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INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:
Diagnosis and Treatment of Obstructive Sleep Apnea

Sixth Edition
June 2008

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- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

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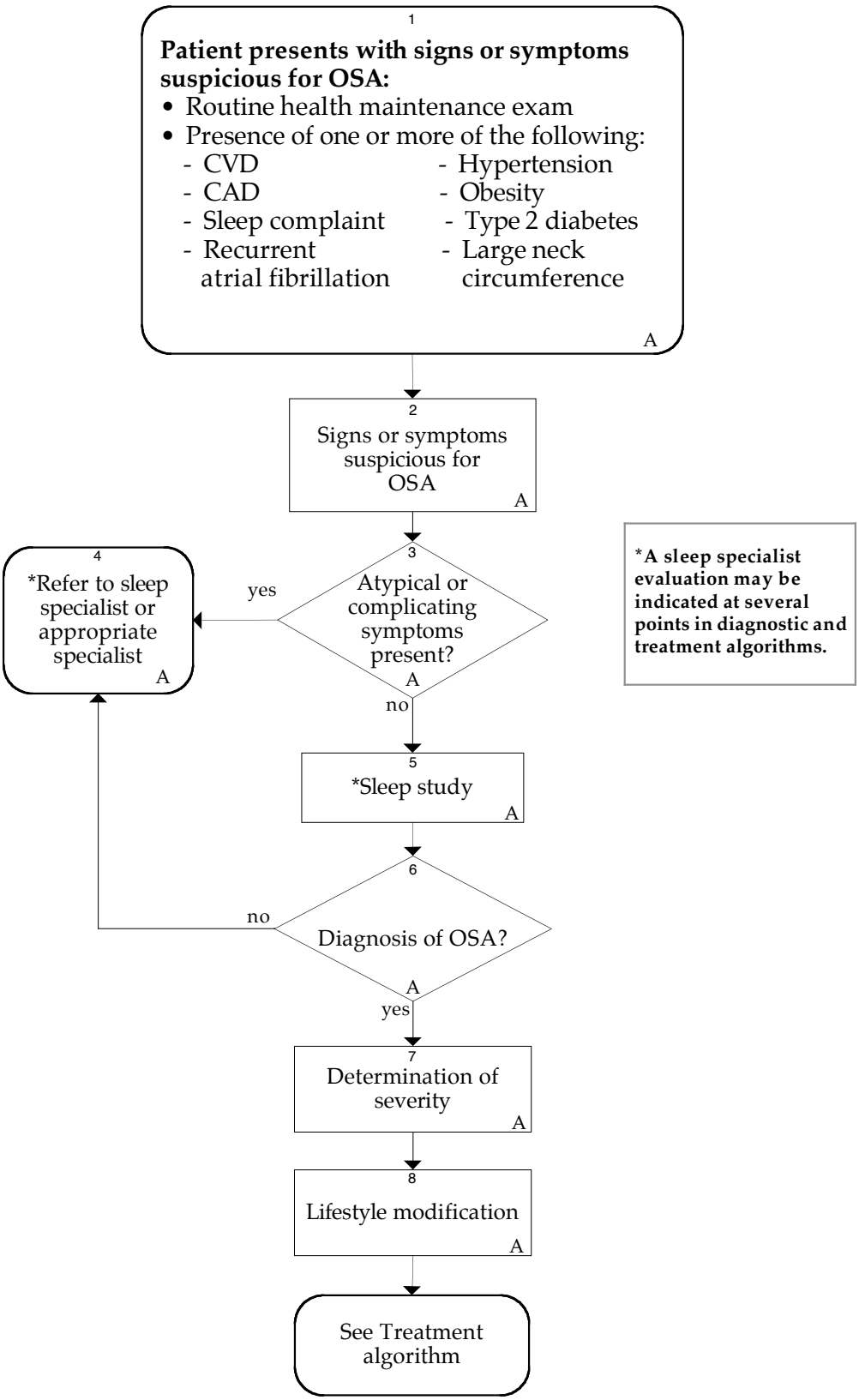
Health Care Guideline:

Diagnosis and Treatment of Obstructive Sleep Apnea in Adults

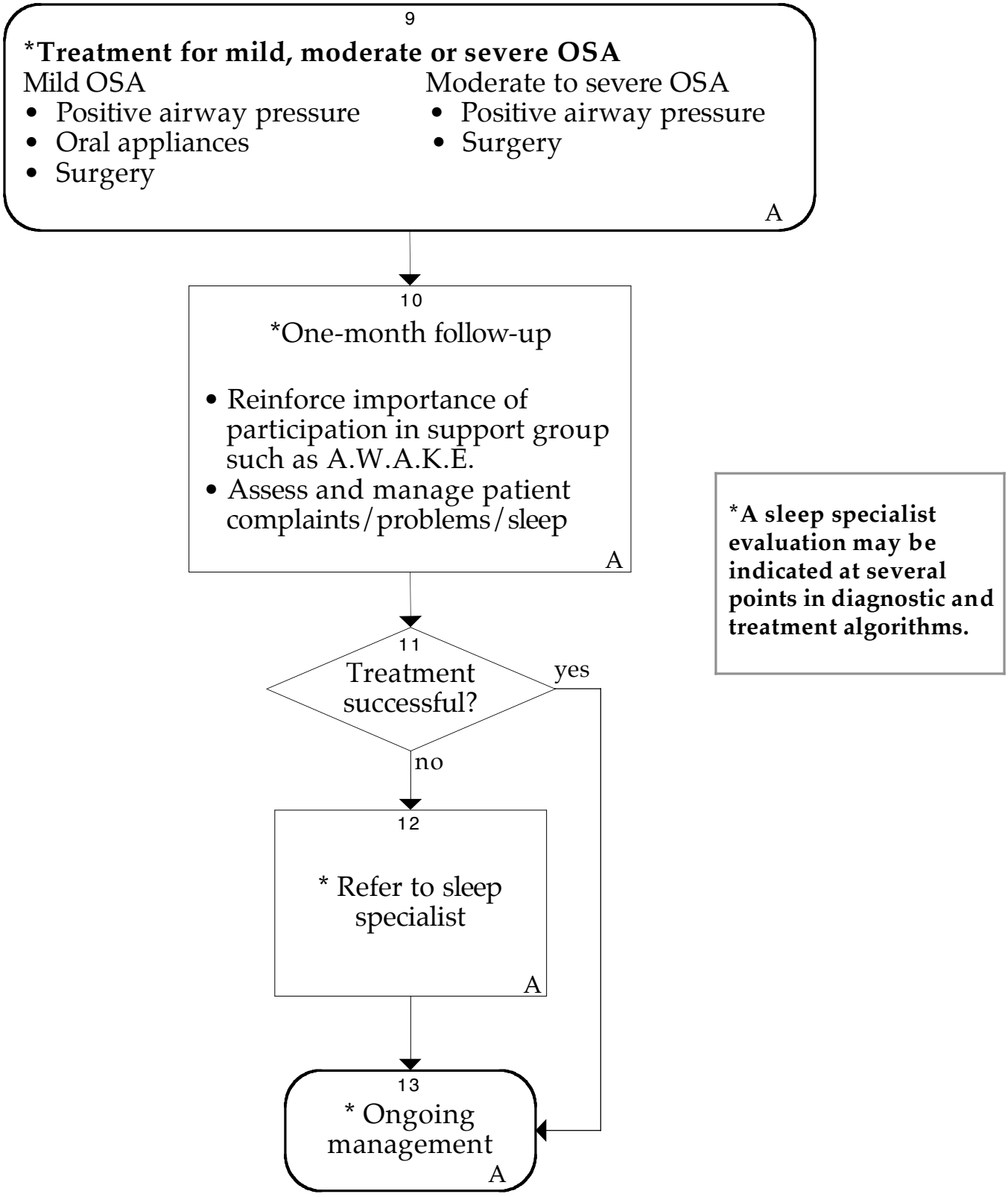
Diagnostic Algorithm

A = Annotation



Sleep Apnea Treatment Algorithm

A = Annotation



***A sleep specialist evaluation may be indicated at several points in diagnostic and treatment algorithms.**

Table of Contents

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Foreword

Scope and Target Population

To identify and appropriately treat adult patients age 18 and older at risk for obstructive sleep apnea syndrome (OSA).

Clinical Highlights and Recommendations

- The following signs and symptoms may suggest significant risk for obstructive sleep apnea syndrome (OSA). The more of these symptoms a patient has and the more severe these symptoms are, the greater the pretest probability that a patient will have moderate or severe OSA *(Annotation #2)*:
  - Awakening with choking
  - Hypertension
  - Intense snoring
  - Large neck circumference
  - Male gender or postmenopausal females
  - Obesity
  - Reported apneas or choking by sleep partner
  - Resistant hypertension and/or atrial fibrillation
  - Daytime sleepiness, especially with impairment of driving
- OSA is a significant risk factor for the development of hypertension and has been associated with type 2 diabetes, coronary artery disease and cerebrovascular disease, and may lead to significant impairment in quality of life. *(Annotation #1)*
- Untreated sleep apnea may mimic or exacerbate depression, ADHD and other chronic disorders. *(Annotation #1)*
- It is important to rule out sleep deprivation (i.e., insomnia or poor sleep hygiene) when evaluating daytime sleepiness. *(Annotations #1, 2)*
- The accepted standard test for diagnosis of OSA is polysomnography, which is indicated for the diagnosis of all patients suspected of having this disorder. *(Annotation #5)*
- All patients with a diagnosis of OSA should receive education guidance in lifestyle modification, especially weight loss as a treatment for sleep apnea and referral to the A.W.A.K.E. program. *(Annotations #8, 10, 13)*
- All patients who have a weight loss or gain of 10%-15% should be assessed for symptoms of OSA and the need to adjust PAP settings. *(Annotations #8, 13)*
- Management of mild OSA may include one or more of the following treatment modalities: oral appliances, positive airway pressure devices, surgery. *(Annotation #*9)
- Management of moderate to severe OSA includes the use of positive airway pressure devices. Patients who are intolerant of positive airway pressure devices, or those who are not adequately managed with positive airway pressure alone, may be considered for surgery. *(Annotation #9)*

Priority Aims

1. Increase the percentage of patients 18 and older who are diagnosed with OSA through a sleep study evaluation.
2. Increase the percentage of patients with OSA who have received appropriate treatment according to guideline.
3. Improve PAP treatment adherence rate for those who are diagnosed with OSA.
4. Increase patient understanding of the health risk factors related to OSA.

Related ICSI Scientific Documents

Guidelines

- Hypertension Diagnosis and Treatment
- Prevention and Management of Obesity (Mature Adolescents and Adults)

Technology Assessment Reports

- Behavioral Therapy Programs for Weight Loss in Adults (#87, 2005)
- Diet Programs for Weight Loss in Adults (#83, 2004)
- Gastric Restrictive Surgery for Morbid Obesity (#14, 2005)
- Pharmacological Approaches to Weight Loss in Adults (#71, 2003)

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Blair Anderson, MD and James Mickman, MD are contracted with Lakeland Health Services for medical directorships.

No other work group members have potential conflicts of interest to disclose.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at http://www.icsi.org.

