A Cost Minimization Analysis of Home versus Lab-based Diagnosis of Obstructive Sleep Apnea

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A thesis

submitted in partial fulfillment of the

requirements for the degree of

Masters of Pharmacy

University of Washington

2014

Committee:

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Program Authorized to Offer Degree:

School of Pharmacy

University of Washington

Abstract

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Importance: Insurers have adopted new reimbursement policies for diagnosing and treating obstructive sleep apnea (OSA) using home sleep testing (HST) instead of laboratory-based strategies.

Objective: We conducted an economic analysis of the HomePAP study, a multi-center randomized clinical trial that compared home-based versus lab-based testing for the diagnosis and management of OSA.

Design: A cost-minimization analysis from the payer and provider perspectives was performed, given that 3 month clinical outcomes (acceptance, adherence, and functional status) were equivalent for the home and laboratory arms. 2011 Medicare price weights were used for the payer perspective. HomePAP sites submitted itemized cost estimates for the provider perspective.

Setting: Seven academic sleep centers.

Participants: 373 subjects at high risk for moderate to severe OSA were randomized to either home-based limited channel portable monitoring followed by unattended auto-titration with continuous positive airway pressure (CPAP), versus a traditional pathway of in-laboratory sleep study and CPAP titration.

Main outcome measure: Per-subject costs, as randomized, in US Dollars.

Results: From the payer perspective, per subject costs for the lab-based pathway were $2,124 (95% C.I. $1,948, $2,308) compared to $1,874 (95% C.I. $1,724, $2,020) for the home-based pathway under the base case. Costs were $250 (95% C.I. $10, $494, p=0.04) in favor of the home arm. From the provider perspective, per subject costs for the lab arm were $1,940 (95% C.I. $1,801, $2,079) compared to $1,992 (95% C.I. $1,870, $2,123) in the home arm, for a difference of $51 (95% C.I. -$235, $142, p=0.59) in favor of the lab arm under the base case. Differences in payer and provider costs resulted in a provider operating margin of $184 (95% C.I. $126, $244, p<0.001) in the lab arm compared to a loss of $118 (95% C.I. -$159, -$77, p<0.001) in the home arm.

Conclusions and Relevance: For payers, a home-based diagnostic pathway for OSA with robust patient support incurs fewer costs than a lab-based pathway, but has comparable if not higher costs for providers, resulting in a negative operating margin for providers. This analysis shows the need to ensure that cost savings under HST are sustainable without potentially compromising patient care.

Introduction

The emergence of home sleep testing (HST) of obstructive sleep apnea (OSA) is transforming the clinical practice of sleep medicine. Several studies over the past decade have demonstrated that in patients with a high pretest probability of OSA, diagnosis and management with an unattended limited-channel portable monitor (PM) followed by continuous positive airway pressure (CPAP) autotitration yields similar outcomes compared to standard laboratory-based diagnostic polysomnography (PSG) and CPAP titration when evaluated and managed by subspecialists.[1-6] In a recent 2013 survey of sleep centers, 64% centers reported that they are offering HST for privately insured patients. Of particular interest, 48% reported they were reducing their plans for expansion of laboratory beds as a result of home testing.[7]

Despite the increasing adoption of HST, its impact on the cost of diagnosing and managing OSA is unclear. While PM may be individually less resource intensive than PSG, clinical guidelines[8] recommend that a diagnostic PSG be performed in patients with a high pretest probability of OSA who have a negative result on PM testing. This is due to concerns that HST may have lower sensitivity for diagnosing OSA. Thus, the HST strategy as a whole may not be cost-effective. A recent economic simulation study concluded that full-night PSG, not PM, was the preferred diagnostic strategy in patients suspected to have moderate-to-severe OSA.[9]

We undertook an economic analysis of a recently completed randomized controlled trial (HomePAP, Home Positive Airway Pressure study) comparing a home-based and laboratory-based management strategy in a population at high risk for OSA.[10] HomePAP reflected current

recommended practice by having all negative or non-diagnostic PM results confirmed by PSG. Given that key clinical outcomes (adherence, sleepiness responses) at 3 months were equivalent for both arms, we pursued an in-trial cost minimization analysis from the payer perspective. In addition, we estimated actual costs of each management arm and undertook a second economic analysis from the provider perspective, to explore the impact of HST adoption on sleep centers.

Materials and Methods

Study Design

More extensive details about the design and results of the HomePAP study can be found elsewhere.[10] The HomePAP trial was a multi-site non-blinded randomized controlled trial that enrolled 373 patients at seven AASM-accredited academic sleep centers with a high pre-test probability of moderate to severe OSA (based on a clinical algorithm). Eligible subjects were evaluated in clinic and randomized to one of two management pathways. Those randomized to the lab-based pathway underwent attended overnight PSG in an accredited sleep laboratory, followed by a second attended overnight PSG for titration with continuous positive airway pressure (CPAP). If the AHI was $\geq$ 15 during the first two hours of the initial PSG, the patient proceeded with CPAP titration in the same night, termed a "split-night" study. Those randomized to the home-based pathway were given a portable limited-channel sleep monitoring device (Embletta™ X-30, Embla Inc., Broomfield, Colorado) which was taken home. These patients received standardized in-person training on how to apply the monitoring device on at night by personnel affiliated with each accredited sleep center, and technicians were available overnight by phone to answer any questions. The monitoring device was returned to the sleep center the following morning by the patient or by courier service, depending on center preference. Those in the home-based arm with an AHI $\geq$ 15 were then provided an auto-titrating CPAP machine (REMStar® Auto-M Series; Philips-Respironics, Murraysville, PA) to use at home for 5-7 nights to perform their CPAP titration. All subjects with an AHI $\geq$ 15 who

underwent a successful CPAP titration study were offered CPAP therapy. Subjects were re-evaluated in clinic after 1 and 3 month follow-up periods.

