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CENTERS FOR MEDICARE AND MEDICAID SERVICES
Medicare Coverage Advisory Committee

September 28, 2004

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland

Panelists

Chairperson
Ronald M. Davis, M.D.

Vice-Chairperson
Barbara J. McNeil, M.D., Ph.D.

Voting Members
David C. Dale, M.D.
G. Scott Gazelle, M.D., M.P.H., Ph.D.
Clifford Goodman, Ph.D.
Alexander Krist, M.D.
Michael Maves, M.D., M.B.A.
Rita F. Redberg, M.D., M.Sc., FACC
Jonathan P. Weiner, Ph.D.

HCFA Liaison
Steve Phurrough, M.D., M.P.A.

Consumer Representative
Joan L. Samuelson

Industry Representative
Michael Lacey, M.Sc.

Panelists (Continued)

Non-Voting Guest Panelists
Robert D. Hoover, Jr., M.D., M.P.H.
S. Satya-Murti, M.D.
Barry Whites, M.D., FCCP, MSHA

Executive Secretary
Janet Anderson Brock

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PANEL PROCEEDINGS

(The meeting was called to order at 8:02 a.m., Tuesday, September 28, 2004.)

DR. DAVIS: I am Ron Davis, chair of the committee today, and I would like to thank the members of the committee and members of the audience for being with us here today along with staff from CMS and AHRQ and other colleagues. Let me turn it over to Janet Anderson, who is going to kick things off with some housekeeping matters.

MS. ANDERSON BROCK: Good morning and welcome, committee chairperson, members and guests. I am Janet Anderson Brock, executive secretary for the Medicare Coverage Advisory Committee. The committee is here today to hear and discuss evidence and testimony regarding the use of unattended portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the diagnosis of obstructive sleep apnea, OSA.

The committee will make recommendations to CMS concerning the quality of the evidence for the use of these home sleep testing devices. In evaluating the information presented to you today, CMS encourages the committee to consider all

relevant forms of information including but not limited to professional society statements, clinical guidelines and other testimony you may hear during the course of this committee hearing. The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record to preclude even the appearance of impropriety. The conflict of interest statute prohibits special government employees from participating in matters that could affect their or their employers' financial interests. To determine if conflicts exist, the Agency reviewed all financial interest reported by the committee participants in their disclosure statements. The Agency has determined that all members may participate in the matter before the committee today.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations to this committee disclose any current or previous financial involvement with any firm on whose products or services they may wish to comment. This includes direct financial investments, consulting fees and significant institutional

support.
I would now like to turn the meeting over to Dr. Steve Phurrough, who will give his opening remarks, and then chairperson Dr. Ron Davis will ask the committee members to introduce themselves and to disclose for the record any involvement with the topic to be presented.
DR. PHURROUGH: Thank you, Janet. Let me offer my welcome to the panel and thank you for your willingness to serve today, and welcome the public also. We think that these are important meetings, we think that the work we do at CMS should be public, and we welcome the opportunity to hear today both from experts and from the public on the evidence around this particular issue.
I want to remind the panel and the public that what we're asking today is that the panel give us recommendations on what the evidence shows, and then we will use those recommendations as we make our decisions around this particular issue. We are not asking the panel nor do we expect recommendations on what we should and should not pay for, we're asking you to provide us some recommendations on what you believe the

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evidence shows.
With that, thank you again for your diligence and willingness to be here, and Dr. Davis.
DR. DAVIS: Thank you, Janet, and thank you, Dr. Phurrough. As Janet mentioned, to kick things off we would like to go around the table and have members of the committee introduce themselves and also declare any involvement, previous involvement in the issue and any possible conflicts of interest. So, let me ask you all to state your name and your pertinent affiliation or affiliations. And so I'll begin.
I'm Dr. Ron Davis, I am the director of the Center for Health Promotion and Disease Prevention at the Henry Ford Health System in Detroit. Another significant hat that I wear is as a member of the board of trustees of the American Medical Association, although I'm not formally representing the AMA here today. And I don't have any previous involvement in this issue.
DR. MCNEIL: I'm Barbara McNeil, I'm head of the Department of Health Policy at Harvard Medical School and a radiologist at the Brigham and Women's Hospital, and vice chair of this

committee. I have no financial involvement with regard to any of the items being discussed.

DR. WEINER: I'm Jonathan Weiner, professor at the Johns Hopkins School of Public Health and the School of Medicine and deputy director of the Health Services Research Center, and I have no conflicts of interest or involvement with this issue.

DR. KRIST: I'm Alex Krist. I'm an assistant professor of family medicine at Virginia Commonwealth University, practice at Fairfax Family Practice Residency. I have no conflicts of interest, but in 2000 I did an evaluation for the Technology Evaluation Center looking at radiovolumetric tissue reduction for sleep apnea disorder.

DR. MAVES: I'm Dr. Michael Maves. I'm the executive vice president and chief executive officer of the American Medical Association and am a clinically trained otolaryngologist.

DR. REDBERG: I'm Dr. Rita Redberg. I'm a professor of medicine at the University of California San Francisco. I direct our cardiovascular women's services. I'm a cardiologist and I have no conflicts of interest.

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DR. DALE: I am David Dale, from the University of Washington in Seattle, and I'm a professor of medicine at the University of Washington Medical School and I have no conflicts.

DR. GAZELLE: I'm Scott Gazelle, I am a radiologist at Massachusetts General Hospital where I direct the Institute for Technology Assessment. I have no financial conflicts.

MS. SAMUELSON: I am Joan Samuelson. I am president of the Parkinson's Action Network, a Parkinson's advocacy organization based in Washington. I'm a lawyer by training and I have no conflicts of interest.

MR. LACEY: I am Michael Lacey, I work for Boston Scientific Corporation and I am the director of the Health Economics and Outcomes Research Group within our company. I work mostly on cardiovascular as well as endovascular technologies. I have no conflicts of interest.

DR. GOODMAN: I am Cliff Goodman, vice president at the Lewin Group, which is a healthcare policy consulting firm. I have no personal conflict of interest. However, in 2002 my firm, the Lewin Group conducted some work for a company that had a product for testing in

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monitoring sleep breathing disorders. I had a small role in this work in 2002 and I checked, and the Lewin Group billed the company for about ten hours of my time.

DR. HOOVER: I'm Dr. Robert Hoover, an internist. I work for CIGNA Medicare as a carrier medical director and I'm also an assistant professor at Vanderbilt University.

DR. SATYA-MURTI: I am Satya-Murti, I am a carrier medical director at Blue Cross Blue Shield in the Kansas City area. I am also a neurologist and have an academic rank at the University of Kansas.

DR. WHITES: My name is Barry Whites, I am a contract medical director and fiscal intermediary for TriSpan in Jackson, Mississippi. I have no interest, or conflict of interest.

DR. DAVIS: Thank you very much and welcome again. We'll proceed to the first item in the agenda today after opening remarks, and that's a CMS presentation of the request and the voting questions by Dr. Tiffany Sanders.

DR. SANDERS: Good morning. I would like to welcome you to today's Medicare Coverage Advisory Committee meeting on the use of

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multi-channel home sleep testing devices in evaluation of obstructive sleep apnea. First I would like to introduce you to members of our CMS team. Our executive secretary is Mrs. Janet Anderson Brock. Mrs. Francina Spencer is our lead analyst. Myself, and Dr. James Rollins. Jackie Sheridan-Moore is our technical advisor. Dr. Louis Jacques is the director of Division of Items and Devices, and Dr. Steve Phurrough, the director of the Coverage and Analysis Group.

The purpose of today's meeting is to discuss and evaluate the available evidence regarding the diagnosis of obstructive sleep apnea using unattended portable monitoring devices. Obstructive sleep apnea, the hallmark of the disease is the episodic cessation of airflow during sleep. The disease prevalence has been noted as being between two to four percent of middle-aged adults, although some epidemiologic studies suggest that as much as nine percent of the population is affected by this disorder. Common symptoms of this disorder include daytime sleepiness, reports of snoring by a nighttime partner, changes in mood and changes in cognition.

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There are several readily available medical and surgical treatments for this disorder. The most commonly known is CPAP or continuous positive airway pressure, and that is simply giving the patient a constant flow of air pressure in order to maintain the airway during sleep. There have been reports of associated morbidities with the disease of obstructive sleep apnea, including cardiovascular complications such as hypertension or cardiac arrhythmias, as well as changes in quality of life as you can imagine, with ongoing daytime sleepiness. The mainstay of the diagnosis at this time has been polysomnography, and the polysomnogram is simply a multi-channel device that records neurophysiologic as well as cardiorespiratory parameters of sleep. CMS' current coverage policy is under the national coverage determination continuous positive airway pressure. This policy's indications and limitations of coverage state that in order to cover a continuous positive airway pressure for the treatment of obstructive sleep apnea, a diagnosis of moderate or severe OSA must be determined, surgery must be a likely alternative, and the use of CPAP devices is

covered for patients with an AHI greater than 15, that's the apnea-hypopnea index, or an AHI between 5 and 14 if the patient also has symptoms such as changes in mood or reports of daytime sleepiness. Our policy also specifically states that the polysomnography must be performed in a facility-based sleep study laboratory and not in the home or in a mobile facility.

Back in April of this year we received a request from Dr. Davidson to modify this policy and to include devices that can be used portable unattended.

These devices, approximately 40 of them have been approved by the FDA for use in the home or portable setting, and they have been cleared by the process of the 510(k) clearance, which simply means that they are substantially equivalent to devices already on the market.

So the questions before the MCAC panel today, there are two sets of identical questions, the first addressing portable devices that measure the same sleep and respiratory parameters as facility-based polysomnography, and then a set of questions for portable devices that measure cardiorespiratory parameters of sleep only.

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The first question is: How well does the evidence address the effectiveness of this type of unattended portable multi-channel home sleep testing device as an alternative to facility-based polysomnography in the diagnosis of OSA?

How confident are you in the validity of the scientific data on the following outcomes? Acquisition of interpretable data. Ability to accurately diagnose OSA. Ability to accurately identify those without OSA.

How likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnography for the following outcomes? Acquisition of interpretable data. Ability to accurately diagnose OSA. Ability to accurately identify those without OSA.

How confident are you that these testing devices are as accurate in the diagnosis of OSA as is a facility-based test?

How confident are you that the use of these sleep testing devices in the diagnosis of OSA will lead to similar or improved health outcomes measured either directly or indirectly through changes in patient management?

How confident are you that the use of these sleep testing devices are as accessible as is a facility-based test for the diagnosis of OSA? And finally, based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to, A, the Medicare population, and B, providers in community practice?

Thank you very much and enjoy the meeting.

DR. DAVIS: Thank you, Dr. Sanders, and members of the committee will find a hard copy of the slides that she just presented in your folder. And as you know, I think already, and as you can see on the agenda, we will be getting to those questions toward the end of the meeting after lunch and after we hear from AHRQ and presenters and members of the public.

So with that, we will proceed to the AHRQ presentation of their technology assessment, which will be done by Dr. Boehleche. Welcome.

DR. BOEHLECHE: I'm Dr. Brian Boehleche, I'm a professor of medicine at the University of North Carolina. I have no financial

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conflicts. Linda Luchs, who is with Research Triangle Institute, who actually did most of the actual logistic work on this, is trapped in Atlanta due to the storm so I will present a few of her slides and then get on to my part. Basically the study was to update a larger study that was done and published which we will allude to in a few minutes, and the methodology used was pretty much the same as had been done to provide the literature search for that evidence review. In this particular case the MEDLINE search was done, providing 172 potential studies. There were no matches on the International Network of Agencies for Health Technology Assessment database. We also did other searches, including hand searches of bibliographies on studies that came up, and came up with two additional potential study articles. The search limitations were for human studies done in adults published in English. The initial date was January 2002 because the previous study had included all articles published up to that date. The studies had to be primary data collection, no reviews or comments or metaanalyses.

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The portable device had to be compared with what is generally considered in most of the studies to be the gold standard, although, as you'll hear, I'm sure, there are issues with that, the in-lab polysomnogram. And the only other exclusion was that after completion of the study, there had to be at least ten subjects in the final analysis.

Data was extracted from articles that were included in the review, and this is all in the slides. There were lots of information that was extracted to provide evidence tables. So there were 172 articles, 15 were deemed to meet the entrance criteria. We were unable to obtain a couple that were in foreign journals. 13 articles were reviewed and the hand search produced two more, and three of those were finally, after the full article was reviewed, were excluded. So we ended up with 12 published studies that are included in the update review.

They were categorized by evidence level using the same criteria used in a previous study. That is, evidence level one is a blinded comparison of the portable device and the in-lab results. Patients were selected consecutively or

with no design influence, that is, they were either consecutively or randomly selected. Evidence level two would be a blinded comparison but nonconsecutive patients or a possibility of some design influence. Three would be a blinded comparison with consecutive patients but the reference standard, in this case the polysomnogram, would not have been performed on all subjects. But we did not include studies of that type, so there would be no level of evidence three in this review.

And then four, reference standard not applied blindly or independently.

There were eight quality indicators that were reviewed from the evidence, or from the material in the published studies: Was the study a prospective study; was the portable device tested outside the laboratory, that is in the home; was the random order of allocation of subjects for the in-lab polysomnogram versus the portable test done randomly; and was there low data loss, that is, less than ten percent of the data from the studies were unusable for analysis; high prevalence percentage of completions, that is

greater than 90 percent of initially eligible patients assigned to the study completing the study; was the methodology for the in-lab and the portable testing fully described; and was the method of scoring the portable testing fully described.

And then if none or one, only one quality indicator was not met, in other words, not of good quality, then this was given an overall quality rating of A. Two not met, B. Three, C. And four or more not met, D. If it couldn't be determined from the published paper whether or not a certain quality indicator was met, then it was assigned that it was not met.

And RTI put together sort of a composite to make it a little easier, I guess sort of a summary, and graded the studies as to quality in good, fair and poor by this algorithm. That is, if it was level one evidence and rated A or B in quality, then that was good. For example, if it was let's say level two evidence but D in quality, that was poor, and so forth. I think you will have that in front of you there, and as I said, there would be no level three studies.

Now, where is mine? So now to the more

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substantive, the previous review because we wanted to put this in context -- our charge was to update the literature review, as I said, from a previous review which has been published and is well known. The previous review was cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians and the American Thoracic Society. There was the same sort of literature search, data abstraction and evidence tables that were produced by the evidence-based practice center of the Research Triangle Institute in North Carolina, and the University of North Carolina that I was part of. And this was presented to the evidence review committee of the sponsoring organizations. The analysis of that evidence was then published by the eight-member evidence review committee in a paper called Home Diagnosis of Sleep Apnea, Systemic Review of the Literature, published in Chest in October 2003. That evidence review was then taken by a guideline committee which considered the evidence and published another paper called Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Sleep Apnea in Adults, published in the

Journal of Sleep in 2003. This is the publication that contained recommendations regarding the use of these devices in attended and unattended settings.

And then a third paper published by the steering committee of that group published something called the Executive Summary, which combined elements of both those two previous papers and was published in the American Journal of Respiratory and Critical Care Medicine in 2004.

The current report, as I said, updates the literature search since the cutoff of the previous review, which was December 2001, review studies published since the prior review which met our inclusion criteria, provided evidence tables and a discussion of the published findings regarding the effectiveness of portable monitoring devices for evaluation of suspected sleep apnea.

I want to make it clear, it does not make specific recommendations regarding the use of portable devices for clinical decision-making or judgments about the previously published recommendations. It's meant to be an evidence review, not a judgmental paper.

So as I mentioned, the polysomnogram is

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the gold standard. I'm going to skip over some of these fairly quickly since you do have them and in the interest of time.

It typically monitors EEG, eye movement, submental EMG, airflow, respiratory effort, which is chest and abdominal movement, limb movement, cardiogram or heart rate, oxygen saturation by pulse oximetry. And it can categorize sleep stages, it can detect and characterize arousals, which are usually characterized as brief EEG changes consistent with arousal whether they're respiratory related, limb movement related, or "spontaneous", meaning unrelated to any recognized change.

It characterizes respiratory events as apneas or complete cessation as obstructive where airway is closed, or central where there's cessation of effort, or mixed. And hypopneas, which are reduction of airflow of defined magnitude associated with either desaturations, oxyhemoglobin desaturations and/or EEG arousals, depending to the definition used. And that's one of the big issues in this area, and that is how one defines hypopneas may well change quite significantly the apnea-hypopnea index that's

derived from either a PSG or a home study. The AHI that was referred to by Dr. Sanders is the number of respiratory disturbances, apneas plus hypopneas, per hour of sleep, and the definition of hypopnea, as I just mentioned, can significantly alter what the AHI is from a given study. Sometimes the term respiratory disturbance index is used, and this is not as well defined in the sense that some people use it interchangeably with AHI, some use it when the time of sleep can't be determined so that the index is derived from monitoring time, or time in bed.

Home study devices in general, although there are some published studies which can characterize EEG, in general home studies do not measure EEG, and none of the studies in this update review did, so that they cannot quantify sleep time or sleep stages or detect directly cortical arousal. So they don't provide direct information on the effect of the respiratory disturbance on sleep quality, the frequency or effect on nonrelated respiratory arousals, for example, periodic limb movements or spontaneous arousals without a specific cause.

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So, as has already been briefly mentioned, what apnea-hypopnea index supports the diagnosis of OSA and therefore the possible indication for CPAP, the Medicare guidelines have been gone over so I won't review those. But the second part there says clinical diagnosis and specifically the management indicated is not solely determined by the AHI, it depends on other factors including the severity of the sleep symptoms, the presence of other causes of sleep symptoms, and the presence of comorbidities such as hypertension and diabetes.

So the previous -- there was actually a fourth paper by Dr. Flemons and Dr. Littner published in Chest as a companion paper to the evidence review, where they looked at measuring agreement between diagnostic devices. And as they point out, the correlation coefficient which is used in many studies is oftentimes not a good measure of agreement and may be misleading. More recently a thing called the Bland-Altman type of plot are being used, and I will refer to those in some of these studies. Also the operating characteristics, the receiver-operator curve which is a plot of basically sensitivity and

specificity. And now that previous review heavily depended on likelihood ratios, which I will discuss briefly, for determining how much knowing the results of the test influenced the probability that the condition of interest is present. And then finally, a Kappa coefficient, which is a measure of agreement beyond chance, because obviously even if two tests are not measuring the same thing, there is some chance that agreement will occur.

Again, in the interest of time, I think I will skip over some of this. Bland-Altman is a plot where the difference between the value obtained from the test of interest, for example in this case would be the home sleep study, and that from the reference test, so the polysomnogram, is plotted against the average values of those two tests. And the mean difference indicates whether there is a bias of this test that's under scrutiny, for example the home test, and the so-called limits of agreement, which are approximately the difference plus or minus two standard deviations, is a measure of the variability and should include about 95 percent of the differences. So it gives one some impression

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of how much the test of interest might differ from the "gold standard" test.

And Bland-Altman actually used a pulmonary example in their published study showing measurement of peak flow by two different meters, a mini-meter and a large meter. And you can see that a typical correlation plot, these look very good, so each subject measured their peak flow, which is a measure of lung function, on both devices, and this is a plot of the value obtained on one device against the other. And that looks quite good. In fact the R, the correlation coefficient was .94, which I think we would all accept as a high correlation.

But when one plots the Bland-Altman plot, which is the difference between the peak flow on the two devices against the average value of the two devices, the average value then being the best estimate of in a sense the true value, one sees that although on average, that mean difference is close to zero, there are some very large differences hidden within what appears to be a good correlation. So that's the basis for why correlation may well not tell the whole story on agreement.

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The Kappa statistic is a measure of agreement beyond chance. A value of one means perfect agreement and zero means the agreement is what would be expected by chance alone, and a popular statistical text interprets Kappa statistic as .75 or above as excellent agreement, .4 to .75 as fair to good, and less than .4 as poor agreement beyond chance.

I'm going to skip over most of this because I'm sure all the committee members are very familiar with sensitivity and specificity, and receiver operator curve, which basically plots sensitivity versus specificity and not the balance between the two. The one point that I do want to make because it comes up in one of the studies that we reviewed is that if one uses two different thresholds to define positive and negative tests, that is, if you increase the sensitivity by using one threshold and then increase the specificity by using another threshold, you can reduce the number of false positives and false negatives.

So for example, if you use the AHI of less than 5 as negative but only greater than 15 as positive, you can do this, the only problem is there are many test values then that will fall

between those two limits and then these patients are considered unclassifiable or indeterminate. Likelihood ratios combine sensitivity and specificity into a number which when multiplied times the prior odds of the condition being present, so if one makes a clinical assessment that it's a 50-50 chance that the patient has, in this case sleep apnea, the test is done, the test is either positive or negative based on the criteria used, the threshold used, and then the likelihood ratio which is derived as shown there from the sensitivity and specificity tells you how much that prior odds has changed by knowing the results of the test. So the posterior odds after the test results are known are the pretest odds multiplied by the applicable likelihood ratio.

And again, interpretation from the Flemons and Littner paper for example, they say that a likelihood ratio of positive, meaning if the test is positive and the likelihood ratio for that test has been determined to be 10, is a large increase in the probability that the condition is present, the test has very significantly improved, or increased, excuse me, the probability that the

test is present. From 5 to 10 they consider modest. Values of negative ratio of .1 or below produces a large decrease, in other words, it is ruling out the condition as present, and .1 to .2 is a modest decrease. Values of the likelihood ration between .2 and 5, they interpret as producing little change from the prior probability.

