-day rule" and provides for effective treatment of acute withdrawal in the emergency department or inpatient setting.
- Myth: There may be possible deleterious fetal effect.
  - Fact: MAT, particularly buprenorphine, is the gold standard for treatment of OUD and is safe during pregnancy. Split dosing or even higher overall dosing may be required during pregnancy. On the other hand, withdrawal is associated with high rates of relapse and poor outcomes for both mother and infant.
- Myth: Neonatal abstinence syndrome (NAS) will be more severe, especially with the higher doses of buprenorphine needed during pregnancy.
  - Fact: Buprenorphine reduces NAS severity and the dose is not correlated with NAS severity.

A clear, informed protocol that providers can leverage for safe management of OUD in

pregnant women will increase provider comfort in caring for these patients and optimizing health outcomes for patients and their newborns.

It is important to recognize that not all areas of the country have access to the same resources for MAT, especially for women who are pregnant. In rural and/or underserved areas, there may be access to only one type of treatment and/or treatment setting, and each group implementing this toolkit should become familiar with the treatment options available in their community. These settings may be integrated into primary care or OB/GYN offices (e.g., office-based outpatient treatment), stand-alone outpatient treatment programs, residential treatment programs, opioid treatment programs ("methadone clinics"), emergency departments, hospital labor and delivery units, or within the general hospital setting. Each of these locations has its own unique strengths and challenges. Referral protocols should be built by individual locations to reflect assessment of the severity of OUD matched with the ASAM level of care resources that are available in the local community with the goal of providing access to treatment for women during their pregnancy and after delivery.

### **Outpatient Services**

Not all women may require or accept inpatient induction of MAT. If a woman presenting for care declines inpatient or emergency department induction, ensure that the institution has referral processes in place to directly connect the patient with outpatient services, such as office-based outpatient treatment or an opioid treatment program, and provide a warm handoff.

# **Strategies for Implementation**

- Utilize a multidisciplinary team, ideally with obstetricians, midwives, psychiatrists, nurses, anesthesiologists, addiction and pain medicine specialists, pharmacists, and social workers to create a facility-specific protocol that addresses the following:
  - Evaluation of patients for OUD with a non-judgmental, trauma-informed approach (please see the Resources section of this Best Practice: Sample Evaluation of Opioid Use Disorder in Pregnancy Checklist).
  - Shared decision making for OUD treatment, emphasizing the risks of OUD in pregnancy and options for MAT, as well as the risks of supervised withdrawal (Please see the Resources section of this Best Practice: Considerations for, Treatment of Opioid Use Disorder in Pregnancy).
  - Development and utilization of a treatment algorithm for inpatient MAT initiation for both buprenorphine and methadone, including adjunctive therapies to optimize MAT induction (please see the Resources section of this Best Practice: Sample Inpatient Medication-Assisted Treatment Induction Algorithms and the Buprenorphine Quick Start in Pregnancy Algorithm).
  - Development and utilization of a treatment algorithm for outpatient buprenorphine induction. If capacity for close follow up with provider(s) comfortable with outpatient induction of buprenorphine in pregnancy is available, develop guidelines for which patients can consider outpatient induction of MAT and develop a protocol for outpatient buprenorphine induction (please see the Resources section of this Best Practice: Sample Outpatient Buprenorphine Induction Algorithm). Consider partnering with local residential treatment facilities and withdrawal management (detoxification) centers.

 Development of a Plan of Safe Care to ensure pregnant patients with OUD are discharged with appropriate transition to outpatient care with a focus on coordination of MAT (e.g., handoffs to methadone treatment programs and buprenorphine prescribing providers) and harm reduction. The "Transitions" section of this toolkit includes multiple best practices that will support development efforts in these areas (See Best Practice #29).

- Educate physicians, nurses, and other care team members on OUD in pregnancy, strategies for caring for patients with OUD, and implementation of developed protocols.
  - Create awareness of OUD in Pregnancy through various mediums to educate hospital staff about OUD in pregnancy (e.g., emails, physical bulletin boards, staff meetings) and mitigate stigma, bias and discrimination toward patients with OUD
  - Create opportunities for the workforce to learn about trauma-informed care in the inpatient setting (See Best Practice #7).
  - Train providers on OUD treatment protocols for pregnancy and encourage them to obtain a waiver to prescribe buprenorphine.
- Train nurses on OUD treatment protocols and the use of the Clinical Opiate Withdrawal Scale and the Ramsay Sedation Scale (refer to the Resources section of this Best Practice) in the care of patients taking buprenorphine and methadone (refer to the Resources section of this Best Practice: Considerations for Administration of Buprenorphine and Methadone).
- Create process metrics to regularly evaluate the implementation of the facility-based protocols.
  - Define target metrics for OUD treatment. Develop facility-specific metrics to track implementation and effectiveness of OUD treatment protocols (e.g., development of a dashboard if enough volume vs. audit of OUD cases if a few cases) and assess for disparities in treatment (e.g., examine outcomes by race, preferred language).
  - Delineate role(s) for assessment and improvement of OUD treatment. Designate either an individual or a team to take accountability for ongoing facility-level assessment and improvement of OUD treatment in pregnancy to ensure access and health equity.



# Kayla

When building an inpatient treatment protocol, consider increasing the total daily dose as we well as dividing the patient's MAT doses to help with acute pain control. For example, if Kayla is taking 24 mg of buprenorphine as an outpatient and has acute pain from her delivery, one may consider increasing her total daily dose to 32 mg but providing it in 8 mg doses every 6 hours. Build a basal/bolus pain control protocol into your admission order sets. Both buprenorphine and methadone can be divided into 6-8-hour dosing regimens to allow for better basal pain control. While it is clear that methadone maintenance therapy usually necessitates increases in the baseline daily methadone dose during pregnancy, especially during the third trimester to account for changes in pharmacokinetics, there is emerging evidence of a similar need to increase the daily dosage of buprenorphine during pregnancy. These recommendations are useful for pain management during the intrapartum and immediate post-partum period, after which a return to pre-labor dosing is appropriate.

Reference: Alford DP, Compton P, Samet JH. Acute pain management for patients receiving maintenance methadone or buprenorphine therapy. Annals of internal medicine. 2006;144(2):127-134.

# **Deep Dive**

For acute pain requiring bolus control, consider using a moderate affinity  $\mu$ -opioid agonist such as morphine IV at 4-6 milligrams or a strong affinity  $\mu$ -opioid agonist such as fentanyl IV 100 micrograms. Evidence shows that total opioid requirements is less when MAT is continued as a basal pain medication.

