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Comparative effectiveness of medical and surgical treatment options for racial/ethnic minority adults with obstructive sleep apnea

Report*

* This report is an update from the April 2013 topic brief developed for PCORI by the Duke Clinical Research Institute.
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**Topic:** Obstructive Sleep Apnea

**Overall Comparative Research Question:** What is the comparative effectiveness of medical and surgical treatment options for racial/ethnic minority adults with obstructive sleep apnea?

1. **Contributors**

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2. **Introduction**

The most common type of sleep apnea is obstructive sleep apnea (OSA). During sleep, individuals with OSA have repeated episodes where their upper airway collapses and becomes obstructed. This results in reduced breathing (hypopnea) or complete stoppage of breathing (apnea). When breathing stops, oxygen levels drop, causing patients to wake repeatedly through the night. Over time, poor sleep quality and chronic dropping of oxygen levels lead to many problems including daytime sleepiness and negative effects on quality of life. Additionally, OSA is associated with other conditions such as obesity, high blood pressure, and diabetes.

Screening to identify undiagnosed OSA followed by appropriate treatment has the potential to prevent adverse health outcomes. Potential screening strategies include formal questionnaires and clinical prediction tools that result in various combinations of subjective and objective findings. For people who screen positive for OSA, a diagnostic test would be used to confirm. However, most primary care clinicians do not routinely screen for OSA, and most patients do not discuss their sleep-related symptoms with their primary care clinician. This may contribute to the fact that OSA is widely underdiagnosed, especially in racial/ethnic minority populations. Guidelines provide differing recommendations regarding screening for OSA. For example, the American Academy of Sleep Medicine (AASM) (2009) Guidelines recommend including questions about OSA in routine health maintenance evaluations, while others recommend screening only when there is a presence of OSA symptoms.

Diagnostic testing to confirm OSA should be performed on patients with typical symptoms of OSA, particularly snoring and daytime sleepiness. There are two main strategies for diagnosing OSA:

- **Polysomnography (PSG)** - Considered the most accurate way to diagnose OSA, patients sleep in a special lab with comprehensive brain, breathing, heart monitoring and observation by a technologist.
- **Portable monitors (PM)** - Smaller monitors collect data similar to PSG; however the device can be used at home.

Polysomnography and portable monitors measure or estimate the apnea–hypopnea index (AHI), a measure of the number of apnea or hypopnea events per hour during sleep. The American College of Physicians (ACP) and AASM guidelines recommend polysomnography (PSG) for diagnostic testing in patients suspected of OSA and recommend PMs as an alternative in patients without serious comorbidities when PSG is not available.

Continuous positive airway pressure (CPAP) treatment is as initial therapy for patients diagnosed with OSA. CPAP machines improve the airway obstruction that causes OSA by delivering compressed air into the airway (via a nasal or oral mask) to hold it open. CPAP has been shown to improve Epworth Sleepiness Scale (ESS) scores, reduce AHI and arousal index scores, and increase oxygen
Patient adherence to CPAP is low, approximately 50%, due to trouble tolerating the device, finding the CPAP mask to be uncomfortable, and considering the treatment burdensome.\textsuperscript{7,8} Alternatives to CPAP include mandibular advancement devices (MADs), surgery, and weight loss. MADs are fitted by a dentist and worn overnight in the mouth to hold the airway open and prevent collapse. MADs have moderate effectiveness, but lower than with CPAP, and they are recommended for those with adverse effects associated with CPAP treatment.\textsuperscript{1,7} Surgery can be performed to open up/widen the airway. The most common procedure is uvulopalatopharyngoplasty, in which the soft tissue at the back, tonsils, and adenoids are removed. Surgery is generally only performed in cases where CPAP or oral devices have not worked. Since obesity is a common underlying cause for OSA, weight loss can be effective in reducing symptoms.\textsuperscript{5} Other less used treatments for OSA may include devices that hold the head/neck in a certain position, as well as pharmacotherapy; however, these treatments have not proven efficacious in research and are less-frequently recommended.\textsuperscript{3}

