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#### **SPECIAL ARTICLES**

# The Veterans Administration and Department of Defense clinical practice guidelines for the diagnosis and management of sleep disorders: what does this mean for the practice of sleep medicine?

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In 2017 the Veterans Administration (VA) and Department of Defense (DOD) launched development of clinical practice guidelines (CPGs) for the diagnosis and treatment of sleep disorders, with the goal of informing and improving patient care. The guideline development process followed GRADE methodology, considering studies and systematic reviews published over the 10-year period prior to guideline development. A total of 41 recommendations were made,18 related to the diagnosis and treatment of obstructive sleep apnea (OSA) and 23 regarding chronic insomnia disorder. In contrast to other published guidelines, the VA DoD CPGs provide a comprehensive approach to diagnosis and management of the two most common sleep disorders, including a discussion of the sequencing of diagnostic approaches and treatment options. Regarding OSA, strong recommendations were made for follow-up evaluation after non-diagnostic home sleep apnea tests, positive airway pressure therapy as first-line treatment, and the incorporation of supportive, educational and behavioral interventions for patients at high risk for PAP therapy non-adherence due to comorbid conditions. Strong recommendations were also made for the use of cognitive-behavioral therapy for insomnia and against the use of kava (an herbal supplement) in the treatment of chronic insomnia disorder. These guidelines, while intended to directly inform care within VA and DOD, are broadly relevant to the practice of sleep medicine. The majority of scientific evidence was based on studies of non-military, non-veteran populations. The CPG is a major milestone for the VA and DOD in recognizing the importance of evidence-based treatments for sleep disorders in military personnel and veterans.

Keywords: sleep management, sleep disorders

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#### RATIONALE FOR CLINICAL PRACTICE GUIDELINES

In an effort to improve practice, quality of care, and outcomes for active-duty service members and veterans, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) develop clinical practice guidelines (CPG) intended to inform delivery of health care within these systems. These guidelines are also intended to serve a broader audience of health care providers and the public. In 2017, the VA and DOD embarked on an effort to develop guidelines for the diagnosis and treatment of sleep disorders. To achieve this goal, a work group was assembled, representing both agencies and multiple provider types and specialties. The guideline development process strictly adheres to the Grading of Recommendations Assessment, Development and Evaluation methods. <sup>2,3</sup>

This state-of-the-art CPG was completed and approved by the VA/DOD Evidence-Based Practice Work Group in 2019.<sup>4,5</sup> This CPG is a laudable milestone for these two organizations in recognizing not only the importance of sleep disorders but also that standardized practices are required to optimize outcomes for patients by standardizing the diagnosis and treatment of these common clinical conditions. Because of the high rates of both insomnia disorder and obstructive sleep apnea (OSA) in

military and veteran populations, <sup>6-8</sup> the work group elected to focus on these two common conditions. In fact, the CPG could not have been timelier, as diagnosis of sleep disorders has markedly increased in military and veteran populations, and comorbid conditions, such as posttraumatic stress disorder, other mental health disorders, and traumatic brain injury, further complicate their management. <sup>6-7,9</sup>

Whereas the VA/DOD CPG is directed toward providers who care for military service members and veterans, the vast majority of the included literature was from civilian studies, which makes the CPG relevant for all patients with chronic insomnia disorder and OSA. Another feature of the CPG is that this guideline is unique in sleep medicine as it is the only one that provides a comprehensive approach to these two most common sleep disorders. This feature contrasts with the current guidelines by the American Academy of Sleep Medicine, American Thoracic Society, and others that focus on one sleep disorder or specific aspects of a disorder, such as a single approach to diagnosis (eg, home sleep apnea testing, in-laboratory polysomnography), treatment (eg. pharmacologic therapy for insomnia, behavioral and psychological therapies for insomnia) but do not take a holistic view of patients with sleep-related complaints. The VA/DOD CPG is an evidence-based reference

# **Table 1**—Summary of the 41 Veterans Administration/Department of Defense recommendations for the treatment of chronic insomnia disorder and OSA.

