EVIDENCE PRESENTATION

Outline

- Summary of AHRQ review
- New evidence following AHRQ review
- Region-specific utilization and cost data
- Clinical guidelines/coverage policies
- Comparative value analyses
  - Cost-effectiveness
  - Budgetary impact

AHRQ Review*

- Diagnosis: 4 key questions
  1. Ability of different sleep tests to accurately diagnose OSA
  2. Comparison of phased to full testing
  3. Effect of preoperative screening for OSA on surgical outcomes
  4. Relationship of OSA severity indices to long-term clinical and functional outcomes
- Focus on *#1 and 2*

*Balk E et al. AHRQ Comparative Effectiveness Review #32.

AHRQ Review*

- Treatment: 3 key questions
  5. Effectiveness of different treatments for OSA
     a) Variation by subgroup
     b) Variation by OSA definition
  6. Association of baseline patient characteristics with nonsurgical treatment compliance
  7. Effectiveness of different interventions to improve compliance on intermediate and clinical outcomes
- Focus on *#5 and 7*

*Balk E et al. AHRQ Comparative Effectiveness Review #32.

OSA Diagnosis Options

- Polysomnography (PSG): gold standard
- Home sleep monitors:
  - Type II: equivalent to PSG
  - Type III: do not record asleep/awake time, but ≥2 respiratory channels
  - Type IV: do not meet Type III criteria, but usually record ≥2 bioparameters
- Sleep questionnaires (e.g., Berlin, STOP-Bang)
- Clinical prediction rules (e.g., morphometric model)

OSA Treatment Options

- Continuous Positive Airway Pressure (CPAP)
- Mandibular Advancement Devices (MAD)
- Surgical procedures (e.g., uvulopalatopharyngoplasty [UPPP])
- Intensive weight loss programs
- Other (e.g., drugs, palatal implants)

Evidence: Diagnosis

- Type II monitors vs. PSG
  - Strength of evidence: low (no recent studies)
  - Accurate at identifying apnea-hypopnea index (AHI) levels suggestive of OSA
  - Measurement differences vs. PSG may be seen
- Type III/IV monitors vs. PSG
  - Strength of evidence: moderate
  - Accurate for OSA diagnosis, but different AHI thresholds often applied
  - No evidence to distinguish performance of Type III vs. IV

Evidence: Diagnosis

- Questionnaires vs. PSG
  - Strength of evidence: low (Berlin questionnaire)
  - Berlin questionnaire "moderately" accurate (sens/spec <90%) to screen for OSA; evidence insufficient for others
- Clinical prediction rules vs. PSG
  - Strength of evidence: low
  - Some prediction rules (e.g., morphometric measurements, pulmonary function) may be useful, but lack independent validation
- Phased testing vs. PSG alone
  - Strength of evidence: insufficient

Evidence: Treatment

- CPAP vs. control
  - Strength of evidence: moderate
  - CPAP has positive impact on intermediate outcomes (e.g., AHI reductions of ~20 events/hr, sleepiness) vs. sham CPAP or no treatment
- Comparison of multiple CPAP types
  - Strength of evidence: variable
  - Evidence indicates either no difference in outcomes or compliance (e.g., fixed vs. auto CPAP) or is insufficient to distinguish performance of different devices

9

Evidence: Treatment

- MAD vs. control
  - Strength of evidence: moderate
  - MAD has positive impact on intermediate outcomes (e.g., AHI reductions of ~12 events/hr, sleepiness) vs. sham MAD or no treatment in those without comorbidity or excessive sleepiness
- Comparison of multiple oral device types
  - Strength of evidence: insufficient
- MAD vs. CPAP
  - Strength of evidence: moderate
  - CPAP superior to MAD when compared on AHI (reductions of ~8 events/hr), no consistent impact on sleepiness

