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Improving the Adherence of Providers to the American Academy of Sleep Medicine Guidelines for the Evaluation, Treatment, and Management of Obstructive Sleep

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IMPROVING THE ADHERENCE OF PROVIDERS TO THE AMERICAN ACADEMY OF
SLEEP MEDICINE GUIDELINES FOR THE EVALUATION, TREATMENT, AND
MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA IN ADULTS

by

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ABSTRACT

The purpose of this project is to increase the adherence of clinic providers to the American Academy of Sleep Medicine's Clinical Guidelines for the Evaluation, Management, and Long-term Care of Obstructive Sleep Apnea in Adults. OSA is a chronic condition that effects from 2% to 10% of the U.S. adult population. Implications of undiagnosed OSA include excessive daytime sleepiness, fatigue, irritability, difficulty controlling chronic diseases including diabetes and hypertension, heart arrhythmias, gastroesophageal reflux disease, mood disorders, attention deficit disorder, and an increased potential for dementia if left untreated. A protocol was created to align providers with the clinical guidelines. Provider responsibilities included screening all patients 18 and over for OSA, referring patients with a positive screen for a sleep study, prescribing CPAP when indicated, and providing short-term follow-up. At project completion 293/405 patients (72%) ages 18 and over had been screened, 58 (20%) had positive screens, 53 (91%) with a positive screen were referred for sleep study, 19 (35%) completed the sleep study, 19 (100%) were diagnosed with OSA and prescribed CPAP, and 18 (95%) were scheduled for short-term follow-up. There were no significant differences noted between age distribution and the receipt of a positive diagnosis of OSA, $F(3,504) = .066, p = .679$. During implementation 19 (7%) patients were identified and treated for OSA. The relationship between using a screening tool to assess risk of OSA and receipt a positive diagnosis of OSA was significant, $\chi^2(1, 505) = 5.982, p < .05$. Only 19 out of 53 patients referred for sleep study completed a sleep study indicating a need for continued work on intervention models that will facilitate patient completion of diagnostic testing with subsequent referral for treatment.

Keywords: obstructive sleep apnea, OSA, sleeping disorder, CPAP, guideline adherence

Obstructive Sleep Apnea (OSA) is a common condition that affects a significant portion of the U.S. population. Although most people have heard of OSA, multiple misconceptions exist among both patients and providers. These are some common misconceptions: all patients with OSA snore, only people who are overweight can have OSA, the only method for diagnosis is overnight polysomnography, OSA has only short-term side effects (daytime sleepiness, fatigue), if you have insomnia you cannot have OSA, sleep studies are not well-covered by insurance, all continuous positive airway pressure (CPAP) machines are loud and blow constant air, and only sleep specialists can diagnose and manage OSA. Providers and patients need to be educated as to the implications of undiagnosed OSA, which include excessive daytime sleepiness, fatigue, irritability, difficulty controlling chronic diseases including diabetes and hypertension, heart arrhythmias, gastroesophageal reflux disease (GERD), mood disorders, attention deficit disorder, and an increased potential for dementia if left untreated.

Obstructive sleep apnea increases the risk for vehicular collisions, poor work performance, workplace accidents, and incidents of aggression, that affect more than just the individual afflicted with OSA. By studying the aspects of OSA and utilizing that knowledge to identify, treat, and manage this patient population, primary care providers (PCPs) have the potential to make a difference in the lives of these patients, their families, and the community.

Statement of the Problem

Obstructive sleep apnea is a complex condition that is caused by a variety of different mechanisms. It is currently estimated that from 2% to 10% of the U.S. adult population has OSA (Epstein et al., 2009; Grover et al., 2011). After the age of 65 the incidence of OSA increases from 12% to 25% (Mold et al., 2011). There are many adults and children in the United States that have unrecognized OSA. Presently there is a lack of screening, diagnosis, treatment, and

management of OSA in primary care (Drager et al., 2011; Epstein et al., 2009; Grover et al., 2011).

Background and Significance

Untreated OSA has a hazardous effect on the individuals that are afflicted. Short-term effects include fatigue, irritability, excessive daytime sleepiness, anxiety, depression, snoring, insomnia, increased blood pressure and heart rate, and an inability to properly control pain (Epstein et al., 2009; Ronksley, Hemmelgarn, & Tsai, 2011). OSA has been linked to difficulty controlling diabetes and other metabolic disorders (Storgaard, Mortensen, Almadal, Laub, & Tarnow, 2014). Storgaard et al. (2014) discovered that approximately one third of the 200 diabetic patients studied had OSA. Patients with OSA are two to three times more likely to be involved in a car accident (Strohl et al., 2013). Untreated moderate to severe OSA is estimated to cost society around 3.4 billion dollars a year in indirect medical costs; this estimate does not take into account money in lost wages and other non-medical side effects (Ronksley et al., 2011).

There appears to be a bi-directional link between GERD and sleep disorders. Evidence suggests that GERD can cause shortened periods of sleep, insomnia, sleep awakenings, poor quality of sleep, and early morning awakenings (Fujiwara, Arakawa, & Fass, 2012; Jung, Choung, & Talley, 2010). Evidence also suggests that loss of sleep itself, due to an underlying sleep disorder, can cause an increase in acid production perfusion leading to many of the symptoms associated with GERD (Fujiwara et al., 2012; Jung et al., 2010). Long-term untreated sleep apnea has been linked to heart arrhythmias, increased risk for congestive heart failure, heart attack, and stroke (Epstein et al., 2009; Ronksley et al., 2011). Scientists believe that a lifetime of untreated OSA may in fact lead to certain types of dementia (Elwood et al., 2011). One of the best ways to prevent dementia is to determine if the patient has OSA and, if so, treat it (Fotuhi,

2009). The failure to diagnose and treat OSA is in part due to a lack of screening by primary care providers (Drager et al., 2011; Epstein et al., 2009; Grover et al., 2011; Storgaard et al., 2014).