Evidence Grading System

A. Primary Reports of New Data Collection:

Class A: Randomized, controlled trial

Class B: Cohort study

Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study

Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis

Class R: Consensus statement
Consensus report
Narrative review

Class X: Medical opinion

Citations are listed in the guideline utilizing the format of *(Author, YYYY [report class])*. A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Algorithm Annotations

Introduction

Sleep apnea is underdiagnosed. Studies indicate that 2%-4% of adult Americans have the disease and that obstructive sleep apnea syndrome (OSA) is as common as asthma. Theta Reports, based in New York, estimates that 40 million Americans may have some type of sleep disorder, 30 million likely have sleep apnea and 28.5 million are still undiagnosed. American Sleep Apnea Association research indicates that up to 12 million Americans may have OSA and 10 million remain undiagnosed. Patients with severe OSA and daytime sleepiness may have an increased risk for motor vehicle accidents. The risk may be reduced by a positive airway pressure device (PAP). The spouses of OSA patients may be sleep deprived because of the severe nocturnal snoring. OSA is an independent potential risk factor for cardiovascular disease and may be especially important in cardiovascular conditions that are resistant to standard therapy. This guideline was developed to identify those patients at risk for OSA who present to the physician's office. Realizing that patients present for well-person exams or for evaluation/follow-up of specific problems, we have identified three entry points for these patients in order to identify them.

Primary care providers should coordinate the diagnosis and management of OSA. The diagnosis and treatment of OSA should be managed by a physician with proper knowledge in this area. Such physicians may include primary care providers, or specialists such as pulmonologists, neurologists, otolaryngologists, psychiatrists or cardiologists.

(Beninati, 1999 [D]; Cassel, 1996 [D]; George, 2001 [C]; Shamsuzzaman, 2003 [R]; Wolk, 2003 [R])

Diagnostic Algorithm Annotations

1. Patient Presents with Signs or Symptoms Suspicious for OSA

Key Points:

- The risk for OSA correlates on a continuum with obesity (BMI greater than or equal to 30), large neck circumference, and hypertension. Combinations of these factors increase the risk for OSA in a non-linear manner.
- OSA occurs frequently in patients who have been diagnosed with cerebrovascular disease or coronary artery disease, or in patients who present with complaints of disturbed sleep.
- The prevalence of hypothyroidism in women with OSA is no higher than the general population. Screening is unlikely to be useful.

A thorough review of symptoms will include questions related to obstructive sleep apnea syndrome (OSA). Physical exam will identify predisposing characteristics that should lead to further in-depth investigation of the possibility of OSA.

There are several different situations where signs or symptoms of OSA could be assessed. Patients may present to the provider for a routine health maintenance exam. During an exam, the practitioner should be aware of physical findings that predispose patients to OSA.

The risk for OSA correlates on a continuum with obesity (BMI greater than or equal to 30), large neck circumference (42 cm), specific abnormalities that could lead to upper airway obstruction, and hypertension. Combinations of these factors increase the risk for OSA in a non-linear manner *(Flemons, 1997 [R]; Redline, 1995 [C])*.

OSA occurs frequently in patients who have been diagnosed with cerebrovascular disease (CVD), coronary artery disease (CAD), or in patients who present with complaints of disturbed sleep. OSA is a significant risk factor for the development of hypertension (HTN) and has been associated with type 2 diabetes and may lead to significant impairment in quality of life. Treatment of OSA may improve ejection fraction and lower blood pressure in heart failure patients, decrease the recurrence of atrial fibrillation after cardioversion and lower daytime blood pressure in hypertensive patients. Obstructive sleep apnea may also elicit nocturnal bradyarrhythmias and nocturnal angina. Treatment of the obstructive sleep apnea may result in resolution of both of these problems. When patients present for evaluation or follow-up of specific complaints that have a high correlation with OSA, further investigation should occur.

The prevalence of hypothyroidism in women with OSA is no higher than the general population. Screening is unlikely to be useful *(Miller, 2003 [C])*.

Untreated sleep apnea may mimic or exacerbate depression, ADHD and other chronic disorders *(Owens, 2005 [R]; Schwartz, 2005 [D])*.

(Becker, 2003 [A]; Franklin, 1995 [D]; Guilleminault, 1983 [D]; Ip, 2002 [C]; Kanagala, 2003 [C]; Kaneko, 2003 [A]; Nieto, 2000 [D]; Peled, 1999 [C]; Peppard, 2000 [B]; Pepperell, 2001 [A]; Reichmuth, 2005 [B]; Somers, 1992 [D])

2. Signs or Symptoms Suspicious for OSA

In evaluating daytime sleepiness, it is important to rule out sleep deprivation (i.e., insomnia and poor sleep hygiene).

* The following signs and symptoms have been found by population studies employing logistic regression analysis to suggest significant risk for OSA. The more of these symptoms a patient has and the more severe these symptoms are, the greater the pretest probability that a patient will have moderate or severe OSA:

- Awakening with choking
- Hypertension
- Intense snoring
- Large neck circumference
- Male gender or postmenopausal females
- Obesity
- Reported apneas or choking by sleep partner
- Resistant hypertension and/or atrial fibrillation
- Daytime sleepiness*, especially with impairment of driving

  * Sleepiness can be quantified with the Epworth Sleepiness Scale (see Appendix A). A high score correlates with the level of sleepiness; however, a low score does not rule out the presence of daytime sleepiness.

In patients with a low clinical suspicion for OSA, overnight oximetry may assist in clinical decision-making. Episodic awakening with choking can also be caused by gastroesophageal reflux disease (GERD).

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: See Conclusion Grading Worksheet A – Annotation #2 (Signs or Symptoms Suspicious for OSA)]*

Because of the significant percentage of the general adult population at risk for OSA, there is a need to identify which patients are at highest risk. The limited availability and cost of sleep laboratories to establish the diagnosis and to implement treatment heightens the importance of accurately predicting patients who have a high probability of OSA.

Many studies have employed logistic regression analysis of various population groups regarding signs and symptoms of OSA, followed by sleep studies in order to detect which factors are most predictive of OSA. Most studies have targeted either patients referred to sleep laboratories or general population samples picked randomly from clinic visits. Studies involving patients referred to sleep centers because of symptoms suggestive of sleep apnea likely minimize the predictive power of symptoms because of selection bias. Consequently, these studies show stronger predictive power of physical signs. Representative of this type of study, Crocker et al. examined 100 patients referred for sleep study. OSA was defined as an respiratory disturbance index (RDI) over 15. Characteristics significantly associated with an AHI greater than 15 included only reported apneas (p-0.01), awakes with choking (p-0.005), BMI (obese) (p-0.01), hypertension (p-0.001), male (p-0.04) *(Crocker, 1990 [C])*.

Studies involving selection of patients from a general population group are more likely to show accurate features helpful to a clinician in choosing which patients are at higher risk of sleep apnea and, therefore, who will benefit most from further investigation of OSA. Kump et al. investigated 465 participants, who included not only 38 previously diagnosed sleep apnea patients (probands), but also included their family members, neighbors and the neighbors' family members. Using logistic regression with backward elimination, the data were able to identify the characteristics that were most predictive of an elevated respiratory disturbance index (RDI). These characteristics are snoring intensity, roommate-observed choking, driving impairment, higher BMI, male gender and increasing age. The more of these characteristics a subject had, the more likely he/she had an RDI diagnostic of OSA. Sensitivity was 65%, and specificity was 90% *(Kump, 1994 [C])*.

The other study employing a random patient sample to evaluate for characteristics most predictive of OSA is by Netzer et al. 744 patients were selected by physicians in the Cleveland, Ohio, area. Using a logistic regression model and risk stratification, they found that the greater the patient's symptoms, BMI and high blood pressure, the greater the risk was of OSA. Risk grouping resulted in a posttest probability of 85% *(Netzer, 1999 [C])*.

Overnight Oximetry as a Screen for OSA

Overnight oximetry has been shown to provide data helpful in identifying patients with significant OSA, especially if combined with signs and symptoms to arrive at a pretest probability of disease. Simultaneous heart rate data provides additional valuable information. Patient cooperation is increased by providing continuous interpretable full-night studies. Tracings need to be interpreted by a clinician experienced in sleep medicine who recognizes validity of data, artifacts and the significance of the various patterns of cyclic oximetric variations and accompanied heart rate patterns. Obstructive sleep apneas create characteristic "saw-toothed" pattern of cyclic oximetric tracings that are often accompanied by heart rate variations attributed to alternating vagal and sympathetic effects of airway obstruction. Overnight oximetry can be useful in clinical decision-making for patients with a low pretest probability of obstructive sleep apnea syndrome. Overnight oximetry with appropriate data frequency (2- to 8-second data point collection) and analysis of low amplitude periodic fluctuations has over 96% sensitivity and a negative predictive value of 93% for obstructive sleep apnea hypopnea syndrome. Specificity ranges from 48% to 61% *(Epstein, 1998 [M]; Sériés, 1993 [C])*.

Overnight oximetry has been criticized as being too insensitive for OSA. Studies that arrived at that conclusion employed devices using technology that underestimates cyclic desaturations, such as collecting data points too infrequently (i.e., every 12 seconds). Another type of data analysis used in many studies defines significant desaturations of greater than 4% from baseline. This type of analysis will miss many cases of clinically significant OSA *(Gyulay, 1993 [C]; Wiltshire, 2001 [C])*.

It is important to emphasize that these studies were done on patients referred to sleep centers and that the sensitivities and predictive values may not be applicable to a general clinic population. Overnight oximetry is best used as a tool to heighten suspicion of OSA; a normal tracing does not rule out mild OSA nor other sleep disorders. It can be useful for follow-up evaluation of treatment effectiveness and as adjunct to symptom response.

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: See Conclusion Grading Worksheet A – Annotation #2 (Signs or Symptoms Suspicious for OSA)]*

3. Atypical or Complicating Symptoms Present?

Key Points:

- Patients should be referred to a specialist if they have severe, complex or central sleep apnea; severe neurologic, pulmonary or cardiovascular disease; careers that require special certification; or problems that may impair PAP adherence.

The following situations should prompt referral of a patient suspected of sleep apnea to a sleep specialist or other appropriate specialist, rather than following the obstructive sleep apnea syndrome (OSA) protocol:

- Heart failure, either stable or severe (NYHA Class I-IV)
- Central or complex sleep apnea *(Morganthaler, 2006a [C])*
- Significant pulmonary disease, including:
  - Severe chronic obstructive pulmonary disease (COPD)
  - Baseline hypoxemia
  - Hypercapnia
  - Pulmonary hypertension
- Inability to tolerate testing or possible PAP (positive airway pressure) therapy
- Unusual sleep-related behaviors (parasomnias) or strong suspicion of sleep disorders other than OSA
- Significant neurological or neuromuscular disease, including but not limited to:
  - Myopathies
  - Amyotrophic lateral sclerosis (ALS)
  - Degenerative neurologic disorder
- Commercial drivers, pilots or others requiring Department of Transportation, Federal Aviation Administration or Department of Defense evaluations should be considered for referral to a sleep disorders center.

Heart failure, either stable or severe (NYHA Class I-IV)

Rationale: Up to 51% of patients with stable heart failure suffer from sleep-related breathing disorders. Forty percent may have central sleep apnea syndrome, about 10% may have OSA. Clinical features and histories do not reliably distinguish these two different disorders, and their therapy may be quite different *(Hudgel, 1998 [R]; Javaheri, 1998 [C])*.

