Obstructive Sleep Apnea in Pregnancy: Early Lessons From Our Sleep Pregnancy Clinic

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ABSTRACT

Problem Considered: Obstructive sleep apnea (OSA) is underdiagnosed during pregnancy, but there is strong theoretical and some empiric evidence that treatment may improve obstetric outcomes. Barriers to screening, testing, and treatment are common during pregnancy. The goal of this described intervention was to reduce these barriers and improve detection of OSA in pregnancy.

Methods: Representatives from sleep medicine and perinatology established a cross-disciplinary, collaborative Sleep Pregnancy Clinic offering a streamlined referral process for multimodal screening, testing, and treatment of OSA during pregnancy. This is a retrospective analysis of data from the clinic's first 19 months.

Results: Between June 2017 and December 2018, 134 pregnant women were referred for OSA testing. Sixty-three (47.0%) completed objective sleep testing, and 38 (60.3%) of the women who completed testing met diagnostic criteria for OSA. This intervention resulted in a statistically significant increase in the number of diagnostic sleep apnea tests performed (average 22.4 tests per year pre-intervention, 77 per year post-intervention [$P = 0.0012$]).

Discussion and Conclusions: Despite a streamlined referral pipeline, completion rates of OSA testing in pregnant women remained below 50%. However, the overall number of women referred and who completed testing increased significantly during this time period. Of those who completed testing, the majority were diagnosed with OSA. Since starting this clinic, we have created resources to familiarize patients with the equipment and worked to reduce other barriers. Assessment of these interventions and the impact of treatment on obstetric outcomes is ongoing, as is assessment of reasons women do not complete diagnostic testing.

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INTRODUCTION

Obesity is the most common comorbid condition of pregnancy, and Obstructive sleep apnea (OSA) is a common comorbidity of obesity.[1] When OSA occurs in pregnancy, it is independently associated with increased risk of gestational hypertension, preeclampsia, gestational diabetes and, possibly, fetal growth restriction and other adverse neonatal outcomes.[2-13]

The prevalence of OSA during pregnancy is unclear, but evidence suggests it complicates 8% to 32% of pregnancies, depending on comorbidities such as obesity and gestational age at time of testing.[14-16] While the literature indicates OSA during pregnancy may be relatively frequent, it remains underdiagnosed.[3-15] There is also evidence, albeit limited, to suggest that continuous positive airway pressure (CPAP)—the first-line treatment for OSA—may have therapeutic benefit for blood pressure control in preeclampsia.[17-18]

Given that treatment may reduce the risk of adverse pregnancy outcomes—specifically preeclampsia, which has limited proven prevention options[19]—identifying OSA during pregnancy is timely and critical. Therefore, we sought to identify and reduce barriers to diagnosing OSA in pregnant patients via a multimodal approach. We aimed to increase screening using the best screening tool available for pregnant patients and to reduce barriers to referral and referral completion. Thereafter, we aspired to increase treatment initiation for those who required treatment, with an overarching goal of reducing adverse obstetric outcomes related to OSA.

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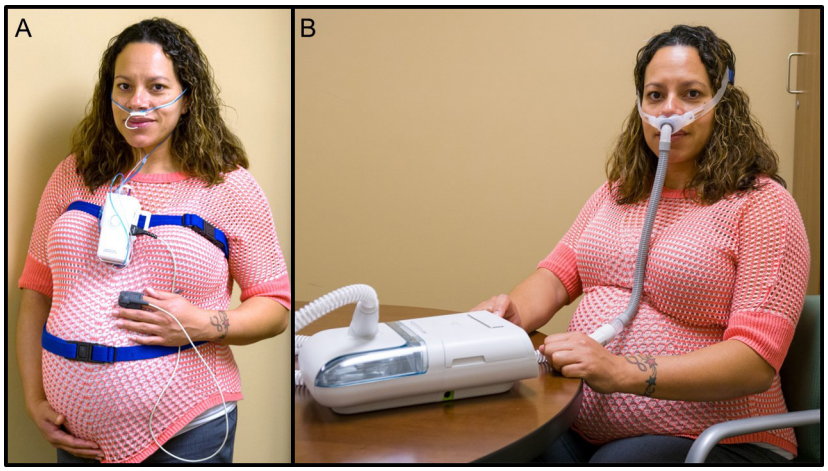
Here, we describe the interventions we undertook to increase the number of women completing indicated testing for OSA during pregnancy. We also report our findings on the characteristics of pregnant women who did versus did not complete referrals and display the general trend in completed referrals both before and after our interventions.