According to the American Academy of Sleep Medicine (AASM) guideline for OSA, routine health evaluations should contain OSA screening questions, and if there is suspicion of OSA, then further testing should be completed (Epstein et al., 2009). According to the AASM guidelines, “Clinically, OSA is defined by the occurrence of daytime sleepiness, loud snoring, witnessed breathing interruptions, or awakenings due to gasping or choking in the presence of at least 5 obstructive respiratory events (apneas, hypopneas, or respiratory effort related arousals) per hour of sleep.” (Epstein et al., 2009, p. 263) An apnea episode is a pause in breathing during sleep (usually greater than 10 seconds in adults) and hypopnea is a substantially reduced or ineffective breath (Eckert & Malhotra, 2008). An OSA diagnosis is based on an individual’s apnea/hypopnea index (AHI). The AHI is obtained by dividing the number of respiratory events by the number of hours of testing (Epstein et al., 2009). If the AHI is five or greater a diagnosis of OSA is made. Degree of OSA is classified into none (AHI <5), mild (AHI of 5-15), moderate (AHI of 16-30), or severe (AHI >30) (Epstein et al., 2009).

The main mechanisms of OSA appear to be upper airway anatomy, upper airway dilator muscle activity, arousal from sleep, ventilator control stability, lung volume, genetics, and several physiological factors (Casale et al., 2009; Dempsey, Veasey, Morgan, & O'Donnell, 2010; Eckert & Malhotra, 2008). There appears to be a strong genetic link to OSA with 35-40% of the risk factors being based on genetic components (Casale et al., 2009). Most respiratory events cause cortical arousal with the length and degree of arousal appearing to be directly related to the severity of the apnea/hypopnea event (Dempsey et al., 2010; Eckert & Malhotra, 2008). When the airway is obstructed, the oxygen levels drop until the brain is aroused enough to

cause the individual to breathe. This leads to cycles of sleep, deoxygenation, and arousal making true restorative sleep difficult (Eckert & Malhotra, 2008). In severe cases, patients can have respiratory events 100 or more times each hour (Eckert & Malhotra, 2008).

The AASM guidelines recommend screening for OSA in primary care to determine which patients should be referred for diagnostic testing (Epstein et al., 2009). The guidelines stress the importance of a thorough history and physical to screen for sleep-related disorders including complications such as excessive daytime sleepiness, as measured by the Epworth Sleepiness Scale (ESS), snoring, and other comorbid conditions (Epstein et al., 2009).

There are two methods for diagnosis of OSA endorsed by the AASM. These consist of nocturnal polysomnography or an at-home sleep study (Epstein et al., 2009). Nocturnal polysomnography requiring a minimum of electroencephalogram, electrooculogram, chin electromyogram, airflow, oxygen saturation, respiratory effort, and electrocardiogram or heart rate, is conducted in a sleep laboratory under supervision of a trained specialist (Epstein et al., 2009). An at-home sleep study requires a minimum airflow record, respiratory effort, and blood oxygenation (Epstein et al., 2009). After sleeping with the device for several nights the at-home monitor is returned, the recording is analyzed, and then a computer generated report is sent to the clinic that includes the AHI, oxygenation statistics, and snoring characteristics per night of study. Regardless of which method is used, the number of respiratory events is divided by the hours of study and if the resultant AHI is five or greater a diagnosis of OSA is made (Epstein et al., 2009; Rosen et al., 2012).

Obstructive sleep apnea (OSA) is rarely curable based on the underlying pathophysiology involved. Most treatment methods aim at life-long symptom management. There are three main categories for treatment of OSA which include medical, behavioral, and surgical

interventions/treatments (Epstein et al., 2009; National Heart Lung and Blood Institute [NHLBI], 2012). There are two main medical treatment methods endorsed by the AASM. One method is the use of an oral appliance that modifies the position of the jaw to help maintain an open airway (Epstein et al., 2009; Lam et al., 2007; Phillips et al., 2013). The other medical treatment method is positive airway pressure (PAP) administered via a nasal mask or full face mask which is connected to a CPAP machine (Epstein et al., 2009; Lam et al., 2007; NHLBI, 2012; Strohl et al., 2013). Behavioral treatment options include weight loss, exercise, and good sleep hygiene which consists of regular bedtimes, avoiding alcohol and caffeine, and only using the bed for sleeping (Epstein et al., 2009; NHLBI, 2012). Surgical treatment methods are aimed at correcting the underlying pathophysiology. Identifying and treating patients that have OSA may lead to a significant reduction in signs and symptoms associated with OSA and improve the future health of these individuals.

Assessment

A family practice clinic in the south central United States was the site for implementation of an evidence-based project related to aligning the practice with the AASM guidelines for the screening, diagnosis, treatment, and management of patients with OSA. The staff involved in this project included the providers (1.0 physician, 1.0 family nurse practitioner [FNP], and 0.2 women's health nurse practitioner), front and back desk receptionists, three medical assistants (MA), the medical records personnel, and the office manager/referral coordinator.

The clinic has an estimated 6,000 active patients and sees an average of 250 patients a week ages 13 and over. Approximately 2% of patients are 13-17, 13% are 18-24, 25% are 25-44, 40% are 45-64, and 20% are 65 or older. The male/female ratio averages 50:50. The patients' ethnic/racial background is 30% Hispanic White, 30% Non-Hispanic White, 30% Non-Hispanic

Black, and 10% of patients classified as other. The majority of patients speak either English or Spanish and the majority of the staff is bilingual English/Spanish.

A June 2016 microsystem assessment indicated that the clinic had a high percentage of patients at increased risk for OSA based on their presenting diagnoses of ADD 4 (4%), hypertension 54 (54%), diabetes mellitus 25 (25%), insomnia 16 (16%), heart arrhythmia 1 (1%), mood disorders 29 (29%), chronic pain 36 (36%), obesity 11 (11%), headache 2 (2%), GERD 22 (22%), and dementia 1 (1%). The AASM clinical guidelines call for screening, referral for diagnostic study when indicated, treatment, and management of patients at high risk for OSA. The clinic had no protocol in place to address the risk for OSA in the clinic's patients.

