

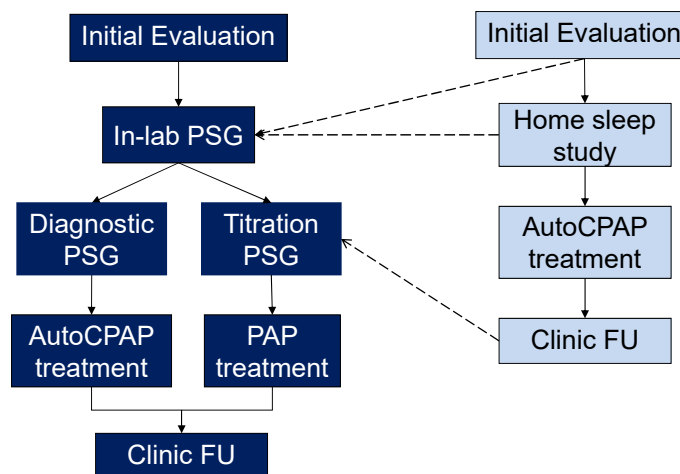
**24th ANNUAL ADVANCES IN SLEEP APNEA AND SNORING**  
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**Grand Hyatt on Union Square • San Francisco, California**

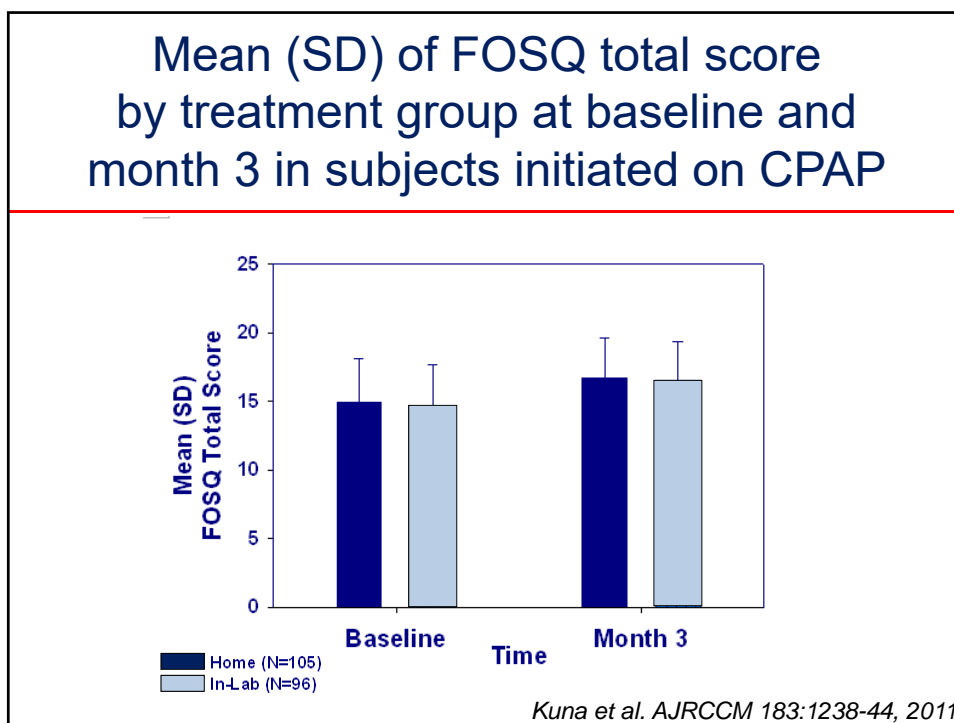
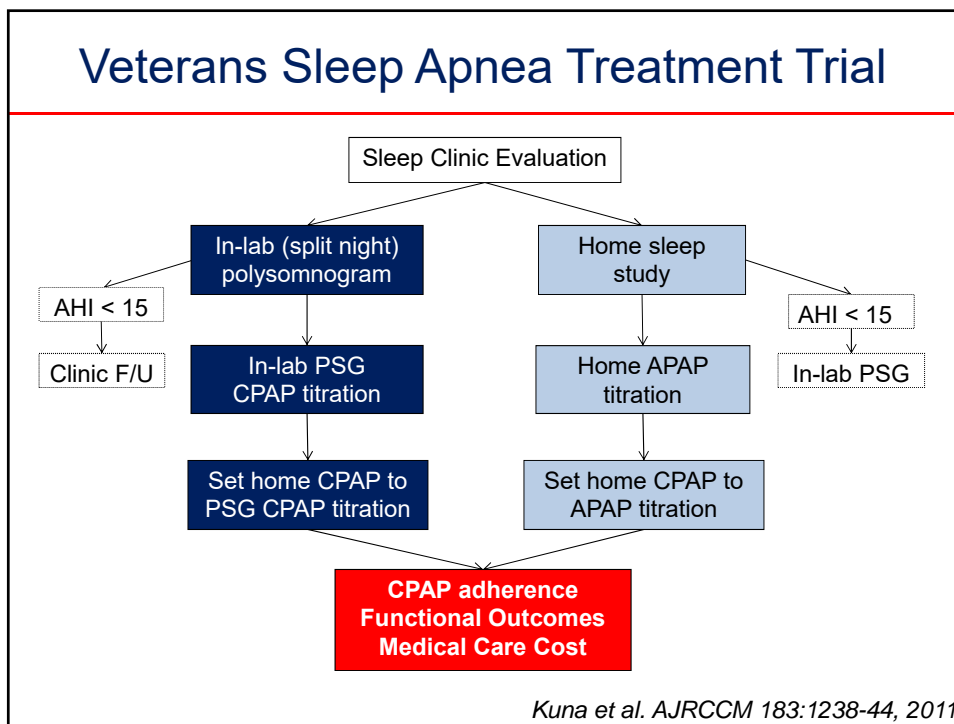
# Clinical Trials in OSA