A CONSORT study flow diagram is seen in Figure 1. In the lab arm, those with an AHI < 15 exited the study, while those with a technically unacceptable study underwent a repeat lab study. In the home arm, those with a technically unacceptable study underwent a second HST. If either the first or second HST yielded an AHI < 15 or the second HST was technically unacceptable, the subject "crossed over" for a confirmatory lab-based overnight diagnostic PSG. The crossover lab-based test was used to determine the final AHI, and those with AHI $\geq$ 15 then continued in the home arm with CPAP auto-titration. In a similar fashion, those who were not able to successfully complete two CPAP auto-titration studies were crossed over for a lab-based overnight CPAP titration study, and then returned to the home-based pathway. All studies (lab and home) were scored at the study site and electronically transferred to the Sleep Reading Center (at Case Western Reserve University, Cleveland, OH) for a confirmatory over-read.

HomePAP was designed as a noninferiority trial. An intent-to-treat analysis of the primary outcomes showed no difference in acceptance of CPAP therapy and in CPAP adherence at 3 months (when defined as using CPAP for >4 hrs/night for at least 70% of nights). The only statistically significant differences were a higher rate of CPAP adherence in the home arm when defined as number of nights with >4 hours usage, as well as a higher average time of CPAP use per night in the home arm. (Table 1) In addition, no difference was seen in the majority of secondary outcomes. These included mean CPAP titration pressure, time to treatment from initial consultation, and a battery of patient reported outcomes including changes in the Epworth Sleepiness Score, European Health Status Questionnaire (EQ-5D), Medical Outcomes Study 36-

Item Short Form (SF-36), Functional Outcomes of Sleep Questionnaire (FOSQ), and Calgary Sleep Apnea Quality of Life Index (SAQLI).

Economic Analysis

For the payer perspective, costs were calculated by multiplying in-trial resource utilization with 2011 Medicare reimbursement price weights, as listed in Table 2.[11] Utilization figures were available for all diagnostic testing, outpatient clinic visits, machine type, and machine accessories. For those in the home arm, the total number of minutes spent providing phone support, including for overnight issues, was also available (Table 3). Health care utilization outside of the trial (e.g. ED visits, medications) was monitored by patient interviews and found to be negligible, and thus not counted in this study. Reimbursement for sleep studies was calculated using Ambulatory Payment Classification (APC) codes under the Hospital Outpatient Prospective Payment System. Medicare price weights for Durable Medical Equipment (DME) from 2011 were used for the reimbursed unit costs of outfitting each patient with either a standard CPAP machine for the lab arm or an adjustable CPAP titrator (auto titrating positive airway pressure, APAP) for the home arm. Medicare price weights for DME were taken for the Cleveland, OH area (as there are no national reimbursement rates), while all other price weights for sleep studies were national figures. While the HomePAP study only followed patients out for 3 months after initiation of CPAP, we chose to model the cost of CPAP/APAP usage for 13 months, assuming that all subjects given CPAP/APAP would meet criteria for full reimbursement from Medicare, and because we chose to take a time horizon of 1 year.

For the provider perspective, selected capital and all labor costs for all seven participating academic sleep centers were obtained and aggregated. These elements are listed in Table 2. We reported per-unit costs under the assumption that all sleep centers were operating at full efficiency. Costs for most capital expenditures in the lab arm were taken from one sleep center under the assumption that these item costs (e.g. EEG, video equipment, disposable equipment) would be very similar for all centers in our study. Overhead costs were aggregated from four reporting sites, which included environmental services, hospital administration, billing and collections, human resources, interpreter services, clinical engineering, patient care services, receptionist, and additional miscellaneous expenses associated with the school of medicine and/or medical center (if applicable). (All seven sites had overhead costs containing similar elements, but not all centers were able to report them.) In terms of specific labor costs, all centers reported the amount of Full Time Equivalents (FTE) assigned for sleep technicians, chief sleep technicians (if applicable), lab managers (if applicable), and a medical director. Non-salary benefits were assessed at 28% of each person's salary. Receptionists and other sleep lab support staff were accounted for in overhead costs. The cost of a home APAP titration was modeled as the cost of a home-based diagnostic sleep test, minus the cost of the portable monitor, given that the cost of providing an APAP machine in the home arm was accounted for separately. The cost of a CPAP machine and APAP machine were obtained from the listed price from a major internet retailer.[12] All capital expenditures were assumed to have a 5 year life span. We were interested in the average unit cost and took a time horizon of one year (approximately the duration of the HomePAP trial).

For the home arm, all participating centers have ongoing home sleep testing programs, but only two centers are doing more than 400 out-of-center-tests annually. To model the costs of

a home sleep testing program running at close to full efficiency, certain variable unit costs that are driven down by higher practice volumes (e.g. per-study cost of the diagnostic PM machine, cost of sleep technicians to manage the machines, overhead costs) were taken from only these two sites. The time spent by sleep technicians in directly managing the home sleep testing program was specifically measured for each of the high volume centers. The relative contribution from those in supervisory roles (medical director, lab manager, chief lab technician) was determined by taking the percentage of total studies performed as HST versus PSG, and multiplying it by the approximate ratio of provider costs between HST and PSG, as a proxy for resource intensity. For example, if a sleep center did 20% of its studies as HST and the ratio of costs between one HST and one PSG was $300:$1000, 20% x 30% = 6% of their supervision time was allocated to HST, and 94% to PSG. Other cost parameters, such as the cost of scoring or having an MD interpret one home sleep study, were not felt to be affected by practice volume. These parameters were aggregated and averaged from all seven centers.