Figure 1. Images of a Pregnant Woman Wearing (A) Sleep Device (Alice PDX 4-channel System) and (B) Nasal Pillows Interface/Mask



Images are shown to patients during their obstetrical visit if they screen positive for possible sleep apnea, prompting a referral for testing.

Study Design/ Intervention

This project was a joint venture between the Division of Maternal-Fetal Medicine at the University of Wisconsin-Madison/ UnityPoint Health-Meriter and the Wisconsin Sleep Clinic at the University of Wisconsin-Madison (UW-Madison). The analysis described was determined consistent with quality improvement and did not meet criteria for human subject research; it was, therefore, deemed exempt from oversight by the Institutional Review Board for both UnityPoint Health-Meriter and the UW-Madison (May 2018).

Together, representatives from sleep medicine (MHB) at Wisconsin Sleep/UW-Madison and perinatology (KMA) at UW-Madison/UnityPoint Health-Meriter met with clinic managers from each site to establish a cross-disciplinary, collaborative Sleep Pregnancy Clinic. This clinic offers a streamlined referral process for multimodal screening, diagnostic testing, and treatment of OSA during pregnancy.

Simultaneously, the Department of Obstetrics and Gynecology at UW-Madison and UnityPoint Health-Meriter created task forces aimed at optimizing care of pregnant women with obesity and jointly generated clinical care guidelines based on best available evidence and national and society recommendations. Overviews of these guidelines were presented to both academic and private obstetricians and gynecologists, certified nurse midwives, and family medicine physicians at faculty meetings and perinatal summit events. Electronic and printed copies of the guidelines were disseminated at these events, and the guidelines remain with other clinical guidelines both on UnityPoint Health-Meriter's website and within the shared files utilized for direct clinical care. These guidelines also were used to generate streamlined order sets and note templates in the electronic health record (UW Healthlink Epic, Hyperspace 2018, Epic Systems Corporation, Verona, Wisconsin) to facilitate order placement. One part of these updated guidelines prompted the obstetric care provider to complete OSA screening using at least 1 published and validated tool, thus ensuring that pregnant women with at least 1 risk factor (pre-pregnancy body mass index [BMI] $\geq$30 kg/m^2) were being screened for OSA.[20-22] Screening tools utilized included the 4-variable tool by Facco and STOP-BANG for all women.[20-22] The Facco tool was published in 2012. In this model, age and BMI are summed and 15 points each are added if the woman has chronic hypertension or snores > 3 nights per week.[20] STOP-BANG, which is commonly used by anesthesia, was also included per the Sleep Clinic's intake protocol.[23] STOP-BANG is an 8-item questionnaire that assigns 1 point for each positive answer to questions about snoring, tiredness, observed apneas, hypertension, BMI >35 kg/m^2, age >50, neck size >16 inches, and male sex.[21,22] Scores of 0 to 2 are low risk for sleep apnea, with higher scores consistent with intermediate to high risk.[21,22]

On the sleep clinic end, to expedite testing, the decision was made to utilize portable 4-channel home sleep apnea testing (HSAT) equipment (Respironics Alice PDx®) currently used at Wisconsin Sleep for home diagnostics in nonpregnant patients as well, rather than in-lab polysomnography (PSG). Prolonged wait-times up to 2 to 3 months are common for PSG testing, but HSAT results are typically available the same day or within a few weeks, if insurance prior authorization is required. We also hypothesized that home testing might reduce barriers to test completion for some pregnant women who might be hesitant to spend a night away from children and family members and in the potentially intimidating and cumbersome environment of the sleep lab. Finally, there is precedent for using portable OSA diagnostic devices in pregnancy, including with the largest prospective study of OSA during pregnancy to date, the nuMoM2b sleep disordered breathing substudy.[4]

While establishing this collaborative Sleep Pregnancy Clinic, patient-facing materials were developed. Some materials addressed

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barriers to completing sleep testing reported by pregnant women. For example, many pregnant women cited concerns about bulky or cumbersome testing equipment and noisy and uncomfortable treatment choices. To address these concerns, photographs were taken of a pregnant consenting volunteer wearing both the home sleep apnea testing device and a continuous positive airway pressure (CPAP) nasal pillows interface or mask, with the CPAP machine on a table next to her for scale (Figure 1A and B). We also created a brochure listing the symptoms of OSA, its significance during pregnancy, and potential treatment benefits (Appendix).