So monitors were classified in 1994 in terms of types by what was called then the American Sleep Disorders Association into Type 1, which was the standard laboratory polysomnogram, Type 2 is comprehensive portable polysomnography with a minimum of seven channels; there were no studies in this update review that fell into Type 2, there were a couple studies in the previous larger review published. Type 3 is a monitor which has a minimum of four channels which includes ventilation or airflow and at least two channels of either respiratory movement or respiratory movement and airflow, so two channels of that, heart rate or ECG, and oxygen saturation. And then Type 4 is continuous single or dual "bioparameters", and if airflow isn't measured, even if it has more than two channels, it's still

considered a Type 4 if it does not measure airflow.
I already went over that and that.
All right. So just, again, to put our update in context, because I want to emphasize again that this was an update looking at things published since the prior review, the previous review results were published in the paper by the eight-member evidence review committee.
There were nine studies that looked at Type 3 devices in the laboratory alone, in other words being compared with the PSG but only in a laboratory setting side by side or simultaneously, no home study. Data loss was about 3 to 9 percent, and sensitivities ranged from 86 to 100 percent, specificities from 88 to 100 percent, false positives were from zero to 22 percent and false negatives zero to 21 percent. They produced -- oh, I'm sorry, the defined true positives by a polysomnogram AHI of over 15.
Likelihood ratios for a positive test were 6 to 23, so you can see that they did fall in the modest to significant increase in probability that the disease would be present, in this case sleep apnea, and negative likelihoods from .03 to .15.

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There were four studies that did Type 3 in home unattended. Data loss was 3 to 18 percent. Sensitivities, as you can see, were a little wider. Specificities, again a little wider, going down to 58 percent. There were up to 31 percent false positives and up to 45 percent false negatives. Likelihood ratios were more modest, from 1.8 which would be considered no change, to 9, which would be a modest increase in probability. Likelihood of negatives were .13 to .43, in the modest to no change range.

So their conclusions were that Type 3 monitors have utility to both reduce and increase the probability that a patient may have sleep apnea in the attended setting. The utility in the unattended setting is not as well established. A limited number of home unattended studies showed a wider range of sensitivities and specificities with likelihood ratios which generally did not markedly improve the probability of sleep apnea with either a positive or a negative study result.

There were eight studies doing Type 4 in home, and I have skipped over in the interest of time any Type 4 just in the lab. Data loss

there was 7 to 10 percent, sensitivities as you can see again, a little wider, down to 31 percent but up to 98, down to 48 for specificity and up to 100. False negatives from a low of 3 to a high of 37 and false positives from zero to 41 percent. Likelihood ratios widespread again, positive from 1.8 which would be no change to 20, which would be a significant increase in probability. Negative likelihoods from .04, significant decrease, to .69, no significant change.

Type 4 devices, that report summary said oximetry alone can reduce the probability of sleep apnea in both attended and unattended settings; however, in the latter situation, the results should be considered preliminary, the addition of a second signal showed results that were similar to those using oximetry alone, although there were fewer studies evaluated. Oximetry alone can increase the probability of sleep apnea in both attended and unattended settings. However, in the latter situation, the utility appeared to be less compared to the attended setting. The addition of a second signal, again, showed similar results to oximetry alone. The evidence is lacking to

suggest that this type of signal can be used in an unattended setting.
So those were the conclusions of the evidence review committee of the previous evidence tables that were presented to them. They mentioned several limitations, the reason I go over those is because most of those apply to our update studies as well. The mean AHIs in most studies was in the moderate, that is over 20, to severe, over 30 events per hour range, so findings may not be generalizable to populations with a lower pretest probability such as the general population, women, and patients from the primary care population.
They said that their findings should be applied only to patients without significant pulmonary or cardiac comorbidities.
They felt research was needed to delineate the utility of portable monitors in populations of nonwhites, because there were very few of those reported in those studies, and those with a greater percentage of women because again, the majority of cases in the published studies were men.
It was difficult to know whether the

results could be generalized to patients who had not been assessed by specialists, that is sleep specialist physicians.

I will skip over this. The executive summary made recommendations on whether or not they felt home sleep studies should be used and I will skip over that, it's all in the slides.

Okay.

So now to the update review. So Research Triangle Institute was contracted to provide the evidence tables and provide a summary of the review of these papers that were found in the literature update. There were 12 studies, as I mentioned, reviewed in detail. There were two studies that were Type 3 monitors that were done simultaneously with the in-lab study only; in other words, there was no home study component. One was rated fair and one was rated poor in quality. There were five studies of Type 4 devices, one rated fair and four poor. There were some studies that did both an in-lab and a home comparison, and there were two Type 3 devices that did both in-lab and home comparison components, one rated good and one rated fair or poor, and I'll discuss that, there was some controversy

about the rating on that. And one Type 4 study rated fair that did both types of comparisons. There were two studies that did only comparisons between their device in the home and the polysomnogram done in the laboratory, one rated fair and one rated poor in quality. General considerations about these studies: Most patients appeared to be referrals from sleep clinics but one study, evidence table four in the report, first Dr. Reichert, stated that referrals were from, quote, many physicians. This was the only study that I saw that appeared to get their studies from a more general population than a sleep clinic or sleep lab. The majority were again, though, male. The mean age of the study groups were from 41 to 53, so not really in the Medicare range. There was a high prevalence of sleep apnea defined by the results of the in-lab polysomnogram. Sometimes this couldn't be exactly determined, that's why I've got an approximate sign because of drop-out and so forth, but it ranged from probably around 45 to 50 percent at a low to 84 percent as a high. There was one study, and I won't try to pronounce that name, I'll refer

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you to evidence table eight, which looked at a large number of patients with a much smaller prevalence because it was a screening study of commercial truck drivers done through multistaging. Most supplied no information on the race or ethnicity or the prevalence of comorbid conditions.

So, in details, Type 3 simultaneous in-lab comparisons. Two studies and then evidence table one and evidence table three, Calleja and Marrone with only in-lab comparisons. There were two studies, table two and table four, Dingli and Reichert, with in-lab and home components, two fair, two poor. The prevalence OSA was 75 to 89 percent, so very high prevalence of OSA by the in-lab study. Sensitivities reported were very high, 91 to 95 percent, and specificities from 81 to 100 percent. One study did not explicitly report sensitivity and specificity. The highest sensitivity and specificity was reported in the study that was rated as poor in quality.

Bland-Altman plots for the study that didn't report sensitivity and specificity, the mean difference in apnea-hypopnea index between the portable device and polysomnogram was very

low, two events per hour. The limits of agreement were about plus or minus ten events per hour. For the study in evidence table one, the mean difference was minus four for manual scoring of the home device, but minus 24 for automated. So what that means is that this home study had a method for automatically scoring events, but it could be reviewed manually and an interpreter interpret those events, and when it was scored manually, there was much -- blindly but manually by an interpreter, there was much better agreement with the results of the in-lab polysomnogram than taking the results from the automated score algorithm of the device. So, the conclusion in our report was that sensitivity and specificity reported from fair to poor quality studies of Type 3 devices used in the laboratory indicated that some Type 3 devices in an attended setting can modestly increase and modestly decrease the probability of sleep apnea in the types of patients selected in these studies. There were five studies of Type 4 devices in the lab listed there. Two of them had both in-lab and in-home components so they will be

discussed in the in-home component comparisons. Sensitivities again, as you see, a little wider spread just as they were in the previous review, from 80 percent to 95. One study didn't report them. Specificities, a wider range, 57 to 95 percent. The highest specificities of 95 there were for this multistage screening model. But using the highest sensitivity, excuse me, the highest specificity, the corresponding sensitivity was only about 89 percent.

This is a Bland-Altman plot from the study evidence table six and you can see that although the mean difference there is pretty near zero, there are some cases where there is a very very wide discrepancy between the results from the home study and the in-lab study up to, as you see there, about 40 events per hour.

So, our report stated that for simultaneous in-lab comparisons for Type 4 devices, there was evidence that Type 4 devices can increase and decrease the probability of sleep apnea in the types of patients in the studies when used in an attended laboratory study but it was not as strong as the evidence for Type 3 devices.

So now to the crux of probably what

most people here are interested in, devices used in the home, Type 3 devices used in home studies. There was a study by Dingli, first author, good quality study, 50 patients, 77 percent were men, mean age was 50 years, approximately 76 percent prevalence of sleep apnea by the in-lab polysomnogram when the cutoff was 15 for the apnea-hypopnea index. They were able to do both automatic and manual scoring. They had 18 percent data loss in the home studies and they stated that manual scoring to determine sleep apnea agreed better with the polysomnogram results than the automated scoring. You can see the Kappa statistic for agreement beyond chance was very poor for the automated scoring but was quite good for the manual scoring.

This is the correlation plot. On the Y axis, vertical axis has the apnea-hypopnea index, or apneas plus hypopneas by the home study device, and on the X axis is the polysomnogram, and this is the Bland-Altman plot. You can see the mean difference there is very very small, but the limits of agreement, and I have penciled in as you can see because they just had that in the legend, plus or minus 1.96 standard deviations. The

limits of agreement are as you see, going up to about 35 and down to about minus 22 or so. So, this study did not report sensitivity and specificity at a single threshold. They used two separate thresholds, that is, they said if we consider a positive test only if the AHI is greater than 20 and a negative is only if the AHI is less than 10, they had absolutely no false positives and no false negatives, compared to a classification by polysomnogram as positive for an AHI greater than 15 and negative below 15. As I mentioned before, though, when one uses two separate thresholds, there are bound to be some study results that are called indeterminate and in this case 36 percent of home studies yielded indeterminate results.

The next in-home study was lead author Reichert, which was ultimately probably characterized as fair quality, although the RTI people felt it was poor quality because the allocation of patients to the home study and the polysomnogram was not considered random and there were several other limitations to the study. So one would consider it fair to poor in quality. There were 45 patients analyzed, 75 percent male,

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mean age was 52. There was a 47 percent prevalence of sleep apnea with a polysomnogram AHI of over 15 based on the article, but they mention in the description that 40 of the 44 patients in one section of the study had "split night" polysomnograms. For those of you who aren't familiar, a split night is to do a diagnostic portion where there is nothing applied, the sleep is observed and respiratory disturbances are observed. If it's felt that the patient has enough respiratory disturbance to qualify for needing treatment, the rest of the night CPAP is applied and titrated, so that's the so-called split night. So there's only a portion of the night that's done diagnostically. That should be at least two hours by Medicare guidelines, it could be longer depending on the discretion of the technician, the severity of the condition, and the lab policies.

The problem is, of course, one has a shorter period of time to assess the overall apnea-hypopnea index. So 40 of these 44 patients apparently had split night studies, suggesting there was a much higher than 47 percent prevalence

of sleep apnea, at least as judged by the technician performing the study, and ultimately putting on CPAP. There was 13 percent data loss and the scoring was done only with an automated algorithm.

As I said, this was the one study that had the distinct positive of having patients referred apparently by community physicians. Another unusual aspect, though, was that they did three nights of home studies, not just one night, and they averaged the results. The sensitivity reported was 91 percent, the specificity was 83 percent. I calculated likelihood ratios from this, a positive of 5.35 and a negative of .11, indicating that based on the method of interpreting likelihood ratios that it can produce a modest increase or a modest decrease in probability of the patient having an apnea-hypopnea index of over 15 by a polysomnogram if positive or negative respectively.

The next slide shows the Bland-Altman plot for this and it shows that there were fairly wide limits of agreement, however. So this is the Reichert study and they didn't put the mean difference but you can see the mean difference is

probably close to zero, but the two standard deviation lines are up there as you see at 60 and minus 60, indicating potentially 95 percent of patients would fall between these lines, but fairly wide limits of agreement, meaning there can be some fairly wide differences between the study results in the home and what would be obtained with a polysomnogram.

So, the conclusions of the study were that Type 3 in-home studies had very limited evidence from fair to good studies that Type 3 devices can modestly increase and modestly decrease the probability of sleep apnea, that is an AHI over 15 in the types of patients in these studies.

Evidence from one study shows that a decreased rate of false negative and false positive studies can be achieved using separate thresholds for positive and negative, but there's a significant proportion of results then that will be indeterminate, and the limitations that will be discussed later apply to these studies.

Type 4 in-home. There was one by Golpe considered fair quality that used both auto and manual scoring. There were 44 patients analyzed,

96 percent male, mean age was 52. 52 percent prevalence of sleep apnea with an index over 10, and there was a single flow measurement channel. Overall data loss in the study was 20 percent but it was 7 percent if technicians did the hookup, and that was done on half the patients, and 33 percent if the patients did their own hookup. Sensitivity and specificity weren't explicitly reported but I estimated from a receiver operator curve approximately a 90 percent sensitivity and approximately 80 percent specificity from what's called the best point on the receiver operator curve, on the knee of the curve where you get the best combination of those two, and this is the receiver operator curve.

So the area under the curve -- oh, excuse me -- the area under the curve for the evidence table seven, the Golpe study, was slightly better for manual scoring, calculated the likelihood ratio positive of 4.5 and the likelihood ratio of .125 from that best point on the receiver operator curve, indicating only marginal increases in probability if the test is positive and modest decreases in the probability if the test is negative.

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This study was unique in that it did report physician decision-making on treatment regarding the indication for treatment with CPAP based on blinded interpretation of the two studies, something that was the only one that I found that actually looked at how would the management of the patient be done based on the two studies interpreted independently. The physician treatment decision based on the home study agreed with that from the polysomnogram in 34 of 44 cases, or 77 percent.

There were obviously then, 10 cases in which the management differed. There were three cases that were just simply false negatives by the home study and three cases that were false positive by the home study. There were, however, three cases in which both the home study and the polysomnogram would classify the patient as having sleep apnea, but the home study indicated greater severity so the treatment decision differed. And there was one home study case that was inconclusive, it wasn't clear whether the patient had sleep apnea or not, but the polysomnogram indicated the patient did, and the physician felt CPAP was indicated. So in 23 percent of cases,

the decision by a physician looking at the study would have differed in terms of CPAP treatment from that interpreted by a polysomnogram.
Type 4 in-home study, Liesching, evidence table nine. Poor quality, auto scoring. 31 patients analyzed, 45 percent male, so a little lower male percentage this time, mean age 50. Sleep apnea 74 percent, and this was just for the PSG apnea index of over 5, 42 percent if it was over 15. They used a technology of sound measurement device for the flow estimate, not a direct estimate of flow or pressure. Data loss for the home study in this one was only 3 percent. Sensitivity was 91 percent, but all eight subjects classified as normal by the PSG were classified sleep apnea by the home study, so one would call that a specificity of zero.
I went and looked, though, at the rating of the subjects in terms of mild, moderate and severe, and of these eight that were called sleep apnea by the home study, six were called mild, one moderate and one severe. So if you looked and considered only the ones called moderate and severe as misclassified by the home study, then you would have a specificity of 75

percent with likelihood ratios of 3.6 and .12, but the actual classification, as I said, gave a specificity of zero.

There was a study by Bar. This one uses a different technology, peripheral arterial tonometry, from the other studies. It was considered fair in quality and had an automated scoring algorithm. 14 patients were analyzed in the home study component, 79 percent were male, mean age 41, prevalence of sleep apnea was 68 percent, and each patient had two nights of home study. This type of technology was not in any of the studies reviewed in that previous paper, so it represented a new technology for the reviewer. Data loss from the home studies was 11 percent. They did not report explicitly sensitivity and specificity but there was a plot of apnea-hypopnea index by the home device and the PSG that I was able to make an estimate, and I got an estimated sensitivity of about 78 to 80 percent and specificity of 60 to 75 percent. And that depended on whether or not I classified some borderline cases, meaning the home study value was very close to the lab study, but it might fall on one side or the other of a cutoff like 15, and

that's also of course one of the criticisms and limitations of studies that use a single cutoff. If a study has a value of 14 and another study has a value of 16, they fall on opposite sides of the cutoff and they would be called disagreement but, you know, obviously from a clinical point of view they actually agree very well. So I tried to look at, you know, if I gave these borderline cases the benefit of the doubt and included them as correctly classified, the sensitivity rose slightly and the specificity rose slightly, as you see.

Using the best values, though, that I could get, I got likelihood ratios of 3.2 and .27, which indicate the test produces, by Flemons and Littner's classification, little change in the probability of sleep apnea for classifying patients as having an AHI of 20 or more.

So the conclusions were that there was evidence from fair to poor quality studies showing some Type 4 devices used in unattended settings can modestly decrease the probability of OSA in the types of patients in the studies reviewed. The evidence is less robust that these devices can reliably increase the probability.

The evidence for efficacy of unattended Type 4 devices is overall less robust than for Type 3. There was evidence from one study that clinical decision-making regarding the need for CPAP based on the results of a Type 4 device home study will differ from that based on a PSG in 23 percent of the cases, a significant proportion. There is evidence from both home and in-laboratory studies that manual scoring of some portable devices produces better agreement with PSG than automated scoring. Evidence from a single study did not indicate improved sensitivity or specificity for sleep apnea using the new technology not evaluated in the previous review. Data loss in these studies averaged 13 percent, with a wide range from 3 to 33 percent. And there was some evidence, limited evidence we called it, that a higher rate of data loss occurs when patients do their own hookup. There was essentially no information given on the effect of age, gender, race, ethnicity on rate of data loss or the false positive and false negative rates. And I felt it was a very significant limitation that there was no information given in any studies that I could

find on the effect of comorbid conditions, especially cardiopulmonary disease, on the false positive and false negative rates. Nobody looked at their false negatives and positives to try to explain if there was an associated comorbid condition.

Only one study provided evidence of efficacy for home studies on patients referred by community physicians as I referred to. Only one study presented evidence comparing the clinical decisions based on home studies compared to those with PSG results. No study provided evidence on the overall clinical outcome of any of these patients based on the home study results or the PSG. No studies provided evidence on the lack of EEG information on whether that affected treatment decisions or outcomes.

So what are the potential limitations to generalizability of these findings in our update study and to generalizability overall, and specifically to the Medicare population that your committee is concerned with? First of all there was, as you saw, a very high prevalence of sleep apnea in the patient sample studied. One of the things that has to be considered is there is a

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very high prevalence of sleepiness reported by the elderly, there is a reference in the public material on that, but many have causes of sleep disruption other than sleep apnea. The association of sleep disordered breathing with snoring and body habitus also apparently is not as close in older people as it is in younger. The predictive value of a test obviously is affected by the prevalence, so the lower the prevalence the more false positives there will be at a given specificity. The mean age of the patients, as you saw, was definitely lower than that of Medicare recipients. It's well known that younger patients may have fewer comorbid conditions, certainly cardiopulmonary conditions and even conditions that cause sleep disruption that are not cardiopulmonary, such as restless legs, periodic limb movements of sleep. The effect of age on data loss in the home studies was not known, but there was a reference from the Sleep Heart Health Study that has been alluded to, which did not show a clear increase in data loss with age, there was no evidence presented that age was a factor in increasing data loss.

So, I think that concludes my remarks.
DR. DAVIS: Thank you very much,
Dr. Boehleche. We have on the agenda time after the break, a half an hour for questions to the presenters, including Dr. Boehleche, but I would be open to encroaching on that half hour now if people have questions they prefer to ask now, so let me see if any members of the committee would like to propose any questions to Dr. Boehleche or any of the other presenters at this point in time.
Yes, sir.
DR. SATYA-MURTI: What is the underlying mechanism for symptoms in OSA or disordered breathing? Is the arousal the main reason for the symptom or is the disordered breathing or some other less proximate problem downstream? I felt that simple behavior observation might give as much information as monitoring physiological parameters when we don't know how closely it is tied to the ultimate morbidity of the condition.
DR. BOEHLECHE: There's a lot of research looking into that, and I would say there is no clear-cut simple answers. I mean, it's I think generally felt that sleep disruption, either

these microarousals, brief electroencephalographic detected arousals or lack of certain stages of sleep, such as so-called slow wave sleep or deep sleep and perhaps interference with rapid eye movement or REM sleep produce some of the excessive daytime sleepiness, some of the mood changes. There's also some correlations between desaturations, the number of desaturations, oxyhemoglobin desaturations below a certain cutoff, be it 3 percent, 4 percent, or the time spent below a 90 percent saturation that correlate with certain physiologic changes.

Not in this review, but there are studies that look at things like insulin sensitivity and finding that patients with sleep apnea have a decreased insulin sensitivity. That seems to correlate with desaturations and time below 90 percent, as well as sleep disruption.

So again, as I said, I would say there is no simple answer but I would think, and others probably will address this, that it may be a combination of things, both less, poor quality sleep defined by stages of sleep that are less refreshing, as well as arousals and desaturations producing sympathetic outflow and physiologic

changes which can lead to things like increased risk for heart attacks, strokes, cardiovascular disease in general. So there's physiologic changes and sort of psychophysiologic changes.
DR. DAVIS: Dr. Hoover.
DR. HOOVER: How do you deal with methodologic issues in these studies where you have an apnea-hypopnea index generated in lab study that uses total sleep time for the AHI and you can't calculate that from in-home studies where you have total bed time? It seems that we see these nice statistics about AHI and you're comparing AHI to AHI, but in fact the AHI generated from a home study is not the same as the AHI generated in the lab, yet they seem to be used synonymously. Have you gone into any more detail in some of your evidence reviews to try to tease out a way to compare apples to apples?
DR. BOEHLECHE: Well as you saw, some of the studies, or many of the studies had in-lab comparisons, and there they can look at the sleep time on the polysomnogram and calculate that to the normal index, but then they can look at what would the index have been on the polysomnogram had they used time in bed the same as they would have

had to use with the home study equipment. And in general, there hasn't been a dramatic influence on that. Now on an individual patient who sleeps very little, I would say there is a dramatic influence as you suggest, that the time in bed would be a gross overestimation of sleep time. I mean, most of the studies say there is no direct way to do that because you can't determine, unless you're doing EEG at home, how well the patient slept at home. There were two studies of home EEG studies in the previous review, which I'm not addressing because that is not part of our review, which is in the published literature for you to look at. But in general, the differences haven't been too dramatic on average, although they can be quite dramatic in a given patient.