Reference: Macintyre PE, Russell RA, Usher KA, Gaughwin M, Huxtable CA. Pain relief and opioid requirements in the first 24 hours after surgery in patients taking buprenorphine and methadone opioid substitution therapy. Anaesthesia and intensive care. 2013;41(2):222-230.

# **Resources**

- 1. COWS: A clinical opioid withdrawal scale designed to monitor signs of opioid withdrawal.
- 2. Ramsay Sedation Scale: Designed for use in critically ill adults that has broad applicability in evaluation of the range between agitation and over sedation in response to sedatives and analgesics.
- 3. Considerations for Administration of Buprenorphine and Methadone.
- 4. Considerations for Treatment of Opioid Use Disorder in Pregnancy.
- 5. Sample Evaluation of Opioid Use Disorder (OUD) in Pregnancy Checklist.
- 6. Sample Inpatient Medication-Assisted Treatment Induction Algorithms.

- 7. Sample Outpatient Buprenorphine Induction Algorithm.
- 8. NNEPQIN Opioid Use Disorder Clinical Pathway.
- 9. ED Bridge. Buprenorphine Quick Start in Pregnancy Algorithm.

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Dr. Stockton is Board Certified in both Family Medicine and Addiction Medicine. Candy's passion is providing patient-centered care to pregnant and parenting women with addiction as well as addressing the upstream causes of addiction in her community. She is Chief Medical Officer at the Humboldt IPA, and is a practicing physician at their Priority Care Center. In her role at the IPA, she oversees the developing School Based Health Center Program and is the clinical champion for the Humboldt RISE Project (a county-wide Perinatal Substance Use Disorder project) and Humboldt County's Jail MAT program. She serves as a consultant for the implementation of the Hub and Spoke project in Northern California and for California's Opioid Response Network, based out of UCLA.

### **Holly Smith**

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Holly Smith is a certified nurse-midwife with 20 years' experience in diverse practice settings. She is the project manager for the CMQCC/CPQCC Mother and Baby Substance Exposure Initiative. Previous to this role, she was a the lead editor for the CMQCC Toolkit to Support Vaginal Birth and Reduce Primary Cesareans, and a clinical lead for the CMQCC Collaborative to Support Vaginal Birth and Reduce Primary Cesareans, a large-scale quality improvement project with over 90 California hospitals. Her primary role as clinical lead focused on assisting southern California hospitals with the implementation of evidence-based practices to reduce cesarean. She is a hospital coach and steering committee member for the American College of Nurse-Midwives' Reducing Primary Cesareans Project, and expert consultant on various national and state quality improvement and health policy initiatives. Additionally, she chairs the Health Policy Committee of the California affiliate of the American College of Nurse-Midwives and is a health policy consultant to the California Nurse-Midwives Foundation.

### Martha Tesfalul

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Dr. Martha Tesfalul is currently a Maternal-Fetal Medicine Fellow at at the University of California, San Francisco. Having served as the Quality Improvement (QI) Chief in her final year of residency, she has a professional interest in health systems strengthening and health equity. She has received local, regional and national recognition for her efforts in clinical care, education, and research including awards from the Pacific Coast Obstetrical and Gynecological Society and the Foundation for the Society for Maternal-Fetal Medicine. In addition to her commitment to improving the care of pregnant patients in California, Dr. Tesfalul engages in QI-focused research in in the East African country Eritrea.

### Tipu V. Khan

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Dr. Khan is an Addiction Medicine specialist and Chief of Addiction Medicine consult-liaison service and outpatient specialty clinic at Ventura County Medical Center. He is the medical director of Prototypes Southern California which has hundreds of residential treatment beds as well as medical-withdrawal (detox) beds throughout Southern California. Dr. Khan is the Medical Director of the Ventura County Backpack medicine group, and Primary Care Hepatitis C Eradication Project. His niche is managing SUD in pregnancy and is a national speaker on this topic.

# Implement evidence-based anesthesia practices in the peripartum period for opioid use disorder in pregnancy

Best Practice No. 12

Labor and Delivery and Treatment

## Overview

Implement evidence-based best practices for anesthesia care and pain relief for pregnant women with opioid use disorder (OUD).

# Why we are recommending this best practice

Pregnant women with OUD have pain relief and anesthetic needs that vary from women without OUD in the peripartum period. Early consultation and use of best practices for management of intrapartum and postpartum pain relief will optimize maternal and newborn outcomes. Individual hospitals/settings will have different availability of anesthetic/analgesic options.

# **Strategies for Implementation**

### **Pre-delivery**

- Consult with an anesthesiologist at the delivering facility who will be able to review and develop an anesthetic plan that addresses the patient's needs and accounts for the options available at the local institution.
- Utilize shared decision making for the degree of pain relief desired during intrapartum and postpartum recovery.
- Provide resources for anesthesia providers about OUD and anesthetic consideration/needs.

### Intrapartum

 Neuraxial anesthesia provides the best quality of pain relief, especially in opioid tolerant individuals. Patients will need adjustment of medication types and concentrations for optimal pain relief that do not interfere with and will not be affected by OUD or OUD medications. Increased strength or concentration of a medication (e.g., local anesthetic or the total dose or frequency of a dose of a medication that has a uniform concentration) will likely be needed. Neuraxial adjuncts may be helpful.

Patients with a prior history of OUD who fear relapse may desire a method of analgesia/anesthesia that omits opioids entirely.

 Avoid nitrous oxide in combination with high dose opioids. Nitrous oxide is not recommended in this setting as nitrous combined with opioids may produce excessive sedation or respiratory depression, causing the patient deep sedation or general anesthesia. When the preferred method, epidural analgesia, is contraindicated, nitrous oxide may be considered under close supervision as an adjunct with other systemic therapies.

### **Cesarean Delivery**

- Adjust use of neuraxial anesthesia according to the individual patient's OUD or OUD medications and tolerances. Adjunct neuraxial medications may be considered.
- Use general anesthesia only as otherwise indicated. This is not the preferred method for routine cesarean in pregnant women with OUD.

### Post-delivery pain relief

- Create a multimodal analgesia and multidisciplinary care plan.
- Understand that multiple non-narcotic adjuncts are available. Choices may be affected by local resources and availability.
- Emphasize local anesthetics used in neuraxial infusion and/or peripheral nerve blocks (e.g, Transverse Abdominis Plan (TAP), Quadratus Lumborum Block (QL2), epidural infusion, and wound liposomal bupivacaine). Consider use of a catheter for continued infusion of local anesthetics and adjuvants, as well as scheduled acetaminophen and NSAIDs.
- IV patient-controlled analgesia (PCA) opioids may be used as a supplement to other multimodal treatment, but the requirements may be higher.
- Post-delivery monitoring requirements should be considered.