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What is the best model of care and who should deliver it?





## Change in FOSQ score from baseline to month 3 between groups

Hypothesis: Ho:  $\Delta H - \Delta L \leq -1.0$  vs. Ha:  $\Delta H - \Delta L > -1.0$

Endpoint	Home adjusted mean change <sup>1</sup> (n=105)	In-lab adjusted mean change <sup>1</sup> (n=96)	Adjusted difference in mean changes (SE)	P-value <sup>2</sup>	Lower bound of 90% CI for difference in mean changes
FOSQ total score	1.79	1.79	0.04 (0.33)	0.99	<b>-0.54</b>

<sup>1</sup> Adjusted mean changes and adjusted differences in mean changes were estimated as site-total sample-size weighted values controlling for treatment group differences in mean pre-treatment values

<sup>2</sup> P-value from Type II sum of squares estimated by way of ANCOVA. To produce site weighted comparisons the ANCOVA model included main effects for type of study (home vs in-lab), site, as well as the pre-treatment baseline value of the outcome measure.

Kuna et al. AJRCCM 2011; 183:1238-44

## Mean CPAP adherence from baseline to month 3 between groups

Hypothesis: Ho:  $\Delta H - \Delta L \leq -0.75$  vs. Ha:  $\Delta H - \Delta L > -0.75$

Endpoint	Home adjusted mean <sup>1</sup> (n=113)	In-Lab adjusted mean <sup>1</sup> (n=110)	Adjusted difference in mean (SE) <sup>1</sup>	P-value <sup>2</sup>	Lower bound of 90% CI for difference in means
Mean CPAP (hr/day)	3.49	2.92	0.55 (0.32)	0.085	<b>+0.03</b>

<sup>1</sup> Adjusted means and adjusted differences in means were estimated as site-total-sample-size weighted values controlling.

<sup>2</sup> P-value from Type II sum of squares estimated by way of analysis of covariance. To produce site weighted comparisons the ANCOVA model included main effects for type of study (home vs in-lab) and site.

Kuna et al. AJRCCM 2011; 183:1238-44

## Change in secondary endpoints within treatment arm from baseline to month 3 in subjects initiated on CPAP

Variable	Home testing			In-Lab testing		
	N	Mean	P-value	N	Mean	P-value
<b>ESS score</b>	95	-2.6 ± 5.2	<b>&lt;0.0001</b>	84	-2.9 ± 4.4	<b>&lt;0.0001</b>
PVT lapses	90	-0.1 ± 3.4	0.77	85	-0.5 ± 4.0	0.26
SF-12 (phys)	91	1.1 ± 7.8	0.18	82	1.6 ± 9.0	0.10
<b>SF-12 (mental)</b>	91	2.5 ± 8.6	<b>0.008</b>	82	3.0 ± 10.2	<b>0.009</b>
<b>CES-D</b>	96	-1.4 ± 5.6	<b>0.013</b>	84	-2.2 ± 6.4	<b>0.004</b>