3. Patient-Centeredness

There are many barriers to providing and receiving care for OSA, such as long wait times for testing, high cost of sleep studies, frequent frustration with standard treatment (i.e., CPAP), and dissatisfaction with sleep specialists’ care of patients after diagnostic tests have been performed.\textsuperscript{9} Many symptoms that patients experience, oftentimes noticed first by the patient’s spouse, include: daytime sleepiness, snoring frequent awakening during the night, awakening with a choking or smothering sensation, dry mouth, sore throat, or chest pain irritability, difficulty concentrating or mental fogging, memory problems, morning headaches, decreased sex drive, depression, and/or body aches.\textsuperscript{2,5}

4. Impact (Burden) of the Condition

While the all-inclusive prevalence of OSA remains unknown due to the high rates of asymptomatic and symptomatic individuals who remain undiagnosed and untreated, the American Academy of Sleep Medicine estimates that at least 25 million adults have the condition. Sleep disorders disproportionately affect minority populations. In one study that compared 225 black and 622 white volunteers, 31% of blacks versus 10% of whites had sleep apnea.\textsuperscript{10} Another recent study documented a higher prevalence of sleep disorders in blacks, Hispanics and Asians compared to Caucasians. Compared to whites, the study found that blacks were almost twice as likely to have sleep apnea syndrome and daytime sleepiness. Additionally, blacks, Hispanics, and Asians were almost two to five times more likely to demonstrate shorter sleep duration compared to Caucasians.\textsuperscript{11} These symptoms are all linked to OSA. Minorities were also less likely to be formally diagnosed, and the increased severity of disease at diagnosis among African Americans suggests a delay in diagnosis.\textsuperscript{4,11}

Disparities in OSA treatment have also been identified, and treatment outcomes are also suboptimal among African Americans.\textsuperscript{12} Among adults, black race and lower socioeconomic residential areas are associated with poorer adherence to CPAP. In a study published in 2011, they found that on average black subjects used CPAP 92 minutes less than white subjects. The lowest quartile ZIP code socioeconomic status score was not found to be significant as a predictor of CPAP adherence, but it did impact the association of race and CPAP use.\textsuperscript{13}

OSA has been associated with a range of adverse health outcomes including hypertension, diabetes, and obesity, all of which are disproportionately more prevalent among racial/ethnic minority groups.\textsuperscript{14}
In addition, bidirectional associations between OSA and the following conditions have been reported: cardiovascular events, coronary heart disease, heart failure, angina, atrial fibrillation, stroke and metabolic syndrome.\(^3\) Other adverse clinical outcomes of untreated OSA that have been reported in various studies include: increase risk of motor vehicle and other accidents, cognitive impairment, lost work days, daytime sleepiness, work disability, impaired work performance, decreased quality of life and mortality.\(^3\)

5. **Evidence Gaps**

We identified evidence gaps in screening, diagnosing, and treating OSA. Evidence gaps were identified primarily through a review of national guidelines (n=2), a comparative effectiveness review (n=1), an evidence synthesis (n=1), and future needs assessments (n=2). We excluded information on preoperative screening for OSA, as this is out of scope.

5.1 **Screening for Obstructive Sleep Apnea in Adults: An Evidence Review for the U.S. Preventive Services Task Force: Prepared for AHRQ. Evidence Synthesis No. 146\(^2\)**

In 2016, AHRQ published this evidence synthesis on screening for OSA in adults. The evidence synthesis published by AHRQ names the future research needs in OSA. These include:

- Randomized trials of asymptomatic people that directly compare screening with no screening and assess health outcomes to better understand the potential effectiveness of screening for OSA.
- Studies to determine the accuracy of screening questionnaires and clinical prediction tools when used in the general population.
- More studies that assess the reliability of portable monitors for home use.
- Trials that evaluate whether CPAP and other common treatments improve health outcomes (except for sleep-related quality of life).
- Studies that determine whether findings differ for subgroups defined by sex, age, body mass index, or OSA severity.

5.2 **Diagnosis of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline from the American College of Physicians\(^6\)**

The American College of Physicians (ACP) developed this guideline in 2014 to present the evidence and provide clinical recommendations on the diagnosis of sleep apnea in adults. The guideline identified the several areas where there is insufficient evidence.

