



NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

MANAGEMENT/TREATMENT OF OBSTRUCTIVE SLEEP APNEA (OSA)

Guidelines

1. **American Academy of Sleep Medicine (AASM)**
 - [Practice parameters for the medical therapy of obstructive sleep apnea](#). *Sleep* 2006a Aug 1;29(8):1031-5. [65 references]
 - [Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005](#). *Sleep* 2006b Feb 1;29(2):240-3. [8 references]
 - [Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders](#). *Sleep* 2006c Mar 1;29(3):375-80. [94 references] [65 references]
2. **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]
3. **Scottish Intercollegiate Guidelines Network (SIGN)**. [Management of obstructive sleep apnoea/hypopnoea syndrome in adults. A national clinical guideline](#). Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jun. 35 p. (SIGN publication; no. 73). [158 references]

INTRODUCTION

A direct comparison of the American Academy of Sleep Medicine (AASM), Institute for Clinical Systems Improvement (ICSI), and Scottish Intercollegiate Guidelines Network (SIGN) recommendations for the management and treatment of obstructive sleep apnea (OSA) is provided in the tables below.

The guidelines differ somewhat in scope. All three AASM guidelines focus on treatment, but the first (AASM 2006a) focuses mainly on weight reduction (including bariatric surgery), positional therapy, and pharmacologic therapy. The second (AASM 2006b) focuses solely on OAs, and the third (AASM 2006c) focuses solely on PAP therapy. In addition to treatment, the diagnosis of OSA is discussed in both the ICSI and SIGN guidelines; however, this synthesis focuses only on treatment of OSA. All three AASM guidelines also provide recommendations for areas of future research.

The abbreviation OSA and OSAHS are used interchangeably in this synthesis.

The tables below provide a side-by-side comparison of key attributes of each guideline, including specific interventions and practices that are addressed. The

language used in these tables, particularly that which is used in [Table 4](#), [Table 5](#) and [Table 6](#), is in most cases taken verbatim from the original guidelines:

- [Table 1](#) provides a quick-view glance at the primary interventions considered by each group and which make up the focus of this guideline synthesis.
- [Table 2](#) provides a comparison of the overall scope of the included guidelines.
- [Table 3](#) provides a comparison of the methodology employed and documented by the guideline groups in developing their guidelines.
- [Table 4](#) provides a more detailed comparison of the specific recommendations offered by each group for the topics under consideration in this synthesis, including:
 - [Lifestyle Modifications](#)
 - [Non-Surgical Interventions](#)
 - [Positive Airway Pressure \(PAP\) devices](#)
 - [Oral Appliances](#)
 - [Pharmacological Therapy](#)
 - [Surgical Interventions](#)
 - [Follow-Up Care and Referral](#)
- [Table 5](#) lists the potential benefits and harms associated with the implementation of each guideline as stated in the original guidelines.
- [Table 6](#) presents the rating schemes used by AASM, ICSI and SIGN to rate the level of evidence and the strength of the recommendations.

A summary discussion of the [areas of agreement](#) and [areas of differences](#) among the guidelines is presented following the content comparison tables.

Abbreviations

- AASM, American Academy of Sleep Medicine
- A.W.A.K.E., Alert Well And Keeping Energetic
- AHI, apnea-hypopnea index
- APAP, automatic adjusting positive airway pressure
- BPAP, bilevel positive airway pressure
- CPAP, continuous positive airway pressure
- DME, durable medical equipment
- ENT, ear, nose, and throat
- ICSI, Institute for Clinical Systems Improvement
- OA, oral appliance
- OSA, obstructive sleep apnea
- OSAHS, obstructive sleep apnea/hypopnea syndrome
- PAP, positive airway pressure
- RDI, respiratory disturbance index
- SIGN, Scottish Intercollegiate Guidelines Network
- SSRI, selective serotonin reuptake inhibitors
- UPPP, uvulopalatopharyngoplasty

TABLE 1: COMPARISON OF INTERVENTIONS AND PRACTICES CONSIDERED
(*"✓"* indicates topic is addressed)

	AASM (2006a)	AASM (2006b)	AASM (2006c)	ICSI (2008)	SIGN (2003)
Lifestyle Modifications					
Weight loss	✓			✓	✓
Position therapy	✓			✓	✓
Other	✓			✓	✓
Non-Surgical Interventions					
PAP devices		✓	✓	✓	✓
Oral appliances		✓		✓	✓
Pharmacological therapy	✓			✓	✓
Surgical Intervention	✓	✓		✓	✓
Follow-Up Care and/or Referral		✓	✓	✓	

TABLE 2: COMPARISON OF SCOPE AND CONTENT	
Objective and Scope	
AASM (2006a)	To provide recommendations regarding the use of medical therapy (defined as therapies other than modification of upper airway patency with devices or surgical interventions) for the treatment of OSA
AASM (2006b)	To reissue, modify, and, if necessary, replace recommendations for the use of OAs in the treatment of snoring and OSA based on the scientific literature
AASM (2006c)	<ul style="list-style-type: none"> • To provide practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders • To provide recommendations that add to the previously published guidelines and practice parameters on the diagnosis and management of OSA

ICSI (2008)	<ul style="list-style-type: none"> To increase the percentage of patients 18 and older who are diagnosed with OSA through a sleep study evaluation To increase the percentage of patients with OSA who have received appropriate treatment according to guideline To improve PAP treatment adherence rate for those who are diagnosed with OSA To increase patient understanding of the health risk factors related to OSA
SIGN (2003)	To produce recommendations which can be used to aid patients, general practitioners (GPs), secondary care physicians, and surgeons to recognize the symptoms of OSAHS, to prioritise referral requests, to understand how sufferers may be investigated and which treatment modalities are currently available
Target Population	
AASM (2006a)	<ul style="list-style-type: none"> United States Adults with OSA
AASM (2006b)	<ul style="list-style-type: none"> United States
AASM (2006c)	<ul style="list-style-type: none"> United States Adults with sleep-related breathing disorders including OSA
ICSI (2008)	<ul style="list-style-type: none"> United States Adult patients age 18 and older at risk for OSA
SIGN (2003)	<ul style="list-style-type: none"> Scotland Males and females over the age of 16 years with OSAHS
Intended Users	
AASM (2006a)	Those involved in the practice of adult sleep medicine
AASM (2006b)	Dentists Physicians
AASM (2006c)	Those involved in the practice of adult sleep medicine
ICSI	Advanced Practice Nurses

(2008)	Allied Health Personnel Health Care Providers Health Plans Hospitals Managed Care Organizations Nurses Physician Assistants Physicians
SIGN (2003)	Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians

TABLE 3: COMPARISON OF METHODOLOGY	
Methods Used to Collect/Select the Evidence	
AASM (2006a)	<p>Searches of Electronic Databases</p> <p>Note from the National Guideline Clearinghouse (NGC): Evidence was collected by the authors of the companion document, Medical Therapy for Obstructive Sleep Apnea: A Review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine.</p> <p>Evidence Review:</p> <ul style="list-style-type: none"> • Veasey, SC, Guilleminault C, Strohl KP, Sanders, MH, Ballard RD, Magalang UJ. Medical therapy for obstructive sleep apnea: a review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine. Sleep 2006 Aug;29(8):1036-44. <p>Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine Web site.</p> <p><i>Described Process:</i></p> <p>A PubMed search (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi) was conducted for key words: sleep apnea or obstructive sleep apnea with bariatric surgery, diet, therapy, oxygen, supplemental oxygen, drug therapy, pharmacotherapy, medical, endocrine,</p>