One study used actigraphy, a device that's put on the limbs for motion, which again, on average has a pretty good correlation with sleep time determined by electroencephalographic monitoring, but for an individual subject it can be off. But they looked at that and I didn't present that, but one of the studies in our review did look at that and looked at calculating the

index for the home study based on estimated sleep time. The bottom line to your question is it didn't change dramatically the kind of overall impression that I got.

DR. DAVIS: Dr. Lacey.

MR. LACEY: I have a couple of questions to help clarify that specific issue. In terms of calculation of the AHI, what is the role beyond time in bed versus time in sleep calculation that the EEG provides in terms of developing a differential diagnosis, so if you could give me a sense for what are those differences and how the ratio is calculated?

DR. BOEHLECHE: Well, I mean, in other words, the apnea-hypopnea index is normally defined as the number of events per hour of sleep, because obviously if a person's awake this is not a sleep-related problem. And people stop breathing when they're awake; when you swallow you have a brief pause or whatever. So it's normally felt that the index of interest is what's happening while the patient's asleep. So if you can't directly measure sleep, then the home studies have to use time in bed or lights out, or monitoring time or something, as a surrogate for

that.
Now, what is the average sleep efficiency? I don't have on the tip of my tongue what it is in home studies that have used EEG. In lab studies I can tell you the average sleep efficiency is around 80 or 85 percent, meaning about 85 percent of the time from lights off to lights on, the patient is judged electroencephalographically to be asleep.
MR. LACEY: So at least in a lab setting there seems to be a good correlation between the proxy measure and the actual measurement?
DR. BOEHLECHE: Reasonable, on average, with obviously individuals -- we have some patients who sleep 10 percent of the time in the lab.
MR. LACEY: So in terms of getting a differential value of having the EEG as opposed to a proxy measure used in the home studies, at least in the lab setting there doesn't seem to be a differential value to the EEG in terms of its index, in terms of understanding the variability?
DR. BOEHLECHE: Well, as I said, on average the two are probably not widely disparate;

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for an individual patient, they can be widely disparate. If the patient sleeps 10 percent of the time, you will have a very very different estimate of the apnea-hypopnea index.

DR. DAVIS: Dr. Dale, did you have your hand up?

DR. DALE: Yes, I did. It seems that the manual interpretation of the test had an important influence on the outcome. Can you explain that?

DR. BOEHLECHE: Well, as I said, the definition of apnea is pretty well standardized, it's essentially complete cessation of airflow for 10 seconds or more, that's kind of the accepted definition. The definition of hypopnea is much more controversial and not only in a sense controversial, but it's not clear what definition is going to correlate best with impact on the patient, as was alluded to with other things. So you know, there have been definitions in the past of at least a 50 percent reduction in airflow or a discernible reduction or at least a 30 percent reduction along with something else, such as a desaturation of 3 percent or 4 percent, or an arousal.

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And so if one is sort of a clinical lumper and says I think any event that seems to show a desaturation or a disruption in sleep should be considered as potentially clinically significant, then you're going to count all those. If another person says, well, arousals are less well defined, we're not sure what they mean, we should really stick to something like 4 percent desaturation, which is much more easily verifiable and is probably more reproducible between two scores, then you're going to count less of them. So I think, and I don't know, many of the algorithms according to the papers are proprietary, in other words they don't tell us how the machine decided what was an event. So, it could be that the definition used by the machine's algorithm differed from the manual scores, and the manual scores agreed more with the PSG because the PSG was also scored manually. Now blinded, remember, because we wouldn't allow them to have considered good quality if they knew what one test showed before they scored the other. So independently blinded scoring of the home study and the PSG agreed better when it was done manually, probably because

the interpretation of these more borderline events was in better agreement by the manual score.
DR. DAVIS: Let me ask members of the committee to be sure to speak closely into your microphone so that the reporter and members of the audience can hear. I have Doctors Goodman, Redberg, Krist and McNeil on my list. Why don't we take their questions and answers and then move on, recognizing that we will have a little more time for Q and A after the break and also if we need to, we can use some of our open panel deliberation time in the afternoon for more questions to the presenters. So, Dr. Goodman?
DR. GOODMAN: Yes, thank you. The reported data loss across studies ranged from 3 percent to 33 percent, you pointed out several times. This reminded me of the need perhaps for an intention to treat analysis and the question is, when there was data loss across studies, these didn't actually mean that they contributed to a zero percent sensitivity or specificity, you merely excluded them from study.
DR. BOEHLECHE: Correct.
DR. GOODMAN: So when you gave sensitivity and specificity figures, they don't

even account for the data loss?
DR. BOEHLECHE: That's correct.
DR. GOODMAN: And question two. Across the studies, were there reports of actually what happened clinically to these patients for whom there was no data reported? What happened to these people, were they followed up one way or another, or just not addressed?
DR. BOEHLECHE: These studies which were published as evaluations of the portable device in my recollection were never reported. I mean they were just excluded from the studies. Presumably they had, you know -- I mean for some of the data loss would have been from the portable studies in the lab and the patient had a polysomnogram. There was data loss from polysomnograms too, though, so they would have presumably had repeat studies for clinical purposes.
DR. GOODMAN: So the need for repeat studies or other sorts of follow-up is not systematically described in these studies, in other words, what actually happened to these people?
DR. BOEHLECHE: No, definitely not.

DR. DAVIS: Dr. Redberg.
DR. REDBERG: I have two questions that aren't exactly within the TA. I'm wondering, what other studies are you aware of that looked at other methods comparing to PSG for diagnosing obstructive sleep apnea such as sleep apnea questionnaires, history, physical, that sort of method of diagnosis, and how did those do compared to the gold standard?
DR. BOEHLECHE: Well, I mean, I am aware of them, I do sleep medicine so I'm generally aware of them although I certainly didn't do a comprehensive review so I wouldn't want to present this as definitive evidence review. I think in general, and I'm sure others will have comments on this, the correlation between subjective measures of sleepiness, subjective measures that would suggest, I would say, and objective measures is not particularly good. That's the reason that we ended up needing to do sleep studies in most patients, although in general there are patients who have very strong histories for sleep apnea and have this very high prior probability of having sleep apnea are most often borne out.

There are some who have severe symptoms who have something else causing their sleep disruption, and although they have risk factors for sleep apnea, that's not the thing that's causing their reported sleep disruption, and vice versa. We've all seen patients that don't fit the profile, and yet maybe if you search back they have a family history that suggests it and they indeed have it, but they have very little, either they deny symptoms or really don't have many, but have severe sleep apnea with what we think is the attendant risk of cardiovascular complications even if they're not reporting that they're sleeping.

So I would say in general the correlation between subjective measures such as questionnaires and also even objective measures such as physical examination for upper airway occlusion and so forth is not as good as the laboratory study.

DR. REDBERG: And my other question, you mentioned on the home study summary that no evidence was presented on overall clinical outcome. When I looked at the literature in general, not just home studies, to look at in

particular whether there was data on the benefit of CPAP treatment for OSA on cardiovascular outcomes, hypertension morbidity, I couldn't find any data. Is there?

DR. BOEHLECHE: Well, the Sleep Heart Health Study is ongoing, as I'm sure you're all aware, a very large study that I'm sure will be referred to that's looking at -- and that's why it's called the Sleep Heart Health Study, it was added onto a heart health study, that's looking at that in the long-term. And there have been some preliminary results presented in terms of treatment and blood pressure effects, some of which have been modest, some of which have been a little better. There have been more experimental, or not experimental, but in short-term studies improvement in insulin resistance when treated with CPAP. I think there have been several published studies showing improvements in subjective sleepiness when adherence to CPAP can be verified.

One of the issues, of course, as again I'm sure will be brought up by others, is adherence to treatment and how often do people prescribe CPAP, are they able to use it, and there

is a whole body of literature there looking at why they might or might not. But I would say there is increasing evidence that treatment of objectively documented sleep apnea produces significant benefits in those who are able to adhere to treatment.

DR. REDBERG: Cardiovascular or are you talking about quality of life?

DR. BOEHLECHE: Quality of life and limited evidence on cardiovascular. Certainly not outcomes in terms of heart attacks and strokes, but blood pressure changes, for example, there is published evidence.

DR. DAVIS: Dr. Krist.

DR. KRIST: Actually my question ties in a little bit to what Rita was asking about and, you know, thinking about outcomes. From a clinical standpoint, what I'm interested in is are my patients who have a portable device, is the same proportion of patients going to have the relative same magnitude of benefit as in lab testing? And in this assessment, one of the restrictions was that every patient had both a lab test and a portable test, to compare sensitivity and specificity. An alternative approach to look

at the benefit of diagnostic tests might be to randomize people to get one test versus another and look at, did the same proportion of people get the same relative magnitude of benefits. I'm just wondering, is there any type of evidence out there that looks at that type of an outcome, if we're missing things by requiring folks to have both of the tests as opposed to looking at objective outcomes.

DR. BOEHLECHE: I would agree with you that the ultimate reason for doing a test is to try to improve management and overall outcome, and that's one of the limitations of comparing AHI by one test versus another, and that will probably be alluded to, and is the gold standard measuring something that's perfectly correlated with patient management decisions and outcome, and it probably isn't, but it probably is the best thing we have now.

I'm not aware because as you said, the methodology -- Linda Luchs, I don't know if she made it yet. She's still in Atlanta. She did some of the preliminary reviewing of abstracts and may have in her head better if there were any studies. I'm not aware of studies that did what

you said, said let's do some home studies on 100 patients who have a certain prior probability of sleep apnea, you know, treat the ones we think need treating and follow them all and see if their outcomes are as good as 100 patients of comparable prior probability studied and treated by a lab test. I'm not aware of that. I mean, it's obviously a somewhat difficult study to do probably from a funding point of view, but I think studies like that might be useful, but I'm not aware of any. Someone in the audience might be.

DR. DAVIS: Dr. McNeil.

DR. MCNEIL: My question is, I'm a little bit unclear of the definitions and I want to make sure I have them right. We're being asked in our second voting question to evaluate questions on portable devices that measure cardiorespiratory parameters only. And when you were talking about the Golpe study in evidence table two, for example, you talked about that as a Type 4 device which has multiple channels on it. Would you call that a study that we should be considering in our voting?

DR. BOEHLECHE: I think if I remember right, isn't that the one that has only one

channel, and in order to be classified as a Type 3 by the classification that the ASDA did in '94, it has to have at least two channels. It did measure flow, so it's kind of a borderline thing.

DR. MCNEIL: It says 14 channels, that's what table seven says, unless it's a typo.

DR. BOEHLECHE: It's probably a typo.

DR. MCNEIL: EEG, electromyograms, electroarthrograms, ECG, tibial echo, oxygen sat, body position, snoring, oronasal, thoracoabdominal movement. What kind of device does that fit into?

DR. BOEHLECHE: If it's got two channels, flow and respiratory movement, then you would call it a Type 3.

DR. MCNEIL: But you called it a Type 4.

DR. BOEHLECHE: Well, maybe there's an error, I don't know. The evidence tables were prepared by RTI and I probably didn't have a chance to review every detail of those, I can look at that and correct it if necessary.

DR. MCNEIL: Well, I guess I'm a little confused, because we do have to make separate judgments between devices that look at, say, four parameters and devices that look at eight, and

that taxonomy is not equivalent to what's being presented for Types 2, 3 and 4, so it would be good if we could get a match.

DR. BOEHLECHE: We can take a look and see if there is an error. The real distinction between Type 3 and Type 4, Type 4 doesn't mean four channels, remember? Type 3 means it mentioned respiratory flow and a measure of effort, and Type 4 is if it only measures one channel or no channels, because some Type 4s just measure oximetry and something else.

DR. MCNEIL: Well, I guess -- am I the only one that's confused by this?

DR. BOEHLECHE: I will look at the evidence table.

DR. DAVIS: Maybe we can sort that out during the break.

DR. BOEHLECHE: I thought I presented in a slide that they had only a single measurement of flow and that's why it got typed as a 4 rather than a 3.

DR. KRIST: I think the 14 is reporting what was done in the lab, not the home test.

DR. MCNEIL: Oh, okay.

DR. BOEHLECHE: I thought on the slide

I reported that that one was classified as a Type 4 because it only had one more measure of flow and to be a Type 3 it has to have two. I still think it's correct, and remember, it said what was measured on that and then what was measured on the home study, so there's always two because all these studies had to have in-lab polysomnograms and they generally were, quote, standard, with 14 to 16 channels measured, so I think that does explain it. The home study portion of it did not measure 14 things, it measured only one flow measure.

DR. DAVIS: Dr. Boehleche, thank you very much, and I understand you will be with us throughout the meeting.

DR. BOEHLECHE: Yeah, most of it, probably, through at least 3:30.

DR. DAVIS: Thank you. We will move on now to the scheduled public comments and we'll begin with Dr. Terence Davidson, who is the requestor for this particular evidence review. And let me just inform the panel as well as members of the audience that we have a list of I believe 14 people who have been scheduled to give public comments. Most of them are using Power

Point slides. We have allocated 15 minutes for Dr. Davidson as the requestor and five minutes for all the scheduled commentators, and we have an hour and a half scheduled for this portion of the agenda. So it's a tight time frame and we will ask the speakers to please stick within that time frame. And there is an electronic timekeeper in front of me and on the podium for the speakers to use, and please do your best to keep within that time frame so we can stay on schedule.
Dr. Davidson.
DR. DAVIS: Good morning, and coming from California, I mean that. I have decided not to go over what I have already submitted to Medicare because you have that in writing, and so the materials that I would like to share with you today are ancillary to that.
I would like to begin just by doing a quick overview of sleep apnea because it has taken me years to understand this and I have trouble imagining that people that don't specialize in it can know as much as they would like to. This is a series of definitions of overlapping words that we use to describe this condition. Sleep disordered breathing, it seems to be the generic, OSA,

obstructive sleep apnea, hypopnea syndrome, and even upper airway resistance syndrome all fall within sleep disordered breathing.

We talked about prevalence and it varies by who does the study, et cetera, but this is the most quoted study. Terry Young, federal workers in Wisconsin, and using apnea-hypopnea index of 5 or more, found 24 percent of adult males, 9 percent of adult females, and using an AHI of 15 or more, 4 percent and 2 percent.

If we look at the more recent data, if you look at the lower such set of data and to the far right, we're talking about moderate or worse OSA and if we look at the bottom column, which is 65 to 100, so the Medicare population, and using an AHI of 15 to 20, 7 percent of women, 13 percent of adult men have significant sleep disordered breathing, so this in indeed a prevalent illness in the Medicare population.

The condition is underdiagnosed, and this number of 10 percent has been repeatedly used as the number of people in the U.S. who are diagnosed and treated.

There has been tremendous interest in the medical scientific community and this simply

lists the number of publications every two or three years on sleep disordered breathing and you can see that they are becoming a substantial part of our medical literature. A friend of mine is an editor of the Journal of Cardiology. He says he gets an article a day now on sleep disordered breathing from cardiologists alone.

Consequences of sleep apnea, or comorbidities, this is a list of those that are commonly recognized, I think the most significant, other than just feeling that it's blood pressure, and I'm going to focus on that for a moment. This is a normal person or a person without sleep disordered breathing, blood pressure at night, and this is their blood pressure, and the lower one is a patient with sleep apnea, and you can see the wild fluctuations that they have in their blood pressure associated with their sleep apnea.

This is the most convincing article for me in which it shows -- we don't have a pointer?

DR. DAVIS: Dr. Phurrough has one.

DR. DAVIDSON: Okay. Anyway, this shows a patient who has sleep apnea. If you look at the respiratory channel, you can see just under where it defines the OSA event here, and this is a

measure of sympathetic neural activity in response to that event. You can see during normal respiration, sympathetic neural activity is minimal, but immediately upon the cessation of breathing, you would get a sympathetic neural activation and you can see that the blood pressure rises in response to that. And if you just remember this, every time one of these poor people stops breathing at night, they get this surge in blood pressure, that's what causes their problem. Comorbidities and the prevalence of sleep apnea in these conditions, drug resistant hypertension, very high; congestive heart failure, 50 percent, I think it's higher than that; atrial fibrillation; all hypertension; coronary artery disease. These are significant relationships for these comorbidities.

The diagnosis of sleep apnea is made by the history, the physical exam, the sleep test and the response to treatment.

The sleep test is not just a stab in the dark, it's not like we just take people out of thin air. People come to us because they have symptoms of sleep apnea, most notably snoring. And anybody that is a significant snorer is

suspect for sleep apnea, and then if you add the comorbidities of falling asleep at night, I get in motor vehicle accidents, I get hypertension, that increases our suspicion that they have the disease, and then the sleep test is used sort of as an objective measurement required by insurance providers before we go on to therapy.

And to a large degree, decisions are made by the patient's response to treatment. If you put anybody on CPAP, they get better, they have the disease whether you can measure it by sleep test or not. I have never seen a patient without sleep apnea tolerate CPAP. Even when you pay them in a laboratory to try to use CPAP, they can't for more than a couple hours.

We have a bunch of sleep tests. ESG and the multichannel home sleep tests are the two that we use. Overnight oximetry, actigraphy would be Type 4, and they are just simply not commonly used in the United States.

This is what a PSG looks like. You have basically everything that's related to your physiology wired and it's a significant assortment of electrodes and wires. And this is what it looks like in bed and with all those wires, for

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the most part people are required to sleep on their back. And this is the kind of information you get out of a PSG. I call it information overload, but there's EEG, there's respiration, there's oximetry, and as we've listed, there's a whole series of channels.

Conversely, this is one of many multichannel home sleep tests and it simply uses the nasal prongs for respiration, it has an oximeter and then it has belts around the chest and the abdomen to measure respiratory efforts to try and separate obstructive from central sleep disordered breathing. This is the kind of automatic report that we get in which it simply lists the time that the patient was in bed, total bed time if you like. It gives you the apnea-hypopnea index for the duration of the study, in this case 45. It corroborates it with a number of oxygen desaturations which you can see is a very similar number, and then it breaks it down into supine, et cetera. But basically when you want to read a sleep test, you look at this number here, corroborated with that number there, and you have pretty much done it.

And this is what these kinds of studies

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look like, and you can look at the oxygen channel and you see during periods of respiratory obstruction that the patients have these desaturations and it measures the obstructions as well as the hypopneas, and tells you the lengths. This is the problem. The upper respiratory tract with the tongue that basically when you fall asleep falls back in your throat, obstructs your breathing and causes sleep apnea. And here we have the solution, a Hoover vacuum hooked in reverse with a Darth Vader mask as it was classically described, but it's a CPAP machine much easier to wear than those from 20 years ago. It simply blows pressure in your upper respiratory tract and holds this upper respiratory tract open so that you can breathe normally during sleep. So a patient with sleep apnea before CPAP, and once the CPAP is attached to them, and this is oxygen saturation, and you can see that this completely smooths out normal sleep. The current science I think is presented best in the report that I gave with 14 studies, 747 patients, eight different home sleep tests, ten different countries, and it shows an excellent correlation with PSG. As I was writing

this, it occurred to me that someone who is an advocate now of home sleep testing, that when I was done getting this through CMS, I was going to write an article proving once and for all that actually home sleep testing was better than PSG. I looked at the data. I can't. The two are so equivalent that you simply can't separate the two. Based on the results of the sleep test, I can't prove one is better, I can't prove the other is better, they are basically identical tests and there are some reasons for this.

So in terms of current science, you have asked about apneas and hypopneas. An apnea is a 90 percent or greater decrease in breathing over a period of 10 or more seconds and the hypopnea is typically a 50 percent or greater reduction, obviously less than 90, but some people use a higher definition of 75 percent and some people require and some do not, a desaturation to go along with it. So there is variability in the definition of hypopnea. And then we tend to use these numbers for mild, moderate and severe. These are confusing metrics, and we talk about an AHI of 15 as if that's somehow some gold number. It's not. Is 14.9 not abnormal but

15 is? These are just sort of estimates, like measuring a tree like this, you know. We can tell whether it's one gallon, five gallon or tall by looking at it, but you have to be very careful about using a specific number. We have had this in medicine with blood pressure, what's abnormal and what's hypertensive, what needs to be treated, what doesn't. Fasting blood sugar of 110. Cholesterol, you know, we used to treat 240, then it was 220, now it's 200. I mean, it changes as we know the disease. And the same with the BMI; if your BMI is 29.9, is it okay to go out and have steak and potatoes for dinner, are you all right? And if it hits 30, it's not so good? I mean, things just don't change over a one percent change in the number. So we have to be very careful about using these metrics.

There is a serious flaw in the concept of sensitivity and specificity. If you're using an AHI of five and you change it by one, it's a 20 percent change. Ten is a 10 percent, 15 is a 6 or 7 percent using an AHI of 20. So you have to be careful of the sensitivity and the specificity and I'm going to go through that with you. But again, I object to data that makes life important

decisions where 14.9, you don't have the disease and 15.0 you do, and that is one of the concerns we have over the current data analysis.

DR. DAVIS: Dr. Davidson, you have about a minute left of your 15 minutes.

DR. DAVIDSON: Okay. Well, I will either finish on time or not, and I'll quit when you tell me to.

There is a night-to-night variability of 10 percent, we've seen that in the Bland-Altman plot. We've talked about abnormalities of scoring. There is age, gender and ethnicity differences. There is the first night effect. Who could sleep with all these wires in a laboratory?