#### Diagnosis and Assessment of OSA and Insomnia Disorder

- 1. For patients who report sleep complaints, we suggest using the STOP questionnaire to stratify the risk of OSA. (weak for)
- 2. We suggest that providers assess for sleep-disordered breathing in patients with a history of cardiovascular or cerebrovascular events, congestive heart, and chronic prescription opioid use. (weak for)
- 3. Among patients with a high pretest probability for OSA, we suggest a manually scored type 3 HSAT (unattended portable monitor) using an event index (ie, respiratory disturbance index, AHI ≥15 events/h to establish the diagnosis of moderate to severe OSA. (weak for)
- 4. For patients with a high pretest probability for OSA and a nondiagnostic HSAT (ie, technically inadequate or AHI <5 events/h), we recommend repeat (home sleep apnea testing or lab-based polysomnography) testing for OSA. (strong for)
- 5. For evaluating patients suspected of having insomnia disorder, we suggest using the Insomnia Severity Index or Athens Insomnia Scale as part of a comprehensive sleep assessment. (weak for)
- 6. No available evidence recommends for or against additional diagnostic testing for patients with chronic insomnia disorder who do not respond to CBT-I or pharmacotherapy. (neither for nor against)

#### Treatment and Management of OSA

- 7. We recommend that patients with OSA on PAP therapy use this treatment for the entirety of their sleep period(s) (strong for).
- 8. We suggest continuing PAP therapy for patients with OSA, even if the patient is using this treatment for <4 h/night. (weak for)
- 9. In patients with OSA, including those at high-risk for poor PAP adherence, such as those with posttraumatic stress disorder, anxiety, or insomnia, we recommend educational, behavioral, and supportive interventions to improve PAP adherence (strong for).
- 10. We suggest that patients with OSA and concurrent diagnoses/symptoms of posttraumatic stress disorder, anxiety, or insomnia be offered interventions to improve PAP adherence upon initiation of therapy. (weak for)
- 11. In appropriate patients with mild to moderate OSA (AHI <30/h), we suggest offering mandibular advancement devices, fabricated by a qualified dental provider, as an alternative to PAP therapy. (weak for)
- 12. Among patients with anatomical nasal obstruction as a barrier to PAP use, we suggest evaluation for nasal surgery. (weak for)
- 13. For patients with OSA with an AHI of 15–65/h and a body mass index <32 kg/m² who cannot adhere to PAP, we suggest evaluation for surgical treatment with hypoglossal nerve stimulation therapy. (weak for)
- 14. For patients with severe OSA who cannot tolerate or are not appropriate candidates for other recommended therapies, we suggest evaluation for alternative treatment with maxillomandibular advancement surgery. (weak for)
- 15. For patients with OSA who cannot tolerate or who have declined all other recommended treatments, we suggest offering alternative/salvage therapies. (weak for)
- 16. We suggest against oxygen therapy as a stand-alone treatment for patients with OSA who cannot tolerate other recommended therapies. (weak against)
- 17. For patients without nasal congestion, we suggest against the routine use of topical nasal steroids for the sole purpose of improving PAP adherence. (weak against)
- 18. Owing to the lack of clinically significant benefit, we cannot recommend for or against
- · autotitrating PAP compared with fixed PAP or
- the use of flexible pressure delivery (eg, C-Flex, expiratory pressure relief) to improve PAP adherence. (neither for nor against)