*Kuna et al. AJRCCM 2011; 183:1238-44*

## Change from baseline to month 3 in subjects initiated on CPAP

Endpoint	Home adjusted mean change <sup>1</sup>	In-Lab adjusted mean change <sup>1</sup>	Adjusted difference in mean changes ± SE	P-value <sup>2</sup>
ESS score	-2.79	-2.66	-0.14 ± 0.61	<b>0.82</b>
PVT (transformed lapses)	-0.29	-0.24	-0.05 ± 0.47	<b>0.91</b>
SF-12 physical score	0.91	1.91	-1.00 ± 1.23	<b>0.42</b>
SF-12 mental health score	2.91	2.52	0.38 ± 1.35	<b>0.78</b>
CES-D	-1.56	-1.97	0.40 ± 0.87	<b>0.64</b>

1 Adjusted mean changes and adjusted differences in mean changes were estimated as site-total-sample-size weighted values controlling for treatment group differences in mean pre treatment baseline values.

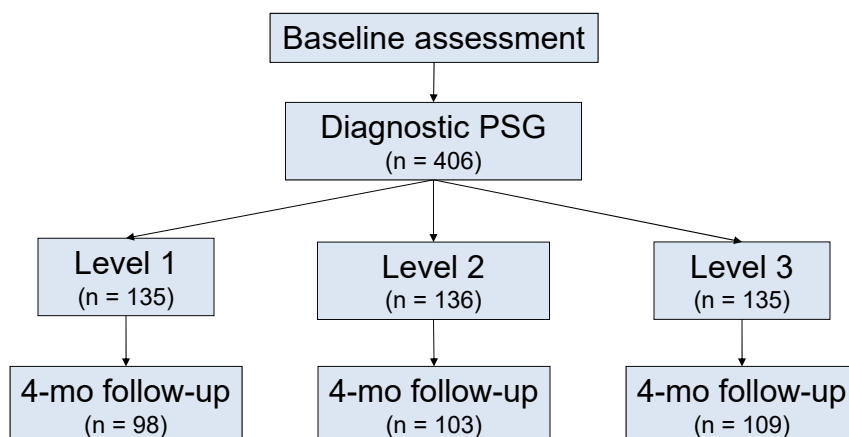
2 P-value from Type II sum of squares estimated by way of analysis of covariance. To produce site weighted comparisons the ANCOVA model included main effects for type of study (home versus in-lab), site, as well as the pre treatment baseline value of the outcome measure.

*Kuna et al. AJRCCM 2011; 183:1238-44*

## Patient-centered outcome research testing ambulatory management of OSA

- Mulgrew et al. Diagnosis and initial management of OSA without polysomnography: A randomized validation study. *Ann Intern Med.* 2007;146:157-66.
- Berry et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep.* 2008;31:1423-31.
- Rosen et al. A multi-site randomized trial of portable sleep studies and PAP autotitration versus laboratory-based PSG for the diagnosis and treatment of OSA: The HomePAP study. *Sleep* 2012; 35:757-67.
- Antic et al. A randomized controlled trial of nurse-led care for symptomatic moderate-severe obstructive sleep apnea. *Amer J Respir Crit Care Med.* 2009;179:501-8.

## Laboratory PSG or limited-channel sleep studies for OSA



*Chai-Coetzer et al. Ann Intern Med 2017; 166:332-240*

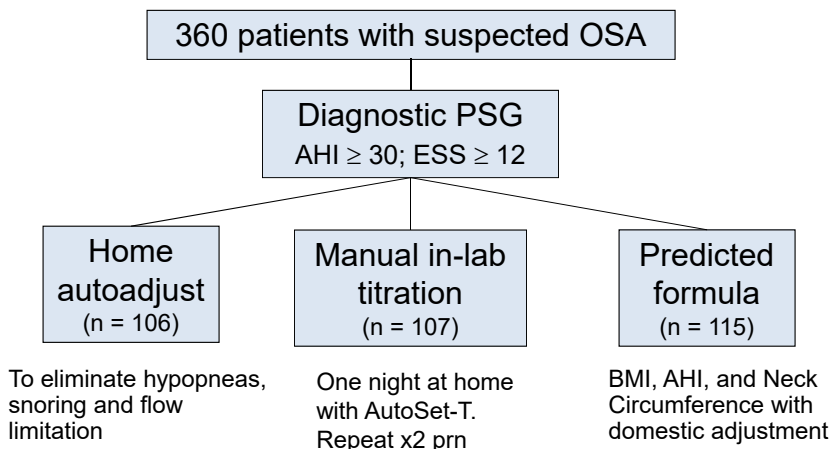
## Laboratory PSG or limited-channel sleep studies for OSA

