

RESONEA

Obstructive Sleep Apnea: Effective Intervention & Care

Provider Training Modules

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Module II: Confirming the Clinical Diagnosis of OSA



Module II: Diagnosis of OSA

OSA is clinical diagnosis based on a combination of symptoms and patient characteristics, supported by the results of sleep testing and a response to therapy.

- The diagnosis of OSA can be approached from the following framework:
 - Index of suspicion
 - Screening
 - Focused physical exam & sleep history /symptom inventory
 - Sleep test (in lab or at home)
 - Response to therapy



Module II: Index of Suspicion - Important

- Care providers should consider the possibility of OSA in a broad range of patients.
 - Sets the stage for establishing the diagnosis

• Detecting OSA is important, as most OSA remains undiagnosed ^{1,2,3}

- Approx. 20% of US adults have OSA, of whom 80-90% remain undiagnosed
- Undiagnosed OSA adds an estimated \$3.4 billion in US healthcare cost burden³
- The onset and natural history of OSA can be insidious:
 - Many patients do not volunteer that they snore.
 - People who live alone or without bed partners may be unaware of their snoring.
 - Sleepiness can develop gradually and patients are not always aware of the severity of their problem, despite
 - ✓ poor performance at work,
 - ✓ deteriorating social interactions, or
 - ✓ increased risk for accidents.



Module II: Index of Suspicion - Other Conditions

It is especially important to consider OSA as a potential contributing factor in these chronic conditions*:

- Hypertension especially if refractory to treatment
- Type II diabetes
- o Obesity BMI >35
- o Depression
- o Cardiovascular disease
 - arrhythmias including atrial fibrillation
 - heart failure
 - coronary artery disease
 - stroke/TIA
- Pulmonary hypertension

It is difficult to optimize treatment for these conditions, if underlying OSA remains undiagnosed and untreated.

Module II: Index of Suspicion - Symptoms

OSA can be a causative or an aggravating factor for:

- Headaches
- GERD
- Nocturia
- Sexual dysfunction
- Poor concentration
- Irritability
- Cognitive impairment

Reduction in symptoms may be difficult to achieve if OSA is not identified and treated.



Module II: Index of Suspicion – Populations & Cardinal Features

It is important to consider OSA in certain populations:

- High risk driving populations (truck drivers, train or ferry operators)
- Other occupations where public safety is at risk if patient is sleepy (air traffic control, power plants, construction equipment, etc.)
- Patients being evaluated for bariatric surgery

And of course in patients with any of the cardinal features of OSA:

- o Loud snoring
- Choking or gasping for breath during sleep
- o Interruptions in breathing during sleep
- o Excessive daytime sleepiness



Module II: Screening

- Screening all adult patients for OSA is a reasonable strategy to avoid missing the diagnosis
- o Over the years questionnaires have been developed to assist in OSA screening
- Two of the most useful include:
 - STOP/BANG used to identify a patient's risk for OSA
 - Epworth Sleepiness Scale quantifies a person's day time sleepiness
- \checkmark Both of these questionnaires should be used
- ✓ They provide somewhat different & complementary information



Take this quick survey to complete your profile: (Check appropriate box)				No
1	S	Do you snore loudly louder than talking or can be heard through closed doors?		
2	Т	Do you often feel tired, fatigued or sleepy during the day? (Driving or talking with someone)		
3	0	Has anyone observed you stop breathing during sleep?		
4	Ρ	Do you have or are you being treated for high blood pressure ?		
5	В	Is your BMI (body mass index) > 35?		
6	Α	Is your age 50 years or more?		
7	Ν	Is your neck size 17 or larger (if male) or 16 or larger (if female)?		
8	G	Is your gender male?		