Split night studies have serious concerns because they knock off the last part of your sleep. So even though we are recommending PSG as the gold standard, it's actually not used; you only get tested for three or four hours and then you're thrown on CPAP, not by any physician evaluation but simply by the technician's assessment.

And the bottom line is that the multichannel home sleep test and the PSG use the

very same equipment for measuring cardiorespiratory matters and they use the same algorithms for evaluating, and I submit to you that these are basically the same tests. Thank you.

DR. DAVIS: Thank you very much. Dr. Davidson, could you just state for the record any past involvement or current involvement in the issue, potential conflicts of interest and so on?

DR. DAVIDSON: I have no conflict of interest with any sleep testing company and I have not had any support for this application. I am a member of the ResMed medical advisory board.

DR. DAVIS: Thank you, and thanks for being with us today. And I would like to remind the others who will be providing comment to also at the outset declare any potential conflicts of interest as well as involvement in this particular issue, commercial interest and so on.

So, the next presenter is Dr. Michael Sateia. I hope I didn't mispronounce that.

DR. HOOVER: Dr. Davis, could we clarify in that last statement of conflict who ResMed is?

DR. DAVIS: Dr. Davidson, could you

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clarify that, please?
DR. DAVIDSON: ResMed is an international company who makes products for sleep apnea, specifically ResMed, R-E-S-M-E-D.
DR. DAVIS: Thank you. Dr. Sateia.
DR. SATEIA: Thank you, good morning. My name is Michael Sateia, professor of psychiatry at Dartmouth Medical School, and I am president of the American Academy of Sleep Medicine. The American Academy of Sleep Medicine paid for my expenses on this trip. Otherwise, I have no conflict of interest to declare.
The academy is a professional organization for the subspecialty of sleep medicine. We represent over 5,000 physicians and healthcare providers in over 750 accredited sleep centers. In addition to other activities, we publish practice guidelines to provide best care for patients, accredit sleep centers, and we have been the moving force behind recent official recognition of sleep medicine as a subspecialty by the Accreditation Council on Graduate Medical Education.
This morning we would like to ask the committee to consider what solid evidence outside

of a somewhat biased selection of literature has been presented to support the reliability and utilization of portable monitoring. We have concerns about the unsupported arguments with respect to access and cost issues, some of which I will discuss. My colleagues will primarily address questions one and two so I will simply review what Dr. Boehleche has already told you regarding the three-society published study by the American Thoracic Society, the American College of Chest Physicians and the American Academy of Sleep Medicine.

The guidelines indicated that unattended portable monitoring is not recommended for diagnosing obstructive sleep apnea based on limited evidence with highly variable and often low specificity. As Dr. Boehleche has already told you, the resent AHRQ report confirms that there is no additional literature that would suggest material support or material change in the data.

My colleague Dr. Chesson will discuss question two regarding competence level and the evidence-based process that occurred, and therefore I will defer to him on this question.

With regard to question three, which is impact on technical outcome, according to the recent AHRQ report, overall proportion of home studies with inadequate data average 13 percent, almost one in seven. Data loss was as high as one in three when patients performed their own hookup in the laboratory. We have also observed in other studies disease misclassification rates up to 65 percent and also as Dr. Boehleche alluded to in the one study by Golpe, treatment decision errors occurring in almost one out of four patients with portable monitoring.

We cannot support the conclusions by Dr. Davidson reached in his original proposal that, and I quote, there are no reports of poor correlation, error in diagnosis or adverse events as a result of multichannel home sleep testing in these studies, end quote. We feel this is an inaccurate representation of the published limitations of portable monitoring.

The upshot of these well-known limitations of portable monitoring include the following: High failure rates that will result in need for repeat studies; negative studies in symptomatic patients requiring repeat studies;

high false positive rates resulting in application of unnecessary treatment as well as missing other sleep disorders; and high false negative rates that result in failure to treat patients who require treatment. In addition, I might also point out that there are additional cost factors attached to a number of these limitations. The prevalence of poor quality sleep reportings and his misclassification rates indicate that portable monitoring studies are not as accurate as facility-based tests. As we've also seen, there are false positive rates reported up to 31 percent, false negative rates up to 45 percent, and the previous data I mentioned regarding data loss and artifact problems. More importantly, I think, the use of portable monitoring invites indiscriminate application of the technology that's likely to occur without benefit of additional clinical evaluation that is routinely a component of facility-based assessment.

With respect to the issue of accessibility, I will just move ahead here, we recently, because of this issue and the attention that it gets, commissioned a survey, we now have

669 sleep centers responding from academy members, and the average wait time to see a physician for a sleep consultation was less than three weeks. The average wait time to receive an in-facility polysomnogram was just over three weeks. Extrapolating from the data that we have, it would appear that there are about 1.5 million PSGs performed per year and that 98 percent of these are in facility, 2 percent are portable studies. Regarding the Medicare population, I would just like to very briefly point out that the only study that has looked at this found that the patients who are actually a younger group preferred in-lab study to portable monitoring by a ratio of almost two to one, 48 percent to 28 percent. With respect to the Medicare population, we need to consider their level of discomfort with the device and the technology, the anxiety, as well as safety issues.

So in conclusion, I would like to simply summarize by stating that the 2003 evidence review and guidelines by the three major societies do not support approval of this proposal for unattended portable monitoring, that the recent AHRQ review found no basis for change in the

evidence, and I would also like to note that the academy does support continued research and development in new technologies, but we strongly counsel against the application, especially the wholesale widespread application of this technology that is likely to occur in an unfettered manner for technology that lacks demonstrated effectiveness in the clinical population and that is being deployed to address some issues which we feel may not be as significant as others have suggested. Thank you very much.

DR. DAVIS: Thank you. Dr. Conrad Iber.

DR. IBER: Thank you. My name is Conrad Iber. I'm director of pulmonary medicine at Hennepin County Medical Center in Minneapolis and associate professor of medicine at the University of Minnesota.

As an investigator for one of the largest field centers for the Sleep Heart Health Study, I have supervised over 1,600 portable sleep studies performed in the home and have authored publications related to the use of portable monitoring in this large multicenter study. I

would like to address the impact of this study on our decision-making today.

Due to the limited time for comments, I am going to focus my response to question items two and three. I am speaking on behalf of the American Academy of Sleep Medicine, who has paid for my transportation expenses today. I have also received an NHLDI grant in the Sleep Heart Health Study that incorporated portable monitoring techniques. Otherwise, I have no other conflicts to disclose.

In the Sleep Heart Health Study, over 7,000 home portable monitor studies have been performed. This was a National Heart, Lung and Blood Institute multicenter, five-center study looking at cardiovascular outcomes. I might mention it is not a treatment study, I think that was mentioned earlier, CPAP was not used in this protocol, but that will be incorporated in the Apple study sponsored by the NIH. This was a highly standardized research protocol that incorporated a rigorous quality assurance program. The data from this study has been extensively quoted as supportive of clinical application of unattended portable home monitoring. In fact,

though some of the submitted comments that follow my comments may suggest that the Sleep Heart Health Study was an unattended home monitoring study, this was not in fact the case. The validity of the data from highly standardized research methods such as the Sleep Heart Health Study should not influence our decisions today regarding clinical use of Type or Level II or III monitoring in the home. Several conditions and methods in the Sleep Heart Health Study were substantially different than clinical practice and some of these are true of other portable monitoring studies as well. In the Sleep Heart Health Study, randomly identified volunteers were studied, not patients identified with clinical sleep apnea who often have comorbidities. Second, in the Sleep Heart Health Study, Level II, not Level III studies were performed. In SHHS, no treatment such as CPAP was given. Such a treatment would require a second study during which CPAP was adjusted to an effective level. This is also true of many of the other Level II and III monitoring studies that have been cited. In the Sleep Heart Health Study,

studies were in fact partially attended with technicians hooking up the patients in the home, assisting elderly patients to bed, and verifying the quality of sleep that was being reported at the time of initiation of the study.

Number five, technicians received training regarding portable monitoring equipment and interpretation of recordings, two different sets of technicians. Technicians were required to pass a certification examination in these specific techniques. Manuals for scoring were available with a library of examples for reading the studies. I might mention, these were manually scored readings as well. Technician performance was continuously monitored for accuracy and reproducibility and technicians were retrained if there were lapses in performance. It is important to note that these quality assurance measures applied extensively to the technicians' practices in a very scripted manner and were incorporated into standardized laboratory policies.

In the only Sleep Heart Health Study publication comparing laboratory and home monitoring, the following caution was cited: Though the highly standardized methodology for

recording of polysomnography in the Sleep Heart Health Study ensure the reproducibility of these techniques, the findings in our multicenter study may not be generalizable to clinical laboratories using substantially different scoring or recording techniques.

In clinical practice, there are currently no standard methods of portable monitoring which emulate the Sleep Heart Health Study. In fact, even research protocols using home portable monitoring studies use extremely variable techniques. In explaining the marked variation in sensitivity and specificity of studies, the AHRQ evidence review identifies an aspect of portable monitoring that should be of substantial concern when concerning the reliability of such studies. Quote, studies of portable devices were variable due to study and device heterogeneity, end quote.

Question three, comparison of facility-based polysomnography. There are currently no processes for quality assurance and standardization of techniques in portable monitoring performed in the home. This lack of standardization and the inherent limitations of

unattended monitoring would be expected to result in marked variations of acquisition and interpretation of data in comparison to standardized techniques performed in facility-based polysomnography. Whether Level II or III monitoring is considered, this lack of standardization would be expected to degrade the accuracy and reliability of portable monitoring as compared to standard procedures for facility-based polysomnography that is performed in, for instance, accredited laboratories.

The previously mentioned evidence-based medicine review published by the academy, the ATS and ACCP, and the updated AHRQ review are current and exhaustive. No doubt these evidence-based reviews represent hundreds of hours of effort using the best analytical techniques that are crafted by experts who are not hampered by conflicts of interest. In my opinion, any considerations regarding the use of portable home monitoring should rest on the up-to-date and extensive evidence presented in previously mentioned evidence-based medicine reviews by the three societies and updated by the AHRQ review. Decisions today should be influenced by

nothing less than the best processes we can offer. It would not seem appropriate to revise recommendations of these documents until there is new evidence to support a change in position. Thank you.

DR. DAVIS: Thank you. Dr. Andrew Chesson.

DR. CHESSON: Hi. My name is Andy Chesson, my background is in neurology and sleep. I am speaking on behalf of the AASM. I have no conflicts of interest as outlined in the disclaimer statements.

I have been involved in the AASM standards of practice committee as chairman for many years and subsequently as liaison to the AASM board of directors. The AASM standards of practice committee has published 19 evidence-based guidelines regarding sleep disorders diagnosis and treatment of the type that Dr. Boehleche described.

The following information can help explain how the papers that Dr. Sateia has referenced and that have been submitted with our packet provide an evidence-based background for the five questions posed, particularly questions

one, two and three. The AASM uses a process of evidence-based methodology for all its practice guidelines, which avoids creating consensus papers by a group who may be strong in their opinions but short on evidence.

In 2000, rather than revising our expiring portable monitoring publication, the ATS, the ACCP and the AASM reached an agreement. The three societies would do a joint project using an evidence-based rather than a consensus process to create a three-society evidence-based guideline paper to help guide patients' care. The three committees were formed, a steering committee, a review paper committee and a guideline committee, so that the evidence was separated from the resulting opinions. Each committee had equal representation from the ACCP and ATS, and AASM. Other interested parties such as NAMDARC and the ASA participated in the review committee. Individuals were selected and screened regarding conflicts of interest, and to assure an absolutely independent literature review and evidence ranking, a contract was developed with the Evidence Practice Center, the Research Triangle Institute at the University of North

Carolina, which Dr. Boehleche described, to conduct an independent systematic literature review and to abstract data in a standard fashion from relevant studies as you've seen, thus creating the database for writing the review paper.

The authors of the review paper then defined the available data, looked at each category of portable monitoring, both home and attended, and detailed the effectiveness of each device in answering a whole series of clinical questions, and many of those are actually the same questions that you're asking now, along with reliability and validity data. Using this information, they wrote the review paper which was the predecessor to the study that you've heard.

Then the guideline writing committee, with representatives from each society and myself as chair, took that review paper data and formulated guidelines predicated on the evidence. Each recommended guideline was referenced to the review paper's specific section supporting that particular guideline.

Then the steering committee headed by the ATS representative oversaw the whole process

and wrote the executive summary which Dr. Boehleche has pointed out. These papers were all approved by each of the three societies' board of directors before publication and the publications were all in peer reviewed journals, Chest, Sleep and the American Journal of Respiratory and Critical Care Medicine during the years 2003 and 2004.

Given these multisociety-sponsored and approved validated evidence-based guidelines, it would seem that the question to address currently would be whether there is new and substantial literature which has been published since these papers came out. To change a nationwide policy, scientific data would seem to be the issue, not whether various individuals or committees believe that in their hands some devices can do better than the scientific literature states.

Recent literature reviews looking at new evidence concerning unattended portable monitoring include: Dr. Iber provided an updated review of the literature for his response to CMS last May. The AASM standards of practice committee has finalized their literature review for an update to our indications for

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polysomnography. And the recent, this month actually, in 2004, AHRQ report which Dr. Boehleche so ably presented information previously. They all came to the same bottom line conclusion. Current literature reviews do not indicate scientific evidence of sufficient magnitude and level of evidence, either independently or as combined series, regarding effectiveness, reliability or clinical utilization to change current portable monitoring policies. These recent papers published by the ATS, ACCP and AASM indicate the type of studies and the data needed, however, for research in scientific communities to effectively lay these issues to rest. That data has not yet come to fruition. It's the AASM's position that it would be inconsistent with providing our patients the best quality of care to develop a national policy that is not based on the weight of scientific evidence. Patients with sleep disorders deserve more from the physicians entrusted with their care. Thank you.

DR. DAVIS: Thank you. Dr. R. John Kimoff.

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DR. KIMOFF: Thank you. I'm Dr. John Kimoff, I'm speaking on behalf of the American Thoracic Society, which is obviously an American society but with an international profile. Most of our membership is American but we have up to 30 percent international membership, and some of the comments that I will make today will actually reflect that. I would like to just state for the committee that I myself am a Canadian and I practice at the McGill University Health Center in Montreal. I have no direct financial, no formal financial conflict or commercial involvement in this area. My trip has been paid for by the American Thoracic Society. But I would state to the committee that I, as many of the people who present today, make my living from running a diagnostic sleep laboratory where we in fact perform both polysomnography and portable monitoring, but I make a lot more money from polysomnography.

So, much of the preamble has -- and I just want to again express the ATS's appreciation to present today, and have been impressed with the presentations so far. Clearly sleep apnea is prevalent, this has been discussed and it does

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represent a major health burden. There is a strong body of evidence now that treatment of sleep apnea improves quality of life, many morbidities.

And in fact something that hasn't been alluded to, there is data which I can cite from Canadian studies by Krieger as well as studies in France, which demonstrate that treatment of sleep apnea leads to reduced healthcare resource utilization, i.e., reduced costs, so that things which improve access and reduce cost of diagnosing sleep apnea have the potential to increase cost effectiveness in this area.

The issue of access has come up and this is, as any issue which is going to be discussed based on statistics is controversial. Ward Flemons' article in the American Journal of Respiratory and Critical Care Medicine in February of this year attempted to assess the issue of access to polysomnography in North America, Europe and Australia. Based on prevalence values from the Wisconsin cohort study and incidents estimates from Wisconsin cohort data as well, Ward and his colleagues identified that there is the capacity in the western world to identify approximately 10

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percent of cases by diagnostic polysomnography using attended in-laboratory testing. Now in fact in all fairness, if you look at the data that Ward presented for U.S. patients, that figure probably rises to about 20 percent, but with a similar rate of polysomnography, about 1.7 million studies per year that was quoted by Dr. Sateia earlier. While ATS does not have data on this, we do believe that access may be particularly an issue to Medicare and Medicaid populations. As Dr. Sateia presented just earlier data on access to assessment in AASM accredited laboratories, and I would submit that that's important data, but we also have to be careful to assess access of patients who don't have an AASM accredited laboratory in their neighborhood or proximity. I want to say that the position of the American Thoracic Society is that laboratory polysomnography remains the gold standard for diagnosis of sleep apnea. However, it needs to be said here today that there are many people in this field and particularly I would say in the international sleep disorder community that question whether indeed polysomnography is a gold

standard. Some of these issues have been alluded to earlier. There is certainly, the term standard is subject to discussion because there are many methodologies for both performing the study and scoring the studies.

Some people have, and some studies have pointed to the fact that there are relatively weak correlations between EEG arousals and various sleep apnea outcomes. One of the arguments for using polysomnography is that we not miss another diagnosis. However, what seems very clear I think from clinical practice is that most people who are studied for obstructive sleep apnea in fact don't have another disease, and our concern is to make sure that all of those people out there suffering from this disease actually get the diagnosis and have access to management.

So, some people do raise the point that insistence upon an expensive and poorly accessible resource may unnecessarily increase costs and I think that's very relevant to Medicare, again speaking as someone who works in an entirely publicly funded system, we are very cost conscious in my area of practice, and this has been a major issue of discussion. So increased costs of

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diagnosis as well, but again, patients with sleep apnea use more healthcare resources before they're diagnosed, so there's increased costs associated with morbidity and mortality that Medicare will also have to pay for.

This is perhaps a controversial statement but I think it needs to be said here, and that is that many of the people, myself included of course, and many members of the ATS who are involved in this area, the expert opinion that is being provided is being provided by people who make their living based on polysomnography, and sleep apnea is the bread and butter of many polysomnography laboratories, whether they're based in neurology departments, psychiatry or pulmonary divisions, and so the committee needs to consider, I think, the issue that there is a potential for conflict there and/or bias and again, that may be true of me as well as many other people presenting here today.

Furthermore, and perhaps a little bit more cynical but something which I think many people do feel, is that one of the issues with the evidence and the body of evidence that's available is that interest groups may, the reason we don't

have better research is because it's not in our interest to have so.

We provided in writing our responses to questions posed by CMS, I won't do a detailed response here. What I would point out is that the task force comments used an evidence-based approach, this was not a clinical consensus, sort of an expert consensus based on a combination of evidence and expert opinion, and we believe that this is something that is important.

The other thing is that the studies that have been presented and again summarized today have focused on correlating the respiratory disturbance index with the apnea-hypopnea index. And we believe in fact that portable monitoring needs to be assessed in the context of management strategies for diagnosis using clinical predictions and prioritization of patients, as well as outcomes-based research.

DR. DAVIS: Dr. Kimoff, could you wrap up, please?

DR. KIMOFF: Yes, I will. So I'll just comment that the ATS supports CMS funding for unattended Level III studies under several specific conditions: If the preferred test of

choice is not available; this test should be applied to patients with a high pretest probability of sleep apnea; we believe that these studies should be used to rule in sleep apnea with a robust cutoff respiratory disturbance index, not relied upon to rule out sleep apnea in a symptomatic patient; the data should be manually scored, full disclosure, and that there do need to be issues of quality assurance.

And one of the main criticisms or concerns raised about portable monitoring relates to this issue of quality. We believe that if CMS were to fund or reimburse portable studies which were done based in centers with expertise in sleep medicine, that while it may not provide quite as broad an access, it would deal with many of the concerns regarding quality assessment. So that's where I will stop, thank you.

DR. DAVIS: Thank you. Dr. Eric Mair.

DR. MAIR: Good morning. While they're pulling up the Power Point presentation, my name is Eric Mair. I am the interim chairman of otolaryngology at Lackland Air Force Base in San Antonio and I'm speaking on behalf of the American Academy of Otolaryngology and Head and Neck

Surgery, who paid for my trip here. As far as financial interests and other conflicts, being in the U.S. military, I can't have any, or I would be in jail right now.

Otolaryngologists provide some excellent medical and surgical treatment for sleep disordered breathing. There are 10,000 physicians in our American Academy of Otolaryngology and they prescribe nearly one-third of all sleep studies.

Subsequently, we and our patients are keenly interested in the subject of multichannel home sleep testing. Unfortunately, our academy was not involved in some of the trials that we've talked about and the reviews of the literature, which I consider unfortunate.

Five minutes is really a short time to cover this subject that's in front of us now. Therefore, I would like to answer all the MCAC questions and what I have tried to do in this Power Point is to be precise and clear in grouping the questions into three categories.

DR. DAVIS: And Dr. Mair, we have received a hard copy of your presentation.

DR. MAIR: The first question that we have is, is there enough evidence that analysis

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based on recordings done by portable recording devices provides reliable data which will be as good as or better than PSG? My answer to that question is yes, there are over 170 studies on this issue that we've talked about. The results indicate that the sensitivity and the specificity or the accuracy levels between the two technologies, they range in most cases between 85 percent and 100 percent, and very rarely at 80 percent or lower. And what that means is that the variations between the scores of PSGs and the scores of home study, the sensitivity between, the variations between the scores of the PSGs and the scores of the home tests is usually lower than 15 percent and almost always less than 20 percent. But the big question is, is this close enough? And reviewing the latest published literature about PSG reveals that the gold standard, as has previously been mentioned, has some reliability problems. There is a saying that a person with one watch knows what time it is, but a person with two watches really isn't so sure. A good analogy will be if you try to compare a mechanical clock which is a gold standard with the accuracy down to one minute per

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day to the accuracy of an atomic clock, and the accuracy here is down to a trillionth of a second per year. But you will only prove that the atomic clock is typically wrong about one minute a day, leading to the false conclusion that the atomic clock is not as good as the gold standard, the mechanical clock. Moreover, if by chance the atomic clock will coincide perfectly with one mechanical clock, the atomic clock would even then be proven wrong or unproven by simply comparing it to other mechanical clocks. Now, a more reasonable test would be to take the multiple mechanical clocks shown here and compare the variation between the mechanical clocks. Then we can compare the atomic clock to the mechanical clocks. If the variation between the atomic clock and the other mechanical clocks is not higher then the variation between the different mechanical clocks, then the atomic clock would be acceptable and may be even better but clearly not worse than the mechanical clock.