**Table 2. Change in FOSQ and ESS Scores at 4 mo Versus Baseline**

Measure	Mean Score (95% CI)		
	Level 1 (n = 135)	Level 3 (n = 136)	Level 4 (n = 135)
<b>FOSQ†</b>			
Baseline	16.1 (15.6 to 16.6)	16.1 (15.6 to 16.6)	15.8 (15.3 to 16.3)
4 mo‡	18.0 (17.5 to 18.4)	18.0 (17.5 to 18.4)	17.4 (17.0 to 17.8)
Change	2.0 (1.5 to 2.4)	2.0 (1.5 to 2.4)	1.5 (1.0 to 2.0)
<b>ESS§</b>			
Baseline	10.4 (9.5 to 11.3)	10.4 (9.5 to 11.3)	10.4 (9.5 to 11.2)
4 mo‡	6.2 (5.3 to 7.2)	6.2 (5.2 to 7.2)	7.8 (6.8 to 8.7)
Change	-4.1 (-5.1 to -3.2)	-4.1 (-5.1 to -3.0)	-2.8 (-3.8 to -1.9)

Chai-Coetzer et al. *Ann Intern Med* 2017; 166:332-240

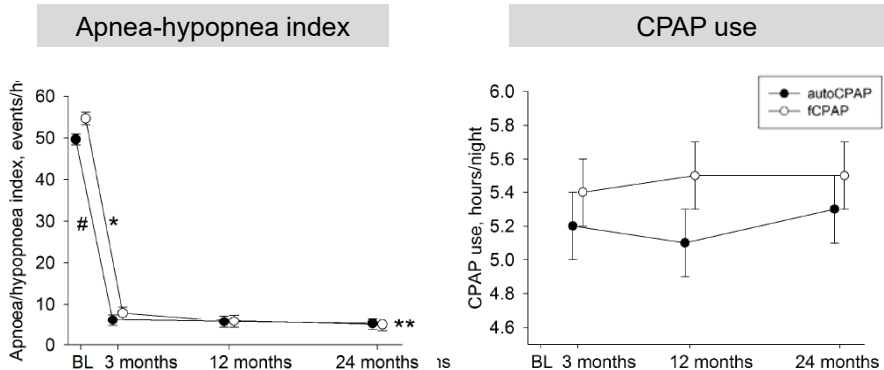
## Alternate methods of titrating CPAP



Outcome measures following 12 weeks CPAP treatment:  
In-lab PSG (AHI), ESS, FOSQ, SF-36, EuroQOL

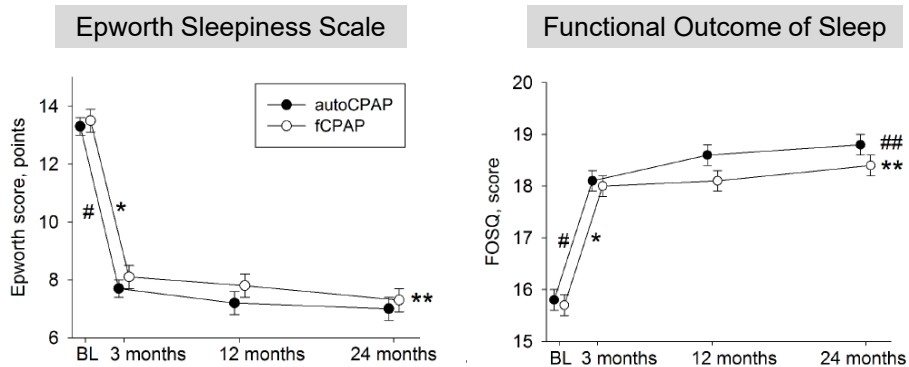
Masa et al. *AJRCCM* 2004; 170:1218-1224