Scoring the STOP/BANG: Total "Yes" Answers 0-2 = Low risk 3-4 = Moderate risk 5-8 = Severe risk



Module II: Validation STOP/BANG Questionnaire

- The STOP/BANG questionnaire was initially validated in pre-operative patients. (Chung et al, Anesthesiology; 2008)
- STOP/BANG was subsequently validated in other populations.
- O In primary care population: (Silva et al, J Clin Sleep Med; 2011)
 - Sensitivity of STOP/BANG score ≥ 3 to detect moderate-to-severe OSA (AHI > 15) and severe OSA (AHI > 30) is 93% and 100%, respectively.
 - Specificity is 30% and 29%, respectively.
 - Consistent with others studies demonstrating that STOP/BANG has high sensitivity but low specificity
- Additional STOP/BANG validation studies discussed & summarized. (Chung et al (CHEST 2016)
- Patient risk for OSA can be determined with STOP/BANG scores:
 - 0-2 = low risk for moderate-to-severe OSA
 - 3-4 = intermediate risk for moderate-to-severe OSA
 - 5-8 = high risk for moderate-to-severe OSA
 - Those at intermediate risk can be further classified to high risk if BMI >35 or neck circumference ≥ 17" for men or ≥ 16" for women.



Module II: Screening With Epworth Sleepiness Scale (ESS)

- The ESS is a patient-rated questionnaire to measure excessive daytime sleepiness.
- Used to assess the patient's likelihood of falling asleep during 8 normal daytime activities or setting.
- Popular screening tool among physicians, as it is easy to score.
- O Developed in 1990 and subsequently validated (John M, Sleep; 1991)
- Slightly modified in 1997.

Epworth Sleepiness Scale is used to:

- o Subjectively measure sleepiness as it occurs in ordinary life situations.
- o Screen for excessive daytime sleepiness.
- Establish a sleepiness baseline prior to initiating a treatment in patients diagnosed with OSA, and in follow-up to help assess patient response to the intervention.



Module II: Scoring The Epworth Sleepiness Scale

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

This refers to your usual way in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation.

Epworth Sleepiness Scale:	Never would doze off	Slight Chance of dozing	Moderate Chance of dozing	High Chance of dozing
1. Do you get sleepy, or doze off, while sitting and reading?	0 🗆	1 🗆	2□	3 🗆
2. Do you get sleepy, or doze off, while watching TV?	0 🗆	1 🗆	2□	3 🗆
3. While sitting or inactive in a public place (meeting, theater)?	0 🗆	1 🗆	2□	3 🗆
4. As a passenger in a car for an hour without a break?	0 🗆	1 🗆	2□	3 🗆
5. Lying down to rest in the afternoon?	0 🗆	1 🗆	2□	3 🗆
6. Sitting and talking to someone?	0 🗆	1 🗆	2□	3 🗆
7. Sitting quietly after lunch without alcohol?	0 🗆	1 🗆	2□	3 🗆
8. In a car, while stopped for a few minutes at a traffic light?	0 🗆	1 🗆	2□	3 🗆

(sum of all numbers checked above) Total Score

Scoring the EPWORTH: 0-10 = Normal range in adults 11-12 = Mild sleepiness 13-15 = Moderate sleepiness 16-24 = Severe sleepiness



Module II: Framework For OSA Diagnosis

$\,\circ\,$ Index of suspicion

 \checkmark You have identified patients in whom you worry about OSA.

\circ Screening

- ✓ You have administered the STOP/BANG and ESS questionnaires to those you suspect of having OSA.
- ✓ Or you screen all your adult patients periodically with these tools.

Now it's time to focus on physical exam findings and obtain an OSA-oriented history.



Module II: OSA-Focused Physical Exam

I. Confirm from STOP/BANG:

- o BMI
- o Neck circumference
- o Blood pressure
- II. Examine the head does the patient have retrognathia?
 - o A congenital condition jaw recessed posteriorly?
 - Most commonly affects lower jaw (mandible), but can also effect upper jaw (maxilla).

III. Examine the pharynx – are there anatomical features that narrow the airway?

- \circ Large tongue?
- o Enlarged uvula?
- High arched palate?
- o Hypertrophy of tonsils or adenoids?