After the aforementioned clinical guideline and patient-facing materials were generated, the typical workflow comprised of (1) screening pregnant women with a pre-pregnancy BMI ≥ 30 kg/m^2 for sleep apnea with screening questionnaires,[20-22] (2) displaying images of a pregnant woman wearing the sleep testing device and CPAP mask, (3) distributing brochures, and (4) placing referrals to the Wisconsin Sleep Clinic, wherein patients receive expedited triage per an established "pregnancy protocol" to HSAT with the Alice PDx 4-channel system (Koninklijke Philips NV, Amsterdam, Netherlands).

To maximally expedite testing and clinical evaluation in the time-sensitive period of pregnancy, significant changes were made to the typical triage for OSA referrals at Wisconsin Sleep. Specifically, whereas triage normally requires evidence of documented symptoms (eg, snoring, insomnia, and/or excessive daytime sleepiness) AND documented airway, cardiovascular, and pulmonary examination by the referring provider, pregnancy referrals were triaged to home OSA testing directly. Medical comorbidities of chronic hypertension and obesity were used as criteria for testing, akin to their use in the STOP-BANG OSA questionnaire[21,22] and Berlin Questionnaire[24] in nonpregnant populations. Both the STOP Bang and Berlin Questionnaire are short questionnaires (8 and 10 questions, respectively) that emphasize obesity and hypertension as risk factors for sleep apnea, in addition to subjective measures of sleepiness and snoring. Frequent (> 3 days per week on average), not just loud snoring was admissible as a symptom. Triage questions where in-lab PSG or clinic visit as the initial step were considered (eg, with documented morbid obesity, previous CPAP noncompliance, and presence of additional sleep disorders such as restless leg syndrome) were forwarded to 1 sleep physician (MHB) for ultimate decision. Finally, in circumstances where face-to-face clinic visits were mandated (for patients with Medicare insurance), such visits were expedited by MHB.

Referrals for the analysis period were tracked via entry into a clinical database created to track sleep testing referrals and results. Data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at the UW-Madison School of Medicine and Public Health.[25] REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources.

For the purpose of this analysis, OSA was defined as a respiratory effort index (REI) with portable HSAT (the vast majority of cases) or, in the case of in-lab PSG testing, apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) >5 events/hour.[26] Both 3% and 4% desaturation criteria were used, as Wisconsin Sleep uses 4% desaturation criteria as default, but sleep physicians can interpret studies using the American Academy of Sleep Medicine's (AASM) 3% desaturation criteria per their discretion. REI, AHI, or RDI of 5 to 15 per hour were classified as mild, 15 to 30 per hour as moderate, and > 30 events per hour as severe, as is standard practice.[27] These severity designations remain widely used in research and clinical practice, with predetermined symptoms or medical comorbidities required for insurance coverage for CPAP therapy for OSA in the mild category. We offered CPAP therapy to all pregnant women with studies demonstrating AHI/RDI or REI > 5 events per hour. In the majority of cases, there were both symptoms and comorbidities that justified CPAP therapy in the "mild" OSA category. In the 3 instances where insurance denied coverage, MHB initiated appeals to the home care company/insurance.

Relevant interventions include development of the clinic and rigorous referral tracking starting in June 2017, the use of photographs to show HSAT and treatment CPAP equipment being worn by a pregnant woman starting in September 2017, and implementation of the standardized obesity order sets, prompting the use of sleep apnea screening questionnaires in September 2018.

Descriptions of barriers encountered were as reported to sleep clinic scheduling personnel and were ascertained pragmatically and for clinical purposes.