10

Evidence: Treatment

- Surgery vs. control, CPAP, or MAD
  - Strength of evidence: insufficient
  - Few RCTs
  - Most available studies: no differences vs. active treatment
- Weight-loss interventions vs. control
  - Strength of evidence: low
  - Statistically-significant reductions in AHI w/diet restrictions (4-23 events/hr)
- Other treatments vs. control
  - Strength of evidence: insufficient

11

Evidence: Compliance

- Interventions to improve compliance
  - Strength of evidence: low
  - Some interventions may improve CPAP compliance (e.g., additional educational materials, cognitive-behavioral therapy) among patients with severe OSA
  - No compliance interventions were shown to have any effect on clinical outcomes

12

NEW EVIDENCE FOLLOWING AHRQ REVIEW

New Evidence

- Search conducted 8/2011 – 9/2012

Diagnosis

- Findings on diagnostic accuracy from new studies of home testing, questionnaires, and clinical prediction rules similar to AHRQ review

Diagnosis + Treatment

- 1 new large RCT* (n=296) found similar improvements in sleepiness symptoms for home-tested patients receiving autoCPAP vs. lab-tested patients receiving fixed CPAP

*Kuna ST et al. *Am J Respir Crit Care Med* 2011.

New Evidence

Treatment

- 1 new RCT of CPAP vs. no treatment[†] found no difference in incidence of hypertension or CV events at 4 years
- 1 new RCT of CPAP vs. MAD[‡] found maintenance of reduced AHI at 1 year for CPAP, but not for MAD
  - AHI reduction of ~6 events/hr vs. baseline for CPAP, increase of 0.1 events/hr for MAD (p=.001)

†Barbe F et al. *JAMA* 2012.
‡Aarab G. et al. *Respiration* 2011.

New Evidence

Treatment (cont'd)

- Surgery: no new RCTs of surgery to nonsurgical control group
- 3 new RCTs of exercise/weight-loss interventions showed statistically-significant reductions in AHI (4-13 events/hr) compared to controls
  - No significant weight loss observed among treated patients

**CLINICAL GUIDELINES/
COVERAGE POLICIES**

17

Guidelines (AASM, ICSI, NICE)

- Diagnosis:
  - AASM considers full-night PSG the recommended approach for OSA diagnosis
    - Split-night studies a reasonable option if AHI ≥40 events/hr or if 20-40 events/hr after at least 2 hours of PSG
  - ICSI considers split-night PSG preferred approach when feasible
  - AASM & ICSI suggest that home monitors be restricted to patients with high pretest probability of OSA or in those who cannot complete PSG
    - ICSI further suggests that negative home tests be followed by PSG
  - NICE considers home testing the first-line option for diagnosing moderate-to-severe OSA

18

Guidelines (AASM, ICSI, NICE)

- Treatment:
  - AASM and ICSI consider CPAP a reasonable option for OSA of any severity
    - NICE considers CPAP appropriate for mild OSA only when lifestyle modifications (e.g., reduced alcohol/cigarette use, weight loss) and other treatment options have failed
  - MADs considered a reasonable option for mild-to-moderate OSA or in those intolerant of CPAP
  - Surgery considered first-line only in patients with anatomic abnormalities or in those intolerant to MAD/CPAP therapy
  - Lifestyle modifications generally recommended as an adjunct intervention where relevant

19

Coverage Policies: Public

Diagnosis

- Medicare NCD published in 2009 covers PSG and home monitoring for patients with clinical signs and symptoms of OSA:
  - Type IV monitors covered if recording 3+ channels (including airflow)
- At least 2 Medicaid agencies in New England do not cover home testing for OSA (CT, VT)

20

5

Coverage Policies: Public

Treatment

- Medicare NCD published in 1986 and updated in 2008 covers CPAP in patients with AHI ≥15 or in those with AHI 5-14 and ≥1 symptom (e.g., insomnia, hypertension)
- Indications for MAD coverage similar to CPAP in LCDs
  - For patients with severe OSA (AHI >30), there must also be documentation of intolerance to CPAP
- Medicaid policies in CT, ME, NH, and RI require prior authorization for CPAP
- CT also requires prior authorization for fabrication of MADs