Significant pulmonary disease, including severe chronic obstructive pulmonary disease (COPD), baseline hypoxemia, hypercapnia or pulmonary hypertension

Rationale: Patients with advanced COPD, baseline ABG (arterial blood gas) abnormalities, or pulmonary hypertension are often found to have sleep disorders that are more complex than OSA, namely "overlap syndrome," alveolar hypoventilation syndrome or obesity hypoventilation syndrome, and management may involve CPAP (continuous positive airway pressure), bi-level positive airway therapy, supplemental oxygen and/or pharmacologic management *(Hudgel, 1998 [R]; Kessler, 1996 [R]; Sampol, 1996 [D])*.

Inability to tolerate testing or possible CPAP therapy

Rationale: The pathway strategy assumes that a patient will be able to tolerate testing and different alternative therapies, including overnight monitoring, and possible application of nasal masks or oxygen on a regular basis. Patients with significant psychiatric, neurological or developmental disorders suspected of sleep disorders may require individualized evaluation or management strategies.

Unusual nocturnal behaviors (parasomnias) or strong suspicion of sleep disorders other than OSA

Rationale: Nocturnal behaviors other than snoring or frequent awakenings may represent manifestations of a variety of sleep disorders, termed parasomnias. Evaluation and management of these disorders may require specialized testing at an accredited sleep disorders center that allows for synchronized electroencephalographic and video monitoring. Patients with multiple or complicated sleep disorders may benefit from individualized evaluation or management strategies *(Kushida, 2005 [R])*.

Significant neurologic or neuromuscular disease

Rationale: Although many patients with neuromuscular diseases, such as myasthenia gravis, amyotrophic lateral sclerosis (ALS) and degenerative brain disorders may have OSA; many have more complicated sleep-related breathing disorders or concurrent sleep disorders. Both evaluation and management of these disorders may require testing and treatment strategies outside these guidelines *(Silber, 2001 [R])*.

Commercial drivers, pilots or others requiring Department of Transportation, Federal Aviation Administration or Department of Defense evaluations

Rationale: Patients in these categories are often required to undergo specialized testing to document effectiveness of treatment, and referral of such patients to a sleep disorders specialist should be considered.

4. Refer to Sleep Specialist or Appropriate Specialist

Patients with significant sleep-related complaints that are not very typical of OSA, who have atypical or complicating situations (see Annotation #3, "Atypical or Complicating Symptoms Present?"), or who have symptoms of OSA but non-diagnostic sleep tests should be referred to a sleep disorders specialist or an accredited sleep center. Other specialists who may play a role in evaluating such patients include neurologists, otolaryngologists, psychiatrists or pulmonologists, depending on the symptoms and suspected diagnoses.

5. Sleep Study

Key Points:

- Selection of appropriate diagnostic tests must take into account the estimated pretest probabilility of the patient having OSA, availability of credible diagnostic tests, and local expertise in interpreting these tests.
- Polysomnography is the accepted standard test for the diagnosis of OSA.

- The benefit of using attended polysomnography for diagnosis is the ability to establish a diagnosis and ascertain an effective CPAP treatment pressure.
- Unattended portable monitoring (PM), in conjunction with a comprehensive sleep evaluation, is an option for patients with a high pretest probability of moderate to severe sleep apnea who do not have significant comorbid medical conditions or other sleep disorders. (See Annotation #2, "Signs or Symptoms Suspicious for OSA.")
- Performance, interpretation and follow-up of unattended portable sleep studies has been validated only by sleep specialists (individuals certified or eligible in sleep medicine).

Selection of appropriate diagnostic tests, as in all clinical situations, must take into account the estimated pretest probability of the patient having OSA, the availability of credible diagnostic tests, and the local expertise in interpreting these complex physiological tests. The diagnosis and treatment of OSA should be managed by a physician with proper knowledge in this area. Such physicians may include primary care providers, or specialists such as pulmonologists, neurologists, otolaryngologists, psychiatrists or cardiologists.

- The accepted standard test for diagnosis of OSA is polysomnography, which is indicated for the diagnosis of all patients suspected of having sleep-related disorders for titration of CPAP therapy, and which can serve as an important tool in evaluating other disorders of sleep. A split-night study should be performed where and when possible.

A benefit of using attended polysomnography for diagnosis is the ability to perform a "split study," wherein the first portion of testing is for purposes of establishing the diagnosis, and the remaining portion of testing is used to ascertain an effective CPAP (continuous positive airway pressure) treatment pressure. This can be achieved in the majority of cases in one night and is the current standard approach. This is the approach required for CPAP authorization by the Centers for Medicare and Medicaid Services (CMS) *(Collop, 2007 [R])*. Use of an unattended polysomnogram or a portable monitor test may yield a tentative diagnosis, but additional steps for determination of treatment will be necessary. The overall costs and effectiveness of combined in-home portable monitor testing followed by autotitrating PAP therapy, as compared to split-night attended polysomnography and CPAP therapy, have not been extensively characterized. Two analyses of differing strategies for diagnosis and treatment of OSA found attended polysomnography to have a superior cost utility compared to home cardiorespiratory testing but did not compare strategies outlined in this guideline *(Chervin, 1999b [M]; Reuveni, 2001 [M])*. Although not duplicative of our guideline recommendations, this analysis highlighted the importance that tests for OSA have very high sensitivity (greater than 93%) in order to provide favorable cost utility.

Although a uniform terminology has not been widely adopted, most consensus statements regarding use of polysomnography for sleep apnea testing assume the presence of a minimum of seven channels, including EEG (C4-A1 or C3-A2), EOG, chin EMG, ECG, airflow, abdominothoracic movement, and oxygen saturation. The requirement to stage sleep dictates the recording of EEG, EOG and chin EMG. In addition, many polysomnographic recording devices allow recording of sleep position (supine, sides or prone) from sensing instruments and auditory signals such as snoring.

(American Thoracic Society, 2004 [R]; Block, 1985 [R]; Kushida, 2005 [R])

All polysomnographic recordings must include measures of airflow. Simultaneous use of an oronasal thermistor and nasal pressure transducer is recommended. The oronasal thermister is the recommended channel for recognition of apnea, and the nasal pressure transducer is the recommended channel for recognition of hypopnea. Respiratory inductance plethysmography or esophageal manometry is recommended for detection of respiratory effort *(Iber, 2007 [R])*.

In patients with a high pretest probability of OSA, unattended portable recording for the assessment of obstructive sleep apnea is an acceptable alternative to standard polysomnogram in the following situations:

- Patients with clinical symptoms that are indicative of a diagnosis of moderate to severe obstructive sleep apnea, and when initiation of treatment is urgent and standard polysomnography is not readily available. *[Conclusion Grade II: See Conclusion Grading Worksheet A – Annotation #2 (Signs or Symptoms Suspicious for OSA)]*
- For patients unable to be studied in the sleep laboratory
- For follow-up studies when diagnosis has been established by standard polysomnography and therapy has been initiated. The intent most often is to evaluate the response to therapy.
- Those with comorbid conditions including but not limited to significant pulmonary, cardiac or neurologic disease should not be evaluated with unattended portable monitoring devices.

Portable monitoring devices have not yet been standardized. Both the American Academy of Sleep Medicine (AASM) and the Center for Medicare and Medicaid Services (CMS) suggest that at least three cardiopulmonary parameters be monitored. Specifically, AASM recommends that such devices record airflow, respiratory effort and blood oxygenation *(Collop, 2007 [R]; CMS Decision Memo for CPAP Therapy for OSA, 2008 [R])*.

In two separate evidence-based reviews of the use of portable cardiorespiratory monitors to diagnose OSA, data to support routine use of home-based studies was found lacking. In-home cardiorespiratory studies can produce false-negative results in patients with mild to moderate apnea and should be reserved for patients for whom the probability of having moderate to severe obstructive sleep apnea is high. If a cardiorespiratory study is used, it should be scored manually with review of the collected data by a qualified interpreting physician *(Chesson, 2003 [R]; Chesson, 1997 [M]; Flemons, 2003 [M]; Ross, 1999 [M]; Yin, 2004 [C]; Yin, 2006 [C]; Zou, 2006 [C])*.

Another technology for home portable monitoring, a device that utilizes peripheral arterial tonometry combined with oximetry and actigraphy (a movement measurement), is not classified as a cardiorespiratory monitor and was not considered in the systematic reviews. The device correlates changes in finger pulse pressure (modulated by sympathetic nervous output), heart rate, oximetry, and actigraphy with proprietary signal analysis, and it provides estimates of the respiratory disturbance index, sleep duration and the occurrence of REM sleep. There is literature to suggest this device may play a role in the diagnosis of OSA, and the committee felt that the device was at least equivalent to available cardiorespiratory monitors. Because it involves fewer sensors, it is simpler for most patients to apply in the home. In addition to excluding patients with atypical or complicating symptoms present (see Annotation #3, "Atypical or Complicating Symptoms Present?"), practitioners using this device must familiarize themselves with other patient conditions that exclude its use, such as Raynaud's, use of alpha-blocking drugs, etc. The analysis of data is very dependent on proprietary software, and a careful review of collected data by the interpreting physician should be performed. Additional clinical studies are needed before the device is employed routinely in the diagnosis of OSA in place of polysomnography *(Ayas, 2003 [C]; Bar, 2003 [C]; Pang, 2007 [C]; Penzel, 2004 [C]; Pillar, 2003 [C]; Schnall, 1999 [C])*.

- Polysomnography is not available in some rural areas. Some patients decline to undergo study in a sleep laboratory. For these and other reasons, some physicians are interested in expanding the use of in-home, unattended, portable recording beyond the three situations listed above. At present the evidence supporting this expansion is limited and at times conflicting, but employment of portable monitoring as a second-best option is not likely to result in harm to patients with a high pretest probability of OSA, and may result in less risk than leaving the condition undiagnosed. Portable monitors should not be used in an unattended setting in patients with atypical or complicating symptoms present (see Annotation #3, "Atypical or Complicating Symptoms Present?"). In a patient with suspected OSA, a negative

study must be followed by a polysomnographic test. The patient and physician must discuss fully the limitations of portable monitoring before employing this strategy.

The diagnostic use of portable monitoring devices for assessing sleep disorders is a highly sophisticated field. For this reason, the individual interpreting the recordings should have knowledge and skills related to the diagnosis and treatment of sleep-related breathing disorders and the ability to recognize other sleep disorders.

Suggested qualifications for such individuals include diplomates of the American Academy of Sleep Medicine, American Board of Internal Medicine with certification in sleep medicine, individuals who have completed a one-year fellowship in sleep medicine, and other physicians who have received additional training in sleep medicine and in interpreting sleep studies.

Unattended sleep studies can be valuable tools in the diagnosis of OSA, providing an accurate and reliable apnea-hypopnea index (AHI) in patients with a high pretest probability but the following limitations: absence of trained technician and therefore inability to enlist patient cooperation, make continuous patient observations, intervene for the medically unstable patient, and provide therapeutic intervention (i.e., CPAP, O_2, supine positioning, resuscitation) *[Conclusion Grade III: See Conclusion Grading Worksheet B – Annotation #5 (Sleep Study)]*

Autotitrating CPAP devices are being used as primary treatment for patients diagnosed with OSA. The devices are inappropriate in patients with atypical or complicating symptoms (see Annotation #3, "Atypical or Complicating Symptoms Present?") *(Fietze, 2007 [A])*. It is important to follow up with patients to determine treatment effectiveness.