We conducted 2 analyses. First, we analyzed demographic variables associated with sleep apnea study completion for women referred between June 2017 and December 2018. Demographic variables of women who did and who did not complete sleep studies were analyzed using Pearson's chi-square test and Student *t* test as appropriate. Second, we analyzed whether our rate of referral completion (determined by sleep test completion) or the number of sleep apnea tests in pregnant women increased prior to or after our interventions. This was accomplished via query of the electronic health record (UW Healthlink Epic, Hyperspace 2018, Epic Systems Corporation, Verona, Wisconsin) for the number of referrals and completed clinic visits. Data for this analysis were analyzed by 12-month interval from January 2012 through October 2019. All statistical analyses were performed utilizing

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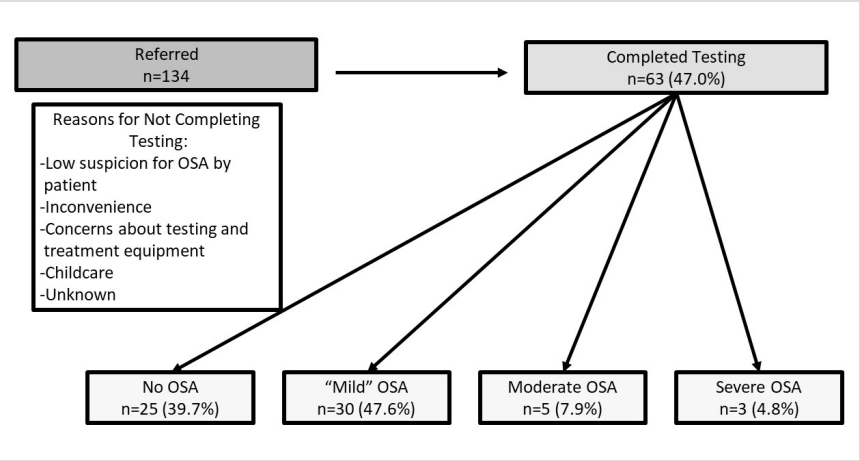
Excel (Microsoft Excel, 2013, Redmond, Washington) and STATA 16.0 (StataCorp, 2017, College Station, Texas).

RESULTS

Between June 2017 and December 2018, 134 pregnant women were referred for OSA testing. Sixty-three (47.0%) completed objective sleep testing (Figure 2). Of those who completed testing, 38 (60.3%) met diagnostic criteria for OSA. Thirty (78.9%) had "mild," 5 (13.2%) had "moderate," and 3 (7.9%) had "severe" OSA. Women who did not complete objective sleep testing cited low suspicion for OSA, inconvenience, and concerns about the testing and treatment equipment.

Figure 2. Obstructive Sleep Apnea Testing Referrals and Results



Of 134 Women Referred for Sleep Testing, 63 (47.0) Completed Testing. Of those who completed testing, 60.3% met criteria for obstructive sleep apnea.

The Table shows the demographic and maternal characteristics of pregnant women who did or did not complete sleep testing. Those who did not complete sleep testing were less likely to be married and more likely to have a diagnosis of hypothyroidism. There was a nonstatistically significant trend toward lower testing completion for referrals that occurred later in pregnancy.

When assessing whether the total number of sleep clinic visits by pregnant women changed over time, the average number of annual referrals pre-intervention was 44.4 per year (SD 3.8), rising to an average of 139.7 referrals per year (SD 34.9) post-intervention, a statistically significant increase ($P<0.001$). This intervention also resulted in a statistically significant increase in sleep tests performed (average 22.4 tests per year [SD 5.3] pre-intervention and 67 [SD 16.6] post-intervention [$P=0.0012$]). However, the sleep study completion rate (as a percent of completed tests per referral) did not improve, as referral completion was 50.3% (SD 10.2%) pre-intervention and 48.0% (SD 2.4%) post-intervention ($P=0.718$). (See Figure 3.)