21

Coverage Policies: Private

Diagnosis

- National payers generally follow the Medicare NCD language for coverage of sleep testing
  - Some variation in AHI thresholds used to determine appropriateness of split-night PSG (range: 6-40)
- Home testing covered by most regional payers subject to certain restrictions (e.g., use of sleepiness questionnaire, duration of symptoms ≥4 weeks)
  - Home testing considered investigational and NOT covered by BCBSRI and BCBSVT

22

Coverage Policies: Private

Treatment

- National and regional payers cover CPAP according to Medicare NCD guidance, without further restriction
  - Some variation in "tiering" of newer forms of CPAP (e.g., flexible CPAP, variable CPAP)
- MADs covered for patients with mild OSA or in those intolerant to CPAP therapy
  - 1 payer (Humana) considers upper airway surgery appropriate before MADs are considered
  - Other restrictions include no periodontal disease (BCBSMA, BCBSVT) and <150% of ideal body weight (Connecticare)

23

PATTERNS OF DIAGNOSIS & TREATMENT IN NEW ENGLAND

24

6

Methods

- Data provided by MassHealth, Vermont Medicaid, and HealthCore (Wellpoint/Anthem for CT, NH, ME)

- Analyses focused on claims for home/PSG testing and CPAP use

- One-year data on testing volume, CPAP use, and associated payments

Sleep Testing Frequency, 2011

Measure	Vermont Medicaid (n=68,000)	MassHealth (n=770,000)	HealthCore (n=1,500,000)
Patients Tested	760 (1.1%)	6,837 (0.9%)	15,479 (1.0%)
In Facility	760 (100%)	6,800 (99.5%)	14,522 (93.8%)
At Home	NC	37 (0.5%)	957 (6.2%)
Number of Tests	974	8,487	NR
Tests per Patient	1.28	1.24	NR

NC: Not covered; NR: Not reported
NOTE: N=# of beneficiaries age >16 years in 2011

Other Data

- CPAP Use (Vermont Medicaid, HealthCore):
  - 2.0 – 2.6% of beneficiaries with CPAP claims in 2011

- Significant variation in payments for lab-based sleep testing:
  - Public: $600-$1,000
  - Private: $1,000-$7,500

COMPARATIVE VALUE ANALYSES: COST-EFFECTIVENESS

Methods: Cost-Effectiveness

- Cost-effectiveness analyses focused on hypothetical cohorts of 1,000 Medicaid patients
- Effectiveness data obtained from high-quality RCTs; cost data from VT Medicaid or Medicare fee schedule
- Diagnostic and "test+treat" strategies focused on:
  - PSGs received
  - # diagnosed w/OSA
  - False negatives and false positives
  - # PSGs averted
  - Total strategy costs

29

Methods: Cost-Effectiveness

- Diagnostic strategies compared to PSG alone:
  - Phased testing with Berlin questionnaire + PSG for test-positive patients (Drager, 2010)
  - Phased testing with morphometric clinical prediction rule + PSG for test-positive patients (Kushida, 1997)
- "Test and treat" strategies compared to split-night PSG with fixed titration CPAP for patients diagnosed with OSA over 1 year of follow-up:
  - Home monitor + autotitrating CPAP (Amir, 2010)
  - Home monitor + split-night PSG for test-positive patients + fixed titration CPAP

30

Methods: Cost-Effectiveness

- Additional comparison of MAD vs. CPAP treatment over 1 year
- Based on head-to-head crossover RCT (Gagnadoux, 2009)
- Treatment "success" estimated based on % of patients achieving AHI <5
- Adjusted for # failing calibration/titration and compliance after therapy initiation

31

Key Assumptions

- In diagnostic and "test + treat" strategies, prevalence of OSA of any severity assumed to be 50%
- In "test + treat" and treatment strategies, severity of OSA assumed to be moderate (AHI 15-30)
- Perspective of public payer assumed:
  - In sensitivity analyses, higher private-pay estimates for sleep testing used ($400, $900, and $1500 for home, freestanding facility, and hospital-based testing respectively)