	<p>position, weight reduction, weight loss, rhinitis, nasal symptoms, nasal therapy. Literature searches were limited to clinical studies published in the English language between 1985 and January 2005. A search update in April 2005 was conducted on PubMed for "obstructive sleep apnea" and "therapy" with screening of abstracts to ensure completeness of review. Inclusion criteria for the articles included: English language, clinical trials, polysomnography end-points of apnea and/or hypopnea indices and adult subjects. Exclusion criteria included case reports, subjects <20 years of age and use of non-United States Food and Drug Administration-approved medications. In addition to reviewing pertinent findings in the studies meeting the inclusion/exclusion criteria, the authors of the companion document presented data from additional studies, where further insight has been gained.</p> <p>Of the 1750 abstracts identified by the key word search, 135 studies were identified as qualifying for the above inclusion and exclusion criteria and relevant to the categories of weight loss, pharmacotherapies, delivery of supplemental oxygen, and positional therapy. Overall, most of the qualifying studies identified provided Level II or Level III evidence for the effectiveness of an intervention (see Rating Scheme for the Strength of the Evidence) on improving the AHI. Very few studies presented data on neurobehavioral, metabolic or cardiovascular outcomes. In addition, very few of the papers compare medical therapies to CPAP outcomes.</p>
<p>AASM (2006b)</p>	<p>Hand-searches of Published Literature (Primary Sources)</p> <p>Hand-searches of Published Literature (Secondary Sources)</p> <p>Searches of Electronic Databases</p> <p><i>Evidence Reviews:</i></p> <ul style="list-style-type: none"> • Oral appliances for snoring and obstructive sleep apnea: a review. Sleep 2006;29(2):244-262. Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site. • Oral appliance review. Evidence tables. Sleep 2006;29(2). Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site. <p><i>Described Process:</i> The data for this review were assembled by searching PubMed for English language peer-reviewed publications containing the key words "oral appliance," "obstructive sleep apnea," "orthodontic appliances," and related terms from 1995 to 2004. The search was restricted to adult patients. Of the 112 articles produced by this search, 45 were rejected because they did not report original investigations, did not describe investigative</p>

	<p>methods adequately, were not studies of oral appliance therapy, or reported data on fewer than 8 patients. Articles known to task force members that met the selection criteria but did not appear in the original search were added to the list. By this means 64 additional articles were added before January 2004, creating a list of 131 articles (Online Evidence Table). The same search process was repeated in July 2004 yielding 10 additional papers included for this review.</p>
<p>AASM (2006c)</p>	<p>Searches of Electronic Databases</p> <p><i>Evidence Review:</i></p> <ul style="list-style-type: none"> • Gay P, Weaver T, Loubé D, Iber C; Positive Airway Pressure Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine. Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. <i>Sleep</i> 2006 Mar;29(3):381-401. <p>Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine Web site.</p> <p><i>Described Process:</i></p> <p>Searches in the English language literature (Medline 1966 - early 2005) of major topics relevant to PAP treatment during sleep-related breathing disorders (SRBDs) were conducted. The initial literature search was done in April of 2001 followed by an update in April of 2002. A final literature search for just Level I studies was done in January of 2005 in order to keep the review as timely as possible and to avoid omission of potentially high impact studies published in the interim. The decision to limit the final search and some entire sections to Level I or II evidence was decided upon by the Task Force for the purposes of simplification and brevity. The Task Force did not feel this would detract from the overall conclusions made within the body of this review. The search focused on peer-reviewed clinical studies, including case-series and controlled trials, which contained information regarding PAP treatment outcomes, methods for polysomnographic titration, factors affecting adherence and side effects. Major search terms are included as Table 2 in the accompanying review paper (see the "Availability of Companion Documents" field in the NGC summary of this guideline or above). Review papers, commentary, case reports, pediatric populations, and studies pertaining to APAP were excluded, except where parenthetical comments are specifically noted.</p>
<p>ICSI (2008)</p>	<p>Searches of Electronic Databases</p> <p><i>Described Process:</i> A literature search of clinical trials, meta-</p>

	analyses, and systematic reviews is performed.
SIGN (2003)	<p>Searches of Electronic Databases</p> <p><i>Described Process:</i> The evidence base for this guideline was synthesised in accordance with SIGN methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer in collaboration with members of the guideline development group.</p> <p>Internet searches were carried out on the Web sites of the Canadian Practice Guidelines Infobase, the New Zealand Guidelines Programme, the UK Health Technology Assessment Programme, the US National Guidelines Clearinghouse, and the US Agency for Healthcare Research and Quality. Searches were also carried out using Google and OMNI search engines, and all suitable links followed up.</p> <p>Database searches were carried out on the Cochrane Library, Embase, Medline, and Psychological Abstracts. With the exception of the Cochrane Library, all searches were restricted to the period 1991 to 2000. The Medline version of the main search strategies is available on the SIGN Web site, in the section covering supporting material for published guidelines.</p> <p>The main searches were supplemented by material identified by individual members of the development group.</p>
Methods Used to Assess the Quality and Strength of the Evidence	
AASM (2006a)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
AASM (2006b)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
AASM (2006c)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
ICSI (2008)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
SIGN (2003)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
Methods Used to Analyze the Evidence	
AASM (2006a)	Systematic Review with Evidence Tables

	<p><i>Described Process:</i> Studies described in this report have each been characterized with evidence levels using criteria listed in Table 2 of the review paper accompanying the original guideline document (see "Availability of Companion Documents" field).</p>
AASM (2006b)	<p>Systematic Review with Evidence Tables</p> <p><i>Described Process:</i> The task force first developed an abstract form in order to create a standardized database for the review, for the subsequent parameter development, and for the critical scrutiny of readers. The elements of this Evidence Table were selected to address the questions in the task force's charge. These data are contained in an Evidence Table, available in an online supplement and as a companion to this summary. In addition, each paper was graded for research quality and evidentiary strength by reference to a scale advocated by Sackett (see "Rating Scheme for the Strength of the Evidence" field in this summary). The studies and papers graded as Level I or II evidence are listed in Appendix 1 of the original guideline document (Evidence Table, selected studies, Level I-II). This evidence table can be accessed on the web at http://www.aasmnet.org.</p>
AASM (2006c)	<p>Systematic Review with Evidence Tables</p> <p><i>Described Process:</i> The level of evidence for the data in each paper relevant to the evaluation is listed in evidence tables specific for each question. Each paper was analyzed independently by 2 task force members. The level of evidence was rated using the AASM classification of evidence for intervention studies, an adaptation of the Sackett criteria (See Rating Scheme for the Strength of the Evidence field in Table 6 of this synthesis). Disagreements between the 2 raters were adjudicated by a vote of the task force members.</p>
ICSI (2008)	<p>Systematic Review with Evidence Tables</p>
SIGN (2003)	<p>Review of Published Meta-Analyses</p> <p>Systematic Review</p> <p><i>Described Process:</i> SIGN carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.</p> <p>Once papers have been selected as potential sources of evidence,</p>

	<p>the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.</p> <p>Additional details can be found in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines" (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.</p>
Outcomes	
AASM (2006a)	<ul style="list-style-type: none"> • Incidence of OSA • AHI • Oxygen desaturation indices • Incidence and severity of excessive daytime sleepiness
AASM (2006b)	<ul style="list-style-type: none"> • Snoring level • Clinical signs and symptoms of OSA • AHI and oxyhemoglobin saturation • RDI • Adverse events
AASM (2006c)	<ul style="list-style-type: none"> • Clinical signs and symptoms of OSA • Quality of life • Optimal PA • PAP utilization • Daytime hypercapnea • Adverse events • Patient compliance/adherence
ICSI (2008)	<ul style="list-style-type: none"> • Signs and symptoms of OSA • Patient risk factors, including comorbidities • Accuracy (sensitivity and specificity, positive and negative predictive value) of diagnostic tests • Effects of treatment on AHI, RDI, and other measures of OSA • Patient adherence and patient satisfaction with treatment • Complications of treatment
SIGN (2003)	<ul style="list-style-type: none"> • Severity of OSAHS using AHI or RDI • Sleepiness measures (cognitive function, vigilance, mood) • Vitals including blood pressure, heart rate, oxygen saturation • Effectiveness of diagnostic tools (sleep studies,