Table. Maternal Characteristics by Sleep Test Completion

	Sleep Test Not Completed N=71*	Sleep Test Completed N=63[a]	*P* value
Age, years, mean (SD)	32.8 (5.0)	34.3 (5.6)	0.106
Age, years by group, n (%)			
18-34	48 (67.6)	35 (55.6)	
≥35	23 (32.4)	28 (44.4)	0.152
Race/ethnicity, n (%)			
White	50 (74.6)	50 (79.4)	
Black or African American	10 (14.9)	5 (7.9)	
Hispanic	2 (3.0)	3 (4.8)	
Asian	2 (3.0)	2 (3.17)	
Other or not reported	3 (4.5)	3 (4.8)	0.782
Marital status, n (%)			
Single	8 (14.3)	3 (5.17)	
Married or committed	15 (26.8)	38 (65.5)	
Divorced or separated	2 (3.6)	0 (0.0)	
Unknown	31 (55.4)	17 (29.3)	<0.001
Parity	1.2 (1.5)	0.9 (1.2)	0.176
Trimester at time of referral			
First trimester	27 (40.3)	33 (54.1)	
Second trimester	26 (38.8)	24 (39.3)	
Third trimester	14 (20.9)	4 (6.6)	0.051
BMI, kg/m^2, mean (SD)	42.2 (8.7)	40.4 (8.7)	0.256
BMI, kg/m^2, by group, n (%)			
<30	5 (7.9)	5 (8.0)	
30-39.99	22 (34.9)	23 (37.1)	
≥40	36 (57.1)	34 (54.8)	0.965
Medical comorbidities (n,%)			
Hypertension	27 (39.1)	20 (31.8)	0.376
Pregestational diabetes	13 (18.3)	8 (12.7)	0.372
Hypothyroidism	4 (6.0)	19 (31.2)	<0.001
Smoking	28 (41.8)	17 (27.4)	0.087
Excess gestational weight gain (n,%)	18 (26.9)	26 (41.3)	0.083

[a] Some electronic health records lacked data

DISCUSSION AND CONCLUSIONS

We describe in replicate detail the steps our clinics undertook to increase indicated testing for OSA during pregnancy. While completion rates of referrals—ie, referrals resulting in completion of sleep apnea testing—did not change, the overall number of pregnant women referred and tested for OSA increased significantly, both statistically and clinically. This increase occurred following the creation of a standardized protocol and order set for managing pregnant women with obesity inclusive of sleep apnea screening (as described above) and a streamlined referral process for objective sleep apnea testing. Of women who completed testing, the majority met diagnostic criteria for OSA, with flexible use of both 4% and 3% desaturation criteria. This underlines the high prevalence of sleep-disordered breathing in

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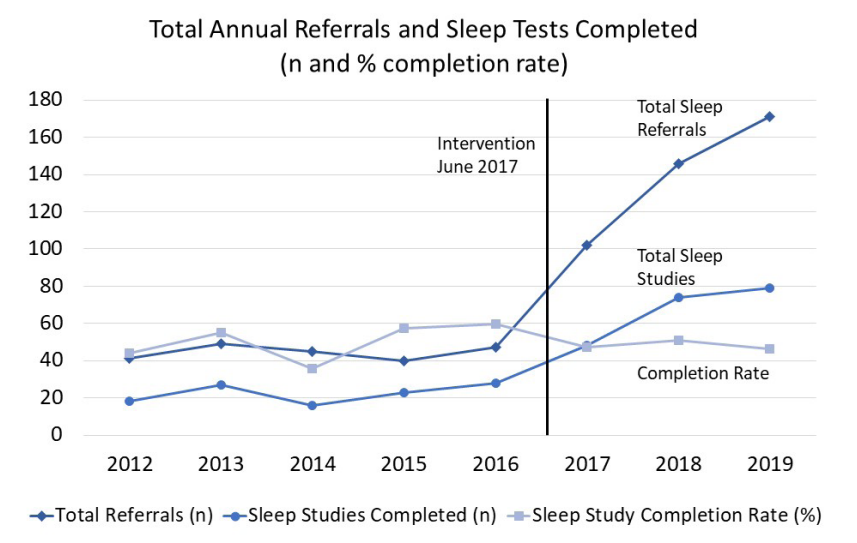
pregnancies complicated by obesity, and the importance of considering and pursuing evaluation of OSA in pregnancy. However, the percentage of women who tested positive cannot be extrapolated to the nontested population because there is likely ascertainment bias.

While the majority of pregnant women with OSA had "mild" sleep apnea, over 20% had "moderate or severe" sleep apnea. The classification of sleep apnea severity based on the number of respiratory events per hour (mild for AHI/RDI or REI 5 to 15/hr and moderate to severe for >15/hr) was formally adopted in 1999 and is based exclusively on PSG data, with scoring of respiratory events incorporating arousals, in addition to desaturations, to arrive at the AHI/RDI. Thus, designations of "mild" versus "moderate to severe" apnea severity remain empiric, have not been adjusted to reflect revised scoring criteria and 4-channel portable testing, and are unlikely to accurately define pathophysiological and clinical consequences of the unique physiology of OSA in pregnancy. In addition, use of 3% versus 4% desaturation criteria can easily change the diagnosis from snoring to OSA or move a diagnostic test from the mild to the moderate to severe category.[28] These limitations remain a challenge in the field of sleep medicine in general and are beyond the scope of this publication, outside of advocating for the use of less restrictive and likely more physiologically relevant 3% diagnostic criteria in the evaluation of OSA in pregnancy.