### **Additional Considerations**

- Develop an informational packet for anesthesia providers.
- If the patient was previously on buprenorphine, continue buprenorphine, although the dose may need to be split (e.g.,TID), and total dose may need to be increased.

• Use of multiple opioids, analgesics, adjuncts, and/or sedatives may result in pharmacologic/pharmacogenetic additive or synergistic effects and result in shifting from minimal sedation to moderate sedation/analgesia to deep sedation/analgesia or even general anesthesia. Caution is urged, and proper monitoring for respiratory depression and oxygenation may be warranted. Underlying medical conditions will amplify the effect of sedatives, analgesics and other medications (e.g., obstructive sleep apnea, chorioamnionitis with fever). Rescue capacity is required under the Patients' Rights standard at §482.13(c)(2), guaranteeing patients care in a safe setting (CMS Interpretive guidelines).



# Kayla

Kayla's physician referred her for a consultation at 36 weeks of pregnancy with the anesthesiologist at her delivering facility. They reviewed together her current medications, any non-prescription medication usage including herbals and marijuana derivatives, medical issues, as well as her personal concerns about pain, pain medications, and her overall pain tolerance. Kayla expressed great concern about getting her regular pain medications and additional oxycodone for pain. The anesthesiologist reassured her that epidural analgesia for labor or post-cesarean does not aggravate her increasing back pain with the pregnancy and provides the highest quality pain relief for labor and post-partum. The use of non-narcotic neuraxial adjuvants is very important, as Kayla's current total opioid and non-opioid pharmaceutical consumption may produce opioid induced hyperalgesia—suggesting use of another type of medication could be very helpful. If Kayla undergoes a cesarean delivery, increased doses of neuraxial narcotic will be needed as well as additional nonnarcotic analgesic regimens (e.g., TAP Quadratus Lumborum type 2 local anesthetic block, or wound infusion). Even a complicated vaginal delivery (for example, a third- or fourth-degree laceration) may benefit from neuraxial morphine and adjuvants for post-delivery analgesia. The anesthesiologist will need to notify the hospital pharmacy if adjuvants will be used, as they may not be standard stock (e.g., clonidine for epidural administration), and if the hospital can accommodate post-delivery epidural infusions for analgesia, particularly adjuvants like clonidine.

Failure to secure a pre-delivery consultation may adversely affect intrapartum or postpartum care. Not all anesthesia providers are familiar with OUD in pregnancy, and a consultation allows discussion and implementation of a multimodal analgesia plan, combining patient preferences and shared decision making with what is available at her particular delivery location. Care coordination becomes even more important if a consultation is not an option.

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# Ensure methadone and buprenorphine doses are not tapered in the immediate postpartum period

Best Practice No. 13

Labor and Delivery and Treatment

## Overview

Implement an inpatient postpartum protocol to ensure that patients on medication assisted treatment (MAT) have a plan for continued treatment in the postpartum period.

# Why we are recommending this best practice

Women whose opioid maintenance therapy is interrupted are at high risk of relapse and overdose during the postpartum period.

# **Strategies for Implementation**

- Train providers on evaluation of opioid withdrawal and over-sedation in women on opioid maintenance therapy. Create opportunities for nurses responsible for caring for pregnant inpatients to learn and ask questions about facility-specific protocols as well as to learn how to use the Clinical Opiate Withdrawal Scale and the Ramsay Sedation Scale in the care of patients taking maintenance buprenorphine and methadone (Please see the Resources section of this Best Practice: Considerations for Administration of Buprenorphine and Methadone).
- Provide information to providers on how to educate women with opioid use disorder (OUD) about MAT. Educate providers on the importance of continuation of maintenance medication in the postpartum period and reassure women on this treatment that it will not be interrupted.
- Develop a protocol for ensuring regular dosing of maintenance methadone and buprenorphine. Work with nursing, obstetrics, and pain/addiction medicine specialists to create a protocol to ensure regular dosing and to assess for the need for increased or split dosing during the postpartum period.
- **Methadone:** Providers should not decrease the methadone dose in the immediate postpartum period unless it is at the patient's request and the provider and patient agree using shared decision making or unless over-sedation is observed. Providers can consider increasing or splitting the postpartum methadone dose for better pain control post-cesarean.

• **Buprenorphine:** Doses should not be decreased in the immediate postpartum period unless it is at the patient's request and the provider and patient agree using shared decision-making or if over-sedation is observed. Providers can consider increasing or splitting the postpartum buprenorphine dose for better pain control post-cesarean. Consider transitioning buprenorphine-only patients to buprenorphine/naloxone prior to discharge.

- Develop a plan for safe outpatient hand-off to a provider who can maintain the patient on MAT. Develop a workflow to ensure pregnant patients with OUD are discharged with a mechanism for uninterrupted continuation of their therapy. Best practice is to continue MAT in the immediate postpartum period. Tapering or stopping MAT in the acute pain or recovery period may increase maternal morbidity and complications. Warn women that relapse and therefore overdose is common in the postpartum period and close follow-up is necessary.
- Ensure follow-up with a physician or midwife who is aware of the patient's OUD and MAT therapy. Ideally the patient will already know this provider. This follow-up should be made within 1-2 weeks of discharge. Postpartum depression should be assessed at this appointment or prior to discharge. Encourage anti-depressant medication for patients with a positive screen to treat their mood and improve MAT retention.
- See Resources section below for tools for evaluating patients on chronic opioids for withdrawal.



# Kayla

Having her baby was one of the most amazing things Kayla had ever experienced. When she held her new baby, she felt like everything was good in the world. Kayla was inspired to take control of her health and her social situation for Baby M.

The postpartum period is a critical time for the mother and baby. Sudden, disruptive changes in the care plan that do not account for the patient's preferences and what is presently working may lead to unintended consequences. As a rule, MAT should not be tapered in the postpartum period. Additionally, switching from methadone to buprenorphine is more difficult than the switch from buprenorphine to methadone, and should be done with caution, with full disclosure, at an appropriate time, and with a careful plan in place.

# **Resources**

1. Ramsay Sedation Scale: Designed for use in critically ill adults that has broad applicability in evaluation of the range between agitation and over sedation in

- response to sedatives and analgesics.
- 2. COWS: A clinical opioid withdrawal scale designed to monitor signs of opioid withdrawal.
- 3. Sample Inpatient Medication-Assisted Treatment Induction Algorithms.
- 4. Sample Outpatient Buprenorphine Induction Algorithm.
- 5. Considerations for Administration of Buprenorphine and Methadone.
- 6. Considerations for Treatment of Opioid Use Disorder in Pregnancy.
- 7. Sample Evaluation of Opioid Use Disorder (OUD) in Pregnancy Checklist.