	<ul style="list-style-type: none"> polysomnography) • Cost effectiveness of treatment • Patient driving/quality of life
Methods Used to Formulate the Recommendations	
AASM (2006a)	<p>Expert Consensus (Refer to Table 6 for rating scheme)</p> <p><i>Described Process:</i> The Standards of Practice Committee of the AASM developed the recommendations based on the companion document, Medical Therapy for Obstructive Sleep Apnea: A Review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine. A Task Force of content experts was appointed by the AASM to review and grade evidence in the scientific literature regarding therapies for obstructive sleep apnea not covered by previous practice parameters.</p>
AASM (2006b)	<p>Expert Consensus (Refer to Table 6 for rating scheme)</p> <p><i>Described Process:</i> The Standards of Practice Committee of the AASM, in conjunction with specialists and other interested parties, developed these practice parameters based on the accompanying review paper. A Task Force of content experts was appointed by the AASM to review and grade evidence in the scientific literature regarding the clinical use of oral appliances in the treatment of snoring and OSA. In most cases, recommendations are based on evidence from studies published in the peer-reviewed literature.</p>
AASM (2006c)	<p>Expert Consensus (Refer to Table 6 for rating scheme)</p> <p><i>Described Process:</i> The Standards of Practice Committee (SPC) of the AASM reviewed the accompanying review (see the "Availability of Companion Documents" field in the NGC summary of this guideline) and cited literature to develop the recommendations. These recommendations pertain to adults and in most cases are based on evidence published in peer-reviewed journals. However, where scientific data are absent, insufficient, or inconclusive, recommendations are based upon committee consensus.</p>
ICSI (2008)	<p>Expert Consensus (Refer to Table 6 for rating scheme)</p> <p><i>Described Process:</i> 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 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</p>

	<p>be recruited from medical groups or hospitals outside of ICSI.</p> <p>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.</p> <p>Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.</p>
<p>SIGN (2003)</p>	<p>Expert Consensus (Refer to Table 6 for rating scheme)</p> <p><i>Described Process:</i> The process for synthesising the evidence base to form graded guideline recommendations is illustrated in the companion document "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines" (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.</p> <p>Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.</p> <p>In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.</p> <p>Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:</p> <ul style="list-style-type: none"> • Quantity, quality, and consistency of evidence • Generalisability of study findings • Applicability to the target population of the guideline • Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.) <p>Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.</p> <p>The assignment of a level of evidence should involve all those on a</p>

	<p>particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.</p> <p>The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation and to emphasise that the body of evidence should be considered as a whole and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.</p> <p>On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is there likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are <u>not</u> an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.</p>
Financial Disclosures/Conflicts of Interest	
AASM (2006a)	<p>This was not an industry supported study. Dr. Morgenthaler has received research support from Itamar Medical Ltd. and ResMed Research Foundation; and has received research equipment from Olympus. Dr. Alessi is a consultant for Prescription Solutions, Inc. Dr. Coleman is a member of the Medical Advisory Board for Influent and is a consultant and speaker/instructor for Acclarent. Dr. Kapur has received research support from Pro-tech Services, Inc.; and has received research equipment from Respironics. Dr. Owens has received research support from Eli Lilly, Cephalon, and Sepracor; is a consultant for Eli Lilly, Cephalon, Shire, and Sanofi-Aventis; and has participated in speaking engagements supported by Eli Lilly, Cephalon, Sanofi-Aventis, and Johnson & Johnson. Dr. Swick has received research support from Sanofi-Aventis, Takeda Pharmaceuticals, Merck, Jazz Pharmaceuticals, Pfizer, Somaxon, Astellas-Pharmaceuticals, and Cephalon; and is on the speakers' bureau of GlaxoSmithKline, Jazz Pharmaceuticals, Sepracor, Cephalon, and Boehringer Ingelheim. Dr. Hirshkowitz has received</p>

	<p>research support from Sanofi-Aventis, Takeda, Merck, GlaxoSmithKline, Cephalon, Sepracor, Respironics, ResMed, and NBI; is on the speakers' bureau of Sanofi, Takeda, and Cephalon; is a consultant for Sanofi-Synthelabo, Takeda, and Cephalon; and has received research equipment from ResMed, Respironics, Sunrise, Puritan Bennett, Itamar, Nasal Aire, and Fisher-Paykel. Drs. Kapen, Lee-Chiong, Boehlecke, Brown, Friedman, and Pancer have indicated no financial conflicts of interest.</p>
AASM (2006b)	<p>All members of the American Academy of Sleep Medicine Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of interest with regard to this subject.</p>
AASM (2006c)	<p>This was not an industry supported study. Dr. Kushida has received research support from GlaxoSmithKline, Boehringer-Ingelheim, XenoPort, Inc., Schwarz Pharmaceuticals, and Kyowa Pharmaceuticals; and has participated in speaking engagements supported by GlaxoSmithKline. Dr. Littner has received research support from GlaxoSmithKline, AstraZeneca, Boehringer-Ingelheim, Dey Pharmaceuticals, and Altana Pharmaceuticals; has participated in speaking engagements supported by Pfizer, Glaxo-SmithKline, and Boehringer-Ingelheim; and is a member of the advisory boards for Novartis, Pfizer, and Dey Pharmaceuticals. Dr. Hirshkowitz has received research support from Sanofi, Merck, Takeda, Somaxon, and Cephalon; is on the speakers' bureaus for Cephalon, Sanofi, Takeda, and Sepracor; and has received research equipment from ResMed, Respironics, and Sunrise. Dr. Morgenthaler has received research support from Itamar Medical, ResMed, and ResMed Research Foundation; and has received research equipment from Olympus, Inc. Dr. Alessi is a consultant for Prescription Solutions, Inc. Dr. Kapur has received research support from the Washington Technology Center and Pro-tech Services, Inc.; and has received research equipment from Respironics. Dr. Owens has received research support from Eli Lilly, Cephalon, Sepracor, and Johnson & Johnson; and is a speaker or consultant for Eli Lilly, Cephalon, Johnson & Johnson, Shire, and Select Comfort. Dr. Swick has received research support from Orphan Medical (Jazz Pharmaceuticals), Cephalon, Sanofi-Aventis, Merck, and Takeda Pharmaceuticals; and has participated in speaking engagements supported by Orphan Medical (Jazz Pharmaceuticals), Cephalon, Takeda Pharmaceuticals, and GlaxoSmithKline. Dr. Coleman has participated in speaking engagements supported by Aventis; and is an investor in the Murphysboro Imaging Leasing Company. Drs. Bailey, Boehlecke, Brown, Friedman, Kapen, Kramer, Lee-Chiong, Pancer, and Wise have indicated no financial conflicts of interest.</p>
ICSI (2008)	<p>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</p>

	<p>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).</p> <p>Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.</p> <p>Blair Anderson, MD and James Mickman, MD are contracted with Lakeland Health Services for medical directorships.</p> <p>No other work group members have potential conflicts of interest to disclose.</p> <p>ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.</p>
<p>SIGN (2003)</p>	<p>All members of the SIGN guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned (e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry); a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible (e.g., endowed fellowships or other pharmaceutical industry support). Details of the declarations of interest of any guideline development group member(s) are available from the Scottish Intercollegiate Guidelines Network executive.</p>

<p>TABLE 4: COMPARISON OF RECOMMENDATIONS FOR THE MANAGEMENT OF OSA</p>	
<p>LIFESTYLE MODIFICATIONS</p>	
<p>AASM (2006a)</p>	<p>Weight Reduction</p> <p>Successful dietary weight loss may improve the AHI in obese OSA patients. (Guideline)</p>