## Autoadjusted vs fixed CPAP for OSA: a multicentre, randomised equivalence trial



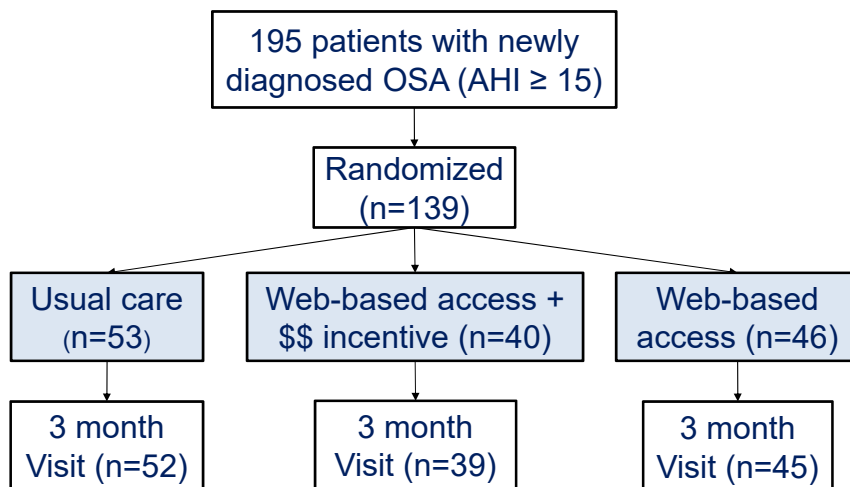
Bloch KE et al. Thorax 2018;73:174–184

## Autoadjusted vs fixed CPAP for OSA: a multicentre, randomised equivalence trial



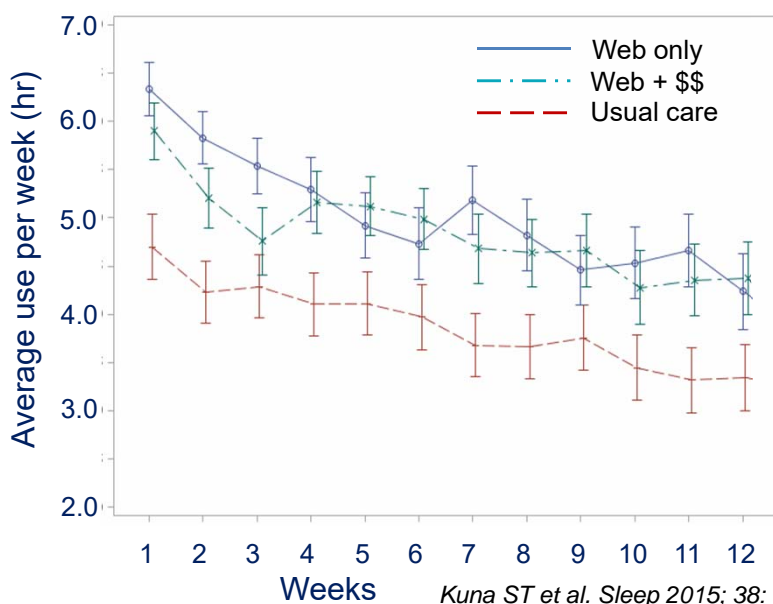
Bloch KE et al. Thorax 2018;73:174–184

## Does giving patients access to their PAP data improve treatment use?



*Kuna ST et al. Sleep 2015; 38: 1229-36*

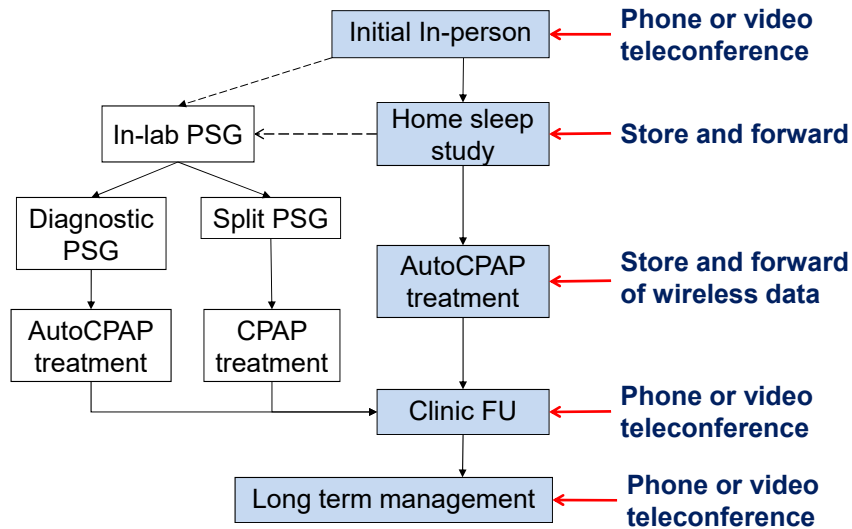
## Mean (SD) hours of use per week over 3 months



*Kuna ST et al. Sleep 2015; 38: 1229-36*



## The emerging paradigm: HSAT, autoCPAP with remote monitoring and videoconferencing



## Primary care practice vs sleep center management of OSA

- 155 patients with OSA recruited from primary care practices
- High diagnostic likelihood of moderate to severe OSA based on a screening questionnaire, ODI-3%  $\geq$  16 events/hr, ESS  $\geq$  8
- Randomized to management at the primary care practice or the sleep center
- Community-based nurse and PCP physician participated in a 6-hour education program on OSA and its management
- Community-based nurses received 5 days of in-service training with specialist nurses at the sleep center

Chai-Coetzer et al. JAMA. 2013;309(10):997-1004

## Primary care practice vs sleep center management of OSA

### Change in Epworth score at 6 months

Epworth Sleepiness Scale Score	Mean (95% CI)	
	Primary Care (n = 81)	Specialist Sleep Center (n = 74)
Baseline	12.8 (12.0-13.6)	12.5 (12.4-13.5)
6-mo <sup>c</sup>	7.0 (6.0-8.0)	7.0 (6.0-8.0)
★ Change <sup>d</sup>	5.8 (4.4-7.2)	5.4 (4.2-6.6)