Module II: OSA-Oriented Medical History

Cardinal features of OSA

• Loud, frequent snoring; pauses in breathing or observed reports of choking/gasping during sleep; daytime sleepiness

$\,\circ\,$ Past Medical History of conditions associated with OSA

Including hypertension, type II diabetes, cardiovascular disease, depression, stroke & TIA

Symptoms associated with OSA

Headaches, GERD, non-restorative sleep, irritability, cognitive difficulties, erectile dysfunction, nocturia,

\circ Symptoms suggesting sleep disorders other than OSA

- Limb movements during sleep Restless Leg Syndrome (RLS), periodic limb movement disorder (PLMD), or seizures?
- Sudden, brief loss of voluntary muscle tone (cataplexy) narcolepsy ?
- Poor sleep hygiene insufficient amount of sleep; caffeine excess; or food, alcohol, exercise too close to bed time? These
 may cause or contribute to excessive daytime sleepiness.

$\,\circ\,$ Conditions that may alter the choice of sleep testing prescribed:

- Severe chronic obstructive lung disease or congestive heart failure?
- Morbid obesity of Pickwickian syndrome?

In clinical practice, it is helpful to gather, organize and store this information using a dedicated sleep history questionnaire or app.



Module II: Use of OSA-Oriented History & Physical Exam

• Supplements the STOP/BANG and ESS questionnaires in assessing OSA risk.

• Helps guide a decision regarding whether sleep testing or other evaluation is needed.

• Assists with the type of sleep testing ordered.

• Provides context for interpreting and acting on the results of sleep testing.

• Establishes a baseline to assess effectiveness of OSA treatment and/or other interventions.



Module II: Indications For Sleep Test

A sleep test should be prescribed if one of the following conditions is met:

○ High risk for OSA on STOP/BANG (score \geq 5)

or

 Unexplained excessive daytime sleepiness on ESS (score > 10)

or

• Snoring plus A or B or C:



Adapted from AASM guidelines (Epstein 2009) and UpToDate: Clinical presentation and diagnosis of OSA in adults (Kline 2016)

- A. Mission-critical occupations: commercial truck drivers, bus drivers, chauffeurs, pilots, etc.
- B. Presence or history of one of these associated conditions:
 - Hypertension
 - Type 2 diabetes
 - Cardiovascular disease (coronary disease, congestive heart failure, arrhythmia)
 - Cerebrovascular disease (Stroke or TIA)
 - Depression

C. 2 or more of these clinical features of OSA:					
Witnessed apneas during sleep	GERD				
Choking during sleep or awakening	Nocturia				
Gasping during sleep	Morning headaches				
Nocturnal restlessness	Vivid, strange or threatening dreams				
Insomnia with frequent awakenings	Non-restorative sleep				
Daytime sleepiness	Large neck: ≥ 17 men, ≥ 16 women				
Cognitive impairment	Crowded airway				
Difficulty concentrating	Obesity – BMI ≥ 35				
Mood changes	Cor pulmonale findings (edema, jugular vein distention)				

Module II: Sleep Testing Options

There are three conventional testing options to confirm a diagnosis of OSA.

A fourth method, using a bedside smartphone app, is currently in development as a novel diagnostic tool to facilitate confirmation of OSA.

Polysomnography (PSG)

• Home sleep testing (HST)

• Test Trial of Auto-titrating Continuous Positive Airway Pressure (APAP)

DROWZLE smartphone app



Module II: Polysomnography (PSG)

- PSG was originally developed in 1972 at Stanford University, as a research tool for the comprehensive study of sleep in a laboratory setting.
- While not intended for OSA, PSG was adapted for testing to support its diagnosis.
- PSG's are performed overnight in a sleep lab.
- Entails monitoring the patient with at least 7 channels, many of which are not needed to evaluate patients with suspected OSA.
- The principal channels focused on OSA are:
 - Airflow sensors to help identify apneas and hypopneas
 - Pulse oximetry to measure O₂ saturation & help identify apneas and hypopneas
 - Chest/abdominal belts to assess breathing effort & help distinguish central vs. obstructive apneas
 - EEG to measure sleep stages and arousals
- o Multiple other channels include measurements of:
 - Chin electromyography (EMG)
 - Electrooculography (EOG)
 - Electrocardiogram (ECG)
 - Leg movements/myotonic function



Module II: OSA-Related Diagnostic Measurements From PSG

• Apneas - cessation, or near cessation, of airflow.