	<p><i>This parameter is based on one Level I, one Level II, and 2 Level III papers.</i></p> <p>Dietary weight loss should be combined with a primary treatment for OSA. (Option)</p> <p><i>This recommendation is based on the same sources as the above recommendation.</i></p> <p>Bariatric surgery may be adjunctive in the treatment of OSA in obese patients. (Option)</p> <p><i>There are no Level I-III studies of bariatric surgery for OSA specifically. However, many non-randomized, uncontrolled investigations are now available, show improvements in AHI with weight loss, and therefore there is consensus among members of the Task Force and the Standards of Practice Committee that bariatric surgery may play a role in the treatment of morbidly obese OSA patients as an adjunct to less invasive and rapidly active first-line therapies such as PAP. A cautionary note is warranted because of reports of recurrence of OSA after several years even without regaining of weight. Also, bariatric surgery is not without complications as is documented in several reviews published in 2004.</i></p> <p>Positional Therapies</p> <p>Positional therapy, consisting of a method that keeps the patient in a non-supine position, is an effective secondary therapy or can be a supplement to primary therapies for OSA in patients who have a low AHI in the non-supine versus that in the supine position. (Guideline)</p> <p><i>Patients who normalize their AHI when they sleep in a non-supine position tend to have less severe OSA, to be less obese, and to be younger. Three Level II studies form the basis for this practice parameter, one of which compared supine with an upright position. Because not all patients normalize AHI when non-supine, the committee's opinion is that correction of OSA by position should be documented with an appropriate test. In addition, 2 papers have described special pillows which improved OSA.</i></p>
AASM (2006b)	No recommendations offered.
AASM (2006c)	No recommendations offered.
ICSI (2008)	Lifestyle Modification

	<p>The following lifestyle modifications can play a significant role in the reduction of severity of sleep apnea symptoms:</p> <ul style="list-style-type: none"> • 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 <p>Obesity</p> <p>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 [D].</p> <p>See Appendix D, "Sleep Hygiene" in the original guideline document for more information.</p> <p>Refer to the original guideline document for more information on alcohol consumption, obesity, and body position.</p>
<p>SIGN (2003)</p>	<p>Behavioural Interventions</p> <p>C - Weight loss should be encouraged in all patients with obesity contributing to their OSAHS. Attempts at weight loss should not delay the initiation of further treatment. Weight loss should also be encouraged as an adjunct to CPAP or intra-oral devices as it may allow discontinuation of therapy.</p> <p><u>Good Practice Points:</u></p> <ul style="list-style-type: none"> • Patients who smoke should be advised to stop. • Alcohol and sedatives or sleeping tablets should be avoided. • Non-sleepy snorers should be discouraged from sleeping on their backs. <p>These measures may suffice in simple snorers or in those with very mild OSAHS and few symptoms but most patients with OSAHS need additional treatment.</p>
<p>NON-SURGICAL INTERVENTIONS</p>	
<p>Positive Airway Pressure (PAP) Devices</p>	
<p>AASM (2006a)</p>	<p>No recommendations offered.</p>

<p>AASM (2006b)</p>	<p>Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. (Guideline)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to clarify treatment of patients with severe OSA. It is based on 1 level II study and 2 lower level studies.</i></p>
<p>AASM (2006c)</p>	<p>Treatment with CPAP must be based on a prior diagnosis of OSA established using an acceptable method (Standard).</p> <p><i>This recommendation is based on previous AASM practice parameters for the indications for polysomnography and related procedures (2005 update).</i></p> <p>CPAP is indicated for the treatment of moderate to severe OSA (Standard).</p> <p><i>This recommendation is based on 24 randomized controlled trials meeting Level I or II evidence-based medicine criteria.</i></p> <p>CPAP is recommended for the treatment of mild OSA (Option).</p> <p><i>This recommendation as an option is based on mixed results in 2 Level I and 3 Level II outcome studies in patients with mild OSA.</i></p> <p>CPAP is indicated for improving self-reported sleepiness in patients with OSA (Standard).</p> <p><i>This recommendation is based on 10 randomized controlled trials in which CPAP reduced sleepiness more than control procedures in patients with OSA.</i></p> <p>CPAP is recommended for improving quality of life in patients with OSA (Option).</p> <p><i>This recommendation as an option is based on inconsistent results from 2 Level I studies and 4 Level II studies with placebo control, and 1 Level II study with conservative therapy as the control.</i></p> <p>CPAP is recommended as an adjunctive therapy to lower blood pressure in hypertensive patients with OSA (Option).</p> <p><i>This recommendation as an option is based on 9 clinical trials, 6 of</i></p>

which did not find changes in mean arterial pressure compared to placebo.

Full-night, attended polysomnography performed in the laboratory is the preferred approach for titration to determine optimal positive airway pressure; however, split-night, diagnostic-titration studies are usually adequate **(Guideline)**.

This recommendation is based on 1 Level II and 6 Level IV studies.

CPAP Usage should be objectively monitored to help assure utilization **(Standard)**.

This recommendation is based on overwhelming evidence at all levels indicating patients with OSA overestimate their positive airway pressure. Level I and Level II studies indicate that objectively-measured nightly CPAP "time on" ranges from 3.5 hours/night in minimally symptomatic new patients to 7.1 hours/night in established users.

Close follow-up for PAP usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of PAP use **(Standard)**.

This recommendation is based on 61 studies that examined management paradigms and collected acceptance, utilization, and adverse events; 17 of these studies qualified as Level I.

The addition of heated humidification is indicated to improve CPAP utilization **(Standard)**.

This recommendation is based on 3 Level I studies. There was 1 Level II study that did not find increased utilization with heated humidification. Three additional studies favored heated humidification over unheated or non-humidified CPAP.

The addition of a systematic educational program is indicated to improve PAP utilization **(Standard)**.

This recommendation is based on 4 Level I studies, 1 Level II study, and 1 Level III study.

After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is indicated yearly and as needed to troubleshoot PAP mask, machine, or usage problems **(Option)**.

This recommendation as an option is based on task force and SPC

	<p><i>member consensus.</i></p> <p>CPAP and bi-level positive airway pressure (BPAP) therapy are safe; side effects and adverse events are mainly minor and reversible (Standard).</p> <p><i>This recommendation is based on more than 23 published reports.</i></p> <p>While the literature mainly supports CPAP therapy, BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present (Guideline).</p> <p><i>This recommendation is based on 2 Level I studies which yielded no evidence that BPAP improves efficacy or adherence in the management of OSA compared to CPAP.</i></p> <p>BPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with daytime hypercapnia (Option).</p> <p><i>This recommendation as an option is based on 11 studies all graded at Level III or better that overall found improvement associated with BPAP therapy.</i></p>
<p>ICSI (2008)</p>	<p>PAP Devices</p> <p>The success of any PAP 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.)</p> <p><u>CPAP</u></p> <p>Positive pressure is the most efficacious (next to tracheostomy) for treating OSA. CPAP is currently the most commonly used PAP device.</p> <p>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].)</p> <p>A heated humidifier is strongly suggested in patients with the</p>

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 by ordering CPAP with heated humidity.

Flexible CPAP is an option that may improve adherence for patients who have difficulty with CPAP.

AutoPAP (AutoPAP, Self-titrating CPAP, Auto-adjust CPAP)

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.

Bi-level PAP

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 COPD 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 re-titration 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 OSAHS, 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.

<p>SIGN (2003)</p>	<p>Non-Surgical Interventions</p> <p>A - CPAP is the first choice therapy for patients with moderate or severe OSAHS that is sufficiently symptomatic to require intervention.</p> <p>C - Persistent low CPAP use (less than two hours per night) over six months, following efforts to improve patient comfort, should lead to a review of treatment.</p> <p><u>Good Practice Point</u></p> <p>CPAP therapy should not be abandoned without:</p> <ul style="list-style-type: none"> • The attention of a trained CPAP nurse/technician • A titration study/use of autotitrating CPAP to troubleshoot problems • The use of heated humidification <p>B - Bi-level ventilation should not be used routinely in OSAHS but should be reserved for patients with ventilatory failure.</p> <p>Effects of Treatment on Driving and Quality of Life</p> <p>A - CPAP should be considered for the improvement of driving ability in patients with severe OSAHS as it reduces daytime sleepiness.</p> <p><u>Good Practice Point:</u> CPAP treatment should be prioritized to sleepy drivers and occupational drivers with OSAHS given the public health consequences of untreated OSAHS, sleepiness, and accidents.</p>
<p>Oral Appliances (OAs)</p>	
<p>AASM (2006a)</p>	<p>No recommendations offered.</p>
<p>AASM (2006b)</p>	<p>Diagnosis</p> <p>The presence or absence of OSA must be determined before initiating treatment with OAs to identify those patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment. Detailed diagnostic criteria for OSA are available and include clinical signs, symptoms, and the findings identified by polysomnography. The severity of sleep related respiratory problems must be established in order to make an appropriate treatment decision. (Standard)</p>

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper. However, there is a higher level of evidence that severity of OSA is predictive of response to OAs.