Although not strictly required for polysomnographic recording, attendance by qualified personnel enhances data quality and allows for recording of clinical information such as volume of snoring, position of sleep, and unusual behaviors, and allows for performance and analysis of response to interventions such as reassurance or CPAP initiation.

(Epstein, 1998 [M]; Kushida, 2005 [R]; Thorpy, 1994 [R])

Most portable monitoring devices are also limited by the inability to document and stage sleep and hence to recognize sleep-stage loss, sleep fragmentation and non-respiratory sleep disorders *(Thorpy, 1994 [R])*.

Despite these limitations, in-home unattended sleep testing may be more readily available in some areas and may be preferred by some patients. In addition, in-home unattended screening devices may be useful for follow-up to assess recurrence of snoring, observed apneas, effectiveness of weight loss/gain, surgical interventions, drug therapy or use of intraoral device *(Coppola, 1993 [D]; Emsellum, 1990 [C]; Redline, 1991 [C])*.

6. Diagnosis of OSA?

Key Points:

- The diagnostic definition of OSA is affected by the presence of signs and symptoms of disease.

One of the primary underlying pathophysiologic abnormalities in OSA is abnormal luminal collapse of upper airway tissues during sleep. The resultant increase in upper-airway resistance most often manifests as decreased flow, causing either apnea or hypopnea and an inappropriate decline in ventilation. Arousal from sleep is often the only way to restore needed ventilation. These repetitive events result in impaired restorative qualities of sleep. The symptoms and associated risk factors caused by OSA have been reviewed in Annotations #1 and #2. Conventional testing for OSA (discussed in Annotation #5) focuses on the detection of inappropriate reduced airflow during sleep, called either apnea or hypopnea. The definition of apnea

and hypopnea and their correlation with morbidity and mortality has received considerable attention and has been recently well summarized. As defined by the American Academy of Sleep Medicine:

- Apnea is a decrease in the peak thermal airflow sensor by 90% or greater of baseline for 10 seconds or longer.
- Hypopnea is a decrease in a nasal pressure airflow sensor excursion by 30% or greater of baseline for 10 seconds or longer with a 4% or more O_2 desaturation

  Or

  A 50% or more decrease in nasal pressure excursion for 10 seconds or longer with either a 3% or more O_2 desaturation or an arousal *(CMS Decision Memo for CPAP Therapy for OSA, 2008 [R])*

There are several definitions of OSA by various institutions, but for practical purposes, the most useful is what the Centers for Medicare and Medicaid Services (CMS) considers as a positive test for CPAP payment:

A positive test for OSA is established if either of the following criteria using the apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is met:

- AHI or RDI greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke

If the AHI or RDI is calculated based on less than two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a two-hour period.

The AASM defines a Respiratory Effort-Related Arousal (RERA) as "… a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea." In practice, RDI is the number of RERAs per hour plus the number of apneas and hypopneas *(Iber, 2007 [R])*.

Adoption of these definitions will likely result in appropriate diagnosis of most patients with OSA and is appropriate for the purposes of this guideline, but some patients may manifest symptoms of OSA caused by increased airway resistance in the absence of discernible flow decrease. For patients with symptoms suggestive of OSA and negative initial sleep tests, further diagnostic testing may be needed to determine the underlying cause of the symptoms, and referral to an accredited sleep center or sleep specialist is recommended *(Guilleminault, 1993 [D])*.

It should be noted that these standards specifically relate to measurements made during full polysomnography with a denominator of hours of sleep. Although most portable monitoring devices do not directly measure sleep, their measurement of disordered breathing events per hour of recording has some correlation to apnea-hypopnea index. The AASM Task Force has now approved the use of unattended portable monitoring devices to diagnose OSA with certain caveats: done in conjunction with comprehensive sleep evaluation, supervised by board-certified/eligible sleep specialist, and performed in those with high pretest probability of having moderate to severe OSA and without significant comorbid sleep disorders. CMS, at the national level, has approved coverage for CPAP when portable monitoring devices are used to diagnose OSA, using apnea-hypopnea index or its related respiratory distress index (which most portable monitoring devices record). Regional coverage for CPAP varies, and at the time of this publication, Upper Midwest CMS has not yet approved the use of portable monitoring devices to diagnose OSA *(Collop, 2007 [R]; CMS Decision Memo for CPAP Therapy for OSA, 2008 [R])*.

7. Determination of Severity

Key Points:

- The severity of OSA is determined by symptoms, frequency of obstructions and degree of desaturation.

The severity of the OSA is determined by the ***most severe*** rating of three domains: sleepiness, respiratory disturbance (AHI), and gas exchange abnormalities (minimum and mean oxygen saturation). The following can serve as a guide:

- Sleepiness:
  - Mild: Describes sleepiness present only when sedentary or when little attention is required, and may not be present every day. Such sleepiness produces only minor impairment of social or occupational function. As a guide, an Epworth Sleepiness Scale result might be less than 12.
  - Moderate: Describes daily sleepiness that occurs when minimally active and a moderate degree of attention (e.g., driving, attending meetings or movies). As a guide, an Epworth Sleepiness Scale result might be 13-17.
  - Severe: Describes daily sleepiness during active tasks or tasks that require significant attention. Examples might include driving, conversation, eating or walking, and usually sleepiness produces marked impairment of social or occupational function. As a guide, an Epworth Sleepiness Scale result might be 18-24.

(See Appendix A, " The Epworth Sleepiness Scale.")

- Gas exchange abnormalities:
  - Mild: Mean oxygen saturation remains greater than or equal to 90% **and** minimum remains greater than or equal to 85%.
  - Moderate: Mean oxygen saturation remains greater than or equal to 90% **and** minimum oxygen saturation remains greater than or equal to 70.
  - Severe: Mean oxygen saturation remains less than 90% **or** minimum oxygen saturation remains less than 70%.
- Respiratory disturbance:
  - Mild: AHI 5-15
  - Moderate: AHI 16-30
  - Severe: AHI greater than 30

Regarding severity of OSA, there are no widely accepted criteria. The severity criteria recommended by our group is an opinion based upon available data. We have assigned the severity rating based on the worst impairment of three domains: sleepiness, respiratory disturbance as measured by the AHI, and gas exchange as measured by oxygen saturation.

Sleepiness is one of the hallmark symptoms and causes of impairment. The categorization of mild, moderate and severe sleepiness corresponds to the description from accepted references. A clinical tool consisting of eight questions that is widely used to aid in assessment of sleepiness is the Epworth Sleepiness Scale (ESS). (See Appendix A, "The Epworth Sleepiness Scale.") Although easy to administer and extensively studied, it should be used only as a rough guide since under scrutiny it does not correlate well with either objectively

measured sleepiness or AHI *(American Academy of Sleep Medicine Task Force, 1999 [R]; Chervin, 1999a [C]; Johns, 1992 [C]).*

The AHI has not corresponded well to degree of sleepiness, but has been linked to cardiovascular risk and to response to treatment modalities such as dental devices. Again, the ranges chosen for mild, moderate and severe vary in the literature and represent a consensus agreement. For comparison, severity criteria proposed for research (not clinical) purposes by the American Academy of Sleep Medicine were based on the most severe degree of subjective sleepiness, similar to our criteria, and sleep-related obstructive breathing events were categorized as mild (5-15), moderate (16-30) and severe (greater than 30), but these criteria included respiratory effort-related arousals, subtle events not included in our definitions for AHI. Hypoxemia was not included in their severity criteria, but additional data linking cardiovascular risk and hypoxemia have been published. Hypertension seems related to desaturation frequency, and oxyhemoglobin desaturations below 70% have been correlated with increasing ventricular ectopy and arrhythmia *(American Academy of Sleep Medicine Task Force, 1999 [R]; Iber, 2007 [R]; Nieto, 2000 [D]; Peppard, 2000 [B]).*

8. Lifestyle Modification

The following lifestyle modifications can play a significant role in the reduction of severity of sleep apnea symptoms:

- Weight loss
- Reduced alcohol consumption, especially before bedtime
- Lateral body position during sleep (versus supine)
- Good sleep hygiene
- Integrate PAP preparation into a bedtime routine and bedroom environment

See Appendix D, "Sleep Hygiene," for more information.

Alcohol Consumption

A bedtime dose of alcohol (0.5-0.75mL/kg) increases inspiratory resistance during stage two non-rapid eye movement (nREM) sleep in young nonsnoring men. The effect on respiratory drive varies upon the method used to measure it. The inspiratory occlusion pressure, considered a measure of the neural output to the inspiratory muscles, tended to increase during sleep after alcohol consumption in the studies cited below. However, ventilatory response to hypercapnia decreased in most subjects, and the response to isocapnic hypoxia was variable, increasing in some subjects. Snorers would be expected to have a higher inspiratory resistance during sleep than nonsnorers, and the aggravation of snoring by ethanol is well recognized *(Dawson, 1997 [C]; Scanlan, 2000 [A]; Tsutsumi, 2000 [A]).*

Obesity

Epidemiological studies demonstrate a strong association between obesity and OSA; however, defining the causal relationship between excess body weight and sleep-disordered breathing remains difficult. Incidence of OSA among morbidly obese patients is 12- to 30-fold higher than other populations, and these patients may benefit from bariatric surgery, although it must be remembered that long-term recurrence of the syndrome is possible. Surgical and non-surgical approaches to weight loss have been evaluated, although most studies to date suffer from methodological limitations including lack of random assignment to treatment groups, confounding of treatment interventions, absence of untreated controls, and lack of adequate follow-up assessment *(American Sleep Disorders Association, 1996 [R]; Itasaka, 2000 [C]; Kyzer, 1998 [R]; Peppard, 2000 [B]).*

Neck circumference, the strongest predictor of sleep-disordered breathing among anthropomorphic variables studied, suggests that upper-body obesity, rather than a more generalized distribution of body fat, may be important for the development of OSA.

Weight loss should be encouraged as a specific treatment for patients with OSA, including those who are only moderately overweight. A nurse-managed program combining a very low calorie diet with behavior management on an outpatient basis is safe and cost effective as a primary treatment for OSA *(Lojander, 1998 [D])*.

Patients who experience weight loss or gain should have their PAP settings reassessed.

Body Position

Keeping patients out of the supine position can be effective in reducing the AHI in many patients.

There are a number of support devices to maintain lateral body position.

The AHI of 60 male positional sleep apneics was analyzed by sleep stage to determine if positional differences limited nREM sleep. Differences in apnea severity by sleep position were found to persist in REM sleep and to be of equal extent to those differences found in nREM sleep, despite the fact that there is also a significant increase in the frequency of apneic events associated with REM sleep. The positional effect persists in REM sleep, making treatments to control sleep posture a viable option *(Cartwright, 1991 [D])*.

Results show that even in patients with severe OSA who have a high number of apneic events in the supine and lateral posture, the apneic events occurring in the supine position are more severe than those occurring while sleeping in the lateral position. Thus, it is not only the number of apneic events that worsen in the supine position but, probably no less important, the nature of the apneic events themselves *(Oksenberg, 2000 [C])*.

