Phase II STTR: Supporting Perinatal Mental Health in Obstetric Settings

Overview

The primary goal of this proposal is to evaluate the effectiveness of 1) e-learning/toolkit and implementation assistance and 2) e-learning/toolkit compared to treatment as usual to improve quality of care for perinatal mental health disorders in outpatient obstetric practices.

Rationale

One in five women experience mood and anxiety symptoms during pregnancy or in the year after birth. Left untreated, perinatal mood and anxiety disorders have deleterious effects on birth outcomes, infant attachment, and children's behavior and development. Perinatal mental health conditions, including suicide, are a leading preventable cause of maternal mortality and morbidity. Thus, the Council on Patient Safety in Women's Health Care has developed a maternal mental health patient safety bundle. While most obstetric providers want to address perinatal mental health disorders, fear of liability, discomfort, and lack of knowledge and resources present barriers. These barriers are compounded by stigma, fear, and discomfort among mothers. The goal of this study is to test different approaches, with varying levels of intensity, to helping obstetric settings address perinatal mental health conditions.

Recruitment and Enrollment of Obstetric Practices

- 25 Obstetric practices will be recruited, enrolled and randomized.
- Eligibility criteria for practices includes:
    - Practice provides prenatal and postpartum care to perinatal women and averages a minimum of 300 deliveries, and ideally 600-1000 deliveries/year
    - As this is an NIH funded study, and thus a central IRB of record is required, ability to cede IRB review to UMass Medical School and/or participate under a data use agreement
    - Ability to allow remote chart abstraction of electronic medical records by the UMass team
    - Ability to provide patient lists
    - All providers in practice agree to participate
    - Ability to provide contact information for all licensed-independent providers (Ob/Gyn attendings and residents, Maternal Fetal Medicine residents and attendings, midwives, nurse practitioners, and physician assistants) so that study materials can be provided
- Providers in the practice will be asked to complete baseline, post and follow-up surveys

Randomization and Interventions

Following baseline data collection, we will randomize Ob/Gyn practices into one of three study arms: (1) e-learning/toolkit and implementation assistance, (2) e-learning/toolkit, or (3) treatment as usual. Practices will be randomized in a 2:2:1 ratio. We will enroll practices with a varied number of providers. By study end, all practices will have access to all intervention components.

We will compare differences in rates and quality of care for perinatal mental health disorders from 2000 patient charts (1000 at baseline and 1000 post intervention; i.e., 40 per practice at baseline and 40 per practice post intervention).

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Treatment as usual	E-Learning/Toolkit	E-Learning/Toolkit & Implementation Assistance
After the 8-month follow-up data collection, will be invited (not required) to complete e-learning and will be given opportunity to participate in implementation assistance (not required).	Completion of *Addressing Perinatal Mood and Anxiety Disorders e-learning which include:* • Introduction, Overview, Workflow, Patient Engagement, Screening • Assessment • Treatment, Referral, and Follow-up Monitoring e-learning duration: 2 hours, in accordance with ACOG on-line training curricula Planned instructional features: high interactivity, judicious use of multi-media, array of interaction formats, immediate and automated feedback, frequent self-check quizzes. Lifeline4Mom Perinatal Mental Health Toolkit After the 8-month follow-up data collection, will be given opportunity to participate in implementation assistance (not required)	Completion of *Addressing Perinatal Mood and Anxiety Disorders* e-learning Lifeline4Mom Perinatal Mental Health Toolkit Implementation assistance (1-3 webinars/virtual calls) to guide practices in a quality improvement initiative designed to assist practices in integrating mental health screening, assessment and treatment into their workflow. Each practice will designate a champion(s) to lead the effort. The champion(s) will dedicate time to accomplish implementation between meetings. Practices will be doing some chart review, as part of QI initiative.

- The Lifeline4Moms Perinatal Mental Health Toolkit was developed by the Lifeline4Moms team in collaboration with ACOG, and funded by the CDC and CDC Foundation
- The Implementation assistance protocol was developed by the Lifeline4Moms team in collaboration with and funded by ACOG
- The e-Learning training curricula was developed by the Lifeline4Moms team in collaboration with ACOG and funded by NIMH
- Participants will be asked to complete e-learning assignments and associated measures within a four-week period. Time needed is anticipated to be maximum of 2-3 hours.
- Participants will receive emailed queries and prompts if assignments and associated testing/surveys not completed in designated time. Time for assessments anticipated to be maximum of 20 minutes at each time point (see schedule of provider measures)

Data Collection

Practice Level Measures

- Baseline and post-intervention data will be obtained through a practice readiness survey completed by the practice manager or designee.