Appliance Fitting

OAs should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion, and associated oral structures. Dental management of patients with OAs should be overseen by practitioners who have undertaken serious training in sleep medicine and/or sleep related breathing disorders with focused emphasis on the proper protocol for diagnosis, treatment, and follow up. **(Option)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to specify the training of the personnel responsible for fitting the oral appliances. It is based on committee consensus.

Although cephalometric evaluation is not always required for patients who will use an OA, appropriately trained professionals should perform these examinations when they are deemed necessary **(Option)**.

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

Treatment

For patients with primary snoring without features of OSA or upper-airway resistance syndrome, the treatment objective is to reduce the snoring to a subjectively acceptable level **(Standard)**.

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

For patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the AHI and oxyhemoglobin saturation **(Standard)**.

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

OAs are appropriate for use in patients with primary snoring who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep-position

	<p>change. (Guideline)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to exclude mild OSA patients; these latter patients are discussed in the next practice parameter. This recommendation is based on 1 level I study and 2 level V studies.</i></p> <p>Although not as efficacious as CPAP, OAs are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. (Guideline)</p> <p><i>This is a new recommendation. It is based on 11 level I, 3 level II, and 16 level III-V studies that used stringent criteria for defining success.</i></p> <p>Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of OAs. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. (Guideline)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to clarify treatment of patients with severe OSA. It is based on 1 level II study and 2 lower level studies.</i></p>
<p>AASM (2006c)</p>	<p>No recommendations offered</p>
<p>ICSI (2008)</p>	<p>Oral Appliances</p> <p>OAs are a recommended treatment for patients with mild OSA who have not responded to lifestyle modification or who are intolerant of PAP devices, though they are not as effective.</p> <p>Mandibular repositioning devices are a successful treatment modality for patients with mild OSA with obstruction in the oropharynx and tongue base region.</p> <p>Tongue retaining devices are helpful for patients with limited or loose natural dentition, temporomandibular disorders, and limited mouth opening.</p> <p>To locate a dentist or orthodontist with special training in sleep</p>

	<p>apnea who can fit oral appliances, consider contacting your local dental society, or check the following Internet Web site: www.aadsm.org.</p>
<p>SIGN (2003)</p>	<p>Intra-Oral Devices</p> <p>A - Intra-oral devices are an appropriate therapy for snorers and for patients with mild OSAHS with normal daytime alertness.</p> <p>B - Intra-oral devices are an appropriate alternative therapy for patients who are unable to tolerate CPAP.</p> <p>D - The use of intra-oral devices should be monitored following initiation of therapy to allow device adjustment and assessment of OSAHS control and symptoms.</p>
<p>Pharmacological Therapy</p>	
<p>AASM (2006a)</p>	<p>SSRIs are not recommended for treatment of OSA. (Standard)</p> <p><i>The above recommendation is derived from 2 Level II publications and one level V using paroxetine and fluoxetine.</i></p> <p>Protriptyline is not recommended as a primary treatment for OSA. (Guideline)</p> <p><i>Three Level II and one Level V papers form the basis of this recommendation.</i></p> <p>Methylxanthine derivatives (aminophylline and theophylline) are not recommended for treatment of OSA. (Standard)</p> <p><i>For this recommendation, there are 3 Level II publications, all of which report similar negative findings.</i></p> <p>Estrogen therapy (estrogen preparations with or without progesterone) is not indicated for the treatment of OSA. (Standard)</p> <p><i>This recommendation, which is based on the results of 4 Level I, 3 Level II, and one Level V publications.</i></p> <p>Modafinil is recommended for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective PAP treatment and who are lacking any other identifiable cause for their sleepiness. (Standard)</p> <p><i>All five studies included in the review (3 Level I, one Level II, and one Level V) attest to the partial effectiveness of modafinil in the</i></p>

	<p><i>management of residual sleepiness in patients with treated OSA who have no other identifiable reason for hypersomnolence.</i></p> <p>Supplemental Oxygen</p> <p>Oxygen supplementation is not recommended as a primary treatment for OSA. (Option)</p> <p><i>There are 2 Level II and 2 Level III studies that show oxygen administration improves oxygenation parameters in patients with OSA.</i></p> <p><i>Although all studies showed favorable effects on oxygenation, the effect of oxygen therapy on apneas, hypopneas and subjective sleepiness was inconsistent.</i></p> <p>Medical Therapies Intended To Improve Nasal Patency</p> <p>Short-acting nasal decongestants are not recommended for treatment of OSA. (Option)</p> <p><i>One level II study showed little additive effect of oxymetazoline to positional therapy in improving AHI.</i></p> <p>Topical nasal corticosteroids may improve the AHI in patients with OSA and concurrent rhinitis, and thus may be a useful adjunct to primary therapies for OSA. (Guideline)</p> <p><i>This recommendation is based upon the results of one level I study that demonstrated an improvement in mean AHI from 20 to 12 events/hr using fluticasone nasal spray.</i></p>
AASM (2006b)	No recommendations offered.
AASM (2006c)	No recommendations offered.
ICSI (2008)	<p>One Month Follow-Up</p> <p>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. 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.</p>
SIGN (2003)	Pharmacological Treatments

	<p>A - Pharmacological therapy should not be used as first line therapy for OSAHS.</p> <p>There is some evidence to suggest that the addition of alerting drugs, such as modafinil, may have a small beneficial effect on sleepiness in some patients who remain sleepy despite good CPAP compliance. However, they may decrease CPAP use and longer term studies of their value and risks are needed. There is no evidence to suggest that they could be used as an alternative to CPAP, and they are not a substitute for careful attention to improving CPAP comfort and efficacy.</p>
<p>SURGICAL INTERVENTIONS</p>	
<p>AASM (2006a)</p>	<p>Bariatric surgery may be adjunctive in the treatment of OSA in obese patients. (Option)</p> <p><i>There are no Level I-III studies of bariatric surgery for OSA specifically. However, many non-randomized, uncontrolled investigations are now available, show improvements in AHI with weight loss, and therefore there is consensus among members of the Task Force and the Standards of Practice Committee that bariatric surgery may play a role in the treatment of morbidly obese OSA patients as an adjunct to less invasive and rapidly active first-line therapies such as PAP. A cautionary note is warranted because of reports of recurrence of OSA after several years even without regaining of weight. Also, bariatric surgery is not without complications as is documented in several reviews published in 2004.</i></p>
<p>AASM (2006b)</p>	<p>Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. (Guideline)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to clarify treatment of patients with severe OSA. It is based on 1 level II study and 2 lower level studies.</i></p>
<p>AASM (2006c)</p>	<p>No recommendations offered</p>
<p>ICSI (2008)</p>	<p>Obesity</p> <p>Incidence of OSA among morbidly obese patients is 12- to 30-fold higher than other populations, and these patients may benefit from</p>

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.

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 OSA. It may be necessary to correct the anatomical obstruction before prescribing an OA or 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 OSAHS.

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 OSAHS.

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 (MMA) — 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. 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].

Refer to the original guideline document for more information on surgical procedures.

**SIGN
(2003)**

Uvulopalatopharyngoplasty

B - Use of UPPP or laser-assisted uvulopalatopharyngoplasty (LAUP) for the treatment of OSAHS is not recommended.