(Morganthaler, 2006b [R])

Sleep Apnea Treatment Algorithm Annotations

9. Treatment for Mild, Moderate or Severe OSA

Key Points:

- The treatment of OSA includes oral devices and various positive airway pressure devices.
- A CPAP with heated humidity is strongly suggested for patients with a past history of ENT surgeries, taking drying medications, or have chronic nasal congestion. In all other patients, it may be cost effective and increase comfort and adherence to order CPAP with heated humidity.
- Surgical interventions may be helpful in the treatment of OSA.

For patients who have not responded to lifestyle modification, additional treatment options are available and are based on the severity of OSA.

There are three options for treatment of mild obstructive sleep apnea syndrome (OSA). A combination of the treatment options listed below may be necessary to adequately manage the symptoms of OSA.

Positive Airway Pressure Devices

According to a retrospective, non-randomized trial, patients with OSA who are not treated with PAP therapy have a higher mortality rate than patients who received PAP therapy and who had a moderate- to high-degree adherence to therapy *(Campos-Rodriguez, 2005 [C])*.

CPAP

Positive pressure is the most efficacious (next to tracheostomy) for treating OSA. CPAP is currently the most commonly used positive airway pressure device. It is a non-invasive/non-pharmacologic method of applying positive pressure to the upper airway via a blower and mask/interface to pneumatically splint the airway, thereby preventing collapse. Therapeutic CPAP pressures are generally determined by manual titration during a polysomnogram, resulting in a final fixed pressure that eliminates apneic and hypopneic episodes in all stages of sleep and body positions, diminishes sleep fragmentation, snoring and oxygen desaturations, thereby improving daytime function. Self-titrating CPAP (AutoPAP) can also be utilized for determining an effective CPAP pressure (see below) *(Barbé, 2001 [A]; Fietze, 2007 [A]; Monasterio, 2001 [A])*.

The success of any positive airway pressure device therapy depends primarily on patient adherence, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the clinician and DME (durable medical equipment) provider, and finally, A.W.A.K.E. (Alert Well And Keeping Energetic) meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy.") A heated humidifier is strongly suggested in patients with the following circumstances:

- The patient is currently taking drying medications
- Past history of ENT surgeries
- Chronic nasal congestion

In all other patients, it may be cost effective and still improve comfort and adherence to order CPAP with heated humidity.

Flexible CPAP is an option that may improve adherence for patients who have difficulty with CPAP *(Aloia, 2005 [C])*.

AutoPAP (AutoPAP, Self-Titrating CPAP, Auto-Adjust CPAP)

AutoPAP is a positive pressure apparatus designed to vary pressures to meet the needs of the patient's sleep-disordered breathing. Pressure changes are determined by monitoring variably a combination of apneas, hypopneas, inspiratory flow limitation and snoring. Instead of constant maximal pressure, these systems provide the minimal pressure necessary to stabilize the upper airway. The pressures found by these machines generally agree well with those established by skilled technicians *(Fietze, 2007 [A]; Gagnadoux, 1999 [D]; Meurice, 1996 [A]; Randerath, 2001 [A]; Strandling, 2000 [A])*.

AutoPAP may be used as an alternative therapy for patients who are intolerant of pressures in conventional CPAP therapy and may be used for an unattended in-home CPAP titration after a positive sleep study or when follow-up indicates a need for CPAP pressure changes *(Sériés, 2000 [A])*. It is important to follow up with patients to determine treatment effectiveness.

The success of any positive airway pressure device therapy depends primarily on patient adherence, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the clinician and DME (durable medical equipment) provider, and finally, A.W.A.K.E. meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy.")

Bi-level PAP

Bi-level PAP is a non-invasive respiratory device that delivers different levels of inspiratory (IPAP) and expiratory (EPAP) pressure to a spontaneously breathing patient to keep the upper airway open. By applying a lower pressure during the expiratory phase, the total pressure applied on the airway can then be reduced, thereby achieving closer to normal physiologic breathing.

Bi-level devices have additional flow delivery methods to meet the ventilatory needs of patients with varied respiratory problems, and have been shown therapeutic for OSA. Theoretical advantages of bi-level devices include reducing the work of breathing, lowering the mean treatment pressure, and a more physiologic breathing pattern. These possible advantages make a trial of bilevel devices an appropriate intervention for selected OSA patients who do not tolerate continuous pressure or autotitrating devices. Patients with concurrent or more severe chronic obstructive pulmonary disease or hypoventilation syndromes may also benefit, particularly if they have awake hypercapnia, but very specific criteria must be met to enable Medicare reimbursement. Although selected patients may benefit, the use of bi-level devices as initial treatment for OSA is not encouraged, since bi-level devices have not been demonstrated to be superior to CPAP in improving adherence, symptom scores, nasal discomfort or patient complaints regarding therapy. If used, the therapeutic IPAP and EPAP pressures must be achieved by manual titration during an attended polysomnogram and many patients can resume CPAP if retitration reveals improvement in sleep-disordered breathing with adjustment of pressure *(Reeves-Hoche, 1995 [A]; Resta, 1998 [C]; Schafer, 1998 [C]).*

Bi-level is applied to the patient via nasal mask interface or a full-face interface. Bi-level is indicated not only to correct OSA, but may also be used as an alternate therapy for patients who are intolerant of conventional CPAP at higher pressures. Bi-level reduces the work of breathing and lowers the mean pressure delivered in the airway.

The success of any positive airway pressure device therapy depends primarily on patient adherence, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the clinician and DME (durable medical equipment) provider, and finally, A.W.A.K.E. meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy.")

(Gay, 2006 [R]; Kushida, 2006a [R])

Oral Appliances

Oral appliances are a recommended treatment for patients with mild OSA who have not responded to lifestyle modification or who are intolerant of positive airway pressure devices (described below), though they are not as effective.

Mandibular repositioning devices can be a successful treatment modality for patients with mild OSA with obstruction in the oropharynx and tongue base region.

Tongue retaining devices are helpful for patients with limited or loose natural dentition, temporomandibular disorders and limited mouth opening.

The role of oral appliances in the management of upper-airway obstruction was recognized as early as 1902. The rationale for use of mandibular repositioning devices is that they may act to increase the size of the pharyngeal airway or otherwise reduce its collapsibility. Despite the considerable variation in device designs, the clinical effects appear to be remarkably consistent. Two recent studies compared the use of a mandibular repositioning device with nasal CPAP. The studies concluded that the mandibular repositioning device achieved substantial success (45% reduction in AHI score), but was less effective than nasal CPAP, which achieved 70% reduction in AHI score *(Ferguson, 1996 [R]; Marklund, 1998 [D]).* Patients preferred mandibular repositioning device treatment to that of nasal CPAP. Depending on the criteria, the percentage of success varies from approximately 50% to 80% with adjustable appliances. The improved efficacy of appliances in the past few years is related to better appliance design, materials and adjustability. Appliances

offer some advantages over other therapies because they are non-invasive, relatively easy to fabricate and well accepted by patients.

(Barnes, 2004 [A]; Ferguson, 2006 [M]; Kushida, 2006b [R]; Lim, 2006 [M]; Pancer, 1999 [D]; Yoshida, 2000 [D])

To locate a dentist or orthodontist with special training in sleep apnea who can fit oral appliances, consider contacting your local dental society or check the following Internet Web site: http://www.dentalsleepmed.org.

Surgical Procedures

The following is a list of surgical procedures available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in mild clinical obstructive sleep apnea syndrome. It may be necessary to correct the anatomical obstruction before prescribing an oral appliance or positive airway pressure (PAP) device. The work group developed this list as examples of the surgical procedures available and it is not meant to be all-inclusive of the different types of procedures available.

Septoplasty – intranasal operation performed to straighten a deviated nasal septum (cause of substantial nasal obstruction). This procedure has a very high rate of success in improving the nasal airway if the nasal septal deviation is the major etiology of the nasal obstruction. There are, however, no controlled studies that evaluate the long-term effect of septoplasty on OSA.

Nasal polypectomy – intranasal operation to remove nasal polyps.

Tonsillectomy – surgical procedure that involves the transoral resection of the pharyngeal tonsils. Typically this is reserved for clinically obstructing tonsillar hypertrophy of the oropharynx. There are no studies that evaluate the long-term effect of tonsillectomy on OSA.

Turbinoplasty – intranasal operation performed to reduce the size of obstructing nasal turbinates. This procedure may consist of partial surgical resection of the inferior turbinates or reduction of the inferior turbinates using other methods including electrocautery, laser ablation and radiofrequency reduction. The results of all these methods are similar. There are no studies demonstrating a beneficial effect of turbinoplasty on OSA.

Tracheostomy – the creation of an airway through the anterior neck into the upper trachea. This airway bypasses the entire upper airway and therefore is 100% successful in curing sleep apnea. However, this method of treatment has significant social stigmata due to the presence of a tracheostomy tube and the associated care of the tracheostomy site. This is typically the treatment of last resort for patients with sleep apnea *(Haapaniemi, 2001 [D])*.

Uvulopalatopharyngoplasty (UPPP) – the surgical resection of the obstructive portion of the velar musculature of the soft palate and the entire uvula. This surgical procedure has an approximately 52.3% rate of long-term reduction of RDI or AHI of greater than 50% of patients with mild or moderate sleep apnea.

Pirsig et al. reviewed 292 UPPP studies of which only six long-term studies were found. These uncontrolled studies demonstrated a success rate of four or more years ranging from 31% to 74%. However, all the studies evaluated different patient populations; i.e., some were selective and some were not *(Pirsig, 2000 [R])*.

UPPP typically is considered a first-line surgical treatment of sleep apnea when clinically the uvula, palate and redundant pharynx are determined to be a major site of anatomic obstruction. Though there are no consistently objective means of determining the exact anatomic site of obstruction in OSA, methods currently used for this purpose include cephalometry and Mueller maneuver *(Boot, 1997 [D])*.

Pillar procedures – the surgical procedure of inserting plastic rods into the palate area of the mouth to prevent the collapse of the soft palate. Small, short-term studies have shown these devices can treat mild OSA in selected patients *(Jacobowitz, 2006 [D]; Nordgard, 2006 [D]; Walker, 2006 [D])*.

Radiofrequency ablation of the soft palate and tongue base – the administration of microwave radiofrequencies to the treated tissue of the soft palate and/or the tongue base with a needle-implanted probe. This modality has been predominantly used for the treatment of snoring by treating the soft palate. Multiple treatments are performed and complications consist of tissue erosion and perforation *(Emery, 2000 [C])*.

Radiofrequency ablation of the tongue base has been described, but there are no studies demonstrating the efficacy of this method in the treatment of OSA.

Hyoid suspension – surgical procedure that results in the hyoid bone being suspended, usually to the mandible, pulling the hyoid bone anteriorly and superiorly. The purpose of the procedure is to pull the tongue base forward, resulting in a larger hypopharyngeal airway. Complications consist of dysphagia posttreatment. There are no controlled studies evaluating this method for the treatment of OSA.