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### **Scott Haga**

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Scott Haga is Senior Consultant wiht Health Management Associates and is a passionate patient advocate with a focus on motivational training, evidence-based treatment, collaboration and tackling the national opioid crisis head-on. He is an experienced medical provider who co-founded and co-led an interdisciplinary complex care intervention for high frequency emergency department utilizers. He has been recognized as a subject matter expert on addiction, medication assisted treatment for substance use disorders, and building well-functioning interdisciplinary treatment teams.

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# Implement care pathways for peripartum and postpartum pain management for pregnant patients without opioid use disorder to minimize opioid use

Best Practice No. 14

Labor and Delivery and Treatment

## Overview

Postpartum pain is common. All women experience uterine cramping in the early postpartum period that is necessary to prevent excess bleeding, and women with lacerations from vaginal birth experience perineal pain. After cesarean birth, women experience pain from the laparotomy. It is necessary to treat pain adequately to support maternal comfort and to reduce the stress response of the mother and newborn. It is also critically important to limit the amount of opioids prescribed on discharge that may lead to prolonged use and possibly misuse. Leftover medication is a common source of opioids that are diverted for misuse. The potential for diversion and misuse of opioids make it a public health priority to prescribe only the minimum amount required by the patient.

Cesarean birth is the most commonly performed surgery in the United States, yet little is known about appropriate pain management at discharge. In general, women consume half the amount of opioids prescribed to them on discharge. For example, a recent study found that the median number of opioid tablets prescribed was 40 and the median consumed was 20 (Bateman BT, et al, 2017). The amount of opioid consumed was directly proportional to the amount prescribed. However, the amount of opioids dispensed did not correlate with patient satisfaction, pain control, or the need to refill the opioid prescription. The majority of women do not require an opioid prescription after vaginal delivery. Despite the well-known risks, 29% of women were prescribed an opioid at the time of discharge after vaginal delivery.

**Enhanced Recovery:** There is a national effort for all surgeries to redesign care for the perioperative period to enhance recovery. In May 2019, the Society for Obstetric Anesthesia and Perinatology (SOAP) released a comprehensive set of guidelines (see Resources) for each phase of care for women undergoing a cesarean birth known as Enhanced Recovery After Cesarean (ERAC). Every obstetric unit should strongly consider these recommended approaches. A part of enhanced recovery is optimizing care so that the need for opioid pain medications is markedly lowered and/or replaced by non-opioid approaches. A Call to Action for ERAC with a comprehensive discussion was published in the August 2019 issue of *The American Journal of Obstetrics and Gynecology*. One of the goals is to ensure that all women have access to adequate pain control while reducing the harms of opioid exposure.

# Why we are recommending this best practice

There is considerable evidence that new mothers are consistently over-prescribed opioids after delivery. Better pain control is achievable with less opioids using a multimodal

approach. There is evidence that most women require fewer than 20 opioid tablets following uncomplicated cesareans and that scheduled non-opioid analgesics provide superior pain relief and facilitate reduced opioid consumption compared to PRN dosing. A similar protocol did not result in an increase in outpatient opioid refill rate.

# **Strategies for Implementation**

- Establish a multidisciplinary team to implement a unit-wide ERAC protocol.
- Scheduled NSAIDs and acetaminophen are the first line agents for postpartum pain control. Ibuprofen 600 mg and Acetaminophen 650 mg PO Q 6 hours can be concurrent or staggered dosing. The oral route is preferred unless inappropriate.
- Offer oxycodone 5 mg PO Q6 hours PRN pain instead of the combination of APAP/oxycodone. Avoid codeine and tramadol in breastfeeding women.
- Consider a lidocaine patch for post-cesarean laparotomy pain. Consider transverse abdominus plane block immediately post-cesarean for post-incisional pain. See <a href="Best">Best</a> <a href="Practice">Practice #15</a>.
- Evaluate the amount of opioids used by the patient in the 24 hours prior to discharge and use shared decision making to decide how many oxycodone tablets to give the patient, but limit the amount to a three-day supply or on average 15-20 tablets.
- Perineal pain requiring opioids should prompt a careful evaluation for hematoma, wound breakdown, or infection.

	Vaginal birth	Cesarean Birth
Non-opioids	Ibuprofen 600 mg Q 6 hours.     Dispense # 30, 600 mg tablets (1-week supply).     Acetaminophen 650 mg Q 6 hours.     Dispense #60, 325 mg tablets (1-week supply).	Ibuprofen 600 mg Q 6 hours. Dispense # 60, 600 mg tablets (2-week supply).     Acetaminophen 650 mg Q 6 hours. Dispense #120, 325 mg tablets (2-week supply)
Opioids	Opioids not prescribed unless required by patient for pain control during the hospital stay.	Use shared decision making and consider CDC safe prescribing of only 3 days' supply.     Oxycodone 5 mg Q 6 hours PRN pain. Dispense 15-20 tablets (3 days' supply).

Sample guideline for oral analgesic prescribed at discharge

Proposed guidelines for uncomplicated normal spontaneous vaginal birth (Mills JR, et al, 2019)

• **Guideline 1:** Long-term opioid use often begins with the treatment of acute pain. When opioids are started, providers should order the lowest effective dosage and prescribe no greater quantity of opioids than needed for the expected duration of pain severe enough to require opioids.

- **Guideline 2:** When starting opioid therapy, providers should prescribe immediate-release opioids instead of extended-release or long-acting opioids. This is especially important on the day of discharge.
- **Guideline 3:** Providers should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible.
- **Guideline 4:** Nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for patients who had a normal, spontaneous vaginal delivery with no complications. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.
- **Guideline 5:** When providers identify a patient with opioid use disorder (OUD), treatment discussions should be prioritized during hospitalization, on discharge, and at the postpartum appointment.

# **Deep Dive**

There are many elements of ERAC that can help limit opioids while providing adequate pain control.

- Neuraxial long-acting opioids.
- Non-opioid analgesia started in the operating room unless contraindicated. These are ideally started prior to onset of pain (ketorolac 15-30 mg IV after peritoneum closed and/or acetaminophen IV after delivery or PO before/after delivery).
- Consider local wound pain control such as TAP block or lidocaine patch at incision site.
- Promote return of bowel function. Constipation can lead to increased unnecessary post-operative gas pain; limiting opioids, scheduled bowel regimen, and mobilization can mitigate this.

For all patients, remember immediate skin-to-skin, early promotion of breastfeeding, early ambulation and promotion of rest periods all improve the maternal psyche and can improve overall perception and coping with pain.