The cost to the provider of seeing a patient in clinic was assumed to be equal to the amount reimbursed by Medicare as the payer. It was felt that any differences in costs between the payer and provider perspectives for a clinic visit would be minimal. However, as there were more patients that were seen in clinic follow-up in the home arm, we chose to include the impact of these clinic visits on our analysis.

The primary outcome variable was the cost per person randomized to receive either home-based or lab-based diagnosis and treatment of suspected OSA. Mean per-patient costs were calculated for each group separately. We performed an intent-to-treat analysis of all patients who were randomized, as those who dropped out in each treatment arm incur costs that

ultimately factor into the per-patient cost of each diagnostic strategy. All 373 patients enrolled in the study were included in the economic analysis.

Cost distributions from the payer perspective for each group in the base case were analyzed and found to have significant rightward skew (0.290) and kurtosis (1.71), but few extreme outliers (maximum cost = $4,691). Cost distributions for the provider perspective in the base case also showed rightward skew (0.261) and kurtosis (2.47), and few outliers (maximum cost = $4,848). Given our sample size, we felt it was reasonable to use the student's t-test to compare the mean per-patient cost between the two treatment arms. However, to account for the non-normality of our distributions, bootstrap resampling with 10,000 replications was used to calculate bias-corrected 95th percentile intervals.[13] Our null hypothesis was that there would be no difference in costs between the two study arms.

Two additional scenarios were considered. We first analyzed a scenario where the diagnostic cutoff for a positive PM or PSG study was an AHI of $\geq$ 5 events/hour, instead of $\geq$ 15 events/hour as was used in the trial. Under the AHI $\geq$ 5 scenario, we assumed the additional subjects who received a diagnosis of OSA had the same pattern of subsequent follow-up (i.e. dropout) as their peers with AHI $\geq$ 15/hr, respective to each trial arm. Furthermore, we assumed that for any PSG studies with an AHI of 5-15/hr that would have been positive for OSA under this scenario, they would not have handled as a split-night study; thus, all of them received a full PSG titration study. Patients in the home arm with an initial AHI of 5-15/hr by PM would not have gone on to receive a confirmatory PSG, but instead would have progressed to APAP titration. This scenario was considered because in symptomatic patients with an AHI $\geq$ 5, many clinicians will consider a trial of CPAP/APAP therapy. The second scenario considered the cost of only performing diagnostic testing for OSA and ignoring the cost of providing CPAP/APAP.

(The cost of followup visits was still included.) Most commercial third-party payers allow for a single sleep center to both diagnose OSA and provide CPAP in the same patient, which is the reason this was modeled under the base case. However, under Medicare, the sleep center that performs diagnostic testing must have a separate provider (e.g. a respiratory devices company) provide CPAP therapy. Hence, this second scenario models the current situation for a sleep center reimbursed by Medicare for diagnostic testing.

Extensive one-way sensitivity analyses were performed on model inputs that affected both the payer and provider perspective. These were performed under all three scenarios (base case, AHI $\geq$ 5, performing only the diagnostic studies). Given the similarity of the one-way sensitivity results under all three scenarios, only the sensitivity analysis for the base case was reported. Finally, a two-way sensitivity analysis looking at various reimbursement levels for home and lab testing was performed to obtain the breakpoint at which providers performing HST would recover their costs, with and without the effects of DME reimbursement for providing CPAP. This was done to assess the impact of current reimbursement levels for providing diagnostic testing and CPAP therapy on operating margins in HST from the provider perspective.

Results

In the trial, 206 PSG studies were performed in the lab arm, whereas 329 PM or APAP studies plus 77 PSG studies were performed in the home arm. In the AHI $\geq$ 5 scenario, we modeled an additional 44 and 35 subjects in the lab and home arm, respectively, to receive CPAP therapy.

Payer Perspective

The mean cost per patient in the lab arm was $2,124 (95% C.I. $1,948, $2,308), compared to $1,874 (95% C.I. $1,724, $2,020) for the home arm (Table 4). The mean difference was $250 per randomized patient (95% C.I. $10, $494, p=0.04) in favor of the home arm.

The default lab arm pathway (Full-night PSG + Full-night titration PSG) incurs $1,561.54 in payer costs, compared to the default home arm pathway (PM diagnosis + APAP titration), which incurs $166.64 (Table 4). The default lab pathway is more costly due to the higher cost of PSG studies, and the fact that home APAP titration is not reimbursed under Medicare. On the other hand, the difference between the two arms in the trial is only $250 because of several factors. The first is that 61 subjects (72%) in the lab arm received a split-night study, eliminating the need for a second PSG titration study. The second is that 74 subjects in the home-lab arm crossed over and obtained a confirmatory PSG diagnostic study, and 3 subjects similarly crossed over and obtained a lab-based CPAP titration study. Third, there were more technical failures in both PM diagnosis and APAP titration in the home arm, requiring

repeat studies. Finally, more subjects were offered CPAP in the home arm, thus incurring higher CPAP/APAP equipment costs to the payer.