Mandibular advancement, genioglossus advancement, and/or maxillary advancement – Orthognathic surgery, a procedure to permanently reposition the jaws, widely accepted for growth deformities and for masticatory dysfunction. The complications are low, and the results reliable. A great deal of established research in orthognathic surgery allows surgeons to use accepted techniques to help this patient population. Maxillo-mandibular advancement (MMA) is successful for patients with base of tongue obstruction, severe OSA, morbid obesity and failure of other treatments. Skeletal movement of the maxilla and mandible has a broad effect on the upper airway without cicatricial scarring and has demonstrated positive results. With careful evaluation, results with MMA surgery equal those of nasal CPAP. The Stanford group has outlined a specific surgical protocol that is phased and tailored to the specific anatomical abnormalities in each patient. MMA surgery is usually a two-phase surgical procedure.

(Hendler, 2001 [D]; Li, 1999 [R]; Prinsell, 1999 [D]; Sundaram, 2006 [M])

10. One-Month Follow-Up

Key Points:

- Follow-up visits must address effective disease treatment and adherence.

There are no published clear guidelines defining success of therapy; therefore, the approach needs to be directed to individual patients, strongly influenced by their goals, specific circumstances and tolerance of discomfort of therapy.

Evaluation to determine the success and acceptance of treatment is necessary for all patients and will indicate if further evaluation and intervention are necessary. Snoring, sleepiness and other presenting symptoms that initiated evaluation should be reassessed at this time. If symptoms are persistent, consider a referral to a sleep specialist. The ESS (Epworth Sleepiness Scale) should be repeated at this time, as well as annually.

Determination of the success of treatment should take into consideration:

- Patient and bed partner satisfaction.
- Complications of treatment (i.e., upper-airway irritation, pain from CPAP or dental device, etc.). Positive airway pressure and dental device discomfort can be problematic for adherence and are influenced by many factors. Some of the most common problems and their solutions are included in Appendix B, "Management Tips to Improve Adherence with Therapy."
- Adherence with therapy.

- Diminished sleepiness, either subjective or measured by ESS.
- Diminished AHI. Since data are available linking hypertension to AHI greater than 20, it is reasonable to attempt to pursue a goal of AHI less than or equal to 20.
- Quality of life improvement.

(Haider, 1999 [R]; Hoy, 1999 [A]; Nieto, 2000 [D])

Patients with persistent symptoms despite adequate treatment and adherence to treatment should be evaluated for other undiagnosed sleep disorders or sleep deprivation. Modafinil has been approved by the FDA for treatment *(Schwartz, 2003 [B])*. However, it is the consensus of this work group that a thorough evaluation of risks and benefits be done before prescribing this medication.

Positive airway pressure and dental device discomfort can be problematic, contributing to non-adherence. CPAP adherence is notoriously poor. Follow-up studies of patients who were prescribed CPAP show that only 50%-65% of patients still use their CPAP, and those who do only use it four to five hours each night *(Grote, 2000)*. Patient adherence may be enhanced by direct inquiries regarding mask fit, nasal issues, PAP use less than four hours, and attending support/education classes. Follow-up questions are reflected in Appendix B, "Management Tips to Improve Adherence with Therapy." It is also important to encourage participation in an OSA educational support group, such as A.W.A.K.E. (For more information on A.W.A.K.E., log on to www.sleepapnea.org, or call 1-202-293-3650 to reach the American Sleep Apnea Association.)

According to a retrospective, non-randomized trial, patients treated with PAP who have a moderate to high degree of adherence to therapy have a lower mortality rate than patients not treated with PAP. This decrease in mortality is independent of the other factors such as apnea-hypopnea threshold, FEV_1 percent, and age *(Campos-Rodriguez, 2005 [C])*.

Patients diagnosed with OSA are at increased risk for intra- and postoperative complications including the use of narcotics for pain management. Patients should inform their surgeon and anesthesiologist of their diagnosis of OSA and bring their CPAP with them for their hospital stay *(Gupta, 2001 [C])*. See Special Considerations, Annotation #13, "Ongoing Management."

Tools available to assess the success of therapy include:

- information from the DME (durable medical equipment) provider and/or sleep lab,
- history, with focus on symptoms (preferably include sleep partner),
- overnight oximetry (see Annotation #2, "Signs or Symptoms Suspicious for OSA"),
- cardiorespiratory sleep study,
- autotitrating CPAP study,
- polysomnogram,
- compliance meter on CPAP machine, and
- Epworth Sleepiness Scale (ESS) (see Appendix A, "The Epworth Sleepiness Scale").

12. Refer to Sleep Specialist

Key Points:

- Treatment failure can be caused by many different issues, and a referral to a sleep specialist should be considered.
- Surgical options may be considered if significant anatomic problems are present.

A sleep specialist evaluation may be indicated to rule out possible causes of unsuccessful treatment, unless physical findings of obvious upper-airway obstruction are present, in which case a referral to ENT would be indicated. Specific anatomic abnormalities that may predispose to OSA include:

- nasal obstruction,
- tonsillar hypertrophy,
- macroglossia,
- retrognathia,
- micrognathia,
- midface hypoplasia,
- elongated uvular length,
- hyoid retrusion,
- large tongue base,
- redundant pharynx,
- laryngotracheomalacia, and
- benign or malignant neoplasms.

The surgical procedures listed above are available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in clinical obstructive sleep apnea hypopnea syndrome. It may be necessary to correct the anatomical obstruction to increase the effectiveness of an oral appliance or positive airway pressure device, and a referral to ENT, a dentist or an orthodontist with special training in sleep apnea would be indicated.

(Sundaram, 2006 [M])

See Annotation #9, "Treatment for Mild, Moderate or Severe OSA," for more information about surgical procedures.

13. Ongoing Management

Continued follow-up should occur no less than annually in the successfully treated patient with OSA. Annual follow-up should include all the characteristics of the one-month follow-up. In addition, it is necessary to ensure annually:

- the patient's equipment has been evaluated by qualified personnel;
- weight and blood pressure are checked;
    - if the patient is medically complicating obese, consideration of a more aggressive weight-loss program should be pursued; and
    - if there is a significant weight loss or gain, consider adjusting PAP.

Follow-up discussions should include:

- verification patient has current patient education materials;
- information regarding PAP and travel issues or hospital admissions;
- use of PAP with colds and sinus infections;

- long-term expectations;
- current mask/interface fit and comfort;
- mask/interface cleaning review;
- plan to replace mask/interface and supplies every six months;
- inquiry about drowsy-driving issues;
- alcohol and medication intake;
- sleep hygiene; and
- participation in the A.W.A.K.E. support group.

Special Considerations

Patients diagnosed with sleep apnea are at risk for perioperative and postoperative respiratory distress. This appears to affect patients undergoing general as well as conscious sedation. Patients at risk for sleep apnea require a thorough preoperative cardiopulmonary evaluation to risk counsel and minimize peri- and postoperative risks.

- Patients with sleep apnea should be instructed to bring their CPAP machine with them to be used while in the hospital.
- Patients should be monitored for a prolonged period of time (usually overnight), as most complications occur in the first 24 hours.
- Avoidance of sedative and opioid drugs is recommended.
- Consideration of postextubation steroids to decrease inflammation in an already compromised / irritated airway should be made.
- Patients will require postoperative O_2 at higher levels than those without sleep apnea.

(American Society of Anesthesiologists Task Force, 2006 [R]; Connolly, 1991 [D]; Gupta, 2001 [C]; Parikh, 2002 [D]; Pawlik, 2005 [A])

Appendix A – The Epworth Sleepiness Scale

Name: _____

Today's Date: _____

Your Age (Years): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following scale to choose the *most appropriate number* for each situation:

0 = would *never* doze

1 = *slight* chance of dozing

2 = *moderate* chance of dozing

3 = *high* chance of dozing

Situation:	Chance of Dozing
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, while stopped for a few minutes in traffic	_____

Key: < 10 points = probably normal
10-12 points = mild sleepiness
13-17 points = moderate sleepiness
18-24 points = severe sleepiness

If it is anticipated that this questionnaire will be duplicated and used by patients, the key to the left should be removed as it may bias patient responses.

Appendix B – Management Tips to Improve Adherence with Therapy

Snoring on PAP:

- Adjust mask/interface if leaking
- Ask bed partner if patient is opening mouth (apply chin strap)
- If there is no leaking around mask/interface and snoring continues, it is recommended that the patient have a follow-up visit or phone call to the primary care provider to reassess pressure level
- Ask if patient had alcohol before bed

Opening Mouth:

- Apply chin strap
- Change interface to full-face mask

Nasal Congestion or Runny Nose:

- Add or adjust humidifier (cool or heated) consider integrated heated tubing system
- Use nasal saline spray during the day and at bedtime
- Use nasal corticosteroid/anticholinergic spray
- Use antihistamine (oral or nasal spray)
- Change or clean machine filter
- If all of the above are ineffective, refer to primary care provider

Mask/Interface Leak:

- Adjust mask/interface straps, forehead pads or nasal cushion
- Refit mask/interface to different size
- Change to a different interface or full-face mask

Complaints of "Air Hunger"

- Check for mask/interface leak
- Check for mouth opening (apply chin strap)
- Increase low APAP level if on an autotitrating positive airway pressure device

Complaints of "Too Much Air," Can't Exhale:

- Use another type of PAP (flexible, B-PAP, or AutoPAP)
- Begin use of ramp/delay on machine
- Increase ramp/delay time
- Change interface
- Add humidifier (cool or heated)

- Use nasal saline spray during the day and at bedtime
- Apply chin strap if opening mouth
- ENT consult for deviated septum or surgical options
- Dental consult for oral appliance options

Nosebleeds:

- Add humidifier (cool or heated)
- Use nasal saline spray during the day and at bedtime
- Use water-soluble nasal saline gel in nares to moisturize

Claustrophobia:

- Try relaxation skills
- Try desensitizing techniques
- Wear PAP while awake and reading or watching TV to get used to equipment
- Consider referral for treatment of claustrophobia

Removing PAP without Knowledge:

- Add chin strap to help secure interface to head
- Safety pin headgear to nightclothes (this is used as a reminder during the night when awakening to keep mask/interface on head)
- Activate disconnect alarm (if available)

Bed Partner Complaints of Cold and Blowing Air:

- Different interface
- Redirect exhalation port if mask allows
- Place a barrier (e.g., pillow/blanket) between bed partners
- Place PAP on the floor

Complaints of Noise:

- Place PAP on the floor
- Wear earplugs
- White noise machine

Complaints of Sleepiness Despite Treatment:

- Reassess adequate sleep
- Reassess returned snoring on PAP
- Reassess sleep hygiene before bed
- Reassess if using PAP all night
- Leaking or poorly fitting mask/interface

- Ask if mask is greater than six months old
- Assess environmental noises (e.g., planes, buses and neighbors)
- Assess bed partner or pet disturbances in bedroom
- Ask if napping during the day and for how long
- Assess bed partner complaints of leg movements
- Assess bed partner complaints of bruxism (teeth grinding)
- Consider retitration of PAP
- Assess for use of alcohol less than two hours before bedtime
- Ask if opening mouth at night while sleeping with PAP
- Consider referral to a sleep specialist

Dental Device Complaints:

- Facial and/or tooth pain
- Appliance not retentive
- Dental occlusal changes
- Above complaints should prompt a return to dental practitioner for evaluation and treatment

Travel and Hospital Visits:

- Remind patient to bring PAP equipment when travelling or admitted to the hospital

Appendix C – Positive Airway Pressure Device Follow-Up Tool

PAP Questionnaire

Please fill out as completely as possible, and return at your earliest convenience. Your comments are welcome as we try to improve our program. For simplicity, "PAP" will be used to signify both "CPAP" and "B-PAP" for this questionnaire. When answering questions with a bar labelled at both extremes, make a hatch mark perpendicular to the bar, indicating your response. Please be as honest as possible.