#### Treatment and Management of Chronic Insomnia Disorder

- 19. We recommend offering CBT-I for the treatment of chronic insomnia disorder. (strong for)
- 20. We suggest offering brief behavioral therapy for insomnia for the treatment of chronic insomnia disorder.
- 21. There is insufficient evidence to recommend for or against group versus individual CBT-I for the treatment of chronic insomnia disorder. (neither for nor against)
- 22. There is insufficient evidence to recommend for or against internet-based CBT-I as an alternative to face-to-face based CBT-I for the treatment of chronic insomnia disorder. (neither for nor against)
- 23. For patients diagnosed with chronic insomnia disorder, we suggest CBT-I over pharmacotherapy as first-line treatment. (weak for)
- 24. We suggest offering CBT-I for the treatment of chronic insomnia disorder that is comorbid with another psychiatric disorder. (weak for)
- 25. There is insufficient evidence to recommend for or against mindfulness meditation for the treatment of chronic insomnia disorder. (neither for nor against)
- 26. We suggest against sleep hygiene education as a stand-alone treatment for chronic insomnia disorder. (weak against)
- 27. We suggest offering auricular acupuncture with seed and pellet for the treatment of chronic insomnia disorder. (weak for)
- 28. There is insufficient evidence to recommend for or against acupuncture other than auricular acupuncture with seed and pellet for the treatment of chronic insomnia disorder. (neither for nor against)
- 29. There is insufficient evidence to recommend for or against aerobic exercise, resistive exercise, tai chi, yoga, and qigong for the treatment of chronic insomnia disorder. (neither for nor against)
- 30. We suggest against cranial electrical stimulation for the treatment of chronic insomnia disorder. (weak against)

(continued on following page)

**Table 1**—Summary of the 41 Veterans Administration/Department of Defense recommendations for the treatment of chronic insomnia disorder and OSA. (continued)

- 31. We suggest against the use of diphenhydramine for the treatment of chronic insomnia disorder. (weak against)
- 32. We suggest against the use of melatonin for the treatment of chronic insomnia disorder. (weak against)
- 33. We suggest against the use of valerian and chamomile for the treatment of chronic insomnia disorder. (weak against)
- 34. We recommend against the use of kava for the treatment of chronic insomnia disorder. (strong against)
- 35. In patients who are offered a short-course of pharmacotherapy for the treatment of chronic insomnia disorder, we suggest use of low-dose (ie, 3 mg or 6 mg) doxepin. (weak for)
- 36. In patients who are offered a short-course of pharmacotherapy for the treatment of chronic insomnia disorder, we suggest the use of a nonbenzodiazepine benzodiazepine receptor agonist. (weak for)
- 37. There is insufficient evidence to recommend for or against the use of ramelteon for the treatment of chronic insomnia disorder. (neither for nor against)
- 38. There is insufficient evidence to recommend for or against the use of suvorexant for the treatment of chronic insomnia disorder. (neither for nor against)
- 39. We suggest against the use of antipsychotic drugs for the treatment of chronic insomnia disorder. (weak against)
- 40. We suggest against the use of benzodiazepines for the treatment of chronic insomnia disorder. (weak against)
- 41. We suggest against the use of trazodone for the treatment of chronic insomnia disorder. (weak against)

AHI = apnea-hypopnea index, CBT-I = cognitive behavioral therapy for insomnia, HSAT = home sleep apnea test, OSA = obstructive sleep apnea, PAP = positive airway pressure, STOP = Snoring, Tiredness, Observed apneas, high blood Pressure.

for primary care physicians who increasingly treat these sleep disorders, as well as a reference for the sleep community potentially to address much needed policy changes to improve overall care for patients with sleep disorders.

Although this is the first time these organizations have addressed sleep disorders in a CPG, there are currently 21 evidence-based CPGs that address a spectrum of clinical disorders. The VA/DOD CPG development process adheres to a standardized evidence-based format, resulting in leadingedge CPGs that have been recognized by the Institute of Medicine, Grading of Recommendations Assessment, Development and Evaluation. 2,3,10,11 Some of the strengths of the process include the following: a working group composed of diverse providers to include primary care physicians, sleep specialists, dentists, otolaryngologists, psychologists, nurses, and pharmacologists, who were closely vetted for any potential conflicts of interest; focus on 20 key questions to address both the diagnosis and management of chronic insomnia disorder and OSA as they relate to military and veteran populations; and a patient focus group comprising active military personnel and veterans with either insomnia disorder or OSA or both. In addition, CPG development involved a rigorously developed peer-reviewed guideline using Grading of Recommendations Assessment, Development and Evaluation methods and working algorithms and provider and patient summaries and handouts. Ultimately, the collaborative and consultative role of the sleep specialist is also clearly highlighted in the CPG, particularly in the included algorithms for patient care.