In one-way sensitivity analysis, the mean difference in favor of the home arm in the trial is robust to different levels of reimbursement for sleep testing, CPAP/APAP reimbursement, and whether or not home APAP titrations are reimbursed. (Figure 2)

In the AHI $\geq$ 5 scenario, the mean cost per patient in the lab arm increased to $2,735 (95% C.I. $2,535, $2,925), compared to $2,128 (95% C.I. $1,976, $2,282) in the home arm, for a mean difference of $607 per randomized patient (95% C.I. $369, $863, $p<0.001$) in favor of the home arm (Table 3). In the scenario where only the cost of diagnostic testing is considered, the mean cost per patient in the lab arm was $1,345 (95% C.I. $1,273, $1,418), compared to $1,011 (95% C.I. $957, $1,068) in the home arm, for a mean difference of $333 (95% C.I. $243, $425, $p<0.001$). Under all three scenarios, a home-based strategy is less costly to the payer.

Provider Perspective

The mean provider cost per patient was $1,940 (95% C.I. $1,801, $2,079) in the lab arm, compared to $1,992 (95% C.I. $1,870, $2,123) in the home arm (Table 4). The mean difference of $51 in favor of the lab arm (95% C.I. -$235, $142) was not statistically significant.

The provider cost of the default lab arm pathway is higher than the default home arm pathway ($1,934.78 versus $633.09). However, the home arm in the trial has equivalent or higher provider costs than the lab arm. Factors such as the use of split-night studies in the lab arm, the use of confirmatory PSG crossovers, more home-arm technical failures, and more CPAP being offered in the home arm, contribute to increased costs in the home arm in the provider

analysis just as they do in the payer analysis. In addition, the cost of providing APAP titration in the home arm is factored into the provider analysis.

In one-way sensitivity analysis, the mean difference in costs between the two arms from the provider perspective was most sensitive to the facility costs, the lifespan of the PM machine, the salary of the sleep technicians, overhead costs, and the cost of providing APAP/CPAP to the patient (Figure 2).

Under the provider analysis, results were sensitive to one of the two additional scenarios considered. Under the AHI $\geq$ 5 scenario, the mean cost per patient in the lab arm increased to $2,418 (95% C.I. $2,261, $2,570), compared to $2,165 (95% C.I. $2,033, $2,295) in the home arm, for a significant mean difference of $253 per randomized patient in favor of the home arm (95% C.I. $59, $460, p=0.01). In the scenario where only diagnostic testing is performed, the mean provider cost per patient in the lab arm was $1,551 (95% C.I. $1,467, $1,639), compared to $1,471 in the home arm (95% C.I. $1,396, $1,544), for a non-significant mean difference of $81 again in favor of the home arm (95% C.I. -$33, $197).

Operating Margin Analysis

The provider operating margin was calculated by subtracting the mean provider cost per patient for each study arm from the mean anticipated amount of reimbursement (i.e. payer cost) per patient. (Table 4). Under the base case, the provider operating margin was $184 (95% C.I. $126, $244) for the lab arm compared to a loss of $118 (95% C.I. -$159, -$77) in the home arm, for a difference of $301 between the two strategies (95% C.I. $227, $374, $p < 0.001$).

Under the AHI $\geq$ 5 scenario, the operating margin increased to $317 for the lab arm (95% C.I. $261, $372) and -$37 for the home arm (95% C.I. -$85, $9), compared to the base case. The mean difference between the two arms was $354 ($95% CI $280, $428, p<0.001). Under the scenario where only diagnostic testing is performed, the operating margin is a loss for both the lab (-$207, 95% C.I. -$221, -$192) and home (-$459, 95% C.I. -$492, -$429) arms, with a mean difference of $253 (95% C.I. $218, $288, p<0.001). Thus, under the base case and two alternative scenarios, there is a significant difference in operating margin between the lab and home arms that is in favor of the lab arm for the provider. Furthermore, the operating margin in the home arm is negative under all scenarios.

The two-way sensitivity analysis in Figure 3 shows the Medicare reimbursement levels for PSG (APC 0209) and HST (APC 0213) at which providers would have a positive operating margin for the home study arm, with and without considering the reimbursement from DME for providing CPAP/APAP. At current reimbursement levels under the base case, providers experience a net operating loss even with DME reimbursement, as noted by the dot in the pink region.

Discussion

Home-based diagnostic testing for OSA in high risk patients is undergoing wide adoption across health care institutions and payers across the US. The HomePAP trial joins a number of similar trials that demonstrate non-inferior outcomes in CPAP acceptance and functional improvements.[1-5,14] The implicit assumption has been that this shift towards HST would be cost-saving for both payers and providers.[15,16] Our analysis of the HomePAP trial shows that the economic implication of this shift clearly depends on the perspective taken. To the payer (specifically Medicare), the home-based strategy is less costly in the base case. This result is found even under a testing strategy where all negative and technically inadequate home-based tests are repeated in the lab setting, and almost three-quarters of all positive lab-based PSG's were performed as split-night studies. To the provider, however, the two strategies are similar in cost, and switching to a home-based strategy incurs a large marginal difference to their net operating margin.