A. Your Equipment Usage:

Are you currently using PAP? (Check only one) ☐ Yes ☐ No ☐ Returned machine
If you have returned your machine, please complete the rest of the questions, as they apply.

Reason for return:

What is the approximate length of time you have been on PAP? _____
months or years (circle one)

Your estimate of the average number of hours per night you wear PAP: _____

Your estimate of the average number of nights per week you wear PAP: _____

Your estimate of the average number of hours per night you sleep: _____

Overall, what percent of the time do you estimate you use your PAP machine? (Make a hatch mark to indicate your response on the scale below.)

0% (Never) 100% (Always)

B. What Equipment Do You Use?

Please check all appropriate boxes

Full-Face Mask ☐ Yes ☐ No

Nose Mask ☐ Yes ☐ No

Nasal Pillows ☐ Yes ☐ No

Chin Strap (to keep mouth closed) ☐ Yes ☐ No

Humidifier ☐ Yes ☐ No

Heated Humidifier ☐ Yes ☐ No

CPAP ☐ Yes ☐ No

Bi-level PAP® ☐ Yes ☐ No

AutoPAP® ☐ Yes ☐ No

If known, please write your pressure setting: _____
_____

C. Do You Have Problems with the Equipment?

Please rate your satisfaction with the following pieces of equipment by making a hatch mark on the scales.

Full-face mask, nasal mask or nasal pillows:

Terrible Terrific

Describe any problems you are having and any solutions you have found:

Headgear (to secure mask):

Terrible Terrific

Describe any problems you are having and any solutions you have found:

Chin strap (if worn; to keep mouth from opening):

Terrible Terrific

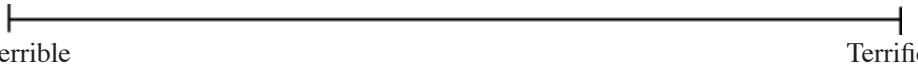
Describe any problems you are having and any solutions you have found:

Humidifier or heated humidifier (if used):

Terrible Terrific

Describe any problems you are having and any solutions you have found:

Tubing:



Terrible Terrific

Describe any problems you are having and any solutions you have found:

PAP machine:

Terrible Terrific

Is the pressure setting causing you difficulty?

Intolerable No problem

Describe any problems you are having and any solutions you have found:

Effects of the apparatus on a bed partner (if present): No bed partner

Intolerable No problem

Describe any problems you are having and any solutions you have found:

Any other problems? ☐ Yes ☐ No Describe:

D. Satisfaction:

Mark the scale with an appropriate hatch mark to indicate your response.

Overall, how would you rate your satisfaction with PAP treatment, if using:
☐ Not using

Terrible Terrific

25. How would you rate your satisfaction with the testing and PAP titration process?

Terrible Terrific

How would you rate your satisfaction with your physician's handling of your sleep disorder?

Terrible Terrific

Did you get a sleep consult? ☐ Yes ☐ No

Was this helpful to you?

Not at all Very Much

Were you adequately informed about the testing process by your physician?

Not at all Completely

Were you adequately informed about the testing process by the technician(s)?

Not at all Completely

How would you rate your satisfaction with your DME provider?

Terrible Terrific

How much did your sleep disorder interfere with your daily life before treatment?

Not at all Tremendously

How much has PAP treatment improved the way you feel?

Not at all Tremendously

Do you feel you need more information about your sleep disorder or its treatment?

Yes, a lot I'm informed enough

Did you have difficulty with insurance coverage for your sleep disorder?

Yes, a lot None at all

Please write any specific suggestions for how we might improve our program:

Are you interested in being part of a patient support or advocacy group?
☐ Yes ☐ No

Thank you very much for your help with this survey!

Appendix D – Sleep Hygiene

Create consistent sleep habits:

Keep a regular bedtime

Maintain a regular awakening time

Have a bedtime routine or a presleep ritual

Maintain an active lifestyle

Maintain a consistent sleep/wake schedule on days off if a shift worker

Have a light snack before bedtime

Sleep when drowsy

Create a restful sleep environment:

Use the bedroom for sleep and sex only

Do not read in bed

Do not watch TV in bed

Have a dark bedroom

Have a "cool" bedroom temperature

Have quiet sleeping environment

The following can interfere with good sleep hygiene:

Avoid smoking/nicotine near bedtime

Avoid alcohol two to four hours before bedtime

Avoid caffeine four to six hours before bedtime

Avoid heavy exercise two to four hours before bedtime

Avoid large meals before bedtime

Avoid spicy foods before bedtime to reduce heartburn

Avoid clock watching

Avoid misuse of sleeping pills or over-the-counter pills that will affect your sleep

Avoid napping during the day

If napping, do not nap for more than an hour and never after 3:00 p.m.

Manage stress/anxiety/depression by:

- Having a designated "worry time"
- Trying repetitious thoughts (counting sheep) to distract the mind
- Practicing relaxation skills, calming thoughts, yoga or stretching

If unable to sleep, leave the bedroom for a short time and have a quiet and non-stimulating activity. Repeat this process as needed throughout the night.

Appendix E – Glossary

AHI – apnea hypopnea index; average number of apneas and hypopneas per hour of sleep.

AutoPAP – (self-titrating CPAP, auto-adjust CPAP, APAP); a non-invasive/non-pharmacologic positive airway pressure device designed to vary pressures to meet the needs of the patient's sleep-disordered breathing. Pressure changes are determined by monitoring variably a combination of apneas, hypopneas, inspiratory flow limitation, and snoring. Instead of constant maximal pressure (as delivered with conventional CPAP), these systems provide the minimal pressure necessary to stabilize the upper airway. AutoPAP is often used to determine effective positive airway pressures for a patient, thus allowing the patient to switch to a conventional CPAP device.

Apnea – a cessation of airflow. For diagnosis of OSA, the cessation should be at least 10 seconds long, and the event can be considered obstructive if during apnea, there is an effort to breathe.

A.W.A.K.E. – Alert Well And Keeping Energetic. An educational support group for patients with obstructive sleep apnea and their significant others.

CPAP – continuous positive airway pressure; a non-invasive/non-pharmacologic method of applying positive pressure to the upper airway via a blower and mask/interface to pneumatically splint the upper airway, thereby preventing collapse.

EPAP – expiratory positive airway pressure

ESS – Epworth Sleepiness Scale

Hypopnea – for diagnostic purposes in OSA, an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

IPAP – inspiratory positive airway pressure

OSA – obstructive sleep apnea

OSA – obstructive sleep apnea syndrome

PAP – positive airway pressure

UPPP – uvulopalatopharyngoplasty; the surgical resection of the obstructive portion of the velar musculature of the soft palate and the entire uvula

Supporting Evidence:

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Brief Description of Evidence Grading System

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in the Foreword and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols **+**, **–**, **ø**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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Conclusion Grading Worksheet A – Annotation #2 (Signs or Symptoms Suspicious for OSA)

Work Group's Conclusion: 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

Author/Year	Design Type	Class	Quality +,–,**0**	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Sériès et al. (1993)	Sens/ Spec of a Diagnostic Test	C	**0**	-240 consecutive outpatients (216M, 24F) referred to sleep clinic for clinical suspicion of OSA; ages 24-68 yrs; mean BMI 31.7 kg/m^2 -Single night nocturnal home oximetry test; 0.5 Hz sampling; abnormal test defined by repetitive episodes of transient deep desaturation followed by rapid return to baseline SaO_2 or low-amplitude periodic desaturations of <4% from baseline -All patients had polysomnographic (PSG) study 1-4 wks later; interpreters unaware of oximetry results; SAHS confirmed if apnea+hypopnea index >10	-Diagnosis of OSA confirmed in 110 of 240 -In OSA group: apnea+hypopnea index (AHI)=38.1±2.5/hr arousal index=36.8±2.7/hr mean total apnea time=13.1% (72.4% obstructive) baseline SaO_2=95.2% (home) and 95.7% (PSG) -Oximetry abnormal in 176 patients (including all but 2 of those with SAHS) -With AHI>10/h as cutoff, sensitivity of home oximetry=98% (2 false negatives), specificity=48%; positive predictive value=61%, negative predictive value=97% -With AHI>20/h as cutoff (75 patients with OSA), sensitivity=100%, specificity=39% (no false negatives)	-A qualitative analysis of the SaO_2 tracing can help in excluding OSA. The use of home oximetry can obviate the need for a conventional polysomnography study. Due to low specificity, positive home oximetry must be followed by complete monitoring. NOTES: home oximetry was abnormal in 19 of 25 patients with abnormal arousal index; oximetry was evaluated for presence of repetitive, short-duration fluctuations in SaO_2 without any absolute value decrease in saturation *Work Group's Comments: selection bias is possible since patients were referred for symptoms of OSA; results may not be applicable to general clinic population; a test with high sensitivity at the expense of low specificity may result in many false positive tests and unnecessary sleep studies*

Author/Year	Design Type	Class	Quality +,-,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Epstein & Dorlac, 1998	Cost-Effectiveness	M	**N/A**	-100 consecutive patients (93M, 7F); underwent sleep study for clinical suspicion of SAHS -Sleep study included oximetry; analyzed saturations>4% (deep) and qualitative method of Séries et al. (low-amplitude periodic fluctuations); blinded to PSG results -2 diagnostic algorithms compared: a) oximetry as initial screen with PSG if abnormal; b) initial PSG for all patients; for both algorithms, if diagnosed with SAHS had CPAP trial	-53 of 100 had SAHS (AHI>10/h) -Diagnostic accuracy of oximetry varied with type of analysis: Sensitivity: Deep 74%, Fluctuating 96% Specificity: Deep 89%, Fluctuating 55% PPV: Deep 89%, Fluctuating 71% NPV: Deep 75%, Fluctuating 93% Both methods more sensitive in patients with BMI>30	-The use of less rigid criteria for interpreting oximetry improved ability to detect SAHS (sensitivity). Specificity was reduced. NOTES: sleep studies retrospectively reviewed; referred to sleep clinic for evaluation of possible sleep-disordered breathing; oximetry done in laboratory; some patients able to have CPAP titration on same night as PSG (split-night studies) *Work Group's Comments: Those with false negative overnight oximetry were regarded as having "treatable disease" – these patients probably have mild OSA, may not tolerate "treatment" with CPAP, and may be candidates for dental devices, positional therapy, lifestyle modification, or surgery; cost data not reported on this worksheet*
Gyulay et al. (1993)	Sens/ Spec of a Diagnostic Test	C	**0**	-98 consecutive patients referred to sleep clinic for clinical suspicion of OSA (77M, 21F) -Excluded: significant chronic lung disease; unable to pursue "in lab" workup -Home oximetry (1 sample/12 sec); calculated SaO_2 falls of ≥2, ≥3, & ≥4 % from baseline; desaturation index (DI) defined as desaturation events/h; determined cumulative percentages of time at saturations <90% (CT_{90}) -All patients had laboratory PSG 2 wks to 3 mos after home oximetry; OSA defined as AHI≥15	-43 of 98 had OSA (AHI≥15); 31 of 43 were given nasal CPAP -34 of the 43 were identified clinically as likelihood of OSA≥15% (sensitivity=79%); 27 of 55 with OSA<15 were identified clinically as having OSA (specificity=49%) -For DI2≥15 (desaturations of >2% per hour): sensitivity=65%, specificity=74% -For DI3≥15: sensitivity=51%, specificity=90% -For DI4≥15: sensitivity=40%, specificity=98% -Using CT_{90}≥1 as cutoff: sensitivity=93%, specificity=51% -Using inspection of oximetry results: sensitivity=72%, specificity=88% -With pretest probability of OSA=30%; positive predictive value of DI4≥15%=83%; if pretest probability≥50%, PPV>90%	-These results suggest that if oximetry data are analyzed by calculating CT_{90} as well as by counting desaturations ≥4% SaO_2, home oximetry can be both sensitive and specific in the diagnosis of OSA. NOTES: 8 patients with grossly abnormal oximetry were excluded from results (could not delay CPAP to await polysomnography)