There are multiple PSG studies comparing technician-to-technician variability in scoring the same patient's records. They reveal a high variation of 30 percent or more. PSG studies

measuring night-to-night variations using the same patients, same laboratory, same equipment, same technician on two different nights show greater than 30 percent deviation as well. Using this criteria comparing the variability between home multichannel sleep testing and the standard PSG to the published intrinsic variability of PSG will lead to the conclusion that the variability of 5 to 25 percent between tests using the portable recorders and the full PSG is smaller in comparison to the variation between the PSGs themselves performed by different technicians or different nights.

Therefore, I'm highly confident that home testing results are valid and reliable, and which are equal or better than facility-based PSGs.

The second question, is there enough evidence that recording unattended studies at home will provide results as reliable as or better than the testing of inpatient in a controlled facility? I think the answer to this question is a resounding yes again. To test a patient at a PSG facility is to test him or her in a very foreign environment that's very unnatural and the patient

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is definitely not accustomed to this. The probability of producing a typical night's sleep which we want to test is very questionable in these types of facilities. And in addition, it is reported that sleeping in a facility, there are causes called the first night effect and there is high variability between the nights associated here.

It's well documented and published that home testing results in smaller night-to-night variability than in a PSG facility. Home testing is practical and can be used for multiple nights at a fraction of the cost, and it's highly, it's minimally invasive and it nearly eliminates the night-to-night variability.

Another common objection to home unattended studies is the 5 or 10 percent failure rate. This should not be a problem since the home test can be repeated for no additional cost in the case of a failure. In contrast, there's a significant number of recordings at a sleep center where the patient just failed to fall asleep because they can't with all the equipment on. The high cost of repeating this prevents the retest, and this can lead to wrong conclusions about the

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patient's diagnosis. And finally, third question, is there enough evidence to conclude that using unattended home testing will make testing more accessible, more affordable, and improve overall health outcome? Again, the answer here is yes. The ability to test a patient at his own home rather than scheduling a bed in the hospital and the significant lower cost of the test guarantees the test will be much more accessible and affordable. Other studies clearly report that sleep apnea can cause high blood pressure and is a strong link to heart attacks, strokes and car accidents. Preventing sleep apnea complications by timely home diagnosis and treatment will result subsequently in substantial savings. In conclusion, current evidence-based medicine appeals here show that home study sleep tests are definitely beneficial. Our academy of 10,000 otolaryngologists trained in sleep disordered breathing appeals to you the board here, most importantly the many Americans with undiagnosed and untreated sleep disordered breathing appeal to your support for multichannel home sleep studies. Thank you.

DR. DAVIS: Thank you. And thank you for putting up with the audiovisual difficulty. Edward Grandi.

MR. GRANDI: Good morning. My name is Edward Grandi. I am the executive director of the American Sleep Apnea Association located in Washington, D.C. The ASAA is a nonprofit patient interest organization dedicated to seeing that all patients with sleep apnea are diagnosed and treated. Thank you for the opportunity to present the American Sleep Apnea Association's view on portable multichannel home testing devices as an alternative to facility-based polysomnography in the evaluation of obstructive sleep apnea. In the interest of full disclosure, I would like to acknowledge that the AASA has received financial support from a number of companies involved in the treatment of obstructive sleep apnea. I personally do not hold any stock in any company in the sleep field other than what may be in an individual retirement account, and the association paid for my expenses to attend this morning. Sleep disordered breathing, including sleep apnea and obstructive airway resistance syndrome, is a common disorder that affects

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millions of Americans of all ages. We believe that it is substantially underdiagnosed, in part because most of the common symptoms, snoring and falling asleep easily and/or sometimes inappropriately are not recognized as symptoms of a potentially serious medical disorder. Consequences of untreated sleep apnea may be significant, including sleepiness, high blood pressure and cardiovascular disease, diabetes mellitus, morning headaches, feelings of depression, impotence and memory problems. Once diagnosed, a patient may be prescribed a course of treatment. Treatment options include oral appliances, weight loss, positional therapy, surgery, and the use of continuous positive airway pressure. Which treatment option is best for the patient depends upon the severity of sleep apnea and other aspects of the patient's medical history. If treated on a consistent basis, studies now show that some of the serious consequences of sleep apnea can be reversed.

The AASA welcomes the discussion of multichannel home sleep testing devices as an alternative to facility-based polysomnography in

the evaluation of OSA. Facility-based polysomnography does offer the diagnostician considerably more information than is currently available from multichannel home sleep test devices, but the concern of the AASA is access to appropriate diagnostic services for the millions of Americans who are as yet undiagnosed. Our organization has had measurable success in providing educational resources to the public and medical community which has increased awareness of this disorder. Now that they're aware, there is a need to get a sleep study done. It is unrealistic to believe that everyone who is made aware of the risk of OSA will rush to get a sleep study done. For some, what keeps them from going is denial. For others, it's a question of accessibility; they may not live close enough to a sleep lab for it to be convenient. There are also those in need of a sleep study who do not have health insurance or the financial resources to pay for PSG. Given any obstacle, however small, a person needing a study may put off getting it done.

We are particularly concerned for the uninsured population. Anecdotal evidence

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collected from telephone conversations and e-mail correspondence leads us to believe that access for diagnosis and treatment is a problem.

The use of portable multichannel home testing devices could increase accessibility to sleep studies and if done at a reduced cost, decrease the expense. We believe that providing access to a sleep study as the primary means of diagnosis as to whether an individual has sleep apnea or not is a significant part of what is most important.

What also matters, beyond that the diagnostic test not stand in the way of access, is that whatever testing is done be coupled with professional input. While this occurs almost automatically with a sleep test done in a laboratory, the issues raised by portable monitoring are inextricably linked with the nature of reimbursed professional care coupled with the actual performance of the test. The best care currently available for obstructive sleep apnea requires both readily accessible testing and incentives for the professional sleep specialist to interact with the patient before and after testing.

We encourage the Medicare Coverage Advisory Committee to keep this in mind while they consider the issue. Thank you again for this opportunity to speak to the committee today.

DR. DAVIS: Thank you. We had scheduled a break for 10:30, so we will go ahead and take a ten-minute break now and then pick up with the other scheduled presenters immediately after the break.

(Recess.)

DR. DAVIS: Dr. Coppola, let's give the members of the committee another 30 seconds or so to take their seats. Please proceed.

DR. COPPOLA: Thank you. My name is Michael Coppola. I'm a practicing pulmonologist in Springfield, Massachusetts, and I have devoted the past 16 years to treating sleep apnea patients. I treat 30 to 50 patients a week and have used portable and facility-based testing, and I can tell you like all the other speakers, I get paid a lot of money to read in-facility polysomnography.

I am on the medical advisory board of ResMed Corporation and I am on the board of directors of the American Sleep Apnea Association.

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My opinions today are expressing my own and do not represent the opinions of any organization. I hope I'm speaking to you on behalf of the thousands of patients I have treated with the help of portable monitoring and on behalf of millions more who I hope collectively we will treat in the future.

Today I would like to give you some anecdotal information on 26,000 portable sleep studies. The problem is that the analysis to date has been a technology assessment comparing polysomnography to portable testing in very small groups of people, 50 studies at a time. Unfortunately, we don't have the data from the first 50 polysomnograms to compare them to, so I hope to give you some real data.

I today present, along with the information in your handout, my own experience with 7,000 sleep studies since 1988 performed in the home. These are Type 3 manually scored full disclosure tests. Along with my colleagues in Seattle, Group Health Associates, Group Health Cooperative in Puget Sound, I helped design their program in 1994. They are an HMO with both commercial and Medicare members representing a

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population of 597,000. Portable four-channel sleep recordings, exactly as we do, is their method of choice. They have an in-lab facility and laboratory, and four certified sleep specialists, but still do 90 percent of their testing for sleep apnea in the home.

I point you to an editorial by Jerry Kucera in the New England Journal of Medicine in 1989. We talked about an intention to treat. We have a low risk treatment which requires less diagnostic density than is being asked for in a polysomnogram.

Group Health looked at their experience with sleep studies in 1993 and although their total medical costs for the plan were level, their polysomnography costs were doubling. They looked at what they got for their money. This is a real world community practice. 90 percent of the diagnoses obtained by polysomnography were sleep disordered breathing. Both we and Group Health have a policy that all patients who are symptomatic who fail to have a diagnostic home sleep study have polysomnography. In our hands and in the hands of Group Health that is necessary in 10 percent of people.

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To date, Group Health associates have performed over 19,000 portable sleep recordings and they have a failure rate of 2.8 percent. We in Massachusetts have a failure rate of one percent using slightly different clinical pathways.

Medical management is more important to positive patient outcomes with CPAP than the diagnostic technology utilized. I'm disappointed to say that there is no current AASM standard for following patients with sleep apnea on CPAP, and I think this is negligent. I believe, and the people at Group Health and others you'll hear from today, that a real medical management model will get enough information from a portable sleep study to determine when a patient has physiology consistent with sleep apnea and then provide an intention to treat. The key to care of these patients is caring for them after they test. It is imperative that whatever CPAP prescription is written, these people are followed probably for life. Thank you.

DR. DAVIS: Thank you very much.

Dr. Steven Slack.

DR. SLACK: Good morning, my name is

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Steven Slack. I am a pulmonary and critical care physician from California. I am also a consultant with SleepQuest in Redwood City. SleepQuest is a disease management company that's dedicated to the identification and referral for treatment of patients with obstructive sleep apnea and we have developed a model for treating and assessing this condition. By way of financial disclosure, I would mention to you that I am not an employee of the company, I do not have an equity interest. I'm a practicing physician. I am a consultant to the firm's CEO, Mr. Robert Konigsberg. SleepQuest purchases devices for testing its patients in its ambulatory care model. It also arranges for the purchase of CPAP devices, masks and supplies for patients who test positive in disease. I am an independent practicing physician in Monterey County, and unlike members of the American Association of Sleep Medicine from whom you've heard testimony today, I do not publish practice guidelines while simultaneously owning or operating a sleep lab. I would like to share with you some of SleepQuest's experience in caring for 5,000 patients in an ambulatory model for obstructive

sleep apnea, where we find that it is safe and a lower cost alternative to the existing paradigm of brick and mortar sleep labs. This approach has been successfully used in Europe and that's where we essentially get our model from. In Marburg, Germany for example, which has a population of a million individuals, they have a sleep lab of two beds and the remainder of the patients are tested through ambulatory testing.

So how is this model possible? You've seen it in the last slide which Dr. Coppola presented which showed that 80 percent of this disease is obstructive sleep apnea with regard to what sleep disorders are about. Our experience has shown that obstructive sleep apnea can be diagnosed and managed without the use of a sleep lab using ambulatory home testing.

If a patient has a high probability of disease based on a thorough physical and history examination and by using a validated screening questionnaire such as the Epworth Sleep Evaluation scoring system, it's possible to identify those people who are going to have a very high percent probability. They undergo testing for sleep apnea; if they're positive they undergo titration

study. This titration study is very important as it demonstrates an objective improvement. For those patients who have a negative study but are positive in symptoms, they are referred to a sleep lab for polysomnography.

The committee has asked, what parameters should be monitored to safely diagnose patients using home testing devices? In SleepQuest's experience, we used two types of testing devices that are used in our care pathways. One device is the Embletta that's produced by MedCare. This measures flow, abdominal and thoracic effort, actigraphy, snoring, pulse oximetry and heart rate. The other device is the WatchPAT 100 that's produced by Itamar, and I think some of their representatives will talk to you about their exciting technology later on during the morning.

I mention these devices not to imply any commercial endorsement. There are dozens of makers of equipment. I just wish to share part of SleepQuest's experience in our choices for creating a successful disease management program.

Rather than ask the questions about which devices and parameters should be monitored,

the committee should focus its attention on what is the outcome of in-home testing. Does approving in-home testing result in improved access to care? Does embracing an ambulatory model for in-home diagnosis and treatment reduce health costs or allow more individuals to be treated than under the current model? Does it make people better? Data acquisition with these devices is extremely simple, safe and reliable, and as you've noted, they have already been approved by the FDA. One of our principal concerns in delivering an ambulatory model is that we allow an increased access to care. In California, for example, there are 41 accredited sleep labs; 19 of them are in northern California. If one assumes that each lab has six beds and the population other over 18 years of age in California is 20 million and the prevalence of the disease of obstructive sleep apnea is about 6 percent, it's going to take 449 years for the existing delivery system to meet the needs of this population. Ladies and gentlemen, there is definitely a problem with access to care. While being both cost efficient and effective, SleepQuest's exceptional disease

management approach is more costly to implement than the current reimbursement structure and at this time when in-home diagnostic studies allow around $220 for California, this barely covers the cost to perform the study. Thus, we would recommend increase in reimbursement for this procedure based on an ambulatory setting.

I would like to offer a couple of comments about the technology and your approval of ambulatory testing and how it will improve access to care, offer quality of care to a larger number of Americans and bring needed therapy to individuals with obstructive sleep apnea who are currently untreated. If we were to make an analogy, Medicare has already allowed approval of diabetics to treat themselves in the home with a glucometer. Similarly, you must allow primary care physicians access to the tools which allow them to treat obstructive sleep apnea in their patients.

Thank you for your time. I thank Janet Anderson for arranging time for our request to speak today, and I wish you well in your deliberations for a favorable outcome.

DR. DAVIS: Thank you. Dr. Anuja

Sharma.
DR. SHARMA: I am Anuja Sharma, a board certified pulmonary critical care and sleep physician practicing in the community of Saint Paul in Minnesota. I am the medical director of Metropolitan Sleep Disorders Center, Minnesota Sleep Link, and HealthEast Sleep Care at this time. I am here on behalf of Metropolitan Sleep Disorders Center and Itamar Medical. My company has been compensated both for travel and time. I will skip most of the preamble here as this has been discussed, only to point out that the prevalence of sleep apnea is felt to be much higher in the primary care population, that is, about 38 percent of males and 28 percent of females have a high probability of sleep disordered breathing based on obesity, snoring, excessive daytime sleepiness, hypertension and witnessed apneas. PSG remains the gold standard, largely for lack of another better standard at this time. It continues to be labor intensive and fairly expensive. The wait time is as long as two to ten months, as shown in the study by Flemons, et al.
Given the extent of the problem and the

importance of making the diagnosis, it is important to rethink the strategy for diagnosis and therapy at this time. Recent technological advances have opened up new possibilities for ambulatory detection of obstructive sleep apnea, such as peripheral arterial tonometry which has been alluded to in the RTI literature. It records episodic changes in the tone of peripheral vasculature in response to bursts of sympathetic nervous system activation. The respiratory events associated with obstructive sleep apnea have been known to cause arousals from sleep. The arousals cause increased sympathetic activity and peripheral vasoconstriction.

The WatchPAT 100 is one such device that utilizes the technology to assess sleep disordered breathing in the ambulatory setting. The device is FDA-approved and assesses peripheral arterial tone in the finger, pulse rate, pulse oximetry and atigraphy, all enclosed within a device worn on the finger and the hand. This makes it simple, reliable to use, and its ability to detect sleep wake makes the calculation of RDI most accurate, since the denominator is not the total recording time but rather the total sleep

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time, unlike any other ambulatory device so far. Automatic analysis saves time and eliminates interscorer variability, which can be fairly high. This has so far been studied in several hundred people. Data indicates good correlation with PSG RDI between .85 and .96. To assess sensitivity and specificity ROC curves have been constructed, showing ROC-AUC between .82 and .96. The PAT RDI scores are reproducible, showing high correlation between home and in-lab studies. Technical failure rate is low to almost nonexistent, even in the ambulatory setting, and rejection rate is close to zero.

I will highlight the study by Pittman, et al., which was published in Sleep, 2004, and there has not been alluded to in any of the reviews that have occurred so far. They studied 30 patients suspected obstructive sleep apnea, with simultaneous PSG and WatchPAT 100 in the sleep lab, and then WatchPAT 100 at home in random order. Data is available in 29 patients. The one patient in which data was not available was because of failure of the polysomnogram, there was too much artifact in the study for a good diagnosis.

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Using Medicare criteria, the in-lab correlation coefficient was .95 and the ROC-AUC of nearly one, for an RDI cutoff of 5 to 30 per hour. Comparison between lab and home RDI revealed a correlation coefficient of .72. Home studies were performed with no technical failures. Consequently, PAT technology should be considered an acceptable method for conducting sleep studies in an unattended setting. As clinicians we know that every test is not suitable for every patient. This is true for the entire field of medicine, not specifically sleep. Therefore, I urge the appeal to consider it to affirmatively diagnose suspected obstructive sleep apnea in patients who otherwise meet criteria, as a follow-up study to evaluate response to therapy after initiation of symptoms, and also to rule out questionable obstructive sleep apnea diagnoses and thereby eliminate need for a polysomnogram. The last point has not been studied greatly in the literature yet.

In summary, PAT technology is accurate, very user friendly, has potential for widespread application and diagnosis in a timely fashion, and though not exclusively studies in the Medicare

population, there is reason to believe that barring the exclusion criteria it can be effectively utilized to diagnose obstructive sleep apnea in this patient population.

In the end, I would like to make a comment since Dr. Krist asked the question regarding a randomized trial for home and for ambulatory studies. We are in the process of carrying out a randomized trial using WatchPAT technology. I'm not prepared to discuss the entire data at this time but preliminary and interim results are very interesting and we hope to take this to the sleep meetings next year. Thank you.

DR. DAVIS: Thank you. Dr. David Barone.

DR. BARONE: My name is David Barone. I am the founder and currently a board member of Sleep Health Centers, a provider of diagnostic and treatment services based in Boston. I am also a consultant to a large number of medical device companies, not necessarily in this field, except Itamar Medical, the producer of WatchPAT. I recognize that you all have copies of the slides; for the sake of time, I will skip a

number of the slides that are redundant to some of the comments that were already made by other speakers, but I will go quickly through some points.

Portable unattended devices have inherent differences, as have been pointed to today. Yet, the published evidence provides ample support to the use of multichannel devices in patient populations suspected of having sleep apnea. And specifically, portable in-home studies have inherent advantages suitable for specific populations and in certain clinical applications. Just pointing to guidelines that were published by the American Academy of Sleep Medicine about ten years ago pointing to the role of portable devices and suggesting a number of indications in the guidelines such as patients with severe clinical symptoms, patients unable to be studied in the sleep lab, or to evaluate response to therapy that has already be initiated. Portable devices have been used for over ten years on hundreds of thousands of patients, and a significant number of papers reported clinical efficacy. People alluded to limitation of sleep studies regardless whether

they are done at home or in the lab. There are limitations all over the place, none of the practices, none of the protocols or technology is perfect. And the comment was made, and I can only second it again, that prudent clinical judgment must accompany any diagnostic study regardless of how it's being done.

The medical field employs alternative diagnostic modalities for numerous illnesses, recognizing that there are tradeoffs among such technologies and protocols, and the use of diagnostic modalities which are simpler than a gold standard is actually a standard practice in medicine. I just bring up as an example and lack of time the use of Holter monitor as an ambulatory methodology to identify cardiac arrhythmia. It's certainly been reported in multiple studies, it's not as sensitive or specific as some of the more elaborate studies available, but yet is suitable to initiate treatment and some fairly complex treatments.

New technologies can offer specific additional benefits to patients. The picture on the upper left slide shows polysomnography. It is certainly a technology that provides a lot of

information, clinical data, but it was designed specifically to be used by technologists. The setup and the monitoring require technologist involvement, considering the complex patient interface. Yet, you have so-called Level III devices that are simpler and were designed specifically for the purpose of diagnosing sleep apnea in a patient's home. They provide for simple interface. If you are to use by patients, they provide the clinical information that's specifically necessary to diagnose sleep apnea, not necessarily all the other sleep disorders that are diagnosed in sleep lab. Some of the technology, specifically I'm pointing to the WatchPAT as an example here, provide also information about sleep quality as well as monitoring the actual sleep time, and those devices provide for full disclosure.
The FDA recognizes the role of such devices and approved specifically for the application of diagnosing people at home a number of such devices.
There is no time to go through all the evidence. I just want to point to this slide, or this chart that suggests that Medicare population,

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in spite of having a higher prevalence of sleep disorders in general and sleep apnea specifically, is underrepresented in sleep labs and that population is currently under diagnosed. The other point that I want to make before I finish here is referring to an evaluation that was done by the Institute for Clinical System Improvements, known also as ICSI, based in Minneapolis. This group actually faced exactly the same questions that this committee is facing, and they've looked at the procedures for sleep apnea or the protocols for sleep apnea in 2003 and again in 2004, and approximately six months ago came with revised guidelines, and I'll just quote a couple of sentences from those guidelines. First, in patients with high pretest probability of sleep apnea, unattended portable recording is an acceptable alternative to standard PSG. They also said, talking about accessibility issues and talking about it stated, employment of portable monitoring as a second best option is not likely to result in harm to patients with high pretest probability of sleep apnea and may result in effect in less risk than leaving the condition undiagnosed.

In summary, presently Medicare beneficiaries suspected of having sleep apnea have only two options, either they can undergo an in-facility polysomnography test or leave the condition undiagnosed. The evidence supports that the modification of the current guidelines to enable sleep specialists or other qualified physicians to use portable at-home sleep studies as another diagnostic option in addition to facility-based testing. Additional testing modalities will increase the number of patients tested and treated, leading to enhanced outcomes in the Medicare population.