Reference: Society of Obstetric Anesthesia and Perinatology (SOAP) Enhanced Recovery After

Cesarean (ERAC) Consensus Statement, <a href="https://soap.org/SOAP-Enhanced-Recovery-After-cesarean-Consensus-Statement.pdf">https://soap.org/SOAP-Enhanced-Recovery-After-cesarean-Consensus-Statement.pdf</a>

# Resources

- 1. Sample patient-oriented teaching regarding multimodal pain management after cesarean delivery: UNC School of Medicine, Center for Maternal and Infant Health.
- 2. Sample discharge instructions regarding pain medication after delivery: UNC School of Medicine, Center for Maternal and Infant Health.
- 3. Society of Obstetric Anesthesia and Perinatology (SOAP) Enhanced Recovery After Cesarean (ERAC) Consensus Statement.

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#### Pamela Flood

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Dr. Pamela Flood is Professor of Anesthesiology, Perioperative, and Pain Medicine at Stanford University. Her research interests include prevention and reduction of pain and opioid use in women after delivery. She divides her clinical time between labor and delivery and her outpatient pain management clinic. She clinical work is directed toward compassionate weaning of high dose opioids and management of pelvic pain syndromes.

# Utilize shared decision making to tailor post-procedure pain control

Best Practice No. 15

Labor and Delivery and Treatment

# Overview

Individual patients often fear the loss of autonomy in a hospital setting and, knowing their increased tolerance for medication, fear for their ability to relieve their pain.

# Why we are recommending this best practice

There is extensive variability in the needs of women with opioid use disorder (OUD) for pain control over and above their maintenance therapy.

Shared decision making is a dynamic process during which the provider and patient engage in an informed discussion to make health related choices that are best for the patient and in alignment with the patient's personal values (refer the Resources section of this Best Practice for more information), Shared decision making has been shown to reduce overall opioid use.

# **Strategies for Implementation**

- For each patient with OUD, engage in an open and honest discussion about pain control and encourage shared decisions about pain management.
- Consider Transverse Abdominis Plane (TAP) block, Quadratus Lumborum Block (QL2), or paravertebral blocks/catheters with the consultation of an anesthesiologist. Create facilities, training, and procedures for providers to maintain these catheters and advise patients on their benefits and use.
- Schedule adjuvant medications including non-steroidal anti-inflammatory medications and acetaminophen to reduce the need for opioid dose escalation. Develop procedures and training for the administration of other adjuvant medications including gabapentin or pregabalin, or short-term ketamine in consultation with and under the supervision of an anesthesiologist.
- Consider local analysesic and other analysesic patches for postsurgical pain.
- Do not routinely give opioids above maintenance doses for vaginal births.



# Kayla

Shared decision making will shift Kayla's focus away from the disease and towards creating a partnership with greater participation and compliance. Individual preference of and tolerance to advanced pain strategies may affect which ones are chosen together. Choices for Kayla include:

- Scheduled (not PRN) non-narcotic pain medications including acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs).
- Local anesthetic to prevent and treat pain. A local anesthetic wound infusion or injection of long acting local anesthetic such as a Transverse Abdominus Plane (TAP) block or Quadratus Lumborum (QL) type2 block single dose or catheterbased infusion.
- Epidural infusion of low dose local anesthetic, preferably with non-narcotic adjuvants (e.g., alpha<sub>2</sub> adrenergic agonists clonidine, epinephrine).
- Administration or infusion of other non-narcotic adjuvants (e.g., gabapentin/pregabalin, infusion of low dose ketamine).
- Avoidance/minimizing regular opioids (e.g., oxycodone) at high doses for postdelivery pain.

# **Deep Dive**

What is shared decision making and why does it matter? Shared decision making occurs when the patient is considered a critical part of the team. Two axioms are important to shared decision making: "No decision about me without me" and "this patient is the only patient." Together, this means each patient is an individual and should be treated as such, and their own individual values and preferences should be the starting point for all conversations. When done right, shared decision making leads to improved quality of care, improved outcomes, and better patient experience.

The basic components of shared decision making are:

- 1. **S**eek your patient's participation
- 2. Help your patient explore and compare treatment options
- 3. **A**ssess your patient's values and preferences
- 4. **R**each a decision with your patient
- 5. **E**valuate the decision

More information and an entire toolkit on the "SHARE Approach" can be found on the ARHQ website at: <a href="https://www.ahrq.gov/health-literacy/curriculum-tools/shareddecisionmaking/index.html">https://www.ahrq.gov/health-literacy/curriculum-tools/shareddecisionmaking/index.html</a>.

# Resources

1. Ramsay Sedation Scale: Designed for use in critically ill adults that has broad applicability in evaluation of the range between agitation and over sedation in response to sedatives and analgesics.

- 2. COWS: A clinical opioid withdrawal scale designed to monitor signs of opioid withdrawal.
- 3. Considerations for Administration of Buprenorphine and Methadone.
- 4. Considerations for Treatment of Opioid Use Disorder in Pregnancy.
- 5. "SHARE Approach" AHRQ. Shared Decision Making.

# References

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# Implement a non-pharmacologic bundle of care for neonatal abstinence syndrome for medical staff and parents to follow

Best Practice No. 16

Nursery/NICU and Treatment

# Overview

Implement a non-pharmacologic bundle of care for neonatal abstinence syndrome (NAS) for medical staff and parents to follow.

# Why we are recommending this best practice

A non-pharmacologic bundle of care for NAS will help to prioritize non-pharmacologic interventions over medication, may reduce the length of stay, and will keep staff and parents aligned on the care being provided to the newborn.

# **Strategies for Implementation**

Collaborate with nursing and health care teams to develop a written guideline with a bundle of care that is specific for your unit. An example of a non-pharmacologic bundle of care for NAS would include:

- Parent/caregiver contact: Emphasize parental presence at the bedside (rooming in, where available), the importance of skin-to-skin/holding the newborn, swaddling with the newborn's hands near the mouth, and non-nutritive sucking/pacifier use. Consider a volunteer cuddler when a parent or caregiver is unavailable.
- **Environment:** Establish an environment that is quiet with low lighting, limit the number of visitors, avoid excessive handling, encourage only one stimulus at a time (e.g., do not walk or sway while feeding). Swinging is okay but should be stopped if the newborn is overstimulated.
- **Nursing care:** Cluster nursing assessments and interventions at times when the newborn is awake.
- **Feeding:** Feed on-demand; encourage breastfeeding and lactation consultation if eligible (in the absence of any contraindications, breastfeeding should be encouraged while the mother is on methadone or buprenorphine treatment as part of a program); prioritize feeding consult if bottle feeding; and if formula feeding, consider reduced

lactose or partially hydrolyzed lactose (not evidence-based) and consider 22 kcal/oz after day 2-3 if there is poor weight gain (loss of >10% of birthweight or not back to birthweight by 7 days of life).

