



Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of obstructive sleep apnea in adults.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jun. 55 p. [119 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Mar. 55 p.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• <u>October 24, 2007, Provigil (modafinil)</u>: Cephalon has agreed to include additional labeling revisions to the WARNINGS, CLINICAL PHARMACOLOGY, PRECAUTIONS, and PATIENT PACKAGE INSERT sections.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT ** SCOPE METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Obstructive sleep apnea syndrome (OSA)

GUIDELINE CATEGORY

Diagnosis Evaluation Management Risk Assessment Treatment

CLINICAL SPECIALTY

Cardiology Dentistry Family Practice Internal Medicine Neurology Otolaryngology Psychiatry Pulmonary Medicine Sleep Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Health Care Providers Health Plans Hospitals Managed Care Organizations Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of patients 18 and older who are diagnosed with obstructive sleep apnea syndrome (OSA) through a sleep study evaluation
- To increase the percentage of patients with OSA who have received appropriate treatment according to guideline
- To improve positive airway pressure device (PAP) treatment adherence rate for those who are diagnosed with OSA
- To increase patient understanding of the health risk factors related to OSA

TARGET POPULATION

Adult patients age 18 and older at risk for obstructive sleep apnea syndrome (OSA)

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Diagnosis/Evaluation

- 1. Physical examination, including review of symptoms and comorbid risk factors
- 2. Overnight oximetry
- 3. Sleep study, such as polysomnography or unattended in-home study
- 4. Determination of severity of obstructive sleep apnea using the three domains of sleepiness, respiratory disturbance, and gas exchange abnormalities

Treatment/Management

- Lifestyle modification, such as weight loss; reduction of alcohol consumption, especially before bedtime; body position during sleep; good sleep hygiene; integration of positive air pressure (PAP) preparation into a bedtime routine and bedroom environment
- 2. Positive airway pressure devices, such as continuous positive airway pressure (CPAP); self-titrating CPAP (AutoPAP); Bi-level PAP
- 3. Oral appliances, such as mandibular repositioning devices and tongue retaining devices
- 4. Patient adherence efforts such as education and Alert Well and Keeping Energetic (A.W.A.K.E.) meetings
- Surgical procedures, such as septoplasty; nasal polypectomy; tonsillectomy; turbinoplasty; tracheostomy; uvulopalatopharyngoplasty (UPPP); pillar procedures, radiofrequency ablation of the soft palate and tongue base; hyoid suspension; and mandibular advancement, genioglossus advancement, and/or maxillary advancement
- 6. One-month follow-up
- 7. Referral to specialists, such as sleep specialist or otolaryngologist
- 8. Ongoing management including special considerations to minimize peri- and postoperative risk of respiratory distress

MAJOR OUTCOMES CONSIDERED

- Signs and symptoms of obstructive sleep apnea
- Patient risk factors, including comorbidities
- Accuracy (sensitivity and specificity, positive and negative predictive value) of diagnostic tests
- Effects of treatment on apnea-hypopnea index, respiratory disturbance index (RDI), and other measures of obstructive sleep apnea
- Patient adherence and patient satisfaction with treatment
- Complications of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analyses, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

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 presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

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.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

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

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

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
- Systemic review
- Decision analysis
- Cost-effectiveness study

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The overall costs and effectiveness of combined in-home portable monitor testing followed by auto-titrating positive airway pressure (PAP) therapy, as compared to split-night polysomnography and continuous positive airway pressure (CPAP) therapy, has not been extensively characterized. Two analyses of differing strategies for diagnosis and treatment of obstructive sleep apnea syndrome (OSA)

found unattended polysomnography to have a superior cost-utility compared to home cardiorespiratory testing but did not compare strategies outlined in this guideline. Although not duplicative of the 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.

A nurse managed program combining a very low calorie diet with behavior management on an outpatient basis was found to be safe and cost-effective as a primary treatment for OSA.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to the Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.

• Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to <u>Summary of Changes</u> <u>Report -- June - 2008</u>.