And finally, clinicians should be able to use any new technology which has been cleared by the FDA for this specific indication. Thank you.

DR. DAVIS: Thank you. Dr. Peretz Lavie.

DR. LAVIE: Thank you very much. My name is Peretz Lavie, I am professor of biological psychiatry at the Technion-Israel Institute of Technology in Haifa. I was the dean of medicine for six years and I am the vice president of the university. I started to do sleep research and

sleep medicine over 30 years ago. I saw my first sleep apnea patient when I was a post-doc in San Diego in 1974. And I also wrote several books; the most recent one is on sleep apnea, Restless Nights, on defending snoring and sleep apnea, Yale University Press.

Disclosure. In fact I am the inventor of one of the first monitoring devices together with Aaron Hobson, it's called the Nightcap, sold to Respironics and I continue to get royalties. I am the founder and board member of Sleep Medicine Center, operating five clinics in Israel, and co-founder and board member of SleepHealth Centers in Boston, also operating five clinics. We developed the technology that is based now in the WatchPAT, and I'm the co-founder of Itamar Medical. They paid for my trip and I am representing them. And I am also a co-founder and board member of SLP, that developed the SleepStrip screener for sleep apnea, and a lot of the diagnostic devices alluded to in one of the previous presentations.

I'm going to skip -- this is the risk of being one of the last, everybody said it before, but I'm going to skip some of the slides.

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I just would like to call your attention to the last line, diagnosis, what then. Compliance with treatment now with CPAP is about 50 percent. My guess is it is a little bit less than that and I will come back to it at the end of my five minutes. I think this is the problem and not diagnosis.

This paper was alluded to before by I think Dr. Kimoff, Flemons, et al. By the way, Flemons is the key, or the senior author on a lot of the position papers analyzing ambulatory devices. He said that in order to provide or to make polysomnographic studies more accessible to people who need it, you need to multiply the number of tests right now five-fold, and this is based on a very conservative estimate that 50 percent of the PSGs would be positive for sleep apnea. I think you could realize from what you heard up to now that about 85 percent of PSGs are positive for sleep apnea, so this number is a very gross underestimation.

But I would like to talk about two issues, the gold standard and what it means. Everybody compared ambulatory devices to all-night PSG, facility-based. But the reality is that in

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the field now, more than 90 percent of the PSGs are not all night, they are split night. Now split night is at the best two hours of study. At the end of the two hours, which is about 2:00 to 2:30 in the morning, the technician makes a decision whether there is an RDI of 20. He doesn't look at sleep stages. Maybe he will look at the REM sleep or shortened sleep, and then he makes a decision whether to do a CPAP titration. This is the practice in the field. Everybody compared portable devices to all night, but what we are doing is not all night, we are doing split night.

Now if you look at the data on split night, and this is a paper that just came in Sleep Medicine Review, the purpose of this abbreviated diagnostic PSG is to more directly determine the presence of OSA. Data indicated a positive study during the initial two hours reliably predicts the presence of OSA, high positive predictive value. But OSA could not be reliably excluded by negative data, so it's a very low negative predictive value, precisely the same for portable devices. So we should recognize that what we are doing now in the field in 90 percent of the cases is a split

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night, which is not an all-night test. I'm not going to talk about Level II, this is redundant. What is done in other countries? The U.K., only 10 percent of sleep studies are all-night PSGs. In fact, 50 percent are unattended at home using only oximetry. Canada, split night and home monitor are used to increase capacity. Australia, some laboratories use split night and some oximetry to monitor moderate to severe cases. This is from the paper by Flemons, et al. just published in the American Journal of Respiratory and Critical Care Medicine. But it's interesting that the editor, Allan Pack, did an accompanying editorial, and he asked the following: Most surprising in the article by Flemons and colleagues is the widespread use of ambulatory approaches to diagnose rather than full in-laboratory PSGs. Several recent reviews and policy documents indicate that this strategy cannot be recommended. Thus, why is the approach being used widely by thoughtful sleep physicians? So why is the unattended Level III being used widely by thoughtful sleep physicians? Because in populations with a very high

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pretest probability of OSA the positive predictive value of unattended Level III and even Level IV type devices is very high, very similar to that of split night. If we use, or if these thoughtful experienced physicians will use some kind of assessment for pretest probability of disease, which can be done by even taking history, you can in fact make sensitivity and specificity of these devices close to one. And believe me, even primary care physicians with proper training can do the same thing.

So, we developed in my laboratory the WatchPAT, which is a new technology, and I just would like to read to you the conclusion of the last study published last month by David White's group in Boston. He said in conclusion, this study indicates that the WatchPAT device is easy to use for home sleep studies with a low failure rate for single use and minimal technician time when compared with PSG. The WatchPAT could become a useful diagnostic tool in diagnosing moderate to severe sleep apnea in high risk populations, where the prevalence of sleep disordered breathing is high, and this should be emphasized. The WatchPAT system could become an important clinical tool and

may play an important role in reducing per patient cost in diagnosing and managing OSA. Thank you very much.

DR. DAVIS: Thank you. Dr. Steve Burton.

DR. BURTON: I'm CEO of Sleepmate Technologies but I don't come formally representing them today. I'm also on the board of a home testing sleep service company. I have not been paid for my presence here today.

When you're in Montreal you don't speak about the referendum, when you're in Richmond you don't talk about abortion, and when you're in a sleep meeting you don't talk about home testing. It's a very emotional event, it is one which has, I've seen the passions of many meetings, this is a very controlled audience today and I commend them. It's much more colorful at the annual sleep meeting, I assure you.

One of the things that's really important is that I feel like I've had exposure at many levels. I was a sleep technician for four years, I conducted hundreds of sleep tests where I set up the patient, I experienced home testing, in-lab testing, so I can appreciate that. I am

board certified in sleep since 1989. I have run thousands of standard sleep tests in a Chicago-based university facility, and I've also been involved in the conducting of over 10,000 home sleep tests. So I have been involved in the whole gamut and my suggestion is that that has provided me the experience to be able to provide insight that goes into some of what we're discussing today.

DR. DAVIS: Dr. Burton, do you have any conflict of interest disclosures?

DR. BURTON: No.

DR. DAVIS: I'm sorry if I missed it. Thank you.

DR. BURTON: One of the, I would say unfortunate things I was able to participate in some of that earlier. To just put it in perspective, it's been briefly alluded to, but sleep physicians billed insurance companies over $10 billion in the last decade. So it is a large sum of money that drives, and it's a little concerning that that bias drives and controls the gate for our published research, for the editing of it, for the review and the conduction of that research. It's impossible to be able to do that

without having some influence.
We have seen that in the scientific report that was presented to this committee in that the number of studies that included were only 12 of 160. If you review many of the other studies, they provide very valuable information relating to home testing. There is, one of the biggest challenges we've got with what has been described as a standard of care today is that the in-lab test is substantially challenged by the variance that you see even between its own scoring of the exact same data. Dr. Mair points that out remarkably well and I amplify the point he raised there.
What is important to focus on is the treatment outcomes, and if in fact we provide a home test or a lab test, will we be able to make the determination of how to treat that patient? In my mind that is an important question that is important to think about, and the challenges around that. One of the complaints in home testing is frequently the collection of sleep data, that this is despite the fact that most of the time we found many studies that exist, two I show here, where sleep data was irrelevant to the

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treatment decision. And that was a question that was raised earlier here today, so take a look at these data real quick. 200 patients were examined, no patient was misclassified by using time in bed compared to sleep. Their conclusion was measurement of sleep has little value. Another study that I personally conducted in '87, 250 patients. 97 of those patients received the exact same treatment if you use time in bed versus sleep time. It's my suggestion that sleep is only recorded because the field evolved from a neurological base before sleep apnea was discovered. Had it not been already studying EEG, it is quite likely that would be a moot point today. The idea that sensors fall off and that data are unusable and that there's a high repeat rate, the reality is that's largely because the people that are doing those studies don't do home testing. The technicians that are doing these studies, in many cases some of those studies is the first time they ever did a home test. The good news is the sleep field will get better at it, they're going to be able to do home testing,

they're going to need to be able to do that, and one day in the future we will see that they will dominate their medical practice.

There is equipment in the field made by very competent manufacturers. There is nothing, the same team is developing the units used in the center or used at home. They are very capable, they are very competent, the equipment is there.

Home testing has a very important role, PSG has a role, and no one wants to try and replace it. But by embracing it, we can direct it, and rather than directing our energy to try to bar this, it's important, I think, that we spend the time it takes to take advantages of it and have the cost effective advantages, the time of delivery and care.

And the important thing to underscore is that one of every three truck drivers has sleep apnea, and most of them don't know it.

DR. DAVIS: Thank you. Robert Heft.

MR. HEFT: My name is Robert Heft. I represent Air Care Home Medical, an HME provider in California. The only financial involvement that I have is that we provide CPAP equipment under the manufacturers, we don't receive any

money from them. My trip was paid for by the company that I work for.
I am a registered respiratory therapist with 18 years experience. I've treated thousands of patients with sleep disorders, I have had several interactions with home sleep testing devices made by a variety of manufacturers, and I also use CPAP therapy myself to treat my OSA condition. I'm well versed in the areas of OSA diagnosis and treatments and I have a strong working knowledge of the equipment technology.
As you evaluate the importance of home sleep testing today, deliberate and present your recommendations, there are three very important points to remain focused on. We must remember that we are focusing on the use of home sleep testing to diagnose OSA only, not other sleep related conditions.
The three parameters needed primarily to make home sleep studies comparable to polysomnography and accurate in diagnosing OSA only are oximetry, airflow and chest excursion. These are also the same primary parameters used by in-lab PSG test to diagnose OSA; there's no difference. All home sleep studies must be

reviewed by trained clinical professionals such as a PSG tech respiratory therapist, or a physician trained in sleep medicine in order to properly identify sleep apnea, eliminate artifacts, inappropriate auto scoring and device malfunction. I would like to respond to the evaluator questions on portable devices that measure cardiorespiratory parameters only. Question one on how well does the evidence address the effectiveness of these types of unattended portable multichannel home sleep testing devices as an alternative to facility-based polysomnography in the diagnosis of OSA? My response is very well. Portable sleep testing devices that measure the primary parameters of oximetry, nasal airflow and chest excursion are as effective as in-lab polysomnography in all cases except when a patient has only REM sleep apnea and no occurrence of REM sleep during the home study. This would result in a nondiagnosis of OSA and due to the patient's continuing symptoms, would trigger a lab bases poly for further evaluation of sleep. In my experience, this is rare and has occurred in less than five patients of mine in the last six years.

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Question two on how confident are you in the validity of the scientific data on following outcomes and how confident are you that these sleep testing devices are as accurate in the diagnosis of OSA? Again, high confidence, same as before, the primary parameters show this. How likely is it that these home sleep testing devices will be as good or better than facility-based polysomnography? Again, the primary parameters of oximetry, airflow and chest excursion are measured in the lab and in the in-home portable units using the same techniques. They both display wave forms of the same caliber. The only difference would be the rare case of exclusive REM-related apnea, and both study types must be interpreted by trained personnel. In addition, the study's performance will be more representative of the patient's actual sleep architecture due to the fact that the patient will most likely be sleeping in their home environment rather than in an unfamiliar and uncomfortable sleep laboratory, which is one of the most complaints that we have. And how confident are you that the use of these sleep testing devices in the diagnosis of

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OSA will lead to similar or improved outcomes measured either directly or indirectly through changes in patient management? In addition to the comfort and privacy benefits of the patients' ability to be tested in their own home, a patient will have a higher probability of a positive experience concerning the testing and upon the diagnosis of OSA will be more apt to accept treatment.

Patients who have had poor laboratory-based experience in the past and who need retesting to reconfirm a diagnosis, or who may need retitration, these patients will be more likely to perform a test at home when previously they might have become noncompliant, thus resulting in significant health risks.

How confident are you that these sleep testing devices are as accessible as facility-based tests for diagnosis of OSA? Very confident. There is no question that home-based sleep studies are more readily available than a sleep lab. Patients have had difficulty scheduling lab-based tests in a timely manner due to a backlog of patients and a minimal amount of centers, techs and beds. Patients awaiting

studies are at high risks for automobile accidents, job injuries, extended hospital stays, psych issues, loss of employment, et cetera. Home-based sleep testing will allow for quick diagnosis of OSA in most cases, the accuracy is excellent, the technology is excellent, the quality of care is excellent, and it is cost effective. Thank you.

DR. DAVIS: Thank you. We have seven people who have requested to participate in the open public comment portion of the agenda and we have asked them to limit their remarks to two-and-a-half minutes so that we can get back on schedule. So we would need about 18 minutes or so for those public comments and if we start those in a few minutes, we will still begin our lunch break around the scheduled time of 11:40. But why don't we just take a moment or two to see if any of the members of the committee would like to ask a question or two of the presenters so far. Yes.

DR. SATYA-MURTI: The WatchPAT measures arterial activity. Have there been studies to show what happens to this reactivity in older patients? A lot of Medicare patients have neuropathies and peripheral arterial disease and

they are also on medications. So, have there been normative data to show that this would indeed be a good surrogate or a direct indicator of what happens?

DR. LAVIE: We didn't address that question specifically. The studies were based on sleep clinic population with AHI of 15. We know that alpha blockers, using alpha blockers is a contraindication, and this question has to be addressed, so we didn't study in that specific manner.

DR. SATYA-MURTI: Have others provided age-based normative data with comorbid conditions?

DR. LAVIE: I don't think so.

DR. DAVIS: Other questions? Barbara, and let me ask you, if there is a specific person you want to direct your question to, make that clear for them.

DR. MCNEIL: I have a very specific question to Dr. Lavie, and maybe I didn't understand it. Did you say that you believe Level II devices are less accurate than Level III?

DR. LAVIE: No. What I said, I think it's redundant to talk about Level II, because the Sleep Heart Health Study, all through its research

has carried more than 7,000 studies with about 15 or 16 publications using unattended Level II without a single paper of criticism. So I think this is proven, there is no need to talk about it. That's what I said.

DR. MCNEIL: Okay.

DR. DAVIS: Dr. Hoover.

DR. HOOVER: My question I believe is directed to Dr. Slack, and correct me if I'm wrong. You made the comment about the bias in the literature from pulmonologists that were also financially vested in sleep centers. Was that your -- correct me if I'm wrong, I may have the wrong presenter. I have heard this comment from multiple people that have come from the audience, and I have also heard another comment that we fully expect that if this were approved, that pulmonologists would be the ones that would stand to benefit from the use of this in-home therapy. It seems to me that that issue of bias, really I can't reconcile that issue of bias because I would fully expect the pulmonary community to embrace home sleep studies. They would be involved in potentially purchasing the devices, using it with their patients. There is

apparently a cash cow out there of undiagnosed sleep apnea and I would think they would want to take an active role without so much being biased, even though they own the brick and mortar sleep lab centers, when there is this great potential to move into this other market with portable devices, and I wonder if you could address that bias.

SPEAKER: I don't believe he was speaking about pulmonologists, I think he was talking about people who only use in-facility polysomnography. There is a financial incentive, and I do both. There is a financial incentive for me to do in-house testing.

I don't believe that there is a financial incentive for us not to do outpatient testing, but there are people who are threatened by this because obviously sleep centers is where we all learned about sleep medicine, and it's very important for training, research, program development, and people may not be positioned like if I'm at a university health center, to design a system designed to give care to millions of people. So we all come from different perspectives, and I think we're all right.

DR. DAVIS: Why don't we take one last

question.
DR. GOODMAN: Cliff Goodman, a question for Dr. Burton. Dr. Burton, you made a comment about knowing sleep stage. The historical precedent notwithstanding concerning how PSG was developed and what channels were used over time, given the best knowledge today, does knowing sleep stage or EEG or arousals, any one or more of the above, does knowing any of those contribute to effecting a choice of treatment or outcomes?
DR. BURTON: There is no data that would support that that consistently plays a role that you couldn't achieve by time in bed.
DR. GOODMAN: So your position is that that information is superfluous, sleep stage, EEG and arousals are all superfluous to effecting the treatment decision, let alone outcomes; is that correct?
DR. BURTON: For a suspected OSA patient, that's correct.
DR. GOODMAN: For a suspected OSA patient. May I ask, is there anybody who spoke that would take an opposite side, or contend otherwise?
DR. DAVIS: Please use the microphone.

DR. SATEIA: I would just like to point out that many of the complications that are related to obstructive sleep apnea are in fact felt to be arousal driven and therefore, recognition of arousal is important. It's also important to recognize that particularly in patients who are, who have mild to moderate degrees of obstructive sleep apnea, where airflow limitations are far more subtle, these are the types of patients for example that will not be readily recognized or diagnosed with portable monitoring. The presence of arousals and detection of arousals is a useful and important diagnostic consideration.

DR. GOODMAN: So a Type 3 device which provides fewer channels than a Type 2 device, in your view provides, or misses information that would be useful clinically, whereas I believe the previous speaker would contend that the useful clinical information, that there is no drop in useful clinical information when one goes from a Type 2 to a Type 3 device.

DR. SATEIA: I could perhaps speak to this best from my own clinical experience, which is 25 years of looking at sleep studies. And when

I review sleep studies, I review respiratory data and I review EEG data both independently and together in order to acquire the information with respect to arousals and sleep disturbance which as I said, drive many of the consequences that we're interested in trying to treat.

DR. SATYA-MURTI: In other words, there could be a disassociation between sleep disturbance and arousal. Sleep disturbance, ergo arousal, is not always consequential?

DR. SATEIA: I'm not exactly sure, could you elaborate on your question?

DR. SATYA-MURTI: Developing on this issue, you could have someone who has a sleep disturbance as identified by different parameters and not still be awake. In other words --

DR. SATEIA: You mean sleep disturbance as in a respiratory --

DR. SATYA-MURTI: A respiratory component without a cerebral or an encephalographic component.

DR. SATEIA: Well, that's an area of some complexity. One has to recognize that we're recording scalp EEGs so it's not always possible to detect arousals. But the point is that yes, I

mean, there are respiratory events that occur with arousals. Although the vast majority of these are associated with arousals, I think the important consideration is that in more subtle cases of obstructive sleep apnea or subtle airflow limitations, that arousal is often an important element in detection of events.

DR. DAVIS: Dr. Boehleche, did you want to chime in on this?

DR. BOEHLECHE: Just quickly. Another aspect similar to what Dr. Sateia just said about arousals is the issue from a clinical point of view many times is determining the impact of sleep disturbance whether it be respiratory or others, on the patient's functioning and the overall clinical need for treatment. So although in some instances there's overwhelming evidence that there is a such a high level of respiratory disturbance one would always want to treat it for the other outcomes, when I look at a sleep study I look at the number of arousals and sometimes in the "borderline" cases, that determines whether or not I feel CPAP treatment is definitely indicated or more conservative therapy, and that may have been what was the difference in the one study that

looked at clinical decision-making. So if a patient has many, many arousals associated with their respiratory disturbance, that pushes you more toward treating than if there are very few arousals associated and their symptoms are borderline.

And as we point out in one of the references, there are many reasons to be sleepy besides sleep apnea, and while it's true that the majority of patients coming through sleep clinics who are sleepy have sleep apnea, or that's why they are there to be ruled out, but there are many other conditions. So if we're starting to apply screening to a broad population who are sleepy, there will be many more people who have other things.

DR. DAVIS: Dr. Weiner, did you have a question? I have Doctors Weiner, Lacey and Maves on my list and then I think we're going to need to move on, if we want to get to lunch by noon.

DR. WEINER: It could be a very quick question or not, for Dr. Coppola. I was very intrigued about your discussion, I guess it's in Springfield 7,000 cases, and in the Group Health Cooperative 19,000 cases. Has there been a peer

reviewed paper on either of the two.
DR. COPPOLA: Group Health has submitted their initial 1994 experience, I think with input from the University of Washington, Washington statisticians. It was rejected.
DR. WEINER: So neither, the Group Health paper has not been published at this point.
DR. DAVIS: Dr. Lacey.
MR. LACEY: Actually, thanks for bringing that up, Cliff. This was the issue I was trying to get out a little earlier and I actually did want to ask Dr. Coppola and others. This data, there are two questions I would like to ask. The first one is, is there a relationship? It sounds like the EEG issue is related to the prior probability of whether you have obstructive sleep apnea. The suggestion there was that the lower probability subtle cases, the EEG may have some additional information. So the key question is, what is the treatment paradigm or the model that you identify high probability patients through questioning or through clinical assessment? So, could you describe your model? Dr. Slack explained sort of the effectiveness of one type of approach.

DR. COPPOLA: I think, I would like to say for a moment, a couple of the speakers like myself have used both technologies. I see things in borderline patients on PSG that provide useful information. But I also ask myself, if I had seen a four channel or Type 3 recording on this patient, would I reach the decision to treat, and the answer often is yes, most of the time. Again, the Group Health data, they are the consumers, they are paying for the care, have all these available to them, and they have an algorithm similar to mine.

Patients are evaluated, a careful history and physical is obtained. In those patients who come back mild to moderate, we recommend a trial of CPAP therapy with a varying degree of follow-up testing. We do sleepiness scales, et cetera. We have invested the resources into medical management, to making sure that these people go on CPAP and are unsuccessful. It is not unusual in the United States to have a wonderful sleep test and never be followed up to find out if you're using your treatment. We will not let that happen.

There are offsets. We miss the EEG in

the milder cases, we'd like to have it to see the arousals. The correlation coefficients in people reading arousals are about 50 percent; I don't think that's worth the investment most of the time. People sleep better in their home. Elderly people don't like driving to the hospital at night when it's dark out to go get a sleep study. There are advantages to sleeping in the home. I slept in the Holiday Inn last night and it wasn't a pleasant experience, and I wasn't wired. So there are offsets. There are benefits to having portable testing, there are benefits to having PSG, I think in the end most of the time it's a washout.