The fact that a home-based diagnostic strategy offers significant cost savings predominantly from the payer perspective suggests that payers will be more motivated than providers to move towards a home-based strategy for OSA. Indeed, many third party payers have moved towards home-based testing as the initial approach for patients with suspected OSA.[17] However, this analysis suggests that there are no cost savings to the provider; in fact, it may be more costly to switch to a home-based strategy for providers. One of the key elements of the HomePAP trial is that the home diagnostic pathway was applied to a population with a high pre-test probability of OSA, with close monitoring and lab-based PSG confirmation at accredited sleep centers. Similar clinical outcomes at 3 months were achieved in the context of resource utilization at the provider level that may not be appreciated by the payer community. If the cost

of providing high quality home-based strategies exceeds reimbursement, long term sustainability is unrealistic. One possible consequence may be the adoption of home-based strategies that are less resource intensive but potentially associated with poorer outcomes. Some have suggested that this financial pressure may be partially responsible for the sharp increase in unfilled sleep medicine fellowship positions.[18]

Previous model-based cost-effectiveness analyses compared lab-based and home-based diagnostic testing for OSA, followed by CPAP therapy, under the societal perspective.[9,19-21] Our economic analysis is distinct from the existing studies in three important ways. First, our analysis, while limited by the short time horizon of the HomePAP trial, incorporates key clinical parameters (i.e. CPAP acceptance, dropout, technical failure) gathered from a multi-center randomized controlled study that used a diagnostic pathway for home testing that reflects clinical guidelines.[8] Second, our costs from the provider perspective are collected from seven different high-volume academic sleep centers across the US, adding generalizability to other academic centers. Prior estimates of PSG and/or HST provider costs in the literature have been taken from non-US settings[22-26] or from a single center[19,27] or geographic region.[28] Third, we consider several unique perspectives and scenarios, most notably the comparison between the payer and provider perspective. This was extended to look at the impact of doing just diagnostic testing without DME, as well as the impact of a lower AHI diagnostic threshold.

From the payer perspective, the finding that the home arm is less costly appeared to be robust to a wide range of scenarios that encompass differences in reimbursement strategies. In contrast, costs from the provider perspective for the home arm appeared to be sensitive to a number of parameters, such as facility, overhead, PM machine lifespan, and CPAP/APAP equipment costs. HST is a maturing technology that may eventually improve upon its current

cost and diagnostic performance, and improvements in these key parameters may significantly impact the cost of the home strategy. On the other hand, the components of patient support needed to optimize adherence and other outcomes for home sleep testing remains to be defined. Ultimately, costs and reimbursement need to reflect an appropriate balance that does not compromise patient outcomes.

There are limitations to any economic in-trial analysis, and this study has several that warrant mention. First, we are unable to assess the long term economic impact of the two diagnostic strategies. A longer perspective would have afforded us the opportunity to consider a societal perspective, incorporating factors such as lost work productivity and traffic accidents from untreated OSA that may have differed between the two strategies.[29] Second, the HomePAP trial was conducted at 7 AASM accredited sleep centers located at academic centers using a defined diagnostic algorithm, and all patients were carefully screened and monitored throughout the study. The generalizability of this economic analysis to community sleep centers using a plethora of different diagnostic algorithms, or the economic impact of outsourcing sleep studies to third party vendors who do not provide the level of patient support mandated in this protocol, is unclear. Third, the payer analysis was based on Medicare reimbursement rates, which may differ from commercial insurance reimbursement rates. While Medicare reimbursement rates and practices often serve as a model for commercial insurance payers going forward, this analysis may not immediately translate to the non-Medicare setting. Finally, our provider cost estimates from participating sites show variability, and we only had two sites with high volume HST programs for volume-sensitive per-unit cost inputs. The fact our study incorporated information from multiple sites, combined with careful one-way sensitivity analysis, helps clarify which particular cost inputs are critical to our results.

In conclusion, these results demonstrate that a home-based management pathway for OSA is less costly to the payer than a lab-based management pathway. However, the home and lab-based pathways are similar in cost to the provider when following standardized protocols designed to ensure patients received high quality care. Furthermore, switching from a lab-based to a home-based strategy results in a negative operating margin for providers. The disparity in costs for payers and providers raises concerns that this will fuel the growth of third party vendors who provide HST services outside the context of management pathways designed to provide high quality care, and that patient outcomes and cost-effectiveness may suffer.

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Table 1: Trial outcomes

	Lab	Home	p-value
Clinical Outcomes			
CPAP Acceptance after completing testing (%)	80/92 (87%)	89/105 (90%)	0.95
CPAP Adherence at 3 months (> 70% of night used, >4 hrs/night)	24/61 (39%)	37/74 (50%)	0.22
CPAP Adherence at 3 months (>4hrs/night)	29/61 (48%)	47/74 (63%)	0.25
CPAP Usage at 3 months (SD), min	219 ± 144	281 ± 126	<0.01
SF-36 Vitality Score at 3 months (SD)	53.5 ± 9.7	52.3 ± 9.9	0.57
Functional Outcomes of Sleep Questionnaire (SD)	18.3 ± 2.0	18.0 ± 2.5	0.38
Notable pathway features			
Home studies that required crossover to lab PSG (%)		74/180 (41%)	
Initial home study negative, lab PSG was positive for OSA (%)		23/74 (31%)	
Initial PSG that diagnosed OSA was a split-night study (%)	61/85 (72%)		
Time spent on phone with tech support (SD), min	8.6 ± 6.6	15.4 ± 7.8	
At least one phone call with tech support (%)	73/80 (91%)	93/96 (97%)	
Rates of Unacceptable Studies			
Split-night (%)	4/61 (6.6%)		
Subsequent full-night lab titration (%)	1/24 (4.2%)		
Initial home study (%)	33/180 (18.3%)		
Unable to get acceptable quality HST in two attempts (%)	21/180 (11.7%)		
Subsequent initial home APAP titration (%)	30/103 (29.1%)		
Unable to get acceptable quality APAP titration in two attempts (%)	10/103 (9.7%)		

Table 2: Payer reimbursements (using 2011 Medicare price weights and coverage policies)