The recommendations for the diagnosis and treatment of obstructive sleep apnea are presented in the form of two algorithms with 13 components, accompanied by detailed annotations. Algorithms are provided for <u>Diagnosis of Obstructive Sleep</u> <u>Apnea</u> and <u>Sleep Apnea Treatment</u>. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) ratings and key conclusion grades (I-III, Not Assignable) are defined at the end of the "Major Recommendations" field.

Clinical Highlights

- 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 impairments in quality of life. (*Annotation #1*)
- Untreated sleep apnea may mimic or exacerbate depression, attention-deficit hyperactivity disorder (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 and guidance in lifestyle modification, especially weight loss as a treatment for sleep apnea and referral to the A.W.A.K.E. (Alert Well And Keeping Energetic) program. (*Annotations #8, 10, 13*)
- All patients who have a weight loss or gain of 10% to 15% should be assessed for symptoms of OSA and the need to adjust positive airway pressure (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*)

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 (body mass index [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 (CVD) or coronary artery disease (CAD), 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 [C].

A thorough review of symptoms will include questions related to 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 risk for OSA in a non-linear manner [C], [R].

OSA occurs frequently in patients who have been diagnosed with cerebrovascular disease, coronary artery disease, 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. OSA may also elicit nocturnal bradyarrhythmias and nocturnal angina. Treatment of the OSA 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.

Untreated sleep apnea will mimic or exacerbate depression, ADHD, and other chronic disorders [A], [B], [C], [D], [R].

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 in the original guideline document). 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.

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) in the original guideline document].

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.

Refer to the original guideline document for more information on signs and symptoms of OSA and overnight oximetry as a screen 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 OSA protocol:

- Heart failure, either stable or severe (New York Heart Association [NYHA] Class I-IV)
- Central or complex sleep apnea [C]
- Significant pulmonary disease, including:
 - Severe chronic obstructive pulmonary disease (COPD)
 - Baseline hypoxemia
 - Hypercapnia
 - Pulmonary hypertension
- Inability to tolerate testing or possible PAP 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 neurological 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.

Refer to the original guideline document for additional information on atypical or complicated symptoms.

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 that 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 probability 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 continuous PAP (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 have 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. (See the original guideline document for more information.) A split night study should be performed where and when possible.
- In patients with a high pretest probability of OSA, unattended portable recording for the assessment of OSA is an acceptable alternative to standard polysomnogram in the following situations:
 - Patients with severe clinical symptoms that are indicative of a diagnosis of moderate to severe OSA 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)] in the original guideline document.
 - 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.
- 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 inhome, unattended, portable recording beyond the 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.

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 they carry 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, O₂, supine positioning, resuscitation) [*Conclusion Grade III: See Conclusion Grading Worksheet B - Annotation #5 (Sleep Study)] in the original guideline document*.

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?") [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 [*M*], [*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 [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 [C], [D].

See the original guideline document for more information.

6. Diagnosis of OSA?

Key Points:

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

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 (AASM):

- 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 [*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.

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 [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 [R].

See the original guideline document for more information.

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 to 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 to 24.

(See Appendix A, "The Epworth Sleepiness Scale" in the original guideline document).

- 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 greater than or equal to 90% and minimum oxygen saturation greater than or equal to 70%.
 - Severe: Mean oxygen saturation less than 90%, **or** minimum oxygen saturation less than 70%.
- Respiratory Disturbance:
 - Mild: AHI 5 to 15
 - Moderate: AHI 16 to 30
 - Severe: AHI greater than 30

Refer to the original guideline document for additional discussion on determination of severity.

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" in the original guideline document for more information.

Refer to the original guideline document for more information on alcohol consumption, obesity, and body position.

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 ear, nose and throat (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 OSA. A combination of the treatment options listed below may be necessary to adequately manage the symptoms of OSA.

Positive Airway Pressure (PAP) Devices

СРАР

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) [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 durable medical equipment (DME) provider, and finally, A.W.A.K.E. (Alert Well And Keeping Energetic) meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy" in the original guideline document.) 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 [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 [*A*], [*D*].

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 change [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 durable medical equipment (DME) provider, and finally, A.W.A.K.E. meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy" in the original guideline document) [*R*].