DR. DAVIS: Dr. Maves.

DR. MAVES: My question is actually for Dr. Boehleche, and I guess the question I want to have asked is that as you looked at these studies and you go from the Type 1 study, Type 2, Type 3, Type 4, and maybe this can't be answered, is the erosion you see in performance in going to home testing a result of loss of information by fewer parameters, fewer channels so to speak, or is it the variability that's been produced in home testing by lack of data acquisition, electrodes

coming off, et cetera? Which of the two -- or it may be an unfair question -- but as I sit here thinking about it, which one causes the deterioration in the results that we're seeing or that at least you have reported in your study.

DR. BOEHLECHE: I think when you look at the overall results from Type 3 and Type 4, I would say that the preponderance is from lack of information versus loss of data. I mean, there are individual studies in each group that show a higher level of "loss of data", but I would say that the Type 3 study tends to have more information and appears then to produce better overall agreement with the whole Type 1 in-lab study than the Type 4.

DR. MAVES: All right, thank you.

DR. DAVIS: Thank you. Let's move on to the open public comments. We now have eight requested speakers, two-and-a-half minutes each should get us to about noon. We'll take an hour lunch break until one. We'll begin with Dr. Charles Weingarten.

DR. WEINGARTEN: My name is Charles Weingarten, I am a practicing otolaryngologist in the metropolitan area of Chicago. I'm a member of

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the American Academy of Otolaryngology. I'm a senior citizen but I'm speaking for myself. I have many conflicts. I have financial interests in Biologic Systems and I'm on the board of the manufacturer of equipment for laboratory-based sleep testing. I'm a medical consultant for SNAP Laboratories; they do home based sleep testing. I have no interest in any sleep laboratories. SNAP Laboratories paid for my trip here.

My issue is that I am part of the main conduit for the management of patients with sleep disorders, breathing particularly, and obstructive sleep apnea, in that I'm an otolaryngologist, and the primary complaint in almost all of these patients is snoring. The fact is that we probably refer about 30 percent of our patients to the sleep laboratory, or have in the past, and the remaining patients are at least initially seen by primary care, not sleep physicians.

As physicians, our mission is to diagnose and treat. In this case we are trying to diagnose sleep disordered breathing and we need a metric, which is sleep testing, in addition to clinical assessment. The problem is access in testing, that is sleep testing. There are delays

due to limited capacity which you heard about, and this is aggravated in my experience based on socioeconomic status of the patient. That is, our suburban so-called white collar patients may be slightly more willing to go to a sleep lab than our blue collar city-based patients. And I would suggest in our blue collar patients, my experience is more than half of the male patients referred for laboratory-based testing failed to comply. This is compounded obviously by the delays you have heard. In our area it is more like eight to 12 weeks.

Assuming an adequate capability of home sleep testing, as a physician I would prefer adequate information versus none. I can't treat a patient without information. Again, regarding my mission, if a patient is not diagnosed, he's not treated, I have really failed my mission and so has society. Physicians and patients need accessible, affordable and convenient access to sleep testing.

I would add parenthetically that I think more important from the perspective of the national interest is disease management guidelines for the management of sleep disordered breathing

and obstructive sleep apnea. That would include treatment guidelines and the implementation of automated home CPAP for the treatment of sleep apnea. Thank you for your time.
DR. DAVIS: Thank you. Let me read off the list so that people will know when they're going to be coming up. Dr. Charles Atwood, David Thorsen, Dr. Thomas LaGrelius, Gary Sagle or Sagley, I can't quite read it, Steven Resnick, Gil Raviv, and Robert Konigsberg. So, Dr. Atwood.
DR. ATWOOD: My name is Dr. Charles Atwood. I am speaking today on behalf of the American College of Chest Physicians. I am an academic pulmonary physician, I'm employed by the University of Pittsburgh and by the VA Pittsburgh Health Care System. I do not have any ownership or financial interests in any company in this field. I have received equipment as a part of research grants from various companies in this field.
The ACCP is the largest professional organization of practicing pulmonary and critical care physicians in the world. A substantial number of our membership is engaged in the practice of sleep medicine. My role today in

speaking before you is as the chair of the sleep network of the ACCP, which is a special interest group of pulmonary physicians and others with sleep disorders. The ACCP receives unrestricted educational grants from virtually every company in the sleep disorders marketplace but has strict policies to minimize commercial bias in its association with industry.

The ACCP supports the use of non-facility-based multichannel sleep apnea studies. We support this because we feel that sleep apnea is an important and highly prevalent disease in the U.S. and that it is very much under diagnosed and that portable monitoring outside traditional sleep lab facilities is likely to be a positive step in increasing access to care.

We are fully aware of the arguments against reimbursement for portable sleep apnea monitoring. They have to do largely with the relative lack of solid clinical evidence in their favor. However, we believe that the lack of evidence is only relative. In fact, as many others have pointed out, the evidence-based review recently conducted and published by the AASM, the ACCP and the ATS tri-society join task force found

really no evidence against their use. What they did find, really, was only a limited number of studies that had examined home testing with Level II or Level III devices. And more recently, we've heard about the AHRQ report basically substantiating the earlier report.

We agree that more evidence is needed and the ACCP strongly supports further research in this area. But we also feel that our current level of understanding and experience with portable monitoring technology is adequate to allow pulmonary and sleep medicine physicians to go forward with its use. If the work is performed for a legitimate clinical purpose then it should be reimbursed.

Much of the medical literature about portable monitoring for sleep apnea has focused on how closely portable monitoring tracks the finding of in-laboratory polysomnography, but we believe the diagnosis is more than just interpreting findings on a multichannel physiological recorder. A sleep apnea diagnosis should integrate clinical history and exam findings with the results of sleep apnea testing. Clinical context is crucial and indispensable.

The ACCP believes that pulmonary physicians and other sleep medicine practitioners are fully capable of putting the results of portable sleep apnea monitoring into its appropriate clinical perspective. The sleep medicine community, probably better than anybody else, really understands the strengths and perhaps more importantly, the limitations of this type of testing. Portable monitoring has to be interpreted in light of its clinical context, and certainly the same is no less true for full polysomnography.

DR. DAVIS: Dr. Atwood, could you wrap up, please?

DR. ATWOOD: In summary, we believe that home portable monitoring will enhance the diagnosis of sleep apnea diagnosis for our patients, we believe that CMS should reimburse physicians for performing and interpreting these types of studies. We certainly support more research, but we feel that enough is known about their limitations and their benefits to proceed with this approach. Thank you.

DR. DAVIS: Thank you. David Thorsen.

DR. THORSEN: Thank you. My name is

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David Thorsen. I'm a board certified family physician. I represent Family Health Services Minnesota, which is a group of 65 family physicians in Minnesota. My travel has been supported from Itamar Medical; however, I have no corporate ties or any other conflicts other than that.

I am on the ICSI work group that talked about sleep apnea and I experienced firsthand the tug that happens when you get a group of people together to talk about home monitoring versus polysomnography. In fact, the first year we had our work group we could not come to consensus about home monitoring where this year after several hours of work we did come to consensus with the statement that you saw previously.

I refer to sleep labs as well as perform home testing in my clinic. I am interested in the identification of at risk populations for multiple chronic problems, including high blood pressure, atrial defibrillation, diabetes. We look at systems approaches to identify people early to enhance treatment.

I would like to appeal to the committee

to understand the problems that access presents. In Minnesota we have a significant rural population which presents access problems. Many of them are more than two or three hours away from the nearest sleep lab. Some of them are six hours away from a sleep lab. They are farmers. They can't afford to be away from their cattle at night; they have to get up at six o'clock in the morning to do their dairy cows. Access is a significant problem.

There are a significant number of patients who refuse overnight sleep labs. That's why in our ICSI guideline we said patients who are unable to have an overnight lab study performed, because people just refuse to do it. In my patient population, which is fairly white collar, I would say up to 50 percent of patients refuse sleep labs. They never even get to the pulmonologist to talk to them about sleep labs. We have a huge number of patients that need to be identified at risk, diagnosed and treated appropriately. We haven't even touched the top of the barrel yet to find out who's at risk.

I am comfortable, as has been stated previously, that in patients with a high prior

test likelihood of sleep apnea, the appropriate use of home testing will allow for the timely diagnosis and treatment of sleep apnea. This will help decrease the morbidity and mortality associated with untreated sleep apnea. It is my vision that patients based on their history and physical exam will be identified as at risk for sleep apnea, they will be tested, diagnosed, and treated with the same urgency as other medical problems are treated. There will not be a delay of six weeks, three months or whatever because they can't get into a sleep lab. The delay in the current system is too long and will only get worse, leading to poor patient outcomes. Thank you.

DR. DAVIS: Thank you. Dr. LaGrelius. I apologize if I'm mispronouncing any of these names.

DR. LAGRELIUS: You won't be the first. I'm Dr. Tom LaGrelius, a graduate of Dr. Dale's institution, I might add. I am a family practitioner and geriatrician in Torrance, California. I am in solo practice but also am president of a large medical group without walls, South Bay Independent Physicians Medical Group,

who does PPO contract management for about 2,000 doctors in California.

My conflict of interest is that I own two home sleep monitor devices that I use out of my own office, one an Embletta, the other the WatchPAT device. I've been using these devices for about three years and have tested several hundred people and diagnosed almost a hundred patients with obstructive sleep apnea during that period of time. I became interested in purchasing such a device in the first place because I could not get my patients tested or they would not go for testing.

I was interested in the disorder, I have a good working relationship with a sleep specialist by the name of Larry Nisley, who runs a PSG lab in the hospital next door to me. We are good friends. He is one of the people who taught me about sleep apnea and made me interested in looking for the disorder. When I started looking for the disorder, I discovered I couldn't make my patients evaluated because his lab had a three-month waiting period and the patients wouldn't go anyway.

Since half my patients are geriatric

patients, Medicare patients, and over half of the ones I tested were geriatric Medicare patients because of the population I work with, I can tell you that far more than 50 percent of geriatric patients refused to go to the sleep lab for studies. It's probably more like 70 percent of the patients I talked to refused to attend a hospital-based sleep study and therefore never get tested.

I found that with the acquisition of a home monitoring device, I was able to convince these people very easily to get the study. The studies are very inexpensive; we're talking about hundreds of dollars instead of thousands of dollars. They are easily repeated if something goes wrong, and almost nothing ever does go wrong. They are reproducible in the PSG lab. In fact, I refer almost all my patients to a sleep specialist for CPAP titration in the hospital and the results are almost identical. In fact, my results at home are a little better because they sleep better at home obviously.

I want to comment that it has been said that 80 percent of the people who are tested in a PSG lab are positive. I can only say that if

that's the case, we are not testing anywhere near enough people. You know, we should probably be testing at a level where 50 percent or 40 percent of the people we test actually have the disorder, because by doing what we're doing now, we're missing millions of people. There is an absolute flood of people out there who need this testing and every primary care doctor in the country, just like he has a blood pressure cuff and an EKG machine in his office, should have a device like a WatchPAT or an Embletta device he can strap on his patients and send home to find out if they have this life-threatening disorder. Thank you.

DR. DAVIS: Thank you very much.

Steven Resnick.

MS. SAMUELSON: Could I ask one quick question?

DR. DAVIS: Very quick.

MS. SAMUELSON: The answer may be obvious, but is there any non-obvious reason why those patients won't go to a sleep lab?

DR. LAGRELIUS: Well, in my experience geriatric patients don't like to go to the hospital, they like to stay at home and stay in their own bed. And you just can't convince them

that because they snore, that this is a reasonable thing to do. But you can bring out a WatchPAT device which straps on their arm, and say will you strap this on and sleep in it overnight, and they say sure. And they even say I'll pay for it, cash, if Medicare doesn't. And so in a way it's against my best interest to have you change the rules, because my geriatric patients will actually pay for this study with their own money if Medicare won't pay for it.

And they may find out they have the disorder, and once you can show them they have the disorder, it's easy to convince them they need additional treatment, they need to see a sleep specialist. That's a piece of cake to convince them then, look at this, you're dying all night long, your oxygen level goes down to 70, you can't let this go on. It's the reason you are tired all day, it's the reason you have hypertension, it's the reason you had a heart attack, it's the reason you had a stroke.

I had an airline pilot in his 70s, retired airline pilot who was demented and had a mini-mental status score in the teens. He had a small stroke and after that I put him on a home

sleep monitor and he had 30 to 40 obstructions an hour. I put him on CPAP. I have normal conversations with this man and his dementia score is 30. He's normal. He could fly.
(Laughter.)
DR. LAGRELIUS: And I'm a pilot. I'd fly with him, really. It's amazing what happens when you find these people, identify them and treat them, and there's millions of them out there who we're not treating and will never get them treated with PSG.
DR. DAVIS: Thank you. Steven Resnick.
DR. RESNICK: Hello. I'm a pulmonary and critical care physician in Annapolis, Maryland, and I don't have any financial investment in any sleep centers or companies. I just wanted to mention a few things. One, I've read prior home studies, and in general I found that they were good when a patients has severe sleep apnea, but when you have someone with mild or moderate, many times the data is not very clear. With the home studies, many times we miss the restless legs syndrome, certainly the upper airway resistance syndrome, and many times alpha waves that come into sleep, which are important,

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that's obviously missed.
The other thing I would like to mention is if we did home studies and you went ahead to do a home titration, many patients have difficulty with the CPAP at first. If the home titration is unattended, I think it may not go well with regards to the patient's satisfaction with the CPAP.
And the other thing I would like to mention is if, I guess otolaryngologists are ordering these studies, are we going to have a flood of surgeries at increased expense? That's just another concern.
And with regard to the delay of getting a sleep study, you know, sleep disorders, it's not an acute problems, it's been something for a patient that has been going for quite a period of time. So it's not like oh, if you don't have one, you all of a sudden are going to die, it just doesn't happen that way. So you know, any delay of a few weeks in a life span is not as critical, it's not like an emergent life saving type thing.
That's it.
DR. DAVIS: Thank you. Gil Raviv. And in some cases the names I have have M.D. after

their name and in some cases they don't, which is why sometimes I say doctor and sometimes I don't, so I apologize again if I miss the M.D.

DR. RAVIV: Yeah. My name is Dr. Gil Raviv. I am the founder of Biologic Systems Corp. We sell equipment to the sleep lab now. I'm not associated with the company anymore but still have stock in the company. I'm also the president of SNAP Laboratories, a sleep at home test company. I think you heard a lot here. Some of the questions became very important, for example about the additional channels. Is the EEG going to make any difference how you classify patients? And you heard from the one person who said that yeah, he might take it into consideration, but with no numbers. If you look at numbers, it's hard to make any difference. You might find out although people will find it helpful, but maybe one in 200 or one in 300 patients it will make a difference. But now you have to look at the total picture. From everything you heard, when you take two people, they score the same sleep, maybe you get a difference of 30 percent. So what does it matter if you have a channel that sometimes maybe one in 200, one in 300 would really make a

difference?
And anyway, Medicare, today the way they are deciding CPAP or not is ignoring and would not take those channels to determine whether to give CPAP or not in the first place.
And also, just to look at the big picture, there is nothing medical, it's not brain surgery to find out if a patient has sleep apnea or not. By definition, sleep apnea, you stop breathing. It's easier to find out if the patient is breathing than, for example, to take the pulse of the patient. If the definition of sleep apnea is if you would have in two minutes stoppage of breathing, then it's sleep apnea, nobody would have sleep today, nobody would go home. In a short period of time of two minutes, it's very simple for the doctor or whoever to find out the implication, he stopped breathing while he was asleep.
The only reason why you have all this is that you need the whole night. No doctor is going to go to the patient's home and spend the whole night listening to his breathing and find out whether he stopped breathing or not. To do that, you don't need over a $2,000 charge or

probably Medicare pays close to $1,000 per test, just to count how many times a patient stopped breathing.

It's very simple to do that, and that's basically the two things, the home testing and the sleep lab are doing exactly the same thing. They find out if it's a single stoppage of breathing, they count it, and the only difference is who's reading it. That's really the only difference, it's not the technology. But the speaker before me told you there is no problem with home testing when the patient is severe, the problem is denial, and he's right. The difference between the sleep lab and the home test is on the very mild where a little bit of difference is going to move you from apnea to not apnea, but the same thing will happen between two sleep laboratories or even the same sleep laboratory, two different technicians will read it, because some of them say don't count this and this I did count, and on the severe it would make no difference because there are so many events, and those are above the line and it would make a difference.

DR. DAVIS: Dr. Raviv, can you wrap up, please?

DR. RAVIV: I've wrapped up, thank you.
DR. DAVIS: Thank you very much. Last, Dr. Robert Konigsberg.
MR. KONIGSBERG: Close enough. I'm not a doctor, and I am the founder and president of SleepQuest, Incorporated, that was founded ten years ago. And how it got started was internists. I was selling Holter monitors and an internist came up to me and said sleep medicine is going to be the big disease state of the 21st century. So I said I'd better learn more about it. So I went to Stanford library, did my medical research, and ended up working with a German manufacturer of a portable device.
I want to transfer now and talk a bit about Bill Dament, the person who founded and started the sleep industry in 1972 with the first sleep lab in the world at Stanford Medical Center. If you talk to him today, he says that I started it for research reasons, I worked with doberman pinschers because they had narcolepsy. I worked with patients that had sleep apnea and at that time they were doing tracheostomies to treat these patients.
A few years ago prior to writing his

best selling book that's in book stores, he went to Stanford Hospital's family practice department, walked into the waiting room and yelled out, anybody here want a free sleep test? And there were 25 patients in the waiting room, and not one of them rose their hand. Is this guy mad, is he crazy? He's asking for a sleep study, he must be nuts. And this one man in the corner sheepishly raised his hand and said I'll do it, I've tried everything else. So he ended up doing a videotape and I'm happy to share with any of the members, I have it in my possession, that was done ten years ago, using a portable monitor.

And he went ahead and interviewed the patient before and asked him about his quality of life. And the patient said I recently got divorced, I lost my job as a high paying person at Xerox as an executive, I'm on 480 milligrams of biropymal (phonetic). I'm on depressant medication. I've seen 15 specialists.

So he went through the diagnosis, got onto treatment, and they did an interview afterwards. And in this interview, Dr. Dament's person had asked this person, how's your life after treatment? And the patient said, it's a

miracle how my life is now. I lost my job, I got a divorce, I went through all this calamity, and now I wake up refreshed, I use my CPAP nightly. And he went on to say, I'm so incensed, I'm so angry at the medical profession for its inability to diagnose such a simple illness. I've seen 15 specialists at Stanford and not one person could diagnose me for such an easy thing, that's as easy to diagnose as a broken arm.

So I'm impassioned here, and I beg you to pass this, because we've got millions of Americans just like the Xerox executive who suffer in silence.

The last thing I would like to say if I could have one more moment is, I want to answer some of the earlier questions about mild sleep apnea. The technology ten years ago when Dr. Coppola started the home industry, the first monitor in the United States was pretty much good for moderate to severe apnea. The technology today is incredible. It uses two different technologies, one called flattening. That was invented by the inventor of nasal CPAP, Dr. Colin Sullivan in Australia, and it measures flow limitation and the instability of the upper airway

to measure mild more subtle forms of breathing. The other technology is peripheral arterial tone, which is just a wonderful invention in that it measures the sympathetic nervous system, and the sympathetic nervous system is what controls, as all of you know, controls stress to the body such as sleep apnea.

I thank you very much, and I hope that my words will have you make the appropriate decision. Thank you.

DR. DAVIS: Thank you very much. Just to remind everybody, the committee is going to come to a conclusion on the state of the evidence, but it will be up to CMS as to what kind of coverage decision to make.

Thank you to all of our presenters from this morning. We'll take a lunch break now and reconvene at 1:00 promptly. Please be back here at one, and at that time we'll go over the questions that have been posed to us and still have an opportunity to ask questions of any of the speakers from this morning. Thank you.

(Luncheon recess.)

DR. DAVIS: Let's reconvene, please, and I would like to start out by having us take a

quick look at the questions that MCAC has been asked to address. We're not going to vote on those for quite some time until we have had the chance for discussion and more questions, but I'm going to suggest that in the next couple of hours, members of MCAC start thinking about how they might want to answer those questions, maybe pencil in some preliminary answers so when we get to the point of voting, which we're going to do probably by raising of hands and we'll try to go fairly quickly, you will be ready to vote at that point without having to think about it and pausing before every question. So as we go through the discussion, please start formulating your at least preliminary answers to the questions, and obviously you can modify those through the afternoon if you deem appropriate. But as you think about those questions and your answers to them, it's important we clear up any ambiguities in the questions.

Dr. Goodman was bringing up some questions about the questions earlier this morning and we were having some side conversations about it, and I thought it would be good to bring that out for the whole committee, so Dr. Goodman, why

don't you lead that off.
DR. GOODMAN: I'll just get started, thanks, Ron. I wanted to align the explanation of the evidence that was led by the RTI technology assessment done for AHRQ, and there is a definition for types of devices. And I know this is quite simple and straightforward to most of the people who have been working on this for years, bur on pages 3 and 4 of the RTI technology assessment are the definitions of the Type 1, 2, 3 and 4 devices. And since the evidence was presented to us largely categorized according to those four types, I wanted to make sure that we understood how those four bodies of evidence per type of technology roll up into the sets of questions that we have for the MCAC panel. And as you know, our questions, we have left-side questions one through five and our right-side questions one through five, and the left-side questions talk about the value of evidence on portable devices that measure the same sleep and respiratory parameters as facility-based polysomnography. And the way that I understand it is that the description of devices of the channels there is congruent with the description of the

Type 2 devices exactly as shown in the RTI technology assessment. So our left set of questions are congruent with the Type 2 set and the body of evidence, number of studies, quality, and all those things rolls up into that set on the left side.