The final guideline document included 41 recommendations (see **Table 1** and www.healthquality.va.gov). Comparison of the CPG with the current American Academy of Sleep Medicine (AASM) guidelines reveals largely consistent recommendations but also some important differences. Because the VA/DOD CPG is directed to primary-care providers and patients, this broader audience for the guidelines necessitated an overarching approach to diagnosis and management, beginning at identifying patients with high risk for insomnia disorder

or OSA. Historically, AASM guidelines have been intended to inform the practice of sleep medicine more directly; therefore, individual approaches to specific treatments are described in a way that can improve practice, primarily for sleep medicine specialists, and simply to inform primary care providers of the course of action a sleep specialist is likely to take. This broader approach can be seen in the overall CPG recommendations (see **Table 1**) and treatment algorithms (see www.healthquality.va.gov), which start with screening symptomatic patients for sleep disorders and highlight the shared decision-making process that is essential when multiple diagnostic or treatment options are available.

Another critical difference is that the evidence review that served as the basis for the VA/DOD CPG was strictly limited to publications within a 10-year window. The review also relied on systematic reviews as primary information sources, and additional evidence was not added beyond the initial literature search. Given the relative youth of sleep science and sleep medicine compared with other fields, this sometimes led to exclusion of seminal studies that have informed the clinical practice of sleep medicine for decades. Furthermore, when systematic reviews and randomized controlled trials were not available, or when there was conflicting evidence about benefits and harms, the recommendations specify "neither for nor against" to indicate that the direction (for or against) cannot be firmly established. Additionally, when looking at specific recommendations, the work group extrapolated from findings based on nonmilitary populations. For example, in developing the recommendation for use of the STOP (Snoring, Tiredness, Observed apneas, high blood Pressure) questionnaire to screen for OSA, the work group found that although the questionnaire has been validated in several populations, 12 it has not been validated in veteran or military populations, where it has instead been shown to perform less consistently. Thus, while aiming for an evidencebased guideline focused on military and veteran populations, recommendations were based on available scientific data that came primarily from civilian populations. Future research on military and veteran populations is needed to inform future guidelines.

#### **SUMMARY OF CPG RECOMMENDATIONS**

The VA/DOD CPG makes numerous evidence-based recommendations that are generally relevant to the management of patients with sleep complaints, a step that is often omitted from disorder-specific guidelines. Regarding chronic insomnia disorder, the CPG includes a strong for recommendation for cognitive behavioral therapy for insomnia as first-line treatment. This recommendation is consistent with current recommendations from the American College of Physicians<sup>13</sup> and other international guidelines where cognitive behavioral therapy for insomnia is recommended as first-line treatment over pharmacotherapy.<sup>14</sup> Of note, the recommendation of cognitive behavioral therapy for insomnia as first-line therapy differs from AASM guidelines, which do not compare pharmacotherapy to nonpharmacologic treatments in addressing how best to treat insomnia disorder. In addition to differences with AASM guidelines, the VA/DOD CPG includes a notable divergence from current practice regarding insomnia management to include a recommendation against sleep hygiene as stand-alone treatment for chronic insomnia disorder. Although this recommendation is unlikely to surprise sleep medicine specialists, who are aware of the other nonpharmacologic approaches with a stronger evidence base to support their use (eg, stimulus control, sleep restriction therapy), many primary-care providers still rely on sleep-hygiene education as their only approach to patients with chronic insomnia disorder.