Item	Cost	OPPS Code	HCPCS Code
Lab-based sleep study[a,c]	$780.77	APC 0209	95810
Lab-based CPAP titration study (includes split-night)[a,c]	$780.77	APC 0209	95811
Unattended home sleep study[a,c]	$166.64	APC 0213	95806
Unattended home APAP titration study[a,d]	$0	N/A	N/A
Initial Clinic Evaluation (Level 4)[a,c]	$347.56		99204
Followup Clinic Evaluation (Level 4)[a,c]	$178.66		99214
Monthly CPAP/APAP Rental, per month[b]	$101.00		E0601
Humidifier filter[b]	$4.15		A7038
Humidifier[b]	$272.33		E0562
Tubing[b]	$60.40		A4604
Mask[b]	$106.35		A7034
Headgear[b]	$35.93		A7035
Total DME for 13 months of CPAP/APAP[b]	$1,812.91		

[a]National price weights
[b]Reimbursement for Cleveland, Ohio.
[c]Includes technical and interpretation (professional) fees
[d]Not currently reimbursed by Medicare

Table 3: Provider costs

Laboratory-based Testing	Per sleep study	Range	Sites
Capital Resources			
Facility (rent, insurance, property taxes)	$172.35	$112.96 - $225.41	4
Bed (not including laundry)	$7.02	$5.60 - $10.71	7
Equipment (EEG, video, audio, plethysmograph, computer, warranty)	$21.43		1
Electrodes (belts, snap leads, thermals)	$7.29		1
CPAP masks and related items (tubing, water chambers, pasteurizing machine, in-lab titration devices)	$4.70		1
Disposable supplies (oximeter probes, nasal canula, EEG/EKG leads)	$23.00		1
Labor Resources			
Scoring the sleep study	$39.82	$28.75 - $70.00	7
Interpretation of sleep study by MD	$37.72	$28.88 - $55.83	7
Salaries			
Sleep Center Medical Director	$10.17	$5.41 - $16.00	7
Chief Lab Technician	$17.83	$14.74 - $30.22	7[a]
Lab Manager	$21.63	$9.78 - $35.29	7
Sleep Technicians	$228.73	$165.71 - $275.50	7
Benefits	$75.09	$55.48 - $90.47	7
Overhead costs[b]	$300.61	$228.57 - $346.98	4
Total provider cost for one lab-based sleep study	$967.39		

Home-based Testing	Per sleep study	Range	Sites
Capital Resources			
Diagnostic Machine	$19.64		2
Disposable supplies	$5.00		1
Computer for downloading studies	$0.75		1
Labor Resources			
Scoring the sleep study	$23.59	$10.94 - $46.00	7
Interpretation of sleep study by MD	$17.63	$10.94 - $24.79	7
Salaries			
Sleep Center Medical Director	$13.66		2
Chief Lab Technician	$7.77		2
Lab Manager	$8.70		2
Sleep Technician	$55.15		2
On-call technician for troubleshooting	$7.96		1
Courier Service[c]	$7.57		7
Downloading the sleep study from the machine	$2.67		1
Instruction by technician (use and proper fit)	$14.36	$5.95 - $23.44	7
Overhead costs[b]	$69.80		2

Total provider cost for one home-based sleep study	$326.36
Total provider cost for APAP titration study[d]	$306.73

CPAP/APAP setup	**Price**[e]
Respironics REMStar 60 Series Plus [CPAP machine]	$449.00
Respironics REMStar 60 Auto CPAP [APAP machine]	$639.00
Humidifier filter[f]	$11.95
Humidifier	$229.00
Tubing	$52.00
Mask	$66.99
Headgear	$36.99
Total cost for 13 months of CPAP	$905.68
Total cost for 13 months of APAP	$1095.68

[a]One center did not employ a chief lab technician.
[b]Includes environmental services, hospital administration, billing and collections, human resources, interpreter services, clinical engineering, patient care services, receptionist, and additional miscellaneous expenses associated with the school of medicine and/or medical center (if any).
[c]Employed by only 3 out of the 7 sites. The other 4 sites have patients return the PM to the center, and thus incur no cost to the provider. This parameter reflects the cost of a courier service averaged across all seven sites.
[d]Estimated as all the costs of a home study, minus the cost of a portable monitor diagnostic machine.
[e]Prices taken from www.cpap.com on 7/5/2013.
[f]Each filter estimated to last 2 months.

Table 4: Costs per subject

Perspective	Lab (n=186)	95% C.I.[a]	Home (n=187)	95% C.I.[a]	Difference	95% C.I.[a]	p-value[b]
Base Case							
Payer	$2,124	($1,948, $2,308)	$1,874	($1,724, $2,020)	$250	($10, $494)	0.04
Provider	$1,940	($1,801, $2,079)	$1,992	($1,870, $2,123)	-$51	(-$235, $142)	0.59
AHI > 5 scenario							
Payer	$2,735	($2,535, $2,925)	$2,128	($1,976, $2,282)	$607	($369, $863)	< 0.01
Provider	$2,418	($2,261, $2,570)	$2,165	($2,033, $2,295)	$253	($59 , $460)	0.01
Only diagnostic testing							
Payer	$1,345	($1,273, $1,418)	$1,011	($957, $1,068)	$333	($243, $425)	<0.01
Provider	$1,551	($1,467, $1,639)	$1,471	($1,396, $1,544)	$81	(-$33 , $197)	0.17
Provider Operating Margin							
Base case	$184	($126, $244)	-$118	(-$159, -$77)	$301	($227, $374)	<0.01
AHI > 5 scenario	$317	($261, $372)	-$37	(-$85, $9)	$354	($280, $428)	<0.01
Only diagnostic testing	-$207	(-$221, -$192)	-$459	(-$492, -$429)	$253	($218, $288)	<0.01

[a] Bootstrapped bias-corrected confidence interval
[b] Two sided Student's t-test, unequal variance