Organization's Readiness for Change

Upon review of the AASM guidelines and the results of the June 2016 microsystem assessment with the key stakeholders it was determined that the clinic was not aligned with the AASM clinical guidelines. Prior to review of the guidelines the clinic providers had been unaware of the severity and potential complications associated with OSA. Following review of the guidelines it was determined that a protocol needed to be established to align the practice with the AASM guidelines. All providers and staff expressed a willingness to participate in a project to implement the evidence-based AASM guidelines for OSA in the clinic as a method of improving the quality of care.

Working with the lead physician and office manager a protocol was established to address OSA. Each provider was interviewed to determine their current knowledge of OSA. Although the providers varied in their understanding of OSA, it was determined that all providers needed more information in order to properly address OSA with patients.

Twenty patients were interviewed prior to project implementation to determine current patient knowledge of OSA and potential barriers to participation. The ESS was presented and the process for diagnosis and treatment explained. Nineteen out of the twenty patients interviewed had no knowledge of OSA. The only patient, with a basic understanding of OSA, had a previous diagnosis of OSA, and was currently receiving treatment with CPAP. All patients interviewed expressed a willingness to participate in the OSA screening. No barriers to patient participation in OSA screening were noted.

Project Identification

Purpose and Objectives

The purpose of this evidence-based project was to increase adherence of the clinic's providers to the AASM *Clinical Guidelines for the Evaluation, Management, and Long-term Care of Obstructive Sleep Apnea in Adults (2009)*, thereby improving the quality of care provided. The AASM guidelines call for screening, referral for diagnostic study when indicated, treatment, and management of patients at risk for OSA in primary care.

The objectives of this evidence-based project to improve quality of care are to:

1. Increase patient screening for obstructive sleep apnea from the pre-intervention rate of 0% to 90% by the completion of the fourth week of project implementation.
2. Increase the percentage of patients who require follow-up that receive a referral for a sleep study from less than 3% to 90%.
3. Increase the number of patients with a positive diagnosis of OSA who are offered a prescription for CPAP from pre-intervention rate of 0% to 90% by the 10th week following project initiation.

4. Increase the short-term follow-up of the clinic's patients who initiated CPAP treatment from 0% to 90% according to recommendations from the AASM clinical guidelines that suggest patient's success with CPAP usage is generally determined within the first few weeks following CPAP initiation, and routine short-term follow-up has been shown to increase CPAP compliance.

Anticipated Outcomes

By meeting these objectives, there will be an increase in patients identified; providers will make appropriate referrals for sleep studies; there will be a decrease in signs and symptoms associated with OSA such as excessive daytime sleepiness, insomnia, and fatigue; there will also be a reduction in the severity of comorbidities, (hypertension, diabetes mellitus, mood disorders, GERD, headaches, and pain) among patients receiving treatment. The clinic will align with Healthy People 2020 goals for OSA and be in compliance with the AASM's guidelines.

Summary and Strength of the Evidence

Multiple studies were appraised that demonstrated the methods by which providers can address the aspects of OSA through screening, referral for diagnosis, proper treatment, and management of patients at high risk for OSA. This information was synthesized and the resultant information was used to create the OSA protocol for the clinic.

Among four studies there was a consensus that there is a lack of screening among primary care providers for OSA (Brostrom et al., 2012; Grover et al., 2011; Mold et al., 2011; Wall, Smith, & Hubbard, 2012). There are multiple comorbidities such as refractory hypertension, mood disorders, obesity, GERD, diabetes, fatigue, and other uncontrolled disorders that have been shown to put a patient at high risk for OSA (Alam, Chengappa, & Ghinassi, 2012; Drager et al., 2010; Fujiwara et al., 2012; Jung et al., 2010; Kleisiaris et al., 2016 ;Wall et al.,

2012). Brostrom et al. (2012) conducted a study of primary care patients that had a diagnosis of hypertension. Polysomnography was performed on the study's 394 patients with 234 (59%) of the patients diagnosed with OSA (Brostrom et al., 2012). Four studies noted as the number of comorbidities a patient has associated with OSA increases, the patients risk for OSA increases (Alam et al., 2012; Drager et al., 2010; Kleisariis et al., 2016; Wall et al., 2012).

Often times the primary care practice is the first place that patients at risk for OSA are seen and according to the literature patients in the primary care setting are not being assessed for OSA even though they are at increased risk (Alam et al., 2012; Brostrom et al., 2012; Drager et al., 2010; Kleisariis et al., 2016; Mold et al., 2011; Wall et al., 2012). Mold et al. (2011) in a study of 725 patients with a positive diagnosis of OSA noted that even though there was a significant portion of patients with a positive diagnosis of OSA, few providers could name a single patient that had symptoms associated with OSA, or a positive diagnosis of OSA. Lack of provider screening and knowledge of OSA has been cited by studies one of the biggest hurdles to proper OSA diagnosis and management (Alam et al., 2012; Drager et al., 2010; Kleisariis et al., 2016; Mold et al., 2011; Wall et al., 2012).

After a patient has a positive screening test the next step in the process is referral for a sleep study. The two main methods for sleep study endorsed by the AASM include overnight polysomnography completed at a sleep center or an at home sleep study (Epstein et al., 2009). No matter which method of sleep study is chosen, diagnosis of OSA is made based on the AHI (number of respiratory events in an hour) with an AHI of 5 or greater confirming the presence of OSA.

After the diagnosis of OSA is confirmed the patient can either be managed by their primary care provider (PCP) or a sleep specialist. The PCP's lack of knowledge about OSA can

serve as a barrier that may be negated by instruction on OSA diagnosis, treatment, and management (Chai-Coetzer et al., 2013). In the study by Chai-Coetzer et al. (2013) it was determined that the PCP could manage OSA patients just as well as specialists, while maintaining a higher level of patient satisfaction. Patients are more likely to follow the advice of their PCP because they have already established a relationship with their provider allowing PCPs to play an integral role in the screening, diagnosis, and treatment of OSA and other comorbidities associated with OSA (Alam et al., 2012; Chai-Coetzer et al., 2013; Drager et al., 2010; Kleisariis et al., 2016; Mold et al., 2011; Wall et al., 2012).