Good Practice Point: The presence of large tonsils in a patient diagnosed with OSAHS should prompt referral to an ENT surgeon for consideration of tonsillectomy

D - Patients being offered palatal surgery should be informed of the risk of difficulty with CPAP use if they later develop OSAHS.

Good Practice Point: OSAHS should be excluded in patients before they are considered for surgery for snoring.

Tracheostomy

Good Practice Point: Tracheostomy should only be considered when all else fails in carefully selected individuals.

Other Surgical Techniques

Mandibular Advancement

One controlled trial has shown that permanent mandibular and maxillary advancement considerably reduces OSAHS severity and improves symptoms in patients followed up for two years. There are no randomized controlled trials (RCTs) and only limited long term follow up data available, and the treatment remains experimental.

Suprahyoid Tensing

A randomized study of a surgical procedure to tense the suprahyoid muscles (hyoid suspension) was halted due to worsening of sleep study indices, despite apparent symptomatic improvement.

Bariatric (Weight Reducing) Surgery

Weight is known to influence the severity of OSAHS and weight loss is likely to be an effective treatment for OSAHS in some patients. Bariatric surgery to provoke significant weight loss has been used to treat OSAHS, assessed in case series. In the absence of a controlled trial, the relative benefits and disadvantages cannot be assessed. This area urgently needs evaluation.

Nasal Surgery

Good Practice Point: Alternative surgical approaches to OSAHS are

	<p>experimental and should not be used outside the context of a randomized clinical trial.</p> <p>Anaesthesia</p> <p><u>Good Practice Points:</u></p> <p>The effect of anaesthesia during surgery may increase the severity of the apnoea postoperatively. When a patient is being treated by CPAP preoperatively this should be continued immediately following surgery.</p> <p>All patients with OSAHS should be monitored with oximetry postoperatively and further management decided on an individual basis.</p> <p>The Effect of Surgery on Sleepiness, Driving and Quality of Life</p> <p><u>Good Practice Point:</u> Pharyngeal surgery for OSAHS has no proven benefit and should only be undertaken as part of a randomized controlled trial.</p>
<p>FOLLOW-UP CARE AND REFERRAL</p>	
<p>AASM (2006a)</p>	<p>No recommendations offered</p>
<p>AASM (2006b)</p>	<p>Follow-Up</p> <p>Follow-up sleep testing is not indicated for patients with primary snoring. (Guideline)</p> <p><i>This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.</i></p> <p>To ensure satisfactory therapeutic benefit from OAs, patients with OSA should undergo polysomnography or an attended cardiorespiratory (Type 3) sleep study with the OA in place after final adjustments of fit have been performed. (Guideline)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to generalize therapeutic evaluation to all patients with OSA, not only patients with moderate to severe OSA. This recommendation is based on 2 level I and 5 level V studies. The reader is also referred to the recent practice parameter paper regarding indications for polysomnography (see National Guideline Clearinghouse [NGC] summary of American Academy of Sleep Medicine guideline Practice parameters for the</i></p>

	<p><u>indications for polysomnography and related procedures: an update for 2005.</u></p> <p>Patients with OSA who are treated with OAs should return for follow-up office visits with the dental specialist. Once optimal fit is obtained and efficacy shown, dental specialist follow-up at every 6 months is recommended for the first year, and at least annually thereafter. The purpose of follow up is to monitor patient adherence, evaluate device deterioration or maladjustment, evaluate the health of the oral structures and integrity of the occlusion, and assess the patient for signs and symptoms of worsening OSA. Intolerance and improper use of the device are potential problems for patients using OAs, which require patient effort to use properly. OAs may aggravate temporomandibular joint disease and may cause dental misalignment and discomfort that are unique to each device. In addition, OAs can be rendered ineffective by patient alteration of the device. (Option)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to generalize follow-up to all patients with OSA, to specify frequency of follow-up visits, and to expand upon the reasons for the follow-up visit. It is based upon committee consensus on factors described in the accompanying review paper.</i></p> <p>Patients with OSA who are treated with OAs should return for periodic follow-up office visits with the referring clinician. The purpose of follow up is to assess the patient for signs and symptoms of worsening OSA. Close communication with the dental specialist is most conducive to good patient care. An objective reevaluation of respiration during sleep is indicated if signs or symptoms of OSA worsen or reoccur (Option)</p> <p><i>This recommendation is a modification of the recommendation of the previous practice parameter paper to consolidate the reasons for follow-up with the referring clinician into a single practice parameter.</i></p>
<p>AASM (2006c)</p>	<p>Close follow-up for PAP usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of PAP use (Standard).</p> <p><i>This recommendation is based on 61 studies that examined management paradigms and collected acceptance, utilization, and adverse events; 17 of these studies qualified as Level I.</i></p> <p>After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is</p>

	<p>indicated yearly and as needed to troubleshoot PAP mask, machine, or usage problems (Option).</p> <p><i>This recommendation as an option is based on task force and SPC member consensus.</i></p>
<p>ICSI (2008)</p>	<p>One Month Follow-Up</p> <p>Key Points:</p> <ul style="list-style-type: none"> • Follow-up visits must address effective treatment and adherence. <p>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.</p> <p>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 which 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.</p> <p>Determination of the success of treatment should take into consideration:</p> <ul style="list-style-type: none"> • Patient and bed partner satisfaction • Complications of treatment (i.e., upper airway irritation, pain from CPAP or dental device, etc.). PAP 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 <p><i>[A], [D], [R]</i></p> <p>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. FDA for treatment <i>[B]</i>. However, it is the consensus of</p>

this work group that a thorough evaluation of risks and benefits be done before prescribing this medication.

PAP 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 www.sleepapnea.org, 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 OSAHS and bring their CPAP with them for their hospital stay [C].

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

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 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

	<ul style="list-style-type: none"> • Benign or malignant neoplasms <p>The surgical procedures listed in Annotation #9, "Treatment of Mild, Moderate, or Severe OSAHS" (in the original guideline document) are available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in clinical OSAHS. It may be necessary to correct the anatomical obstruction to increase the effectiveness of an OA or PAP device and a referral to ENT, a dentist or an orthodontist with special training in sleep apnea would be indicated [M].</p> <p>Ongoing Management</p> <p>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:</p> <ul style="list-style-type: none"> • The patient's equipment has been evaluated by qualified personnel. • Weight and blood pressure are checked. <ul style="list-style-type: none"> • 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. <p>Follow-up discussions may also include:</p> <ul style="list-style-type: none"> • 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
<p>SIGN (2003)</p>	<p>D - The use of intra-oral devices should be monitored following initiation of therapy to allow device adjustment and assessment of OSAHS control and symptoms.</p>

TABLE 5: BENEFITS AND HARMS

Benefits	
AASM (2006a)	Decreased incidence and severity of obstructive sleep apnea (OSA) and associated excessive daytime sleepiness, cognitive disturbances, depression, hypertension, cardiovascular disease, and cerebrovascular disease
AASM (2006b)	<ul style="list-style-type: none"> • Reduction of snoring to a subjectively acceptable level • Resolution of the clinical signs and symptoms of obstructive sleep apnea • Normalization of the AHI and oxyhemoglobin saturation
AASM (2006c)	<ul style="list-style-type: none"> • Increased correct patient utilization of positive airway pressure (PAP) devices • Improved clinical management of OSA • Identification of appropriate indications for BPAP as a second-line therapy
ICSI (2008)	Appropriate diagnosis and management of patients with OSA
SIGN (2003)	<ul style="list-style-type: none"> • Reduced daytime sleepiness • Improved driving performance • Improved quality of life • Reduced blood pressure • Improved mood
Harms	
AASM (2006a)	<ul style="list-style-type: none"> • Use of modafinil: Blood pressure must be monitored because of mild elevations reported in some OSA patients using modafinil. • Use of bariatric surgery: A cautionary note is warranted because of reports of recurrence of OSA after several years even without regaining of weight. Also, bariatric surgery is not without complications.
AASM (2006b)	Investigations show that there are many potential side effects and complications associated with OA therapy but most are minor and temporary and do not significantly affect appliance use. Many of the minor side effects (discomfort or excessive salivation) improved even with continued appliance use. However, others are more significant and do not necessarily resolve over time and may lead to discontinuation of oral appliance treatment. Some of the bite changes