- Determine contraindications for maternal breastfeeding by unit for consistency. There are no medical contraindications to breastfeeding based on maternal methadone (prescribed as part of a treatment program), buprenorphine, or short-term low-dose prescription opioid use alone. The concentrations of methadone that can be found in human milk are low, and women on stable doses of methadone maintenance should be encouraged to breastfeed regardless of maternal methadone dose if they are in a treatment program. Buprenorphine has low levels in breastmilk and poor oral bioavailability in newborns.
- Use breastmilk when not contraindicated to reduce the severity of NAS and to minimize the need for pharmacologic exposure. Ensure a mother eligible for breastmilk use has a lactation consultation, access to a breast pump, and adequate instructions for its use.
- Feed based on hunger cues/ad lib (usually g2-3 hours), if medically appropriate.
- Anticipate possible increased caloric needs.
- Rule out non-NAS causes of poor feeding including transitional sleepiness or frequent spit-ups in the first 24 hours of life, poor latch due to newborn/maternal anatomic factors or immature gestational age, and physiologic cluster feeding.
- **Skin:** Practice proactive prevention of diaper dermatitis and skin breakdown. Start diaper/barrier creams on day one and treat other areas of skin excoriation due to newborn tremors promptly.
  - Frequent stools increase the risk of perianal breakdown. This can be prevented by:
    - Starting diaper creams/barrier creams on day one
    - Frequent diaper changes
    - Liberal application of emollients and/or moisturizers
    - Careful assessment with each diaper change
  - Excoriation from tremors is most common on the extremities, face, chin, knees, and gluteal folds.
    - Applying a medical dressing over the knees and other body surfaces that are being rubbed can be protective.
    - Using mittens to decrease scratching can also be helpful.
    - Avoid friction with cleansing. Do not use harsh wipes.
    - Use only water for cleansing; a sitz bottle works well.
    - Use gentle patting to dry.
    - Apply a no-sting barrier to areas of skin breakdown.
    - Apply a skin protectant to areas of skin breakdown.
    - Leave areas of skin breakdown open to air as much as possible.
    - Treat areas of breakdown for at least 24 hours.
    - Teach parents proper skin care techniques.



# **Baby M**

Baby M is now 24 hours old and is being assessed for withdrawal based on functional impairment (his ability to eat, sleep, and be consoled within set periods of time). The hospital has recently implemented this system in place of the traditional Finnegan score assessment, and the staff has found that fewer newborns need medication and many are able to go home sooner. A nurse performs the assessment after Baby M awakens and is concerned because he slept less than an hour and has high-pitched cries. However, Kayla is able to breastfeed, and Baby M is calmer after feeding. The nurse is pleased that Baby M was adequately consoled. She talks to Kayla about keeping Baby M calm by decreasing environmental stimulation with low light, fewer visitors, and low sound. She also shows Kayla various techniques of how to console Baby M such as speaking to him softly, bringing his hands to his mouth, bringing his flexed arms and legs to the center of his body, placing him skin-to-skin or swaddling him, gently rocking him, giving him a pacifier, or feeding him if he shows hunger cues. The nurse talks to the charge nurse and moves Kayla and Baby M to a single room in the postpartum unit to minimize environmental stimulation.

# Resources

- 1. PQCNC and MAiN resources under pharmacological section.
- 2. ILPQC Newborn Care Diary.
- 3. Ohio Perinatal Quality Collaborative Provider Resources.
- 4. Ohio Collaborative Crib Card.
- 5. NeoQIC Resources for Hospitals.

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# Priya Jegatheesan

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# Develop guidelines for inpatient monitoring of newborns managed with a non-pharmacologic bundle of care

Best Practice No. 17

Nursery/NICU and Treatment

# Overview

When a newborn who is exposed to opioids in utero does not require pharmacotherapy and is managed solely with a non-pharmacologic bundle of care, we recommend a minimum of 72 hours of inpatient monitoring.

# Why we are recommending this best practice

Opioid clearance in newborns is variable due to patient clearance characteristics, type of opioid, and the presence of other drugs. Most newborns will present with withdrawal symptoms by 24–72 hours, depending on the half-life of the opioid used by the mother and the potential for exposure to multiple substances. Inpatient monitoring is important to allow for potential symptoms to present and for the newborn to receive the appropriate treatment.

# **Strategies for Implementation**

- A recommended observation period should be included in each hospitals' written guidelines.
- Documentation of potential opioid exposure should be included in the medical record to provide medical necessity justification when the observation period exceeds the otherwise expected length of stay.

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#### Priya Jegatheesan

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# Consider parental rooming-in with the newborn when safety of mother and newborn can be ensured

Best Practice No. 18

Nursery/NICU and Treatment

# Overview

Parental rooming-in with a newborn should be considered when a plan can be implemented to ensure safe care of the mother and newborn.

# Why we are recommending this best practice

Rooming in and/or parental presence at the newborn's bedside supports dyad care and bonding, and can reduce pharmacotherapy use and length of stay.

# **Strategies for Implementation**

- If rooming in is being considered, it is important to establish a patient care plan that includes assessment of the patient for appropriateness to room in and nursing vigilance to prevent and monitor for potential adverse events due to rooming in.
- It is also important to ensure that staff approach mothers with opioid use disorder (OUD) in a respectful and non-judgmental manner to optimize use of non-pharmacologic methods for managing neonatal abstinence syndrome (NAS).
- Safe sleep habits should be taught and reinforced by staff throughout the hospital stay to prepare for discharge.

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#### Priya Jegatheesan

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# Prioritize measurement of functional impairment as a basis for initiation and escalation of pharmacologic treatment

Best Practice No. 19

Nursery/NICU and Treatment

# Overview

Instead of basing pharmacologic initiation and escalation of treatment solely on a total Finnegan score, consider prioritizing measures of functional impairment. A functional impairment-based strategy for managing neonatal abstinence syndrome (NAS) should employ staff who have been trained in engaging mothers with opioid use disorder (OUD) and in using non-pharmacologic interventions for the newborn. The use of a functional impairment-based treatment strategy should be designed and tailored to a specific unit within the context of a formal quality improvement initiative so that safety may be routinely monitored and reviewed.