Once a patient receives the diagnosis of OSA, it becomes the responsibility of the PCP to explain the implications of the disease and the different methods for treatment and management (Epstein et al., 2009). The two methods of OSA medical management endorsed by the AASM are CPAP and the use of an oral appliance (Epstein et al., 2009; Lam et al., 2007; Phillips et al., 2013). Of the two methods, CPAP was proven to be the most effective form of treatment for OSA having the largest reduction in OSA signs and symptoms (Lam et al., 2007; McMillan et al., 2015; Phillips et al., 2013). It was noted however that oral appliances had a slightly better compliance rate (Phillips et al., 2013). McMillan et al. (2015) reported that sleep hygiene had a positive effect on the symptoms associated with OSA, but the impact was greater when combined with CPAP. Treatment with CPAP lowered the degree of excessive daytime sleepiness as evidenced by a reduction in scores on the ESS after treatment with CPAP in four studies (Chai-Coetzer et al., 2013; Lam et al., 2007; McMillan et al., 2015; Phillips et al., 2013). Adults 65 and older also experienced significant improvement in OSA signs and symptoms by using CPAP (McMillan et al., 2015). Alam et al. (2012) conducted a study of patients with a diagnosis of a mental health disorder being treated in primary care to determine the willingness of this

population to participate in diagnostic study and treatment for OSA when applicable. When interviewed the majority of patients with mental health disorders expressed a willingness to undergo sleep study and if found positive for OSA be treated with CPAP (Alam et al., 2012).

It is not enough to prescribe CPAP for patients who test positive. Between 29-83% of patients are non-adherent to CPAP usage (Weaver, 2014). The more severe OSA a patient has, the better the compliance with CPAP (Pruitt, 2008). Several studies have shown that the risk for non-compliance is usually determined within the first few weeks of initiation of therapy (Pruitt, 2008; Weaver, 2014). There are several interventions that can be done to address non-compliance. First, it is important to have follow-up within the first few weeks of initiation of CPAP to address any questions or concerns (Epstein et al., 2009; Pruitt, 2008). It is also suggested that because OSA is a chronic condition, patients with this diagnosis should be evaluated again within three to six months, and then on a yearly basis to continue to monitor disease progression, CPAP usage, and address concerns that may arise (Epstein et al., 2009; Pruitt, 2008; Weaver, 2014). Even though there are various studies that show the multiple aspects of OSA, there is not any one study or improvement project that provides an effective protocol for screening, diagnosis, treatment, and management of OSA.

Methods

Project Intervention

A pre-intervention chart audit was performed on 100 patients seen in the clinic during the week of 5/9/2016-5/13/2016. The data, analyzed in IBM® SPSS® version 23, demonstrated that 91 (91%) of the patients had diagnoses placing them at high risk for OSA, 0 (0%) of the patients had been screened for OSA, and only 4 (4%) of these patients had been referred in the past for a

sleep study. There was no evidence that follow-up appointments to monitor OSA progression and CPAP usage had been conducted in the charts of patients with a positive diagnosis OSA.

Prior to implementation, one-on-one interactive education was conducted with each provider on the aspects of OSA including background, significance, screening with the ESS, referral for sleep study, interpretation of sleep study results, treatment, and management of OSA (see Appendix A). Each provider was given a copy of the clinic's Provider OSA Handbook to use as a resource during implementation. The handbook included the ESS in English (see Appendix B) and Spanish, official office protocol (see Appendix C), patient teaching materials obtained with permission from the AASM, a checklist for follow-up appointments, sample CPAP prescription (see Appendix E), and a copy of the AASM guidelines. Prior to initiation of the new OSA protocol interactive education was conducted with members of the staff discussing the different roles and responsibilities during implementation of the clinic's OSA protocol.

Starting on day one of implementation each patient 18 and older entering the clinic was given a copy of the ESS to fill out in English or Spanish based on the language of their choice by the front receptionist. After completion, the patient gave the form to the medical assistant (MA). The MA totaled the ESS and placed the total score at the top of the form. The ESS was then given to the provider along with the patient's paperwork prior to seeing the patient.

If the score was 10 or more the provider explained the risk for OSA to the patient and offered a referral for a sleep study. If the patient accepted the referral, the provider wrote a sleep study prescription. The front desk then made an appointment with a representative for a home sleep study.

Once the study was completed the patient returned the sleep study machine and scheduled an appointment to discuss the sleep study results. One week before the return visit, the

records department checked to see if the sleep study results were obtained. If no results were available the sleep study representative was contacted. If results were still unavailable the day before the visit the patient was notified by the MA and offered a chance to reschedule at their convenience. Upon return for the follow-up appointment, the provider reviewed the sleep study results with the patient.

Patients with a positive diagnosis were educated on treatment and management of OSA. All patients that tested positive for OSA were prescribed CPAP. If the patient agreed to CPAP initiation, a task was sent to the referral coordinator along with the prescription, for an automatic titrating CPAP machine and supplies. Upon referral for CPAP the patient was scheduled for a follow-up appointment within two to six weeks to discuss CPAP initiation and OSA progression.

The referral coordinator then sent a referral to a Durable Medical Equipment (DME) vendor for the auto-titrating CPAP machine and supplies. The patient was called by a MA two weeks after referral was sent to the DME to determine if the CPAP machine and supplies were received. When the patient returned for the follow-up appointment the provider assessed CPAP usage and OSA status by utilizing the checklist to help guide the follow-up visit. The patient was given a copy of the ESS to fill out at all follow-up visits to determine impact of CPAP treatment on OSA progression. After the visit was concluded the patient was scheduled for a follow-up visit 3-6 months later to discuss CPAP usage and OSA progression.