Adjusted difference in mean change	0.13
Lower bound of 1-Sided 95% CI	-1.5

Chai-Coetzer et al. JAMA. 2013;309(10):997-1004

## Primary care practice vs sleep center management of OSA

### No difference in secondary outcomes at 6 months

	Primary Care	Specialist Sleep Center	Adjusted Difference <sup>a</sup>	Value
FOSQ <sup>b</sup>	Change at 6 mo 2.8 (2.0 to 3.6) <sup>c</sup>	Change at 6 mo 2.8 (2.2 to 3.4) <sup>c</sup>	0.18 (-0.58 to 0.94)	.64
SASQ <sup>d</sup>	-29.7 (-23.0 to -36.4) <sup>c</sup>	-31.2 (-23.8 to -38.6) <sup>c</sup>	0.78 (-7.22 to 8.78)	.85
SF-36 <sup>e</sup>				
Vitality	16.1 (11.0 to 21.2) <sup>c</sup>	19.9 (14.4 to 25.4) <sup>c</sup>	2.51 (-3.88 to 8.90)	.44
Mental health	7.9 (4.0 to 11.8) <sup>c</sup>	8.4 (4.5 to 12.3) <sup>c</sup>	1.57 (-3.41 to 6.55)	.54
Blood pressure, mm Hg				
Systolic	-2.2 (-6.3 to 1.9)	-4.4 (-9.1 to 0.3)	1.52 (-4.14 to 7.18)	.60
Diastolic	-1.4 (-4.3 to 1.5)	-0.5 (-3.6 to 2.6)	-1.32 (-4.97 to 2.33)	.48
Weight, kg	-0.1 (-2.5 to 2.3)	0.3 (-1.5 to 2.1)	-0.43 (-3.43 to 2.57)	.78

Chai-Coetzer et al. JAMA. 2013;309(10):997-1004

## Conclusions

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- Functional outcomes and CPAP use with ambulatory management of patients with OSA is not clinically inferior to that with in-laboratory management
- Management and outcomes are improved using a type 3 rather than a type 4 portable monitor
- Application of telehealth, HST, and autoCPAP with wireless monitoring is enabling patient access to care without traveling to a sleep center
- Emerging evidence that non-MD healthcare providers can manage patients with OSA