**Screening/Diagnosis**

- **Phased Testing for OSA** - The current evidence from one low-quality study was insufficient to draw conclusions about phased testing compared with full PSG testing for diagnosis of OSA.
- **Assessment in Patients With Comorbid Conditions** - The utility of portable monitors for diagnosing OSA in patients with comorbid conditions, such as chronic lung disease, congestive heart failure, or neurologic disorders, is unknown because few studies included these patients.

5.3 **Management of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline from the American College of Physicians\(^7\)**
The American College of Physicians (ACP) 2013 guideline presents the evidence and provide clinical recommendations on the management of OSA in adults. These guidelines primarily focused on the comparative effectiveness of OSA treatments and identified the following gaps in evidence.

Treatment

- **Weight loss vs. control** - Three trials (one high- and two moderate-quality) found reductions in apnea-hypopnea index scores with intensive weight-loss programs
- **Continuous Positive Airway Pressure (CPAP)** - The guidelines reviewed various studies comparing different continuous positive airway pressure (CPAP) devices and methods including:
  - **CPAPflex vs. fixed CPAP** - CPAPflex (C-Flex™) is a proprietary technology that slightly reduces the pressure at the beginning of exhalation. In four studies (two low- and two moderate-quality) these CPAP devices showed no significant difference for adherence, AHI score, minimum oxygen saturation, arousals, sleep stages, or quality of life.
  - **Oral CPAP vs. nasal CPAP** - Three small trials (one moderate- and two low quality) had inconsistent results and generally imprecise effect estimates. One study found increased adherence to nasal CPAP treatment; two studies found no significant difference.
  - **Bilevel CPAP vs. fixed CPAP** - Bilevel CPAP devices are designed to alleviate the difficulty and discomfort of exhaling against the fixed pressure of the CPAP by delivering lower pressure during exhalation rather than during inhalation. Five small, heterogeneous trials (one moderate- and four low-quality) showed mostly null findings for efficacy and no difference for adherence.
  - **Flexible bilevel CPAP vs. fixed CPAP** - Flexible bilevel CPAP delivers reduced positive airway pressure at the end of inspiration and beginning of expiration, which is determined partly by the user’s respiration. One moderate-quality study showed that more patients used flexible bilevel CPAP devices for >4 hours per night (49% vs. 28%; \(P=0.03\)) and for more hours per night (3.7 vs. 2.9 h/high; \(P=0.05\)) compared with fixed CPAP devices.
  - **CPAP with or without humidification** - Five small, heterogeneous studies (three moderate- and two low-quality) reported inconsistent results in improved adherence.
- **Pharmacotherapy**
  - **Drug therapy vs. control** - Seven trials (one low-, five moderate-, and one high-quality) assessed a different drug as treatment for OSA. Many drugs showed adverse effects. Evidence to show that drug therapy is superior to control treatment of OSA was insufficient.
- **Surgery** - The guidelines reviewed many studies that compared surgery to alternative treatments including CPAP and MADs.
  - **Surgery vs. control** - Seven studies were reviewed that compared surgery to a control group. Each assessed a different types of surgery and results were inconsistent.
  - **Surgery vs. CPAP** - Twelve studies (one high- and 11 low-quality) compared surgery to CPAP as treatment for OSA. Evidence was insufficient to show that the five studied surgical interventions were more effective than CPAP to treat OSA.
  - **Surgery vs. MADs** - One moderate-quality study was available, which found that MADs improved AHI compared with uvulopalatopharyngoplasty.
5.4 Future Research Needs for Diagnosis of Obstructive Sleep Apnea. Prepared for AHRQ. Future Research Needs Paper: No. 11

To determine research priorities in diagnosis of OSA, the authors engaged 17 panel members representing patients and the public, providers, purchasers of health care, payers, policymakers and PIs (2012). High Priority research needs include:

- Age- and gender-specific criteria for defining OSA syndrome.
- Value of having a sleep medicine specialist involved in the diagnosis of OSA (in addition to or instead of a nonspecialist).
- The prognostic accuracy of clinical prediction rules (CPRs) to predict clinical outcomes.