Following implementation of the protocol, every patient 18 and older entering the office for provider visit during the first four weeks of project implementation was included in post-intervention data collection and analysis. There were 407 patients seen at the clinic during these four weeks. All patients were tracked through each step of the protocol from the first week of implementation through the tenth week following project initiation.

Prior to initiation of the project, the proposed plan was submitted to the University of the Incarnate Word Institutional Review Board (IRB) for approval. The project was approved by exempt review as it was determined to be less than minimal risk indicating no known physical, emotional, psychological, or economic risk for the individual participating. The IRB approval number is 16-05-013.

Organization Barriers and Facilitators

The organization experienced multiple challenges with the implementation of the new protocol. Barriers included failure to screen patients, fluctuation with provider coverage, and fluctuation with MA staffing levels, patient misconceptions, and receiving CPAP equipment and supplies in a timely manner. Staff had difficulty remembering to give patients the ESS. During the first week of project implementation the screening rate was 65.8%. Adjustments were made to the screening process based on data obtained during the first two weeks of implementation and input from staff and providers. By the fourth week of project implementation the clinic screening rate had increased to 80.5%.

Fluctuation in provider coverage occurred. The Provider Handbook for OSA served as a valuable tool to keep all providers informed about the aspects of OSA and the clinic protocol. Fluctuation in MA staffing levels occurred. After an initial period of adjustment, the MA's increased compliance to the OSA protocol.

Patient barriers to OSA protocol implementation were mainly due to misconceptions and lack of CPAP machines and supplies. Misconceptions were related to the causes and symptoms of OSA, types of methods for diagnosis of OSA, cost of sleep studies and treatment methods, and outdated information on CPAP machines and supplies. Patient education provided by the clinician regarding signs, symptoms, co-morbidities, diagnosis, treatment, and management of

OSA reduced the patient's reluctance to consider treatment. Because patients had difficulty receiving CPAP machines and supplies in a timely manner the referral coordinator followed up with the DME to ensure equipment and supplies were delivered to patients. If necessary, follow-up appointments were rescheduled to accommodate for the lack of CPAP equipment and supplies.

Facilitators to the new protocol included staff familiarity with stages of the OSA protocol, an affiliation with a home sleep study vendor and DME companies, increased revenue from enactment of the OSA protocol, and patient willingness to participate in project. The clinic staff was familiar with the process of scheduling a patient for a sleep study and follow-up appointment for results. An affiliation with a home sleep study vendor made it easier to refer patients for a study. The referral coordinator already had affiliations with two DME vendors that supply CPAP equipment and supplies.

The clinic received increased revenue based on increased visits and billable procedures involved with operationalization of the OSA protocol. Utilization of an official protocol for OSA increases insurance reimbursement, decreases the chance for denial of benefits, which may lead to an increase in the number of patients with a high risk of OSA that can receive diagnostic testing, and treatment of OSA if found positive. Most patients in the clinic expressed willingness to participate in the OSA project. There were 294 patients approached for screening using the ESS and 293 (99.7%) agreed to be screened. The clinic has the paperwork and information necessary to help patients that are unable to afford the CPAP machine and supplies to apply for the CPAP Assistance Program, and if eligible they will receive the machine and equipment for a nominal fee (American Sleep Apnea Association, 2015).

Results

The total number of eligible patients that entered the practice during the four weeks of implementation was 405. Of these eligible patients 293 (72%) were screened using the ESS. The overall clinic rate fluctuated throughout the course of project implementation. The percentage of patients screened each week increased by provider throughout project implementation with some fluctuation.

Table 1

Weekly Screening Rate

Week	Provider 1	Provider 2	Provider 3	Total Clinic
Week 1		61%	92%	65.80%
Week 2	100%	67%	93%	76.50%
Week 3	89%	44%	100%	57.00%
Week 4	100%	73%	86%	71.00%

In the four weeks of implementation, 58 (20%) patients screened had positive ESS screen for OSA. Of the 58 patients with a positive OSA screen 53 (91%) were referred for a sleep study. The information was further broken down by provider to determine each provider's adherence. The weekly percentage of patients with a positive screen that were referred for a sleep study increased steadily for each provider with some variability. The clinic rate increased week to week with some fluctuation (table 2).

During the course of the project 19 patients completed a sleep study with 19 (100%) receiving a positive diagnosis of OSA. Of the 19 patients receiving a diagnosis for OSA, 19 (100%) were initiated on CPAP. Based on the data collected throughout the ten weeks of project implementation, 18 (95%) of patients who initiated CPAP were scheduled for a follow-up

appointment but at conclusion of the project only 13 (72%) of those appointments had been completed.

Table 2

Weekly Referral Rate

Week	Provider 1	Provider 2	Provider 3	Total Clinic
Week 1		25%	100%	40%
Week 2	100%	75%	100%	88%
Week 3	100%	0%	100%	60%
Week 4	100%	100%	100%	100%

Of the 19 patients diagnosed with OSA 7 (37%) had diabetes, 12 (63%) were obese, 8 (42%) had insomnia, and 10 (53%) had hypertension. Of the 274 patients that were screened and not diagnosed with OSA 80 (29%) had diabetes, 126 (46%) were obese, 60 (22%) had insomnia, and 144 (53%) had hypertension.

Age distribution was comparable between both the screened and non-screened population with the largest population falling within the 25-44 year olds and the smallest population in the 18-24 year olds.

A one way ANOVA was run to determine if there was statistical significance in age distribution and receiving a positive diagnosis of OSA. There were no significant differences noted between age distribution and the receipt of a positive diagnosis of OSA, $F(3,504) = .066$, $p = .679$ (table 3).

A chi-square test of independence was performed, including both the pre-intervention and post-intervention data that was collected, to examine the relationship between using a screening

tool to assess risk of OSA and receipt of a positive diagnosis of OSA. The relationship between these variables was significant, $\chi^2 (1, 505) = 5.982, p < .05$ (table 4).