Figure 3. Referrals and Sleep Studies Completed by Pregnant Women at the Wisconsin Sleep Center From January 2012 Through October 2019.



There was a statistically significant increase in the number of referrals and completed studies performed on pregnant women after the intervention (average 22.4 tests per year before [SD 5.3] and 67 [SD 16.6] after the intervention [$P = 0.0012$]).

Women who did and did not complete testing had demographic differences that we will use to inform our ongoing efforts to increase diagnostic testing. Women who did not complete recommended sleep testing were less likely to be married and may be concerned that a sleep test would require them to be away from home, which would pose challenges if there are additional children in the family that require care. Thus, assuaging these concerns will be a priority for future interventions; the sleep test used in our clinic is a home test, and we will emphasize that. We are also working to determine best ways of distributing the PSAT devices to women at their obstetric clinic rather than requiring a trip to the sleep clinic to pick up the equipment, as the sleep clinic may not be near their home or work. Recommended sleep testing completion was also higher among women with hypothyroid disease, which may reflect worsened symptoms of fatigue. We also noted that testing completion was (nonstatistically) lowest in advanced pregnancy and, therefore, suggest screening in early to mid-pregnancy. This would also allow any indicated treatment to commence—and potentially have an effect—earlier in the pregnancy.

When OSA is diagnosed, systematic reviews and meta-analyses have demonstrated increased risk of adverse pregnancy outcomes.[2-4,6-12] Assessment of the impact of OSA on obstetric outcomes in our population is ongoing, as is assessment of whether treatment is beneficial. Here we demonstrate that while the overall referral completion rate was low, of the women who completed testing, over half were diagnosed with OSA, and treatment was recommended. CPAP remains first-line therapy for OSA.[3] While large trials of CPAP tolerance and efficacy in pregnancy are lacking, the findings of small studies suggest that treatment may improve obstetric outcomes with regards to preeclampsia.[17,18]

Strengths of this study include the detailed review of the sleep testing results and treatment plan to ensure that all women with sleep apnea were accurately diagnosed and evaluated in sleep clinic and treatment was initiated expeditiously.

Limitations include the use of the electronic health record (EHR) to extract referrals retrospectively. The EHR occasionally lacks diagnostic codes for pregnancy, particularly for women whose prenatal care is not within the same health care system or EHR as the system where the sleep test occurs. This would be expected to reduce the capture of pregnant women seen at the sleep clinic. To account for this source of bias, our analyses of referral completion and sleep clinic visits utilized data exclusively from the electronic health record query and did not include data from our clinical database, as this would introduce understandable ascertainment bias. Retrospective analysis occasionally also lacks

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relevant clinical information. Some referrals lacked demographic characteristics as seen in the Table. Another important limitation is the performance of sleep apnea screening questionnaires during pregnancy. Most screening tools used for the nonpregnant population perform poorly during pregnancy, including the Berlin and STOP-BANG questionnaires and the Epworth Sleepiness Scale, although each have some useful components.[14,23,29,30] We opted for Facco's 4-variable tool, which had the highest accuracy for predicting sleep apnea in pregnancy at the time our intervention was designed, although more recently, it has been demonstrated to have poor specificity among women with BMI ≥ 40 kg/m^2.[20,30] Our assessment of reported barriers was obtained by the sleep clinic schedulers and was limited by ascertainment bias due to the retrospective approach.

Future analyses of our clinical database will focus on assessing obstetric outcomes associated with sleep apnea diagnosis in this population, evaluating the currently utilized sleep screening tools, and measuring the impact of treatment on established obstetric outcomes. We will also plan a patient-focused exploration of the barriers to OSA testing via systematically performed interviews of recently delivered postpartum and will study the percentage of tests performed that yielded positive results before and after the intervention. Our intention with this manuscript is to demonstrate 1 feasible workflow to allow other clinics to emulate this model, improve the number of women referred and screened for OSA during pregnancy and, hopefully, reduce adverse obstetric events associated with OSA.

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Appendix: Available online at www.wmjonline.org.

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