- Documentation of \geq 90% decrease in airflow, compared with preceding signals, for a minimum of 10 seconds.
- Hypopneas reduced airflow that does not meet apnea criteria, but includes all of the following:
 - Reduction of airflow decreases at least 30 percent compared with the pre-event baseline
 - The diminished airflow lasts at least 10 seconds
 - The event is associated with either ≥3% oxygen de-saturation from baseline and/or an EEG arousal (or ≥4% de-saturation if arousals not counted)*

• Apnea/Hypopnea Index (AHI) - The number of apneas + hypopneas identified, divided by the total sleep time in hours

- Related measurement terms referred to by the American Academy of Sleep Medicine (AASM):
 - Arousal EEG disturbance during sleep lasting at least 10 seconds
 - Respiratory Effort Related Arousal (RERA)- An event that causes an arousal or a decrease in oxygen saturation, without qualifying as an apnea or hypopnea
 - Respiratory Distress Index (RDI) The number of apneas + hypopneas + RERAs identified, divided by the total sleep time in hours

Note that Medicare does not consider RERA's for supporting a diagnosis of OSA for CPAP coverage.

*Medicare also considers a 4% oxygen de-saturation the threshold criteria for hypopneas

and most sleep labs are now report AHI based on 4% de-saturations.



Module II: PSG Findings To Support An OSA Diagnosis

○ **≥5 apneas or hypopneas per hour of sleep (AHI ≥ 5)** in a patient with one or more of the following:

- Sleepiness, non-restorative sleep, fatigue, or insomnia symptoms
- Waking up with breath holding, gasping, or choking
- Habitual snoring, breathing interruptions, or both noted by a bed partner or other observer
- Hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus
- ≥15 apneas or hypopneas per hour of sleep (AHI ≥ 15), regardless of the presence of associated symptoms or co-morbidities.
- Response to treatment: Medicare will cover treatment for CPAP when the diagnosis of OSA is supported by the findings above and the patient subsequently demonstrates an improvement in symptoms while on CPAP during a 12 week period.



Module II: Advantages of PSG

- Long history as the reference standard test to support the diagnosis of OSA.
- Patient is tested under controlled/monitored conditions
 - Allows of identification of central sleep apnea in patients with heart failure, COPD, and obesity hypoventilation syndrome, Pickwickian syndrome
 - Many of these patients have coexisting OSA and central apnea
 - Allows for identification and diagnosis of other sleep disorders:
 - Periodic leg movement disorder (PLMD)
 - Narcolepsy
 - Nocturnal seizures

Fixed-dose CPAP can be titrated

• 'Split night study' – Usually if AHI >30 during a 2 hour period, then CPAP is initiated.

• EEG channels allow:

- Determination of actual sleep time (versus monitoring time)
- Detection of arousals, which can be a subtle effect of OSA
- However, PSG measurement of arousals has its problems:
 - ✓ Some arousals may not be clinically significant rationale for Medicare not to recognize Respiratory Effort Related Arousal (RERA) and RDI.
 - ✓ Reader variation on what constitutes an arousal also muddles the scoring of hypopneas.
 - ✓ The same PSG study can have variable AHI scores, depending on how arousals are interpreted.



Module II: Disadvantages of PSG

• Sleep labs are an uncomfortable environment for sleeping – not patient-friendly

- Multiple sensors and wires
- Common for patients to lie awake and not sleep, resulting in a false negative test result "first night effect"
- Single night studies have demonstrated 9% 43% false negatives due to first night effect & night-to-night variability¹

○ Expensive

- Professional + facility fees paid = \$1,000-3,000 depending upon the payer and location
- Co-pay a hardship for patients, especially those in high deductible plans
- **o** Not available in all regions, especially rural areas

$\,\circ\,$ Conducted over a single night

- Numerous studies have demonstrated that OSA has considerable night-to-night variability
- Diagnosis can be missed in a single night test²

o Inconsistent scoring has been documented with considerable inter-rater variability²

- Arousal issues are not uniformly recognized and scored
- Other hypopnea scoring issues are affected by changing scoring criteria in AASM Guidelines every 3-4 years
- AHI measurement is flawed (despite being considered the standard)
 - AHI correlates poorly with consequences of OSA, such as daytime sleepiness and cognitive impairment
 - AHI does not predict the response to CPAP therapy