Provider Level Measures

- Pre-, post intervention and follow-up data will be obtained through individual surveys to evaluate perinatal mental health care practices, knowledge, and attitudes.

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- Surveys will be administered via REDCap.

Schedule of Provider Measures

Outcome/endpoint	Measure	Administration	Time Points		
			Baseline	Post	8 months post
PARTICIPATION	• Practice provider and staff participation in Lean Implementation based on randomization group	Implementation virtual meeting attendance and activity completion log (RC to collect)	Ongoing		
	• Obstetric provider participation in treatment as usual vs e-Learning curriculum based on randomization	E-learning completion log Online surveys	√	√	
Knowledge acquisition	• Multiple-choice case-based knowledge questions	Online survey	√	√	√
ATTITUDES AND PRACTICES	• Adapted Knowledge, Attitudes, and Practices Instrument, a tool created for use in obstetric settings	Online survey	√	√	√
SATISFACTION	• Usability and satisfaction survey (only e-learning groups)	Online survey		√	

Patient Level Measures

- Rates and quality of care for perinatal mental health conditions will be assessed pre- and post- via a chart abstraction using our established approach and tool to evaluate practice readiness to evaluate and address perinatal mood and anxiety disorders (Masters et al., manuscript in prep).[6] Abstraction for study purposes will be done remotely by the UMass team and thus not require practice resources. Some abstraction for QI initiative is being requested of the group randomized to the implementation assistance arm.
- 80 charts (40 at baseline, 40 at 8 months follow-up) will be abstracted by the UMass team from each practice.
- No patients are being recruited. Patient-level data will be obtained via a chart review during which no identifying information will be collected.

Medical Record Review/Chart Abstraction

- Each practice site will be asked to facilitate a medical record review/chart abstraction by providing a list of perinatal patients receiving care. The UMass team will then randomly select pregnant and postpartum patient medical charts (electronic charts) for review
- The charts will be selected proportionately from all enrolled providers at the practice
    - Pre and post-intervention, 40 charts each time will be randomly selected from all those available pregnant and postpartum patients seen in the previous 8 -12 months.
- Eligible charts will be grouped into two categories: patients with and without a positive mental health screen. We will then conduct chart abstractions to look for documentation of screening, assessment, and treatment planning for perinatal mood and anxiety disorders, ensuring that a proportion of those charts are from the patients with a positive mental health screen.
- No PHI/PII will be collected from charts. We will use our Assessment and Treatment Chart Abstraction tool as a data collection sheet via a form in REDCap.

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Benefits of Study Participation

This study aims to assist providers and practices in integrating mental health and obstetric care. Participation may help us to gain knowledge about the effectiveness of our e-learning training curriculum and implementation assistance protocol. Providers may gain knowledge from the course content, which is expressly designed to inform individuals about best practices for detecting, assessing, and treating perinatal mental health conditions. That said, the course to be developed is purely educational in nature. It is not designed or presented as a replacement for hands-on clinical, public safety, or public health training. Similarly, the implementation assistance protocol is expressly designed to help practices implement the maternal mental health patient safety bundle.

Obstetric practices and providers participating in this study will play a critical role in the development and evaluation of a novel approach to addressing perinatal mental health in obstetric practices. Should the results of this study be promising, the UMass team, NIH and ACOG will facilitate dissemination of our results, which will inform the creation of national resources for addressing mental health in obstetric settings. If found to be effective, these resources will help women, their families and children get the help they need.

We will share the results of the study when they are available.

Appreciation/Compensation

- Upon completion of the interventions, practices in each group will receive a **certificate of completion**, a thank-you letter, and an invitation to participate in other distance learning activities that might be developed.
- The **ABOG MOC** standards now allow participation in Quality Improvement Efforts to meet the annual Improvement in Medical Practice (Part IV) MOC requirement. **The e-learning activity has been approved to meet ABOG Improvement in Medical Practice requirements until 12/31/2021**. Please review the current MOC Bulletin for further information: https://www.abog.org/about-abog/bulletins. The UMass team will submit participants names to ABOG before December 10th of each year during the approval period.
- As a thank you for participation, upon completion of the 8-month follow-up provider and practice surveys, a **stipend** recognizing study efforts will be provided to the practice, in the form of a gift card in the amount of $1000.

Timeline:

Onboarding and approvals – By October 2020

Baseline data collection – By December 2020

Training and implementation – By February 2021

Follow-up data collection – Fall 2021

More Information:

For more information or questions, please contact:

Tiffany A. Moore Simas, MD, MPH, MEd
TiffanyA.MooreSimas@umassmemorial.org

Nancy Byatt, DO, MS,
MBANancy.Byatt@umassmemorial.org

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