Figure 1

Diagnoses present among screened patients associated with OSA

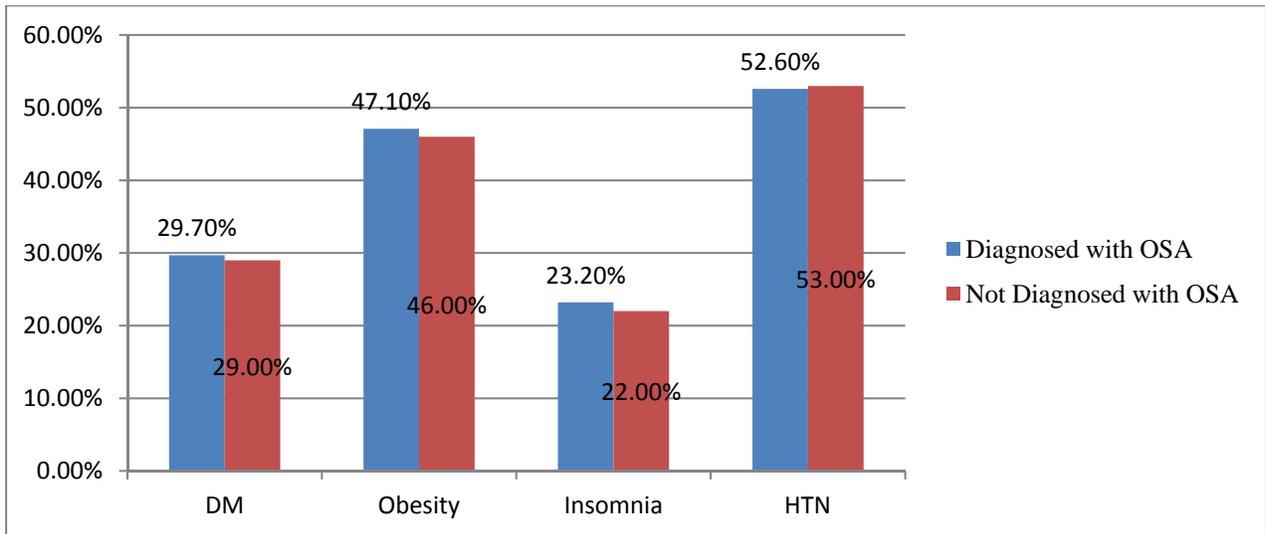


Figure 2

Age distribution of patients

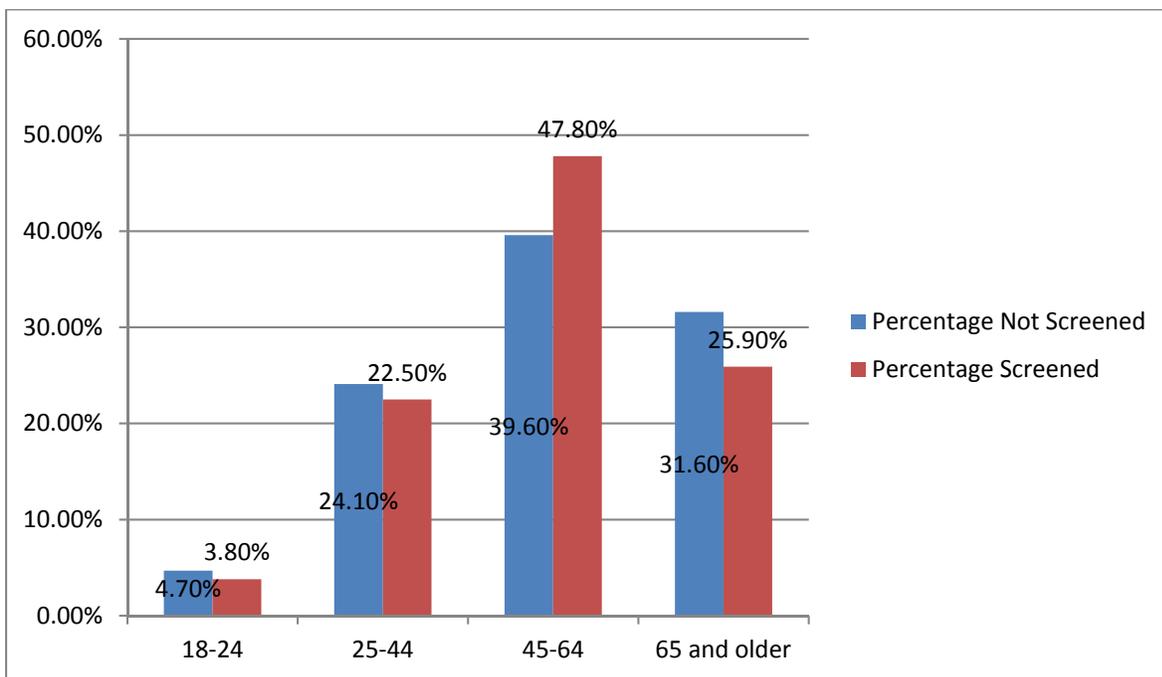


Table 3

ANOVA: Age Distribution Diagnosis of OSA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.066	3	.022	.505	.679
Within Groups	21.886	501	.044		
Total	21.952	504			

Table 4

Chi-square: Relationship Between Screening for OSA and Diagnosis

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.982 ^a	1	.014		
Continuity Correction	4.971	1	.026		
Likelihood Ratio	6.649	1	.010		
Fisher's Exact Test				.016	.010
Linear-by-Linear Association	5.970	1	.015		
N of Valid Cases		505			

Note. a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 9.66.

There were 23 (10%) patients that did not have a positive screen that could name at least one person they knew that fit the criteria of high risk for OSA. Many of these patients stated that they would recommend a sleep study to these individuals. There were approximately

15 (5%) of patients screened that had previously received a diagnosis for OSA that were not presently being treated. According to the providers, the most frequently stated reason given by the patients for lack of treatment was patient misconceptions of CPAP treatment. After explanation of the at-home sleep study and the newer CPAP machines, most of these patients agreed to a repeat sleep study and use of CPAP if they were still found to have a positive diagnosis of OSA. The majority of patients screened expressed interest in the information obtained on OSA and many expressed gratitude for being included in the screening process.