In the VA/DOD CPG, pharmacotherapies are designated as second-line treatments, and recommendations are made in that context. Only low-dose doxepin and nonbenzodiazepine receptor agonists received favorable (weak for) recommendations, and all pharmacologic agents were recommended for short-term use only. The VA/DOD CPG also differs from AASM guidelines<sup>15</sup> regarding the use of ramelteon and suvorexant (insufficient evidence to recommend for or against) and benzodiazepines (weak against). The AASM's current guidelines include a weak for recommendation supporting use of these medications; however, this may be due to differences in the timing of publication of these two documents. These differences may be attributed to the fact that the CPG working group deliberated on new evidence addressing the efficacy and adverse effects associated with these drugs and took into consideration the potential harms that are of concern for activeduty military personnel in combat operations and the comorbid medical conditions present at higher rates in veterans that may further increase these risks (eg, traumatic brain injury, chronic respiratory disease). Finally, the VA/DOD CPG more fully addressed the use of complementary and alternative therapies, finding that diphenhydramine, melatonin, chamomile, and cranial electrical stimulation are not generally recommended (weak against) and noting a strong against recommendation for the use of kava in chronic insomnia disorder.

In the diagnosis and treatment of OSA, the VA/DOD CPGs also note that although both home sleep apnea testing and

polysomnography are viable options for the diagnosis of OSA in general, there are nuances to consider, including the patient's baseline risk, comorbid conditions, and the need for definitively ruling out sleep-disordered breathing in military populations with high occupational risk from sleepiness. AASM CPGs address each diagnostic method separately. In terms of treatment, positive airway pressure (PAP) therapy is the recommended treatment in both the AASM and VA/DOD CPGs; however, there is a key distinction in the recommendations. The AASM CPGs16,17 did not make recommendations regarding duration of PAP therapy; however, in light of concerns about withdrawal of treatment from patients who use PAP for <4 hours, the work group examined the literature on duration of use and concluded that evidence to support discontinuation of treatment <4 hours was not available, and some patients do receive benefit from treatment for <4 hours of use. The VA/ DOD CPG rendered a strong for recommendation, explicitly stating that patients with OSA treated with PAP therapy "use this treatment for the entirety of their sleep period(s)," making a weak for recommendation for continuation of PAP therapy even when used <4 hours per night. Recognizing that PAP adherence is a major barrier to effective OSA therapy, the CPG also made a *strong for* recommendation for use of educational, behavioral, and supportive interventions to improve PAP adherence, specifically noting those at high risk for poor adherence, such as those with posttraumatic stress disorder, anxiety, or insomnia disorder. As there are times when alternative treatments for OSA are required, the CPG made weak for recommendations regarding mandibular advancement device therapy for patients with an apnea hypopnea index <30 events/h and evaluation for surgical treatment with hypoglossal nerve stimulation or maxillomandibular advancement device use in appropriate candidates who were intolerant of PAP.

The newly released VA/DOD CPG provides an up-to-date comprehensive document designed to promote high-quality care of patients with chronic insomnia disorder and OSA. We envision that the CPG will provide a standardized framework for adoption and implementation of evidence-based management of chronic insomnia disorder and OSA in active-duty military personnel and veterans by clinicians both within and outside the DOD and VA systems and for those outside these systems who provide care to service members and veterans. We expect the guideline recommendations to have a direct and far-reaching clinical impact on the diagnosis and treatment of sleep disorders in VA and DOD patient populations. This CPG may also serve as a stepping stone toward developing additional guidelines for other sleep disorders by VA and DOD, such as hypersomnias and nightmare disorders. We encourage future studies assessing the outcome and costeffectiveness of the implementation of these guidelines with the VA and DOD health care systems.

#### **ABBREVIATIONS**

AASM, American Academy of Sleep Medicine CPG, clinical practice guidelines DOD, Department of Defense PAP, positive airway pressure VA, Veterans Administration

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#### SUBMISSION & CORRESPONDENCE INFORMATION

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