Module II: Home Sleep Tests (HST)

o Accepted alternative test to help support a diagnosis of OSA

- Testing done in the patient's home, often over several nights
 - Testing in natural sleep environment facilitates accurate results, reduces "first night" effect seen in PSG labs
 - Facilitates multi-night testing, for more accurate picture of sleep breathing patterns¹
 - Less expensive alternative to in-lab testing
- Entails a portable monitor to measure the **most pertinent channels for OSA**: ventilation, airflow, heart rate and oxygen saturation

• HST has been validated vs. PSG ²

- Head-to-head comparisons in the same patient on the same night
- PSG vs HST in the same patient on successive nights
- Comparison studies have demonstrated reasonable correlation, although not 100%
- Randomized controlled trials comparing outcomes (improvement with CPAP) in patients getting PSG + in-lab CPAP titration vs. HST + auto-titrating APAP
- Compelling results: several randomized controlled trials have demonstrated outcomes as good or better in the HST+ auto-titrating APAP arms than with PSG³

• Since 2007, Medicare has accepted HST as an alternative for patients with a high pre-test probability for OSA

- Private payers also cover HST
- Many private payers now require HST as an alternative to PSG





Module II: HST Findings To Support An OSA Diagnosis

$\circ \geq 5$ apneas or hypopneas per hour of sleep (AHI ≥ 5) in a patient with one or more of the following:

- Sleepiness, non-restorative sleep, fatigue, or insomnia symptoms
- Waking up with breath holding, gasping, or choking
- Habitual snoring, breathing interruptions, or both noted by a bed partner or other observer
- Hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus
- ≥15 apneas or hypopneas per hour of sleep (AHI ≥ 15), regardless of the presence of associated symptoms or co-morbidities.
- Response to treatment: Medicare will cover treatment for CPAP when the diagnosis of OSA is supported by the findings above AND the patient subsequently demonstrates an improvement in symptoms while on CPAP during a 12 week period.

These are identical to the PSG criteria to support a diagnosis of OSA.



Module II: Advantages of HST

- **o** Testing is conducted in the patient's own natural sleep environment
 - Allows privacy and comfort of testing in patient's own home and bed, without sleep tech observation
- Allows for multiple nights of testing without prohibitive additional testing charge

$\circ\,$ Less expensive than PSG

- \$300-500 for HST vs. \$1,000-3,000 for PSG
- Automated scoring without the confusion of an "arousal" factor
 - Less variability than technician scoring in a sleep lab

• Auto-titrating APAP is dynamic and more physiologically responsive than the titration of fixed-dose CPAP

- Auto-titration alters the air pressure based on the patient's current needs
- APAP pressures can change as the patient's condition changes (i.e. weight gain or reduction)
- APAP is more comfortable and generally better tolerated by patients than CPAP
- APAP eliminates the titration step of another sleep lab visit



Module II: Disadvantages of HST

○ Logistical challenges

- Getting the device to the patient
- Proper assembly & hook up
- Returning the device for data extraction, cleaning, etc.
- Cost better than PSG, but still an issue for patients who have not hit their insurance out-of-pocket maximum

Patient is not monitored during the study

- HST not a good alternative if there is a need to distinguish central apnea vs. OSA, or if needed in patients with severe CHF or COPD.
- HST not an appropriate test if attempting to rule-in or rule-out narcolepsy, nocturnal seizures, or periodic limb movements.
- Auto-titrating APAP may not be the best option for patients with Pickwickian syndrome.

• AHI is calculated based on the duration of the study (recording time), not duration of sleep

May result in an underestimating of AHI, in comparison with PSG

• As was the case for PSG, AHI is the principal measured outcome:

- Correlates poorly with consequences of OSA, such as daytime sleepiness and cognitive impairment.
- Does not predict the response to CPAP.
- AHI is an inherently poor measure of symptoms and response to treatment.