Discussion

The ESS was not consistently given to all patients that entered the office during the first four weeks of project initiation. Without completed ESS forms the provider was not prompted to proceed in the OSA protocol. The lack of receipt of the ESS form impacted the overall screening adherence rate leading to missed opportunities to identify patients that may benefit from further testing. Provider adherence in both screening and referral for sleep study improved over the course of the project enabling more patients to be identified and referred for testing.

Many patients had misconceptions about aspects of OSA. Common misconceptions stated by the patients included:

- “I thought the only way a person can find out if they have sleep apnea is by going to a sleep center to have a sleep study done.”
- “I thought only people who snore can have sleep apnea.”
- “You have to be overweight to have sleep apnea, right?”
- “I don’t want to use CPAP because I heard that the machines are loud.”
- “Aren’t CPAP machines loud and bulky?”

- “My grandma used to have CPAP and it sounded and looked like she was sleeping in a wind tunnel because there was so much air pressure.”
- “Isn’t it hard to get insurance to pay for a sleep study or a CPAP machine?”
- “Sleep apnea can only be diagnosed and treated by a sleep specialist.”
- “I already know I have sleep apnea but I don’t want to use CPAP because I heard the machines are loud, large, and blow air all the time making it hard to breathe!”
- “I know I have sleep apnea but I refuse to go to one of those creepy overnight sleep studies where people stare at you while you sleep and they put a bunch of wires on you!”

After patient education, approximately 48 (91%) of patients with a positive screen for OSA, referred for a sleep study, expressed a willingness to participate in an at home study, and if diagnosed with OSA, consider treatment by CPAP.

Patients that use CPAP have been noted to have an improvement in excessive daytime sleepiness by as much as 10-15 points (Chai-Coetzer et al., 2013). There was a noticeable improvement in the signs and symptoms associated with OSA in clinic patients that received treatment. Patients placed on CPAP were re-screened with the ESS upon their follow-up appointment. Every patient that was placed on CPAP had reduction in their ESS score to a mean of 5 from their pre-intervention mean score of 16. One patient diagnosed with severe OSA (AHI: 76.8), had no known comorbidities associated with OSA, and upon treatment with CPAP, the patient had a reduction in ESS score from 16 pre-intervention to 6. Not all patients that have OSA have multiple comorbidities associated with OSA. The AASM guidelines for OSA call for routine screening for OSA by use of a tool, such as the ESS, in primary care to aid in the identification of patients at risk for OSA that might otherwise be missed (Epstein et al., 2009).

The rate of sleep apnea among adults in the U.S. is estimated to range between 2-10% of the population (Epstein et al., 2009; Grover et al., 2011). Of the 293 patients screened in the practice, 19 (7%) received a positive diagnosis for OSA which falls within the national average. Of the 53 patients referred for sleep study 19 (35%) completed the sleep studies indicating a need for continued work on intervention models that will facilitate patient completion of diagnostic testing with subsequent referral for treatment. Of the 19 patients that followed through with the sleep study, 19 (100%) received a positive screen. Analysis of the chi-square demonstrated that patients that are screened for OSA by use of a screening tool are more likely to receive a positive diagnosis of OSA.

Obesity defined as a BMI >30 was present in 30% of patients with mild sleep apnea and 60% of patients with severe sleep apnea in a study by Brostrom et al. (2012). In the project patient population obesity was present in 50% of patients with mild sleep apnea and 60% of patients with severe sleep apnea. In the project patient population 10 (53%) of patients with a positive diagnosis of OSA had hypertension and 7 (37%) of patients with a positive diagnosis of OSA had diabetes. Four studies noted as the number of comorbidities a patient has associated with OSA increases, the patients risk for OSA increases (Alam et al., 2012; Drager et al., 2010; Kleisaris et al., 2016; Wall et al., 2012). Of the 19 patients that were diagnosed with OSA, 14 (74%) had three or more comorbidities that are associated with OSA supporting the claim that the number of comorbidities has an effect on the risk for OSA.

In the clinic, it was discovered that 58 (20%) of patients screened were at high risk for OSA. Of the 293 patients screened in the clinic, 20 (34%) of those with a positive screen had a documented sleep related complaint compared to Mold et al. (2011) where less than one third of their patients with a positive screen had a previous documented sleep related complaint.

The protocol as it stands has been shown to be a viable method for identifying and treating patients at high risk for OSA. Having a provider handbook was a practical method for keeping all providers informed of OSA facts, and provided the tools necessary for protocol completion. One of the most important aspects of the OSA protocol is that it is transferable to other practices. This project is replicable and the protocol can be taken by any primary care practice and adjusted as needed to fit the individual office and staff.

Limitations

There were several changes in providers and staff throughout the course of project development and implementation that may have affected the overall screening and referral rates. The addition of new providers and staff required education and the opportunity to incorporate the process into their routine. There were only 293 out of 407 patients that entered the clinic during the first four weeks of project implementation that were screened using the ESS. The lack of screening of the other 114 patients affected the total number of patients screened potentially decreasing the number of patients identified and treated for OSA. Out of the 53 patients with a positive screen that were referred for a sleep study, only 19 completed a sleep study. Had the other 34 patients completed a sleep study there may have been more patients with a positive diagnosis of OSA.

Recommendations

There were a significant number of clinic patients that met the criteria of high risk for OSA based on the signs, symptoms, and comorbidities associated with OSA. Since OSA is classified as a chronic condition, the AASM recommends that routine screening be performed in primary care practices and patients receiving a positive diagnosis of OSA be followed up at least yearly. Only 293 (72%) of patients were screened for OSA and 19 (36%) of patients referred for

sleep studies completed the sleep studies indicating a need for continued work on screening methods that will increase provider and staff compliance, and intervention models that will facilitate patient completion of diagnostic testing with subsequent referral for treatment.