	<p>did not resolve with cessation of therapy and more information is needed about the significance of these occlusal changes and the risks of long-term appliance use. Conceivably, these changes may be due to frank tooth movement, remodeling of the temporomandibular joint (TMJ) complex, or neuromuscular adaptation that may have an influence on the posture of the mandible. The response of some patients to exercises suggests that it may be related to a failure to reposition the mandible into the glenoid fossa. Additional cephalometric, radiographic, and clinical studies are needed to elucidate the importance of these changes.</p> <p>For further details on adverse events, see the companion review document listed in the "Availability of Companion Documents" field of the NGC summary.</p>
<p>AASM (2006c)</p>	<p>While sinusitis, mask leaks, and dermatitis are not infrequent, tinnitus and dyspnea occur more rarely. A listing of adverse events associated with PAP therapy is presented in Table 3 of the accompanying review paper (see "Availability of Companion Documents" field in the NGC summary of this guideline).</p>
<p>ICSI (2008)</p>	<p>PAP and dental device discomfort can be problematic, contributing to non-adherence. (Refer to Appendix B in the original guideline document for more information.)</p> <p>Potential Adverse Effects of Surgical Procedures</p> <ul style="list-style-type: none"> • <i>Tracheostomy</i> has been associated with significant social stigma due to the presence of a tracheostomy tube and the associated care of the tracheostomy site. • <i>Radiofrequency ablation of the soft palate and tongue base</i> requires multiple treatments and is associated with tissue erosion and perforation. • <i>Hyoid suspension</i> complications include dysphagia post-treatment.
<p>SIGN (2003)</p>	<p>Side Effects for CPAP</p> <p>Major side effects of CPAP use (e.g., significant epistaxis, paranasal sinusitis) are rare, but minor side effects (rhinitis, nasal bridge sores, discomfort, claustrophobia, abdominal bloating, noise) are common. Nasal symptoms are usually due to mouth leaks causing high flows of cool air through the nose. Attempts should be made to reduce these using chin straps or full face masks. In a few patients nasal corticosteroids can be useful. A heated humidifier may help to improve comfort and compliance.</p>

TABLE 6: EVIDENCE RATING SCHEMES AND REFERENCES

<p>AASM (2006 a-c)</p>	<p>Classification of Evidence</p> <p>Level I (Grade A Recommendation): Randomized well-designed trials with low-alpha and low-beta errors*</p> <p>Level II (Grade B Recommendation): Randomized trials with high-alpha and beta errors*</p> <p>Level III (Grade C Recommendation): Nonrandomized controlled or concurrent cohort studies</p> <p>Level IV (Grade C Recommendation): Nonrandomized historical cohort studies</p> <p>Level V (Grade C Recommendation): Case series</p> <p>*Alpha (type I error) refers to the probability that the null hypothesis is rejected when in fact it is true (generally acceptable at 5% or less, or $p < 0.05$). Beta (Type II error) refers to the probability that the null hypothesis is mistakenly accepted when in fact it is false (generally trials accept a beta error of 0.20). The estimation of Type II error is generally the result of a power analysis. The power analysis takes into account the variability and the effect size to determine if sample size is adequate to find a difference in means when it is present (power generally acceptable at 80 to 90%).</p> <p>Levels of Recommendations</p> <p>Standard: This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.</p> <p>Guideline: This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.</p> <p>Option: This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.</p>
<p>ICSI (2008)</p>	<p>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</p>

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:

	<ul style="list-style-type: none"> • Medical opinion
<p>SIGN (2003)</p>	<p>Levels of Evidence</p> <p>1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias</p> <p>1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</p> <p>1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</p> <p>2++: High quality systematic reviews of case control or cohort or studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</p> <p>2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</p> <p>2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</p> <p>3: Non-analytic studies, e.g., case reports, case series</p> <p>4: Expert opinion</p> <p>Grade of Recommendation</p> <p>The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.</p> <p>A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or</p> <p>A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</p> <p>B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or</p>

	<p>Extrapolated evidence from studies rated as 1++ or 1+</p> <p>C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or</p> <p>Extrapolated evidence from studies rated as 2++</p> <p>D: Evidence level 3 or 4; or</p> <p>Extrapolated evidence from studies rated as 2+</p> <p>Good Practice Point: Recommended best practice based on the clinical experience of the guideline development group</p>
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GUIDELINE CONTENT COMPARISON

The American Academy of Sleep Medicine (AASM 2006a, AASM 2006b, AASM 2006c), Institute for Clinical Systems Improvement (ICSI), and Scottish Intercollegiate Guidelines Network (SIGN) present recommendations for the management and treatment of OSA and provide explicit reasoning behind their judgments.

Guideline Methodology

The five guidelines were developed using similar methods. Electronic databases were searched to identify relevant publications (in the case of AASM 2006b, additional literature was identified by hand searches), the evidence was weighted according to a rating scheme, a systematic review of the evidence was conducted, and recommendations were formulated using expert consensus. With regard to the review of the evidence, AASM based their guideline statements on separately-prepared, systematic evidence reviews. Each of AASM's recommendation statements includes a grade denoting the strength of the recommendation. Each recommendation statement is also accompanied by narrative discussion that refers to the relevant supporting sections in the accompanying review paper or references found at the end of the guideline.

SIGN provides its guidance through explicit graded recommendations statements supplemented by narrative discussion. The ICSI guideline is presented in the form of an algorithm. It does not provide explicit recommendation statements; its guidance is provided entirely in narrative form. The class of research reports of supporting evidence is indicated for each algorithm annotation.

All guideline groups provide reference lists (65 references for AASM [2006a], 8 for AASM [2006b], 94 for AASM [2006c], 119 for ICSI, 158 for SIGN), and all also address potential conflicts of interest.

Areas of Agreement

Weight Reduction

AASM (2006a), ICSI, and SIGN agree that there is a strong association between obesity and OSA and that weight reduction may improve the condition. The AASM guideline recommends combining dietary weight loss with a proven treatment (such as PAP, oral devices, or surgery) in obese patients with OSA. According to ICSI, weight loss should be encouraged even in those OSA patients who are only moderately overweight, and a nurse-managed program of calorie restriction and behavior management is safe and cost-effective as a primary treatment for OSA. SIGN states that a weight loss of 10 to 15% has been associated with improvements in some markers of OSA (e.g., desaturation index), but there is only a weak correlation between the amount of weight lost and clinical improvement. Nonetheless, SIGN recommends encouraging weight loss in obese patients, with the caveat that weight loss attempts should not delay initiation of other treatment. The role of bariatric surgery in OSA patients is discussed below.

Position Therapy

AASM (2006a) and ICSI agree that sleeping with the body in a non-supine position can be effective for reducing apnea/hypopnea. According to ICSI, both the frequency of apneic events and their severity are worse in the supine than the lateral position. AASM indicates positioning is most likely to be effective in patients who are younger, less obese and have less severe OSA, and states that positioning should be used only as a supplement to primary therapies for OSA. AASM also recommends that when position therapy is used, an appropriate test should be performed to document the correction of OSA. The SIGN guideline addresses the topic of body positioning only briefly, stating that "non-sleepy snorers" should be advised to not sleep on their backs.

Positive Airway Pressure

Although the scope of the AASM guideline (2006a) does not include PAP therapy, the introductory section of the guideline states that PAP is the most effective therapy for OSA. While the AASM (2006b) guideline primarily focuses on the use of OAs for the treatment of OSA, they do recommend that patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. One AASM guideline (AASM 2006c) is devoted solely to PAP therapy. SIGN recommends CPAP as the first choice therapy for patients with moderate or severe OSAHS that is sufficiently symptomatic to require intervention. Mild OSA can also be treated with PAP, according to ICSI. AASM (2006c) similarly states that CPAP is indicated for the treatment of moderate to severe OSA, and is an option for the treatment of mild OSA.