# Why we are recommending this best practice

Subacute symptoms of NAS can continue for weeks or months. Prolonged inpatient management and pharmacotherapy may lead to adverse infant neurodevelopment and poor parental engagement. Focusing on a newborn's functional impairments to guide pharmacotherapy may reduce length of stay and pharmacotherapy exposure. Studies of this method indicate no increase in readmission rates; however, there are no long-term studies to evaluate benefit versus harm of this method.

# **Strategies for Implementation**

- Create a unit protocol for nurse scoring of functional measures, conduct nursing and staff education prior to implementation, and educate health care providers regarding guidelines for use of pharmacotherapy. Monitor acceptability and feasibility of this protocol within the hospital as well as readmission rates for infants.
- Examples of published methods emphasizing functional impairment are:
  - Finnegan Symptom Prioritization focuses on certain function-based items in the Finnegan score. Most recent reports include poor feeding, poor sleep, and continuous crying as prioritized functional measures. Other components of the Finnegan score that are sometimes included are emesis, diarrhea, tachypnea, or fever.
  - "Eat, Sleep, Console" prioritizes a newborn's inability to take an age-appropriate volume of food, sleep more than one hour after feeding, or be consoled within ten minutes.
- Functional-based assessment and management of newborns with NAS should be

designed for the specific hospital. The formal "Eat, Sleep, Console" (ESC) approach was initially developed by Dr. Matthew Grossman at Yale New Haven Children's Hospital. Similar quality improvement programs are being successfully implemented at both academic centers and community hospitals as part of a non-pharmacologic approach.

- These are emerging (best) practices with encouraging short-term outcomes, and about which further study is needed to confirm long term outcomes.
- Alternative strategies employ the use of a modified Finnegan checklist with the mother scoring subjective functional items (e.g., quality of cry, stool consistency, tremulousness, etc.).

# **Deep Dive**

The total Finnegan score describes NAS symptoms, but it does not reflect how NAS severity affects the infant's ability to function. Several of the symptoms included in the Finnegan scoring system can be attributed to cluster feeding or other normal newborn behaviors. This symptom-based score may lead to unnecessary opioid treatment of infants without functional impairment. Studies show that opioid pharmacotherapy and length of stay decrease significantly with use of a function-based assessment compared to use of the total Finnegan score alone. Use of a function-based assessment can avoid initiation of opioid treatment, separation of the dyad, and a newborn's transfer to the high-stimulation NICU environment.

# Resources

- 1. Eat Sleep Console as part of neoQIC
- 2. Eat Sleep Console Pathway, Yale New Haven Children's Hospital

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If pharmacotherapy is indicated, consider a trial of morphine every 3 hours PRN as an initial strategy for the treatment of neonatal abstinence syndrome instead of scheduled dosing or more long-acting pharmacotherapy options

Best Practice No. 20

Nursery/NICU and Treatment

# Overview

If criteria for pharmacotherapy are met per a hospital-specific written guideline, morphine every3 hours as needed (PRN) may be trialed as an initial strategy for the treatment of neonatal abstinence syndrome (NAS) instead of scheduled dosing or more long-acting pharmacotherapy options.

# Why we are recommending this best practice

Signs of NAS are not consistent throughout the day, nor is parental presence. Pharmacologic treatment may not be necessary every 3 hours. PRN dosing of morphine may minimize pharmacotherapy exposure and therefore side effects from scheduled morphine doses (e.g., respiratory depression, bradycardia, hypotension, urinary retention, decreased intestinal motility) or long-acting pharmacotherapy such as methadone.

# **Strategies for Implementation**

Incorporate guidelines for initiation of PRN morphine for the treatment of NAS into the hospital's guideline when a newborn meets criteria to initiate pharmacotherapy. Consider including guidelines to describe a threshold for escalating to scheduled q3 hour dosing and when to escalate the dose of scheduled morphine. Consider cardiorespiratory monitoring continuously or intermittently when the newborn is receiving morphine.



# **Baby M**

Kayla continues to care for Baby M with breastfeeding, holding skin-to-skin, and minimizing overstimulation. A nurse assesses Baby M and notes at 2 days old that he is unable to sleep for at least one hour after feeding and has continuous crying. The nurse confirms that both she and Kayla have had difficulty consoling Baby M and that at the time of the last assessment he was still crying after 10 minutes of attempts at consolation. He also has moderate tremors when disturbed, a hyperactive Moro reflex, and nasal stuffiness. The nurse assists Kayla with trying to optimize non-pharmacologic interventions, but Baby M continues to have poor sleep and persistent crying. Kayla and the medical team discuss the situation and, given their concern for functional impairment, Baby M is moved to an inpatient room where he is given one dose of PRN morphine by mouth and placed on a cardiorespiratory monitor. Medical staff have recently worked with hospital administrators to ensure newborns with NAS can be placed in private rooms to preserve the mother/baby dyad. After Kayla is discharged, she can stay with him and continue to provide his care.

Non-pharmacologic measures continue to be optimized. After feeds, Baby M is occasionally irritable, but with swaddling and holding he soothes quickly. Once soothed, he sleeps until the next feeding. He requires one additional dose of PRN morphine the following day for poor feeding and inconsolability, after which his symptoms do not recur. He completes a period of monitoring without medication for a day and a half, with Kayla providing all of his care. Baby M is discharged home to Kayla with close follow-up from the outpatient pediatrician.

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# Consider methadone as first-line pharmacotherapy for the treatment of neonatal abstinence syndrome following evaluation of its benefits/risks

Best Practice No. 21

Nursery/NICU and Treatment

# Overview

Methadone may be considered as first-line pharmacotherapy for the treatment of neonatal abstinence syndrome (NAS) following evaluation of its benefits/risks.

# Why we are recommending this best practice

- Multiple studies have shown decreased length of treatment with methadone compared to morphine for the treatment of NAS. The decreased length of treatment varies from 2–7 days. One single site randomized controlled trial (RCT) reported a shorter length of treatment on methadone versus morphine with a median of 14 vs. 21 days.
- Multiple studies have also shown decreased length of stay with methadone compared to morphine treatment. The decreased length of stay varies from 2–5 days.
  - One multi-site RCT reported decreased mean length of stay by 2.7 days and decreased mean length of treatment by 2.3 days in NAS infants treated with methadone compared to morphine.
  - A multicenter, non-randomized, retrospective study (Pediatrix dataset) showed a decreased median length of stay of 18 days with methadone vs. 23 days with morphine.
  - An analysis of 14 children's hospitals showed NAS infants treated with methadone had shorter mean length of treatment (17.4 days with methadone vs. 22.2 days with morphine) and mean length of stay (21 days for methadone vs. 25 days for morphine) compared to those treated with morphine.
- Methadone's longer half-life allows for fewer swings in NAS symptoms and fewer drug administrations per day. The longer half-life, however, also makes it more complicated to titrate.
- Methadone is associated with prolonged QTc in adults and in newborns exposed to maternal methadone in the first two days of life, but it is unclear if this is clinically significant or an issue with doses used to treat newborns.