To determine research priorities in treatment of OSA, the authors engaged 88 panel members representing patients and the public, providers, purchasers of health care, payers, policymakers and PIs (2012). High Priority research needs include:

- What is the impact of treatment of sleep-disordered breathing on major long-term clinical outcomes, including mortality, CVD and diabetes?
  - What are the long-term outcomes of MAD treatment?
- Comparative studies of different sleep apnea treatments based on patient characteristics
- Trials to improve compliance with CPAP, MAD and other treatments, particularly evaluating cognitive therapy approaches
- The association between sleep apnea severity and long-term clinical outcomes

5.6 Diagnosis and Treatment of Obstructive Sleep Apnea in Adults; Comparative Effectiveness Review No. 32. AHRQ

AHRQ published a comparative effectiveness review on OSA in 2011. This evidence review identified areas with low or insufficient evidence.

Screening

- *Questionnaires vs. PSG* - There were six studies that compared six questionnaires with PSG to diagnose OSA. Based on these studies, the strength of evidence is low that the Berlin Questionnaire is moderately accurate to screen for OSA. The strength of evidence is insufficient to evaluate the other questionnaires, but one study found that STOP-Bang questionnaire may have high enough sensitivity to accurately screen for OSA.

- *Clinical Prediction rules vs. PSG* - There were seven studies that compared ten validated clinical prediction rules to PSG. A single morphometric model and a model that included a pulmonary function test data had near perfect discrimination or sensitivity (100%), but neither was independently validated. The other clinical prediction rules had variable accuracy for predicting OSA. Therefore, the strength of evidence is low that some clinical prediction rules may be useful in the prediction of a diagnosis of OSA.

Diagnosis

- *Type II Portable monitoring (PM) vs. Polysomnography (PSG)* - Type II PMs are portable but record the same information as facility-based monitors (PSGs). There are no recent studies that have
compared Type II PMs to PSG. Thus, the strength of evidence is low that Type II monitors can accurately diagnose OSA.

- **Phased testing** - A single study partially addressed the value of phased testing, but had substantial verification bias due to implementation of the phased testing. The strength of evidence is insufficient to determine utility of phased testing.

**Treatment**

- **C-Flex vs. CPAP** - As previously mentioned as an evidence gap in the ACP guidelines, four studies were reviewed comparing C-Flex™ to fixed CPAP. No statistically significant differences were found for compliance, sleep study measures or other tested outcomes.

- **Treatments to improve compliance** - There were 18 trials evaluating interventions to improve CPAP compliance. These studies are mostly applicable to patients with an AHI greater than 30 events/hr and with a BMI greater than 30kg/m². Nine studies viewed education or extra support, three studied telemonitoring, two evaluated hypnotic zolpidem and nasal pillows, three evaluated nursing care models and one used cognitive behavioral therapy. The findings provided low evidence that some interventions may improve CPAP compliance and no general type of intervention was more promising than the others.

- **OSA treatments surgery** - The evidence review compared OSA surgery to other treatments including: MADs, a control group, and CPAP. The review concluded that the strength of evidence is insufficient to determine the relative merits of surgical treatments versus MADs, to evaluate the relative efficacy of surgical interventions for the treatment of OSA, and to determine the relative merits of surgical treatments versus CPAP.

- **OSA treatment oral devices vs. each other** - There were five trials comparing different oral devices. Three compared different MADs; two compared different tongue devices. The studies found no differences among devices in sleep study or other measures. Only one study evaluated compliance and found no difference.

**6. Guidelines**

Table 1 lists professional health organizations that offer guidelines screening, diagnosis, and treatment of OSA. In general, these guidelines recommend the use of comprehensive sleep evaluations to diagnosis OSA and CPAP as the initial therapy for treatment.