Module II: Test Trial of Auto-titrating APAP

• This is an **emerging diagnostic approach**, in which patients with high pre-test probability of OSA are placed on auto-titrating APAP and **followed for their clinical response**.

o Rationale:

- Properly screened patients referred for OSA testing have high likelihood of having OSA
- AHI derived by PSG or HST does not predict response to CPAP.
 - ✓ This is why Medicare requires documentation of response to CPAP as part of the diagnostic workup of OSA.
- CPAP is safe.
- People without OSA do not respond to CPAP.
- It is logical to use a clinical response to CPAP as a key factor to support the diagnosis of OSA- as long as the patients are followed carefully.
- Two randomized controlled trials support this approach:
 - Senn et al, *Chest;* 2006 and Drummond et al, *J Clinical Sleep Med;* 2010
 - In both studies, patients with a high pre-test probability of having OSA were randomized to either 1) usual care, 2) PSG & inlab CPAP titration, or 3) a test trial of auto-titrating APAP.
 - Similar improvements in symptoms (ESS) were achieved with both strategies, PSG + CPAP or trial with auto-titrating APAP.
 - ✓ Senn: At 4 months, symptom response to auto-titrating APAP had positive and negative predictive values of 92% and 100% respectively. Of those who initially responded to auto-titrating APAP at 2 weeks, 94% remained on treatment at 4 months.
 - ✓ Drummond: The auto-titrating APAP arm had initial ESS improvement at 1 month, which was sustained at 2 months.
 - Patient responses to auto-titrating APAP assisted in supporting the diagnosis of OSA.

Module II: Advantages of Test Trial of APAP

• The empiric approach makes sense.

• Avoids costs and hassles of PSG and HST.

• The strategy directly addresses the core issue: the **patient's clinical response to treatment**.



Module II: Disadvantages of Test Trial of APAP

o This is an emerging strategy

- Not mentioned in the American Academy of Sleep Medicine Guidelines for the evaluation and management of OSA (last updated in 2009).
- Some insurers may require that the patient fails a test with fixed-dose CPAP before paying for APAP.
- Because it's not mentioned in guidelines, instructions in text books and review articles are lacking.
 - Wise to initiate test trials of auto-titrating APAP in conjunction with an OSA care management program, ideally with a therapy adherence component.

- **Requires close follow-up** (and may still require conventional testing):
 - Those who do not improve with APAP will require PSG or HST test.
 - Those who do respond and adhere to treatment can be managed with a presumptive OSA diagnosis.
 - ✓ Some may not be comfortable with a presumptive OSA diagnosis supported by a test trial of APAP and will want additional testing with PSG or HST.



Module II: DROWZLE Smartphone App

- An **app-based method** uses proprietary software algorithms to interpret sleep breathing sounds & patterns, recorded overnight with a bedside smartphone app, to accurately detect the presence and severity of OSA.
- The app also establishes probability and risk factors for OSA:
 - Collects STOP/BANG and ESS data from user.
 - Collects personal risk factors, such as comorbid diseases and ethnicity.
 - Collects and tracks nightly sleep diary information, such as caffeine or alcohol usage.

• Cost-efficient method for screening & monitoring of risk factors for OSA.

- Currently for screening purposes only
- Not yet cleared as a diagnostic tool, although that is the ultimate goal.

• **Removes major patient barriers to OSA diagnosis:**

- Helps to overcome poor consumer education & risk awareness about OSA.
- Counters limited PCP training for sleep health assessment.
- Provides alternative to patients who avoid sleep labs.
- Eliminates variability in sleep lab tech interpretations.
- Affordable alternative to high cost of sleep labs (\$1500 3000) and traditional home sleep tests (\$300 500).
- Patients test in the **natural sleep environment** of their own home.
 - Multi-night testing improves any sleep test accuracy.
 - App makes multi-night testing feasible at no additional cost.



Module II: Diagnostic Evaluation for OSA

• Challenges

- Onset and course can be insidious
- Many patients to evaluate
- Clinical diagnosis no single "test"

• Framework

- Index of suspicion
- Screening tools (ESS, STOP/BANG, DROWZLE)
- Focused history and exam findings
- Supporting the diagnosis (PSG, HST, EMPIRIC APAP)
- Evaluation results should be interpreted and acted upon in the context of the patient's symptoms:
 - Criteria for supporting diagnosis of OSA include symptoms/response to therapy
 - Symptomatic patients in whom a diagnosis is not supported will require further monitoring & evaluation (e.g. re-testing, alternative test strategy, specialty consultation)



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