Bi-level PAP

Bi-level PAP is a non-invasive respiratory device which 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 of mean treatment pressure, and a more physiologic breathing pattern. These possible advantages make a trial of bi-level devices an appropriate intervention for selected OSA patients who do not tolerate continuous pressure or auto-titrating 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 [A], [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 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 provider, and finally, A.W.A.K.E. meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy" in the original guideline document) [*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 above), though they are not as effective.

Mandibular repositioning devices are 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.

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: <u>www.dentalsleepmed.org</u>.

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 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 [*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.

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 [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 [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 post-treatment. 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. Maxillomandibular 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 [D], [M], [R].

10. One Month Follow-Up

Key Points:

• Follow-up visits must address effective 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 is 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 is 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" in the original guideline document.

- 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

[A], [D], [R]

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 U.S. Food and Drug Administration (FDA) for treatment [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. 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 Compliance with Therapy" in the original guideline document. 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 <u>www.sleepapnea.org</u>, or call 1-202-293-3650 to reach the American Sleep Apnea Association.)

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 *[C]*. See Special Considerations, Annotation #13, "Ongoing Management" below.

Refer to the original guideline document for information on tools available to assess the success of therapy.

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 an ear, nose, and throat specialist (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
- Benign or malignant neoplasms

The surgical procedures listed in Annotation #9, "Treatment of Mild, Moderate, or Severe OSA" 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 [*M*].

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.
 - 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
- 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 O₂ at higher levels than those without sleep apnea.

[A], [C], [D], [R]

Definitions:

Classes of Research Reports:

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
- Systemic review
- Decision analysis
- Cost-effectiveness study

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

Medical opinion

Conclusion Grades

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 that directly supports or refutes the conclusion.

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided in the original guideline document for:

- Diagnosis of Obstructive Sleep Apnea
- Sleep Apnea Treatment

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of patients with obstructive sleep apnea syndrome (OSA)

POTENTIAL HARMS

Positive airway pressure and dental device discomfort can be problematic, contributing to non-adherence. (Refer to Appendix B in the original guideline document for more information.)

Potential Adverse Effects of Surgical Procedures

- *Tracheostomy* has been associated with significant social stigma due to the presence of a tracheostomy tube and the associated care of the tracheostomy site.
- *Radiofrequency ablation of the soft palate and tongue base* requires multiple treatments and is associated with tissue erosion and perforation.
- *Hyoid suspension* complications include dysphagia post-treatment.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they form a guideline action group.

In the action groups, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

The following detailed measurement strategies are presented to help close the gap between clinical practice and the guideline recommendations.

Priority Aims and Suggested Measures for Health Care Systems

1. Increase the percentage of patients 18 and older who are diagnosed with obstructive sleep apnea syndrome (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, coronary artery disease (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 that 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:

- 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," in the original guideline document)
- b. Percentage of patients with diagnosis of OSA who have had a onemonth device follow-up evaluation, including hours on PAP machine, mask fit, comfort assessment. (See Appendix C, "Positive Airway Pressure Device Follow-Up Tool" in the original guideline document)
- 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 the development of the guideline, there are no specifications written for possible measures listed above. The Institute for Clinical Systems Improvement (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.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms Clinical Algorithm Pocket Guide/Reference Cards

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jun. 55 p. [119 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Apr (revised 2008 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Respiratory Steering Committee

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ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee, Respiratory Steering Committee and the Patient Safety & Reliability Steering Committee).

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

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GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Mar. 55 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Institute for Clinical Systems Improvement</u> (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: <u>www.icsi.org</u>; e-mail: <u>icsi.info@icsi.org</u>.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Diagnosis and treatment of obstructive sleep apnea. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2008 Jun. 2 p. Electronic copies: Available from the <u>Institute for Clinical Systems</u> <u>Improvement (ICSI) Web site</u>.
- ICSI pocket guidelines. May 2007 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2007.

The Epworth Sleepiness Scale and a positive airway pressure questionnaire are available in the Appendices of the <u>original guideline document</u>.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: <u>www.icsi.org</u>; e-mail: <u>icsi.info@icsi.org</u>.

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on January 28, 2004. This summary was updated by ECRI Institute on July 28, 2004, June 28, 2005, May 10, 2006, and on June 4, 2007. This summary was updated by ECRI Institute on August 13, 2008.

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