**Table 1. Guidelines for Screening/Diagnosis/Treatment of OSA**

<table>
<thead>
<tr>
<th>Organization, Year</th>
<th>Diagnosis/Screening or Treatment</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Physicians (ACP) (2014)</td>
<td>Diagnosis</td>
<td>A sleep study should be done for patients with unexplained daytime sleepiness (weak recommendation; low quality evidence)</td>
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<tr>
<td></td>
<td></td>
<td>Polysomnography (PSG) should be conducted for diagnostic testing in patients suspected of OSA. (weak recommendation; moderate-quality evidence)</td>
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<tr>
<td></td>
<td></td>
<td>Portable monitors can be used in patients without serious comorbidities as an alternative to PSG when PSG is not available for diagnostic testing. (weak recommendation; moderate-quality evidence)</td>
</tr>
<tr>
<td>American College of Physicians (ACP) 2013</td>
<td>Treatment</td>
<td>All overweight and obese patients diagnosed with OSA should be encouraged to lose weight (strong recommendation; low quality evidence)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CPAP treatment as initial therapy for patients diagnosed with OSA. (strong recommendation; moderate-quality evidence)</td>
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</tbody>
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Mandibular advancement devices as an alternative therapy to CPAP treatment for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse effects associated with CPAP treatment (weak recommendation; low-quality evidence)

**American Academy of Sleep Medicine (AASM) (2009)**

**Screening/ Diagnosis**
Routine health maintenance evaluations should include questions about OSA (e.g., history of snoring and daytime sleepiness), as well as an evaluation for the presence of obesity, retrognathia, and hypertension. Positive findings should trigger a comprehensive sleep evaluation.

The diagnostic strategy includes a sleep-oriented history and physical examination, objective testing, and education of the patient. The presence or absence and severity of OSA must be determined before initiating treatment to identify those patients at risk of developing the complications of sleep apnea, guide selection of appropriate treatment, and provide a baseline to establish the effectiveness of subsequent treatment.

**Treatment**
Once the diagnosis is established, the patient should be included in deciding an appropriate treatment strategy that may include CPAP devices, oral appliances, behavioral treatments, surgery and adjunctive treatments. OSA should be approached as a chronic disease requiring long-term, multidisciplinary management.

**Institute for Clinical Systems Improvement (ICSI) (2008)**

**Screening**
 Appropriately sensitive overnight oximetry (when combined with history and physical) can be a useful tool in screening patients with a high pretest probability of OSA and excluding patients with a low pretest probability of OSA. (Conclusion Grade II)

Unattended sleep studies can be valuable tools in the diagnosis of OSA, providing an accurate and reliable AHI in patients with a high pretest probability, but they carry the following limitations: absence of trained technician means no one can enlist patient cooperation, they cannot make continuous patient observations, they cannot intervene for the medically unstable patient and they cannot provide therapeutic intervention (i.e., CPAP, oxygen, supine positioning, resuscitation). (Conclusion Grade III)

PSG = polysomnography; OSA = obstructive sleep apnea; CPAP = continuous positive airway pressure

### 7. Ongoing Research

#### 7.1 Current Obstructive Sleep Apnea Trials on ClinicalTrials.gov

As of October 2016, there are currently 3 ongoing studies in the US listed on ClinicalTrials.gov using the search terms “Obstructive Sleep Apnea,” “Race,” “Ethnicity,” and “Minority.” Please see Table 2.

- Almost all studies currently taking place are RCTs (n=2) or a Non-randomized trial (n=1).
- Two studies are studying behavioral interventions through education to improve:
  - Adherence to recommended OSA evaluation and treatment
  - Sleep Hygiene Index
- One study is looking to find the hypertension response to CPAP in blacks vs. their white counterparts

<table>
<thead>
<tr>
<th>Study (Clinical Trial Identifier)</th>
<th>Funding Agency</th>
<th>Location</th>
<th>Population; Sample Size</th>
<th>Investigations</th>
<th>Outcomes; Duration</th>
<th>Status as of 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer-Enhanced Education to Reduce Sleep Ethnic Disparities (PEERS-ED) (NCT02427815)</td>
<td>Dr. Girardin Jean-Louis, New York University Langone Medical Center</td>
<td>NY, NY, USA</td>
<td>18-90 years ago, men and women, OSA, black; 398</td>
<td>RCT of Health education/social support from a Peer Health Educator versus Control</td>
<td>Number of participants to complete a home study; 0-12 months</td>
<td>Recruiting</td>
</tr>
</tbody>
</table>

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8
Two other studies have been completed that focus on obstructive sleep apnea and minority populations and are listed below (Table 3).