32

8

Cost-Effectiveness: Diagnostic Testing Strategies

Measure	PSG alone	Morphometric + PSG	Berlin Q + PSG
Total cost	$652,830	$674,621	$518,066
Received PSG	1000	488	670
Dx with OSA	500	488	465
False negatives	N/A	12	35
False positives	N/A	N/A	N/A
Averted PSGs	N/A	512	330
Difference vs. PSG alone	N/A	$21,791	($134,764)

All numbers are for 1000 patients at high risk of OSA diagnosis

- Increase in specificity of Berlin questionnaire from 59% to highest observed level (95%) doubled cost savings

33

Cost-Effectiveness: Test+Treat Strategies

Measure	Sleep lab PSG + fixed titration CPAP / BiPAP	Home monitor + autotitrating CPAP / BiPAP	Home monitor, PSG, fixed titration CPAP / BiPAP
Total cost			
CPAP	$1,244,905	$811,129	$1,112,731
BiPAP	$1,615,695	$1,193,414	$1,473,139
Diagnosed with OSA	500	516	486
True positives	500	486	486
True negatives	500	471	471
False positives	0	30	0
False negatives	0	14	14
Difference vs. sleep lab strategy			
CPAP	N/A	($433,776)	($132,174)
BiPAP	N/A	($422,281)	($142,556)

All numbers are for 1000 patients at high risk of OSA diagnosis; difference in CPAP and BiPAP is cost only

- Sensitivity analysis using private-pay estimates results in savings of nearly $900K (~50%) for home monitor + auto CPAP strategy

34

Cost-Effectiveness: Treatment Strategies

Measure	MAD	CPAP
Total cost	$2,011,940	$1,184,150
Failed calibration/titration	120	30
Patients treated	880	970
Number w/treatment success*	378	689

All numbers are for 1000 patients with OSA diagnosis

*Treatment success calculated as success rate X probability of tolerating calibration/titration

- At compliance rate of 55%, CPAP and MAD equally effective
- MAD strategy cost-saving relative to CPAP after 25 months of continuous treatment

35

COMPARATIVE VALUE ANALYSES: BUDGETARY IMPACT

36

Methods: Budgetary Impact

- Based on population age >16 years in New England
- Prevalence of sleep testing (~1%) and baseline distribution of home (6%) vs. lab-based (94%) monitoring derived from HealthCore data
- Strategy costs estimated from cost-effectiveness models
- Two scenarios evaluated:
  - Changes in distribution of home-based vs. lab-based testing strategy
  - Introduction of phased testing using Berlin questionnaire vs. split-night PSG in all patients

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Regional Budgetary Impact: Change in Mix of Home vs. Lab Testing

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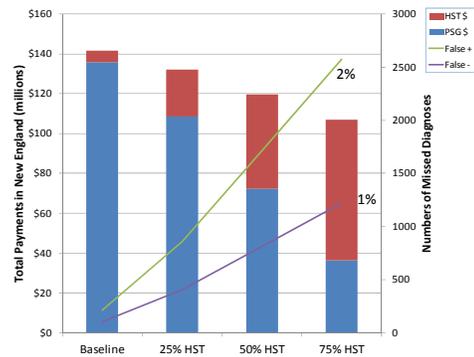
Regional Budgetary Impact: Change in Mix of Home vs. Lab Testing

- As with cost-effectiveness results, private-pay estimates for home ($400), freestanding sleep lab ($900), and hospital-based sleep lab ($1500) also considered
- Assumed mix of freestanding vs. hospital labs: 35/65
- Cost savings if 75% of testing is home-based: $69.8m

Regional Budgetary Impact: Replacing PSG with Phased Testing

- Potential impact if phased testing strategy introduced to replace PSG in all:
  - PSGs averted in ~38,000
  - Cost savings ~$16m (based on Medicaid/Medicare payment rates)
  - False-negative results in ~3.5%

BACKUP SLIDES