APAP

ICSI recommends autoPAP for patients who are intolerant of pressures in conventional CPAP therapy; autoPAP may be used for in-home CPAP titration after a positive sleep study or when follow-up indicates a need for CPAP pressure changes. While autoPAP machines theoretically should be more comfortable than

conventional CPAP machines for long-term use, SIGN cautions that there is no strong evidence that autoPAP produces better outcomes. According to SIGN, autoPAP machines can be useful for troubleshooting problems with CPAP or when there are pressure requirement changes, such as following a change in weight. SIGN states that CPAP therapy should not be abandoned without using autotitrating CPAP to investigate problems. AASM (2006c) does not address APAP in this particular guideline, noting that it was not incorporated in the accompanying review paper since an earlier review and practice parameters for APAP was published in 2002.

BPAP

According to ICSI, bi-level PAP can have advantages for selected patients who do not tolerate CPAP or autoPAP. AASM (2006c) similarly notes that BPAP may be appropriate in cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present. AASM (2006c) and ICSI agree that bi-level PAP may also benefit those with concurrent or more severe lung diseases or hypoventilation syndromes associated with daytime hypercapnia. Both AASM (2006c) and ICSI note, however, that bi-level devices have not been demonstrated to be superior to CPAP and they should not be used as initial treatment for OSA. The SIGN guideline agrees, stating that bi-level PAP should be reserved for patients with ventilatory failure. All three guidelines refer to the same randomized study which found no advantage for bi-level PAP over CPAP for treating straightforward OSA.

The AASM (2006c), ICSI, and SIGN guidelines all stress the importance of patient compliance with PAP therapy, the need for proper mask/interface fit, and the need for frequent follow-up. AASM (2006c) and ICSI also notes that the addition of heated humidification and patient education program are indicated to improve PAP utilization.

Oral Appliances

There is general agreement among AASM (2006b), ICSI, and SIGN that patients with non-severe OSA are the most appropriate candidates for OAs.

According to AASM, OAs are appropriate for patients with mild to moderate OSA who: are not candidates for CPAP, prefer OAs to CPAP, or fail attempts at CPAP treatment or lifestyle modification. Although OAs can be used to manage severe OSA, AASM states that patients should first try CPAP because of its greater effectiveness; upper airway surgery may also supersede use of OAs for patients with severe OSA. Similarly, both ICSI and SIGN recommend OAs for patients with mild OSA; ICSI qualifies its recommendation, stating that these patients should have first tried and failed at lifestyle modification. Like AASM, ICSI and SIGN recommend OAs for patients who cannot tolerate PAP. SIGN states that evidence of the effectiveness of OAs in more severe OSA is limited by a lack of identifiable prognostic indicators for success.

AASM recommends that qualified dental personnel fit the OA and that a practitioner with training in sleep medicine oversee the dental management of the patient; the other guidelines do not specifically address this topic, although ICSI provides resources for locating qualified dental practitioners. Both AASM and SIGN

recommend follow-up care to allow adjustment of the appliance and assessment of OSA control. AASM recommends that patients undergo polysomnography or an attended cardiorespiratory sleep study with the OA in place after final adjustments of fit have been made. In addition, AASM specifies that once a good fit has been attained, patients should have follow-up visits with the dental specialist every 6 months during the first year and annually thereafter. Patients also should have follow-up visits with the referring clinician to monitor OSA control and, if control appears to worsen, clinicians should objectively reevaluate respiration during sleep.

Pharmacologic Therapy

SIGN states that pharmacologic therapy should not be used as first line therapy, noting that the main systematic review of pharmacotherapy concluded that no medication demonstrated a consistent response. AASM (2006a) concludes that SSRIs, protriptyline, methylxanthine derivatives, and estrogen therapy cannot be recommended. In addition, AASM recommends against short-acting nasal decongestants. They suggest, however, that topical nasal corticosteroids may be a useful adjunct to primary therapy in patients with comorbid rhinitis.

With regard to modafinil, AASM and SIGN agree that it may have a beneficial effect on residual daytime sleepiness in patients who have sleepiness despite effective PAP treatment. ICSI notes that while modafinil has been approved by the FDA for treatment, they recommend that a thorough evaluation of risks and benefits be done before prescribing this medication.

Surgical Interventions

The two AASM guidelines (2006a and 2006b) exclude upper airway surgical interventions from their scope, although AASM (2006a) does address bariatric surgery, and AASM (2006b) states that upper airway surgery may supersede the use of OAs in patients for whom these operations are predicted to be highly effective in treating OSA.

Tracheostomy

Both ICSI and SIGN agree that tracheostomy, which bypasses the obstruction completely, is a treatment of last resort, given the potential complications and social stigma associated with presence of a tracheostomy tube.

Tonsillectomy

SIGN notes that only case series are currently available to support use of tonsillectomy to improve OSA, but recommends referral of OSA patients with large tonsils to an ENT surgeon for consideration of tonsillectomy. The ICSI guideline states that it may be necessary to correct asymptomatic anatomical obstructions, including tonsillectomy, that contribute to mild OSA before prescribing an OA or PAP. The guideline notes, however, that there are no studies that evaluate the long-term effect of tonsillectomy on OSA.

The guidelines differ regarding the value of UPPP, mandibular advancement surgery, and bariatric surgery; these differences are discussed below.

Areas of Differences

The ICSI and SIGN guidelines differ in their assessment of certain surgical interventions to treat OSA.

SIGN explicitly recommends against UPPP, stating that no randomized clinical trials have been conducted and uncontrolled case series suggest at best only a 50% improvement in 50% of patients. In discussing the procedure, SIGN cites two review papers and a meta-analysis of laser-assisted UPPP. In contrast, the ICSI guideline cites similar figures for efficacy of the procedure (no citation provided), but is more supportive of the procedure, stating that "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." However, ICSI notes that a review of 292 UPPP studies by Pirsig and Verse (*Eur Arch Otorhinol* 2000;257:570) found only 6 long-term studies; the studies were uncontrolled and used different patient populations.

Mandibular Advancement

According to SIGN, there are no RCTs and only limited long term follow up data available, and the treatment remains experimental. ICSI, in contrast, concludes that mandibular advancement is successful for patients with base tongue obstruction, severe OSA, morbid obesity, and failure of other treatments. They add that with careful evaluation, results with maxillo-mandibular advancement surgery equal those of nasal CPAP.

Nasal Surgery

While SIGN states that nasal surgery may play a role in improving compliance with PAP, it recommends against its use outside of the context of a randomized clinical trial because there is no evidence that it produces an improvement in OSA symptoms. In contrast, ICSI includes septoplasty, nasal polypectomy and turbinoplasty in 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", and which, it says, may be necessary to correct before prescribing an OA or PAP.

Bariatric Surgery

Neither ICSI nor SIGN make an explicit recommendation for or against bariatric surgery, but acknowledge that it may be considered in appropriate patients. According to SIGN, the relative benefits and disadvantages of bariatric surgery to reduce weight in OSA patients can't be assessed based on available data, and this area is urgently in need of evaluation. ICSI notes that 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. They add that most relevant studies conducted to date have significant methodological limitations and lacked

adequate follow-up. In contrast to ICSI and SIGN, AASM makes a formal recommendation that bariatric surgery may be used as an adjunctive treatment for OSA in obese patients. Although AASM acknowledges that high quality clinical trial data for OSA patients is lacking, it supports bariatric surgery as an adjunct to first-line therapies based on the "many non-randomized, uncontrolled investigations" that show AHI improves with weight loss.

This synthesis was prepared by ECRI on May 17, 2007. The information was verified by ICSI on August 8, 2007, by SIGN on August 24, 2007, and by AASM on October 31, 2007. This synthesis was revised February 4, 2009 to update ICSI recommendations.

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