<table>
<thead>
<tr>
<th>Study (Clinical Trial Identifier)</th>
<th>Funding Agency</th>
<th>Location</th>
<th>Population; Sample Size</th>
<th>Investigations</th>
<th>Outcomes; Duration</th>
<th>Status as of 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparative Effectiveness Research to Enhance Outcomes in African Americans with Obstructive Sleep Apnea (NCT01997723)</td>
<td>University of Illinois at Chicago</td>
<td>Chicago, IL, USA</td>
<td>18 years or older, men and women, African American; 75</td>
<td>RCT comparing the validity of a comprehensive and current PM technology to standard in-laboratory full PSG.</td>
<td>Apnea Hypopnea Index (AHI);</td>
<td>Completed, Has Results (2013)</td>
</tr>
<tr>
<td>A Pilot Study of CPAP Adherence Promotion by Peer Buddies with Sleep Apnea (CPAPPs)</td>
<td>VA Office of Research and Development</td>
<td>Tuscon, Arizona, USA</td>
<td>21 to 85 years, men and women; 60</td>
<td>Randomized Pilot Study comparing peer-driven education and support to usual care</td>
<td>Functional Outcomes of Sleep Questionnaire, CPAP Adherence; 3 months</td>
<td>Completed (2012)</td>
</tr>
</tbody>
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7.2 Currently funded sleep apnea studies at PCORI

PCORI is currently funding a number of research and engagement awards that address sleep apnea.

Two Broad Funding Announcement Awards

- **Comparison of Sleep Apnea Assessment Strategies to Maximize TBI Rehabilitation Participation and Outcome**
- **Peer-Driven Interventions as an Alternative Model of Care Delivery and Coordination for Sleep Apnea**

Two Patient-Powered Networks within PCORnet
• Sleep Apnea Patient Centered Outcomes Network (SAPCON)
• Monitoring and Peer Support to Improve Treatment Adherence and Outcomes in Patients with Overlap Chronic Obstructive Pulmonary Disease and Sleep Apnea via a Large PCORnet Collaboration

Two Engagement Awards

• Using Social Media to Develop and Maintain Patient and Stakeholder Relationships in the Sleep Community
• Strategically Leverage Engage and Empower PCOR in Sleep

8. Likelihood of Implementation of Research Results in Practice

Currently, there are many uncertainties in clinical decision making as it relates to OSA and racial/ethnic minorities. There are few comparative effectiveness research studies on screening, diagnosis, and treatment for racial/ethnic minorities or on effective strategies for tailoring care to improve outcomes. Appropriately designed research would have a high likelihood of answering critical gaps, supporting provider–patient medical decision making, and improving outcomes for racial/ethnic minorities.

9. Durability of Information

Well-designed comparative effectiveness research studies are needed that include active comparators, large sample sizes of racial/ethnic minorities, and patient-centered outcomes.

10. Potential Research Questions

The evidence gaps identified by our review (section 5) are not adequately addressed by ongoing research. We highlight comparative effectiveness research areas in which PCORI can offer funding opportunities for impactful research on OSA in racial/ethnic minorities.

• What is the comparative effectiveness of strategies for screening and diagnosing OSA in racial/ethnic minorities?
• What is the comparative effectiveness of different available strategies (e.g., CPAP, MADs, surgeries, weight loss strategies) for OSA treatment on patient-centered outcomes, as well as short-, intermediate-, and long-term clinical outcomes for racial/ethnic minorities?
• What is the comparative effectiveness of strategies to improve adherence to OSA treatment for racial/ethnic minorities?

11. Conclusion

OSA is a common clinical problem with rising prevalence. Additionally, racial/ethnic minorities have a higher prevalence of the condition, inadequate treatment outcomes, and adverse health outcomes associated with hypertension, diabetes, and obesity. Future comparative effectiveness research in OSA may fill evidence gaps by focusing on strategies for screening and diagnosing, strategies for addressing barriers to treatment, patient-centered outcomes. This focus could reduce disparities in OSA for racial/ethnic minorities.
REFERENCES

1. What is Sleep Apnea? [Internet]. 2012;Available from: http://www.nhlbi.nih.gov/health/healthtopics/topics/sleeppapnea/#