Figure 1: Participant flow diagram for the HomePAP trial

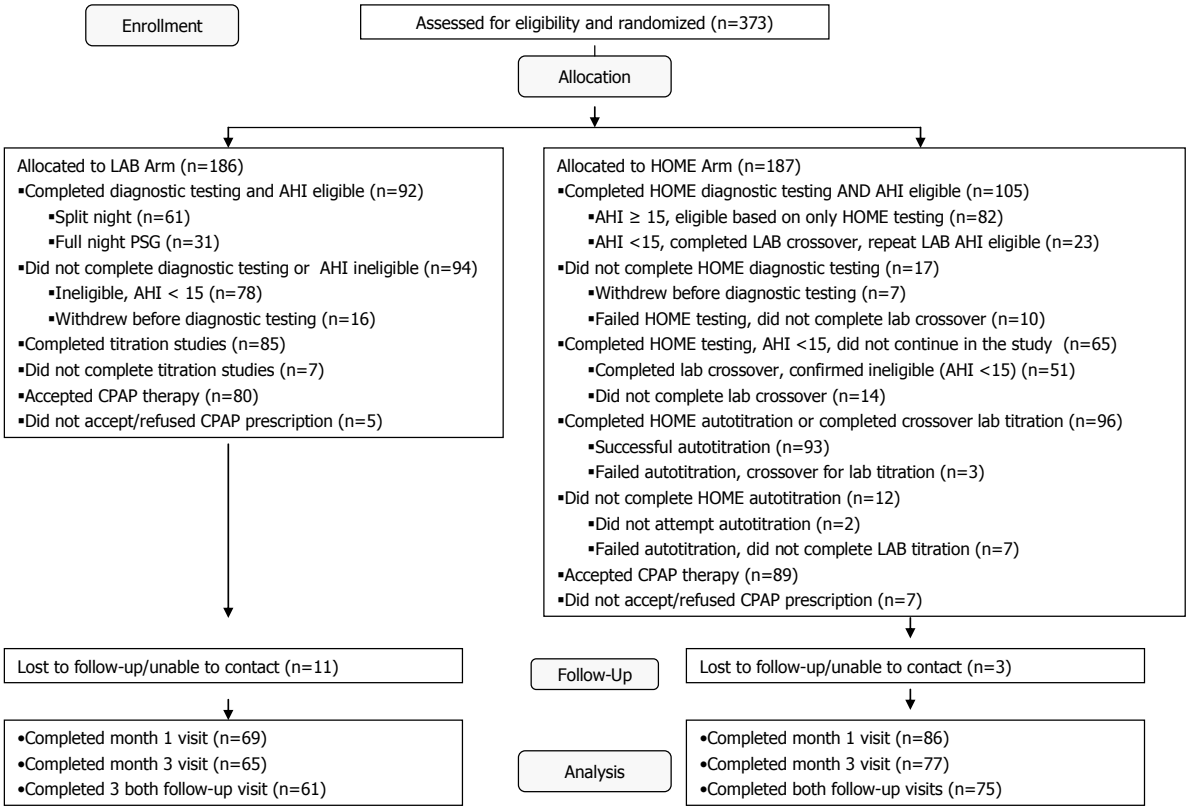
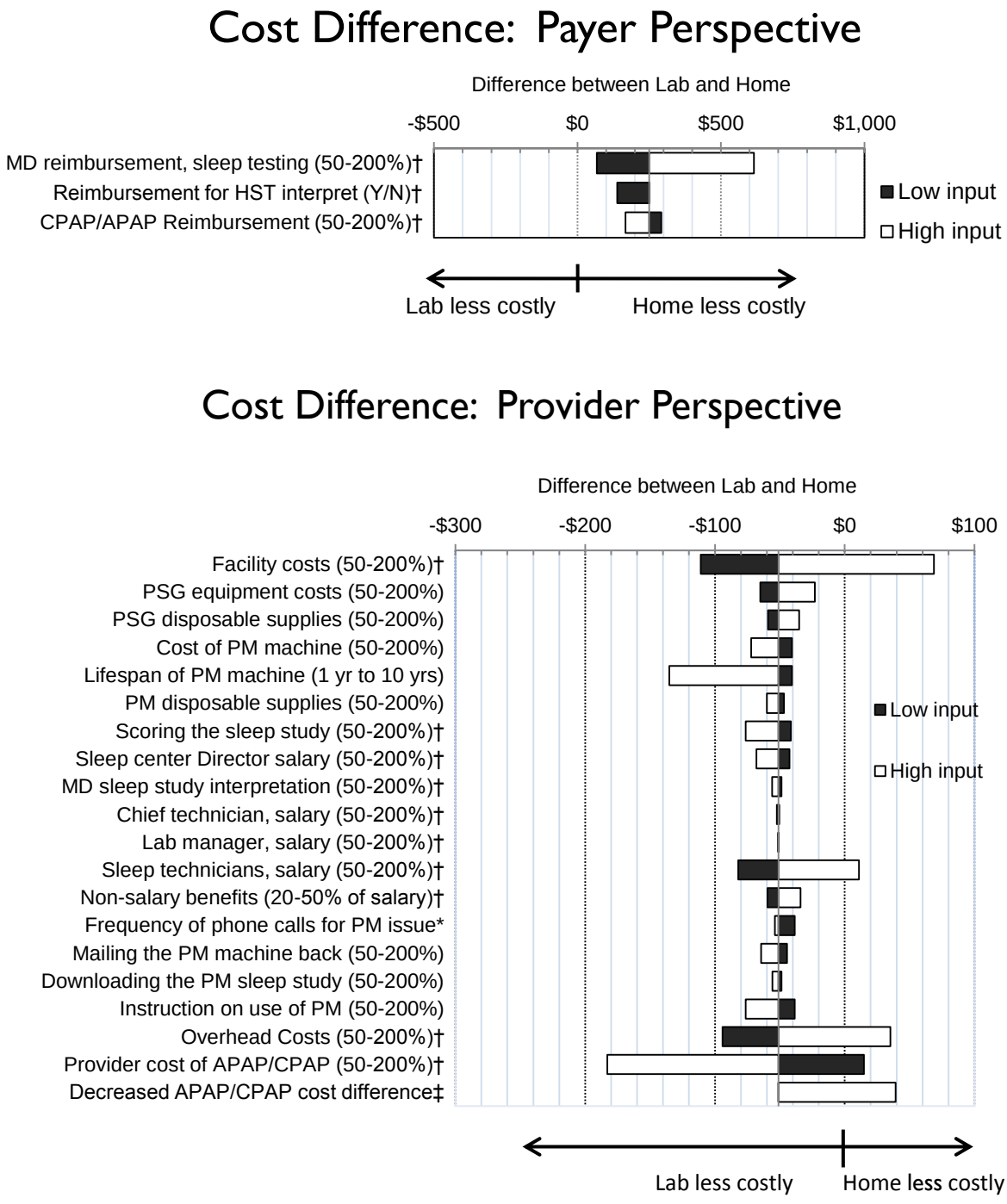