Implications for Practice

There were 0/212 (0%) patients diagnosed with OSA in the non-screened patient population. Of the patients screened during project implementation there were 19/293 (7%) diagnosed with OSA. The results of the QI project demonstrated that screening patients for OSA using the ESS can help in the identification and treatment of patients with OSA. In the clinic 58 patients were identified as high risk for OSA out of 293 patients screened indicating that 58 (20%) screened had a positive screen for OSA. From this knowledge one can infer that other primary care practices and their patients could benefit by putting a protocol in place to address the risk for OSA in primary care.

Even though this project was implemented at a primary care office, a similar protocol could be implemented at other specialty practices that care for patients with one or more of the major comorbidities associated with OSA. By use of a modified version of the protocol, more patients potentially at high risk for OSA could be identified increasing the identification, treatment, and management of patients that were previously underdiagnosed.

The ESS is available free of charge for providers making it a simple and cost-effective method to screen patients for OSA. The ESS has been translated and validated in multiple languages around the world making it an optimal tool to identify patients at increased risk for OSA. The protocol is applicable not just in the United States, but could be implemented in provider offices across the globe with slight modifications based on location and practice.

For a protocol to be successful there must be a method of oversight to ensure proper implementation, including changes as necessary, to increase adherence by providers and staff. The Advanced Practice Registered Nurse (APRN) is in a key position to offer this oversight. Implementing guidelines to screen, diagnose, treat, and manage patients at high risk for OSA has the potential to have a significant impact on the patient population. The APRN is capable of screening, referring for diagnostic testing, giving a comprehensive explanation of results, and referring for initiation of CPAP when warranted. Operationalization of an OSA protocol similar to the one implemented in this practice can allow APRNs in multiple countries to identify patients with OSA, having the potential to improve the lives of patients, families, and communities around the world.

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Appendix A

Obstructive Sleep Apnea Education Plan for Providers

Materials: Copy of Clinical Guideline for each provider, patient handout for each provider, copy of ESS in both English and Spanish, copy of Project Clinic OSA protocol, copy of a sleep report de-identified

Education:

- 1) Screening procedures using ESS
 - a. How to fill out form
 - b. How to score form
 - c. Score of 10 or more equals high risk for OSA
- 2) How to refer for a sleep study
 - a. Explain to patients risk for OSA
 - b. How to schedule a sleep study
 - c. Need to schedule follow-up appointment
- 3) How to interpret sleep study results
 - a. Where to find AHI
 - b. Level of OSA: mild, moderate, severe, none
 - c. Desaturations
- 4) How to explain to patients results
 - a. Patient information sheet for reference
 - b. Keywords for explanation
 - c. Discuss disease progression and treatment options
- 5) How to prescribe CPAP
 - a. Offer CPAP as choice to patients
 - b. How to write auto-titrating prescription
 - c. Send task to referral coordinator
 - d. Have patient set follow-up appointment
- 6) How to conduct a follow-up appointment after CPAP prescribed
 - a. Review provider check-list
 - b. Discuss how to approach items on checklist
- 7) Importance of routine follow-up
 - a. Discuss chronic nature of disease
 - b. Patients need to return in 2-6 weeks following CPAP initiation, 3-6 months, then on a yearly basis to discuss CPAP usage and OSA progression

Appendix B

Epworth Sleepiness Scale

Name: _____ Today's date: _____

Your age (yrs): _____ Your gender (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired?

This refers to your usual way of life recently.

Even if you haven't done some of these things recently, try to figure out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

- 0 = **no chance** of dozing
- 1 = **slight chance** of dozing
- 2 = **moderate chance** of dozing
- 3 = **high chance** of dozing

It is important that you answer each item as best as you can.

Situation

Chance of Dozing (0-3)

Sitting and reading _____

Watching TV _____

Sitting inactive in a public place (e.g., a theater or a meeting) _____

As a passenger in a car for an hour without a break _____

Lying down to rest in the afternoon when circumstances permit _____

Sitting and talking to someone _____

Sitting quietly after a lunch without alcohol _____

In a car or bus, while stopped for a few minutes in traffic _____

THANK YOU FOR YOUR COOPERATION

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Appendix C

Obstructive Sleep Apnea Protocol

1. Every patient 18 or older that enters the clinic will be given the Epworth Sleepiness Scale by the front desk staff in either English or Spanish to complete.
2. The medical assistant will obtain the completed form and calculate the score and place the score at the top of the form.
3. The form will be given to the provider by the medical assistant.
4. Any patient with a score of 10 or more will be referred for a sleep study.
5. When the sleep study is completed the patient will make an appointment to return in 3 weeks for results.
6. All patients with a positive diagnosis of OSA will be taught sleep hygiene, given a patient handout on OSA, and prescribed CPAP.
7. If the patient accepts a CPAP prescription they will be scheduled for a follow-up appointment in approximately one month to discuss CPAP usage and concerns.
8. A task will be sent to the referral coordinator to initiate CPAP referral to a Durable Medical Equipment vendor.
9. The patient will be called by the MA 2 weeks after a referral is sent for CPAP to determine whether the machine and supplies were obtained. If the machine and supplies were obtained the patient will return for their scheduled follow-up appointment. If the machine and supplies were not obtained the DME vendor will be contacted by the referral coordinator and the process will begin again and a new follow-up appointment will be set after equipment has been received.
10. After successful initiation of CPAP the patient will return in 2-6 weeks, 3-6 months, then on a yearly basis to discuss CPAP usage and OSA progression.

Appendix D

Example CPAP prescription

DX: OSA

Auto-titrating CPAP

Pressure Settings

4-20 cm H₂O

Heated Humidifier

Mask to fit

All necessary supplies

Appendix E

Provider Checklist

OSA follow-up appointment areas to discuss	Discussed
Present ESS score	
Patient BMI	
Patient sleep related complaints	
Blood Pressure	
Last blood sugar	
Headache	
Pain level	
CPAP usage (how many nights a week)	
CPAP usage (number hours a night)	
Problems with CPAP	
Overall feeling of health	