• Infants treated with morphine or methadone have similar short and long-term neurobehavioral outcomes.

• There are no studies to date comparing scheduled methadone to PRN morphine treatment strategies.

# **Strategies for Implementation**

Develop a unit-specific guideline for initiation, escalation, and weaning of methadone to promote consistency and safety of practice.

# **Special Consideration**

Buprenorphine pharmacologic treatment in newborns is not yet recommended until additional studies regarding safety and efficacy are available. A small phase one clinical trial in newborns has been conducted. There is currently minimal safety data on use in newborns and the phase one trial formulation contained 30% ethanol. However, breastfeeding for mothers on buprenorphine is recommended (refer to **Best Practice #30**).

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# **Deep Dive**

Some centers have studied and adopted a practice of using methadone as first-line pharmacotherapy for the treatment of NAS. Methadone has a longer half-life and provides a steadier exposure. However, the longer half-life may also make dose adjustment more complicated. Hospitals should develop a protocol that addresses all available options for pharmacotherapy for NAS within that institution, including information on initiation, monitoring with PRN dosing, when to escalate to scheduled dosing and strategies for using methadone. Developing such a protocol is likely to facilitate standardization of practice and reduce cumulative pharmacotherapy received.

While most newborns that require pharmacotherapy for NAS will need only one medication, some newborns with NAS whose symptoms are not controlled with first-line agents such as morphine and methadone may benefit from a second-line medication/adjunctive therapy. While phenobarbital has been a traditional second-line treatment, it is not an ideal therapy for opioid withdrawal. Therefore, clonidine is recommended as the second-line treatment of choice. Because of the theoretical risk of an effect on autonomic function, newborns receiving clonidine should have their heart rate and blood pressure closely monitored during the first two days of administration and also for 48 hours after discontinuation.

Regardless of which medication(s) are used, a pharmacotherapy weaning protocol should be established to guide practice. During the weaning process and for several days after completing pharmacotherapy, newborns should be monitored as an inpatient and assessed for rebound symptoms. Newborns that receive morphine or clonidine for NAS should receive inpatient monitoring for at least 48 hours and those receiving methadone for at least 72 hours after receiving the last dose of medication.

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# Priya Jegatheesan

MD

# Consider clonidine instead of phenobarbital as a potential second line/adjunctive therapy for neonatal abstinence syndrome

Best Practice No. 22

Nursery/NICU and Treatment

# Overview

Clonidine may be considered as a second line/adjunctive therapy for neonatal abstinence syndrome (NAS). Studies are ongoing on the use of clonidine as a first-line agent.

# Why we are recommending this best practice

Phenobarbital is a nonselective central nervous system depressant that is sometimes used in combination therapy for NAS. It has been recommended mainly for non-opioid withdrawal in polysubstance exposure as an adjunct therapy. Its role is limited in opioid withdrawal given several disadvantages, such as lack of relief of gastrointestinal symptoms, impaired bonding and feeding in infants due to central nervous system depression, and potentially more long-term neurodevelopmental effects. Clonidine is an alpha-2 adrenergic receptor agonist that inhibits central nervous system sympathetic outflow and reduces norepinephrine levels. It reduces the autonomic symptoms (mediated in the locus coeruleus) of NAS. Clonidine has at least one high quality RCT supporting its use as an adjunctive agent to reduce length of pharmacotherapy treatment for NAS.

# **Strategies for Implementation**

- Develop unit-specific guidelines for initiation of clonidine as adjunct therapy if NAS is not adequately controlled with first-line therapy alone.
- Establish guidelines for escalation of clonidine.
- When weaning clonidine, consider a two-step reduction of the clonidine dose over 48
  hours or weaning of opioids before stopping clonidine. This may reduce rebound NAS
  withdrawal symptoms.
- Clonidine has the potential to cause heart rate or blood pressure changes and monitoring is recommended. Monitor heart rate and blood pressure more closely during the first two days of clonidine therapy and for 48 hours after discontinuation.

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# Priya Jegatheesan

MD

# Develop guidelines for inpatient monitoring of newborns receiving morphine, clonidine, or methadone pharmacotherapy prior to discharge

Best Practice No. 23

Nursery/NICU and Treatment

# Overview

When morphine and/or clonidine are used for pharmacologic treatment in a newborn with neonatal abstinence syndrome (NAS), our consensus-based recommendation is that the newborn be monitored as an inpatient for a minimum of 48 hours after the last dose. A newborn treated with methadone, given the longer half-life, should be monitored as an inpatient for a minimum of 48–72 hours after the last dose of methadone is administered.

# Why we are recommending this best practice

Medication clearance in newborns is variable. There are no well-established, evidence-based guidelines for duration of monitoring after pharmacotherapy cessation for NAS.

# **Strategies for Implementation**

A recommended observation period after discontinuation of medication should be included in a hospital's written guidelines.

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#### Priya Jegatheesan

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# Establish a pharmacotherapy weaning protocol

Best Practice No. 24

Nursery/NICU and Treatment

# Overview

Hospitals should establish a clear weaning protocol for all potential pharmacotherapy treatments of neonatal abstinence syndrome (NAS) rather than relying on individual approaches that are likely to yield patient outcomes and experiences that are highly variable.

# Why we are recommending this best practice

Regardless of the treatment opioid chosen, newborns receiving protocol-based weans experience a significantly shorter duration of opioid treatment (17.7 vs. 32.1 days, P < .0001) and shorter hospital stay (22.7 vs. 32.1 days, P = .004).

# **Strategies for Implementation**

Collaborate with members of the care team to establish an acceptable weaning protocol for all pharmacologic therapies for NAS. Some hospitals may consider weaning opioid doses q24-48 hours if meeting criteria; others may wean as rapidly as 10% up to three times a day.

# **Special Consideration**

We do not recommend routine discharge of newborns while still weaning pharmacotherapy due to the evidence for longer length of pharmacotherapy exposure associated with this practice. However, we recognize that this strategy may be utilized in specific situations in which a well-established structure between the discharging hospital and the community PCP exists for close monitoring, strict follow-up criteria and prescription tracking are used, and the family is deemed reliable to follow-up.

While discharging home on outpatient pharmacotherapy decreases the initial hospital length of stay, outpatient NAS pharmacotherapy has been associated with longer length of treatment (60 vs. 19 days) and higher rates of emergency department utilization within 6 months of discharge compared to infants treated exclusively as inpatients.

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