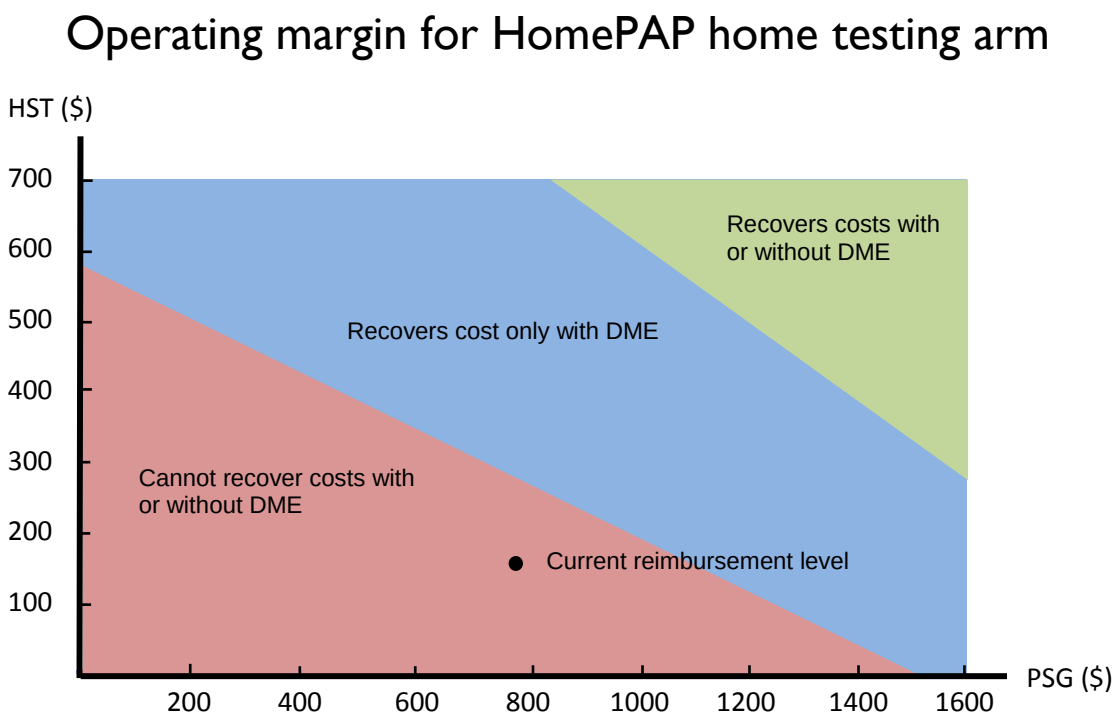
Figure 2: One–way sensitivity analysis of cost inputs



Legend for Figure 2

† Inputs affect both PSG and PM costs.
* Ranges from 1 15-min call for every patient, to 1 call for every 10 patients. Base case was the rate of phone call support seen in the HomePAP trial (approximately a 12-minute phone call for 95% of patients)
‡ Blue reflects base case, or 100% of the additional cost of providing APAP to the home arm, and CPAP in the lab arm. Red reflects the case where the cost of APAP in the home arm is reduced to the point it is equivalent to CPAP in the lab arm.

Figure 3. Two-way sensitivity analysis of reimbursement



Legend for Figure 3

This two-way sensitivity breakpoint analysis shows the combinations of lab and home sleep reimbursement where the sleep lab has different levels of profitability, assuming that all patients are tested under the HomePAP home arm algorithm. The pink region indicates the combinations of reimbursement where a sleep lab realizes a net operating loss even after assuming that the sleep lab is reimbursed for providing every patient with CPAP/APAP equipment (i.e. DME). The blue region is where the sleep lab has a positive net operating margin only after DME reimbursement for all patients. The green region is where the sleep lab has a positive net operating margin before DME reimbursement is considered. The current reimbursement level for lab and home studies is noted above. For comparison, in the HomePAP lab arm, where the only relevant reimbursement is APC 0209, the break point for a net positive operating margin after DME is an APC 0209 of $615, and the break point for a net positive operating margin before DME is $967.