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Wiltshire et al., 2001	Sens/ Spec of a Diagnostic Test	C	–	-100 consecutive patients referred for assessment of suspected SAHS with PSG -Home oximetry (1 sample/12 sec); SaO_2 changes ≥4% and lowest SaO_2; calculated dips/hr -3 lab studies 1) software validation check (n=16); 2) PSG within 3 days of home study (included oximetry on-line with 1 sample/2 sec); 3) confirm home (stored data)/lab (on-line data) comparison with oximetry and PSG (n=16)	-Study 1: software was comparable (r^2=0.99 with mean difference of 0.1 dips/h) -Study 2: 84 patients studied; PSG within 3 days of home oximetry; home study mean 5.3 dips/h, lab study 13.7 dips/h (r^2=0.64); with a cutoff of 10/h for SaO_2, 52 studies both negative, 13 both positive (sensitivity=41%, specificity=100%); with a cutoff of 15/h, sensitivity=35%, specificity=100%) -Study 3: mean difference of 5.2 dips/h (r^2=0.69)	-Home oximetry with the oximeters used in the present study in patients with suspected SAHS significantly underestimates the number of episodes of hypoxemia during sleep and may therefore miss more clinically significant SAHS than oximeter studies analyzed on-line in the laboratory. *Work Group's Comments: this study compared an insensitive sampling technique(O_2 saturation every 12 sec) with on-line (every 2 sec) sampling; little information given on patient population*

Conclusion Grading Worksheet B – Annotation #5 (Sleep Study)

Work Group's Conclusion: Unattended sleep studies can be valuable tools in the diagnosis of OSA providing an accurate and reliable apnea-hypopnea index (AHI) in patients with a high pretest probability but carries the following limitations: absence of trained technician and therefore inability to enlist patient cooperation, make continuous patient observations, intervene for the medically unstable patient, and provide therapeutic intervention (i.e., CPAP, O_2, supine positioning, resuscitation).

Conclusion Grade: III

Author/Year	Design Type	Class	Quality +, –, **0**	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Emsellem et al. (1990)	Sens/ Spec of a Diagnostic Test	C	**0**	-67 patients; ages 22-79 yrs; M/F; referred to sleep clinic for possible OSA -Polysomnography (PSG) overnight; simultaneous study with portable device -Disordered breathing event (DBE): ≥ 50% decrease in amplitude of airflow for ≥ 10 sec -Apnea-hypopnea index (AHI): (total #DBEs/total sleep time) X 60 -Portable respiratory index (PRI): (total #DBEs/quiet recording time) X 60	-4 patients excluded (technically unsatisfactory portable tracings for 3, PSG for 1) -Compared PRI to AHI (with AHI as standard test and AHI ≤ 5 considered normal): sensitivity=95% (2 false-negatives), specificity=96% (1 false-positive) -No difference in #DBEs with either device -Quiet recording time was not significantly different from total sleep time -If normal defined as < 32 DBEs: sensitivity=97%, specificity=96%	-Portable devices designed for ease of use and low cost can provide accurate, reliable information only when used appropriately as screening devices for sleep apnea. Patients identified as having sleep apnea by the portable system should have a complete study in a sleep laboratory. A negative result with the portable device **only** rules out sleep apnea. NOTES: recruited consecutive patients; "refusal to participate was infrequent"; tests were scored independently *Work Group's Comments: unclear how many refused to participate; some data lost due to unsatisfactory studies*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Redline et al. (1991)	Sens/ Spec of a Diagnostic Test	C	–	-4 normal volunteers, 16 relatives of OSA patients, 24 patients referred to sleep laboratory for evaluation of suspected sleep disturbance, & 7 patients followed for obstructive or restrictive pulmonary disease -25 had overnight PSG; defined event as reduced airflow for ≥10 sec, ≥4% decrease in saturation, or ≥2% decrease in saturation with an arousal; respiratory disturbance index (RDI)=total events/total sleep time -Portable device used for respiration during sleep in 66 home studies and 20 lab studies; similar definition of events	-PSG/Portable device comparison based on n=25 (20 with simultaneous lab monitoring, 5 with PSG in lab and portable at home 9-56 days later) -Duration of events averaged 10 sec longer with portable device ($p<0.05$); no difference in average low O_2 saturation or RDI; RDI values highly correlated ($r=0.96$); 95% of subjects classified as abnormal with PSG (defined as RDI≥10) would be classified as abnormal with portable device -32 subjects had duplicate in-home testing at 1 to 300 days (mean of 19 days); 3 studies (9%) were unsatisfactory due to technical failure; based on 29 subjects - no differences in total sleep time, degree of saturation, duration of events; high correlation ($r=0.94$); no suggestion of "first-night" effect	-Measurement of the RDI with in-home monitoring provides a valid and highly reproducible index for assessment of sleep-related respiratory disturbances. NOTES: with the portable device, evidence of an arousal was not required with ≥2% decrease in saturation; tests were scored independently; relationship between RDIs determined simultaneously or on separate occasions did not differ so data were pooled *Work Group's Comments: not specified which patients participated in which studies; insufficient data to determine sensitivity/specificity; some data lost due to unsatisfactory studies*
Coppola & Lawee (1993)	Case Series	D	–	-11 patients whose diagnosis of OSAS and initiation of nasal CPAP was done at home (unattended); signs and symptoms predicted high probability of positive test -Portable device used for one night; AHI=sum of all respiratory events/total recording time -Repeated home sleep study when snoring and witnessed apneas had ceased -9 patients interviewed at regular intervals for compliance, level of relief, & side effects (info. from physicians for other 2)	-Results: Apnea 78 5.8 <0.05 Hypopnea 200 8.7 <0.001 Total respiratory events 284.5 16.2 <0.001 Minimum O_2 saturation 66.1 87.1 <0.01 AHI 40.9 2.4 <0.01 *at least 2 weeks after final NCPAP level was reached -Patients reported improvements in symptoms of daytime hypersomnolence, daytime energy levels and sleep quality; at 18-month follow-up all patients reported compliance; no serious complications from initiation of NCPAP at home	-This preliminary report shows that an unattended sleep apnea recorder can be used to assist in the diagnosis and treatment of OSAS in some patients. NOTES: eligibility for home NCPAP determined by one of the authors; excluded from self-titration if serious coexistent medical problems, cor pulmonale, or serious arrhythmias; cases were reviewed retrospectively *Work Group's Comments: subjects were selected for inclusion in the series; no "gold standard" for diagnosis*

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
- Knowledge Products
- Resources Available

Priority Aims and Suggested Measures

1. Increase the percentage of patients 18 and older who are diagnosed with OSA through a sleep study evaluation.

   Possible measures for this aim:

   a. Percentage of patients 18 years of age or older who present for health maintenance exam who are asked about the quality of their sleep and presence of snoring.

   b. Percentage of patients presenting with high probability symptoms (see Annotation #2) or sleep complaints who have been evaluated with a sleep study.

   c. Percentage of patients presenting with a diagnosis of hypertension, CAD, type 2 diabetes or stroke who have been asked about the quality of their sleep.

   d. Percentage of patients who are identified at risk for OSA and are offered a sleep study.

2. Increase the percentage of patients with OSA who have received appropriate treatment according to guideline.

   Possible measures for this aim:

   a. Percentage of patients who have documented follow-up evaluation of sleep study results.

   b. Percentage of patients with a positive sleep study who have been offered treatment.

   c. Percentage of patients receiving OSA treatment who have documentation of relief and/or resolution of symptoms.

   d. Percentage of patients with mild OSA who have been prescribed positive airway pressure (PAP), a dental appliance and/or a surgery referral.

3. Improve PAP treatment adherence rate for those who are diagnosed with OSA.

   Possible measures for this aim:

   a. Percentage of patients who have documentation of evaluation of barriers to adherence to therapy (nasal congestion and dryness). (See Appendix B, "Management Tips to Improve Adherence with Therapy.")

   b. Percentage of patients with diagnosis of OSA who have had a one-month device follow-up evaluation, including hours on PAP machine, mask fit, comfort assessment. (See Appendix C, "Positive Airway Pressure Device Follow-Up Tool.")

   c. Percentage of patients diagnosed with OSA who have documentation of receiving education on follow-up required for OSA patients (barriers effectively addressed).

4. Increase patient understanding of the health risk factors related to OSA.

   Possible measures for this aim:

   a. Percentage of patients with a high probability pretest for OSA with documentation of education on the health risk factors.

   b. Percentage of patients who, after participating in OSA program, demonstrate understanding of OSA.

   c. Percentage of patients with OSA attending A.W.A.K.E. (Alert Well And Keeping Energetic) or other education/support group for OSA.

At this point in development for this guideline, there are no specifications written for possible measures listed above. ICSI will seek input from the medical groups on what measures are of most use as they implement the guideline. In a future revision of the guideline, measurement specifications may be included.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Diagnosis and Treatment of Obstructive Sleep Apnea in Adults guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/knowledge. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American Academy of Dental Sleep Medicine	Provides patient and provider information on oral appliance therapy.	Health Care Providers; Patients and Families	http://www.aadsm.org
	American Academy of Sleep Medicine	Provides patient resources, sleep quiz, fact sheet and lists other related Web sites.	Health Care Providers; Patients and Families	http://www.aasmnet.org
	American Sleep Apnea Association	Promotes general information on sleep apnea, meeting information, and related links.	Health Care Providers; Patients and Families	http://www.sleepapnea.org
	Mayo Clinic	Promotes general information on sleep apnea and related health issues.	Health Care Providers; Patients and Families	http://www.mayoclinic.com
	National Sleep Foundation	Offers basic information on all sleep disorders and treatment. Promotes patient education materials.	Health Care Providers; Patients and Families	http://www.sleepfoundation.org
	Talk About Sleep, Inc.	Provides patient and provider information on sleep disorders, diagnosis and treatment.	Health Care Providers; Patients and Families	http://www.talkaboutsleep.com

* Available to ICSI members only.