The second set of questions on the right are pertaining to portable devices that measure cardiorespiratory parameters only, and there's an i.e., string of channels and so forth. And the way I read this literally, this literally applies to Type 3 devices but not to Type 4 devices. Read literally, it says i.e., respiratory movement, airflow, oxygen saturation and heart rate or ECG, and if you take that literally, the Type 3 body of evidence rolls into that set of questions but not the Type 4 body of evidence.

So I just wanted to confirm our understanding of that insofar as how we use the evidence to help answer the questions.

DR. DAVIS: Dr. Phurrough.

DR. PHURROUGH: That's correct. The plan was that the first set of questions would compare Type 2 to Type 1, the second set of

questions to compare Type 3 to Type 1.
DR. GOODMAN: The evidence pertaining to Type 4 devices does not seem to be directly relevant to either set of questions.
DR. PHURROUGH: There obviously is the potential for, in some people's minds, Type 4 to bleed into Type 3 and the panel could choose to look at that if they wish, but it's not our preference that you do that. We were specifically looking at Type 3 compared to Type 1.
DR. GOODMAN: That's how I understand it, thank you.
DR. GAZELLE: Just as a further point of clarification, so the AHRQ report didn't concern Type 2 devices, the current AHRQ report, nor has the discussion today for the most part concerned Type 2 devices, we have been talking about Type 3 and Type 4 devices. The prior reports that were referenced did include a discussion of Type 2, as did the prior decision focus, I think, on Type 2 devices. Am I correct in that?
DR. PHURROUGH: Well, you are correct that the current TA, the update to the previous evidence report did not identify any Type 2

articles. There are articles on Type 2 devices, there were I think five studies in the original TA that looked at Type 2 devices and if the panel would like, we could have one of our staff or someone discuss those particular articles. But that is the body of literature that you would need to be familiar with to address the first question.

DR. GAZELLE: Which was referenced in the prior report, but today's discussion has not really focused on the Type 2 or the left side question.

DR. GOODMAN: But the Type 2 evidence that existed prior to the AHRQ report still rolls up into the Type 2.

DR. PHURROUGH: Yes.

DR. DAVIS: Any other questions? Yes.

DR. ZARIN: I just wanted to clarify that the RTI team looked for newer Level II studies and there weren't any, they didn't identify any.

DR. DAVIS: Thank you, Dr. Zarin. Another issue that came up was related to the fact that references were made during the morning to the multiplicity of studies that had been done covering the different technologies that we have

been discussing and why was it that the evidence report focused in on a small subset of those studies. And this was discussed in the evidence report that we considered, but perhaps we might ask Dr. Linda Luchs, I think, to speak to that, I think she's here now and thank you for joining us, and perhaps you might want to come to the microphone and speak to the issue of how the original cache of studies was distilled down to the small number that ultimately comprised the AHRQ review.

DR. LUCHS: We did an evidence-based or systematic review using MEDLINE going through the literature and using certain search terms, polysomnography, oximetry, physiological monitoring, sleep apnea, like a catchall to go after everything. We had limitations, though. We wanted only human studies, no animal studies. We wanted studies of adults, not children. And we were looking for studies that did a portable device and compared it to a PSG. We wanted English only studies.

And when we got our first group out, my major criteria for exclusion was if they were not primary data collection studies, they were

reviews, meta-analyses, case reports, abstracts, letters, editorials, languages other than English, and next came studies that involved children. So, is that enough?

DR. PHURROUGH: Why were most of the articles that were excluded excluded?

DR. LUCHS: Because it wasn't a comparison of portable device to PSG.

MR. LACEY: I guess my question would be, what was the rationale for that exclusion criteria, because it would seem for example that acquisition of interpretable data or some unusual care studies might have provided some useful information, whether or not they did a comparison.

DR. LUCHS: We were replicating the work that had been done in the earlier review and in that case was looking at the portable device compared to the gold standard or PSG, so we used the same criteria again.

DR. SATYA-MURTI: We heard about the morbidity of the end result of having sleep disordered breathing. How confident are we or do we even know that this morbidity indicated by disordered breathing is additive or separate from other types of morbidities these folks have? We

aren't able to attribute cause and effect. Are we focusing on sleep disordered breathing and leaving apart other types of more readily identifiable morbidities in this age group, smoking, diabetes and generalized vascular disease?

DR. LUCHS: Of the 12 studies that finally made it into our review, there was only one that brought in the issue of comorbidity, but it isn't an issue that's usually brought up and dealt with in these analyses.

DR. HOOVER: I think that raises an important point that we rarely heard mentioned this morning in the literature that was presented. In fact, in the ICSI report and a couple others, there were things that were quoted in there and, you know, left out what I think in the Medicare population, which is one of the questions that the panel that is to ask, is comorbidities. And the fact that many of these studies did not address the sensitivity or the specificity or the patient selection, and patients were specifically excluded in many of the studies when they had comorbidities. The ICSI statement that was read, that you know, was underlined in the presentation about employment of portable monitoring as the

second best option is not likely to result in harm to patients with a high pretest probability, and so forth.

But I think in the Medicare population, the next statement is probably even more germane to this discussion, which says portable monitors should not be used in an unattended setting with a patient with a difficult or complicating symptom. I think we all recognize that in the Medicare-age population, rarely do we find someone that doesn't have some level of comorbidity and I think as our population ages, that's going to be an even more critical factor as we look at these kinds of technologies and try to translate what we're seeing in an average age group of 50, which if you look at most of the studies that was the average age, and try to translate that into a population that's 65 or 67 or 70, and finding patients that this is going to be applicable to.

DR. DAVIS: Yes, Dr. Boehleche.

DR. BOEHLECHE: I just wanted to get quickly back to the issue of the exclusion so it's real clear. When there were 172 "hits" or articles identified, you see, they could have been of children, they could have been case reports,

they could have been metaanalyses reviews. So it's not like there was some exclusion of studies for anything other than the inclusion-exclusion criteria. That's why with the systematic review we tried to be as objective as possible, list all the inclusion and exclusion criteria, and anything that fit got reviewed. Those criteria came from the previous big review that had been decided upon by multiple groups as the appropriate inclusion and exclusion.

So I don't have on the tip of my tongue exactly how many were excluded by each criteria, but there would be something among the criteria that excluded any of the 172 that didn't make it.

DR. DAVIS: And were those criteria developed a priori?

DR. BOEHLECHE: They were developed in conjunction with the American Thoracic Society, American College of Chest Physicians, American Academy of Sleep Medicine, and the evidence-based practice center that is experienced in doing evidence reviews -- right, Linda -- and how one develops a set of criteria to make it a systematic review, and she can speak to that part of it better than I can.

DR. DAVIS: Thank you. Open discussion. Any issues that people would like to bring up are fair game, or further questions to any of the presenters. Yes.

DR. WEINER: This is my first meeting so I can be particularly honest. In terms of the grading, we're supposed to focus on the studies before us and then the Medicare issue is handled separately? In other words, most of the studies as we've seen, don't include Medicare-age individuals. So, are we supposed to comment and focus on the veracity of the study as conducted?

DR. DAVIS: The generalizability is addressed in question five, where we're asked, based on the literature presented, how likely is it that the evidence can be generalized to the Medicare population, that is people 65 and over, and to providers, including facilities and physicians in community practice?

DR. WEINER: And again, to make sure I'm very clear, we should then gauge the studies based on the populations that were in the studies, so generalizability, external validity, we should take on the -- let me try it again. So the Medicare issue is only addressed on the last point

and not in the previous?
DR. DAVIS: That's right, and we could have some discussion about how you make a determination on generalizability. If we're talking about a procedure that's easy to master, then it might easily be generalizable to physicians in the community. If you're talking about generalizability to seniors, even though studies have typically not included large numbers of seniors, then maybe it gets to the issue of whether the biology of the condition may be affected by age.
DR. WEINER: And it's the senior one that I'm particularly concerned about, and I hope we can take advantage of the expertise on both sides of the argument perhaps on that issue. In other words, these studies, some of them even excluded, and certainly most didn't have an adequate number of elderly and, you know, whether or not that would lead to the generalizability issue in either direction.
DR. DAVIS: Why don't we take up that issue right now?
DR. PHURROUGH: It's very common, in fact it's the rule rather than the exception, that

the evidence that we're presented around things that we make our coverage decisions on does not include populations that we're interested in, 65 and over. And if we always based our coverage decision on having evidence in that age group, then we would have a lot of money in the bank, we would not be paying for anything.

So we always, because of that lack of evidence, want you to first determine, is there evidence that's out there that says for some group of patients, is this a benefit? And then the last question, if the answer to that is yes, then can you in some manner or fashion generalize that to our group? And in some cases the answer to that is no, you can't, there is too much difference, and that's the kind of discussion we need to have.

DR. WEINER: Would it be acceptable to have one of the proponents, a clinician who has patients in his or her practice talk about why the home testing would be good for the elderly, and then one of the sleep lab folk perhaps develop a counter argument in hope of having elderly hooked up to these things?

DR. DAVIS: Maybe we could get them up to the podium at the same time and have a Point

Counterpoint. But Rita -- I'm happy to put that query out to some of our morning presenters, but Rita, first you wanted to chime in?

DR. REDBERG: I just wanted to comment while it is true that we often are in the position of having to decide without the benefit of trials in the elderly I think is far from optimal, and I don't think we should continue to try to make decisions in the Medicare-age population when we don't have data on the Medicare age. I mean, in this in particular, I think it's important because the data we do have is not just middle-aged people, it's almost entirely men and most of the Medicare-age population is women. And the population is totally different because we have such a high rate of comorbidities in the Medicare population.

And so we try to extrapolate and it's never ideal, sometimes it's better than others. I'm concerned in this case because there are differences in the disease that appear as you get older and we have no data on the effectiveness of treatment in the elderly, we really have a harder time extrapolating, as far as I can see. I would certainly be open to comment, but I really would

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like to see trial data.
DR. DAVIS: And just to again get back to a point that I think was discussed earlier on today, we are answering the questions and that's the limitation for our input to CMS. CMS will make a coverage decision down the road. If we feel that a particular treatment is generalizable to the Medicare population but we don't believe that the treatment is generalizable to providers in community practice, that doesn't mean that CMS wouldn't make a positive coverage determination. They may simply limit coverage to certain kinds of providers or certain kinds of facilities, and I'm sure Dr. Phurrough could elaborate on that if you'd like.
But let's see if any of our morning presenters would like to address this issue of generalizability to seniors. Dr. Weiner, was that your interest, the generalizability issue as it regards everybody.
DR. WEINER: Well, I don't know if we'd want to hear everything from everybody, but a couple of points, why if anything it's more relevant to the elderly and a couple of points on perhaps why it's less relevant.

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DR. DAVIS: And let me ask folks to perhaps repeat their name for our recording.
DR. COPPOLA: Michael Coppola. In my testimony that you have, I did address this issue, but I didn't get a chance to orally present it. I see three things.
First of all, there's a Medicare population that's not elderly that you need to think about, that's the disabled. One thing about home testing is that the patient's environment has already been adapted to their disability and it is far preferable to study them in a home environment.
I put in my testimony some caveats. There are some people who I think are okay to test in the home but I certainly wouldn't want to do a CPAP in an unattended setting, and that's anybody with a history of serious stroke or CNS disease, Class III or IV heart failure. Those people develop a lot of central apneas, and I assist that they have at least an attended CPAP titration. I see no problem with them having a portable see.
We do see, there is a real problem with elderly driving at night to sleep labs. In New England, it's dark at 7:30, our sleep labs are at

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9:30, and as previously addressed, there's an access issue there.

The very elderly over age 85, we then have to wonder how many of those people are going to benefit from CPAP. I would certainly be cautious at that age about doing any unattended therapeutic interventions.

We use, in Medicare managed care today, there is a good deal of experience with portable monitoring because we can use it in those settings. I was medical director of a Secure Horizons Medicare program and it was, we saw no difference between the 65-to-85-year-old group and the 55-to-65-year-old group. Thank you.

One more group. Mentally challenged patients with congenital neurocognitive dysfunction do much better in the home with portable testing.

DR. EPSTEIN: I didn't have a chance to speak earlier. My name is Larry Epstein. I am board certified in both sleep medicine as well as pulmonary and critical care medicine, run a sleep center in Boston, and I am the president-elect of the American Academy of Sleep Medicine, and speak on their behalf.

I think you were very right to be concerned about the generalizability of this to the elderly population, for several reasons. First is what you brought up, it's a very different disease in the elderly from what is typically thought of as the male overweight middle-aged person. We don't know that much about treatment effects or treatment efficacy. There are also concerns that the diagnosis is a little bit different for several reasons. This group has a lot of comorbidities. It's a group that also is prone to other sleep disorders as well, leg movements, central sleep apnea, and the accuracy of this diagnostic testing is not validated in that group. I think it is something that we need to be concerned about. All those things are better picked up and described in laboratory polysomnography.

DR. LAGRELIUS: Tom LaGrelius. I have about, unpublished, about 200 patients that I've evaluated myself with home and laboratory sleep monitors. Probably 60 percent of them are Medicare-age population patients, and since the incidence of sleep apnea is about double in males as it is in females, that ratio is about the same

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in the patients I have looked at. I don't really -- and I've studied a lot of people in their 20s and 30s and 40s too, you know, as part of that group and I, it's not published data and I'm not a researcher and I'm not really qualified to analyze the whole literature, and I haven't looked at the whole literature. But from my own personal experience, there isn't a lot of difference in the way the sleep apnea patients who are over 65 or 70 look compared with the younger ones.

Yeah, they've got more comorbidities, but some of those comorbidities are actually caused by their sleep apnea, their hypertension, their cerebral vascular disease, their coronary heart disease, their inability to lose weight, there are comorbidities that are connected with the disease that you're looking at. So I don't think there is a lot of difference and I do think the elderly population do respond pretty well to treatment unless they're demented and don't comply with treatment. So it's my own personal experience that it should generalize to this population. I am a geriatrician and I have been doing this for a long time and I think it does

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generalize.
DR. THORSEN: Dave Thorsen, I spoke earlier. I would like to at least raise a question from the ICSI work group. I was on that work group, I'm not speaking for the group, but when we talked about the comorbidities, we were not talking about diabetes, hypertension, obesity. We were talking about major issues like a significant stroke, neuropathies that could affect some of these things, so it was not to be not used for people with comorbidities, it was significant contraindications.
I have done in my practice and our group practice has done over 200 ambulatory studies involving ages up into the geriatric year and for the healthy elderly, for the people who are out walking, not nursing home bound, that are out playing golf, this technology works very well. It's not hard for them to put on, and in all honesty, it's more convenient for them. They do not like driving down to the sleep labs at ten o'clock at night, they do not like sleeping in different beds. They are kind of set in their ways and they don't take change real well.
So your answer to the question of how

well this applies to the elderly, being able to put it on, being able to use the information, being able to apply the technology, it works very well.

The question of we don't have studies with the elderly, that's a different question, but for people that I've used it on, and I have used it on people up to age 70, who are very functional people.

DR. MCNEIL: Could I just interrupt for a second? I very much appreciate hearing these testimonies but it strikes me that the question we should be asking is not what you think but what the data show, and if there are no data, then I actually don't frankly want to hear any more comments about what you think, to be perfectly blunt. So if there are no data, I would just as soon move on to another topic.

DR. BURTON: I brought two studies with me, so I appreciate your interest. Basically, these are two studies that are on elderly apnea studies and their primary conclusion is that there is no difference in the study between them and normal age, with the single exception that they had poor sleep in the sleep lab and required more

than one night. So the ability, it emphasizes the point of the importance of them having an environment which is more normal for them to have a better study.

And there's two studies, both published in the Journal of Sleep, both by researchers that are very well respected in the field, Night-to-Night Variability of Disturbed Breathing During Sleep in Elderly, Night-to-Night Variability in Sleep Apnea and Sleep Related Periodic Leg Movements in the Elderly.

DR. REDBERG: And what method of diagnosis did those studies use?

DR. BURTON: I'm sorry?

DR. REDBERG: What methods of diagnosis did those studies use?

DR. BURTON: I'm happy to provide them to you if you have an interest.

DR. REDBERG: Were they home studies or laboratory studies?

DR. BURTON: They were studied in the laboratory, yes.

MR. LACEY: So just to study the age effect?

DR. BURTON: Yes, to study the age

effect, so that you could look to generalization. And what they found in fact, and the other amplification that's important that was raised by the previous speaker, is that the comorbidities were not talking about hypertension. Again, it's critical illnesses that would result in someone not wanting to have someone alone; it's not just the fact that they are overweight or diabetic, or hypertensive. Those are not concerns. In fact, they don't present a query or question at all. Thanks.

DR. MAIR: Eric Mair from San Antonio. I would like to share our study that we have. We have a study coming out next month in the publication of the American Academy of Otolaryngology and my particular study we just presented. It involves PSGs, looking at reading PSGs, and there are basically two ways to read PSGs. There's many different ways but there are two categories.

One is the Medicare category and that's looking mostly for desats, and the other is -- and looking at hypopneas especially, and the other is the Chicago criteria that looks mostly at arousals. Very different ways of reading PSGs.

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We've taken 60 patients and had a full PSG and a home sleep study on them, and took that same data -- we sort of talked about the atomic clock and mechanical clock idea -- we sent the data out to different laboratories, approved accredited laboratories in San Antonio, and looked at the AHI in each of these different places.

What we found is that -- we also took out the home sleep studies and looked at them in several different readings. What we found was that the correlation between PSG to PSG was much poorer than the association between PSG and home study. And where I'm going with this is that the Medicare criteria looks at O2 desats. Many of the home sleep studies look at O2 desats. The older population when they hold their breath are going to have desats, it's much easier to read.

The Medicare criteria which is most commonly used to read PSGs, lines up much more closely with the home study that we have. The Chicago criteria on the other hand, didn't line up hardly at all, had a very poor correlation. We looked at plots for this, we looked at raw curves and have the data available, which I will be happy to present. Again, it's not in the published

format now, but we have one in press and then also one in review.

Medicare, again, you have the sats go down and that's very closely related to the Medicare criteria for PSG and the home studies.

DR. HOOVER: May I ask a question? It's a key for the Medicare policy for medical equipment in CPAP. I'm not sure what you're talking about in terms of the Medicare policy, because we have a policy that says if your AHI is 5 to 14 with symptoms, or 15 and above without --

DR. MAIR: What I'm talking about is reading the hypopneas, which is a significant difference in how we read the studies. If we look at primary --

DR. HOOVER: Well, in your lab, because I think that has been one of the major issues for us all --

DR. MAIR: Right.

DR. HOOVER: -- is that if your lab is reading desaturations but his lab may be a 30 percent reduction in airflow and another one is 50 percent reduction in airflow, so I wouldn't call those Medicare criteria.

DR. MAIR: I think most people read by

what's commonly called in sleep circles the Medicare criteria versus the Chicago criteria. The Chicago criteria is more based on arousals, it's very different. It's like comparing apples to oranges.

DR. HOOVER: I agree, but I guess my question was the Medicare criteria, because there is no set Medicare criteria for what is a hypopnea, that is just not published.

DR. MAIR: I don't think for any hypopnea there is a set criteria, and that's the main problem that we have. In the elderly, though, it's the desats that we look at mostly, and that's compared with looking at a 4 percent desat, holding your breath for a period of time. That definition of hypopnea lines up very closely with the home studies which measured the pulse oximetry.

MR. LACEY: In your practice, do you treat elderly veterans as well, and their family members? What portion of your population is over 65?

DR. MAIR: I treat a high population. We treat military and military dependents, so we treat many older people. A young buck for

instance, a young sergeant who has apnea measured by the desats will not have a hypopnea, but measured by arousals -- because they can hold their breath for a long time and not desat, so in one study the same data will show that there is obstructive sleep apnea but the same exact data by looking at desats and not arousals primarily, will show no apnea for the younger patients. The older patients that we see, the dependents, the people who fought in the wars, et cetera, and their dependents, will very readily have desats.

MR. LACEY: So in terms of the measurements, that's one aspect. But the other aspect is a very practical one in terms of acceptance in that population. So you don't see a difference in sensitivity by age and you also, what has been the experience of the over 65 in terms of acceptance of technology? People have been referring to that. Do they seem to prefer it?

DR. MAIR: For the home sleep studies, we find that much like what's been said here before, again, this is mostly just testimonial and not really much of the data, but by far that they will be willing to undergo the studies. In our

sleep lab there's about a 40 percent cancellation rate and some of them are from the people that decide not to come, or they can't come, or they have some difficulties coming into the area, and we usually see that in the older population.

DR. DAVIS: Why don't we move on to the other gentlemen who are waiting to get into this discussion.

DR. SLACK: Thank you. Steven Slack, from Salinas, California. About 65 percent of my practice is Medicare, or when one adds in the MediCal it jumps to about 70 percent. You had asked for information. Many of these elderly people since they're covered by Medicare, they have essentially an 80-20 plan, and many of them are very resistant to any sleep lab, paying the high price of what they need for their contribution to receive that care, so the aspect of ambulatory modeling is very appealing to them. You asked for information. Medicare spent $2 billion last year in diagnosis of obstructive sleep diseases, $1 billion in treatment. You have today before you an opportunity to change the paradigm of care. You may treat and diagnose three people where you

would now be diagnosing and treating only one.
DR. SATEIA: Michael Sateia from the American Academy of Sleep Medicine. In addition to the concerns registered regarding comorbidities and the markedly higher rate of other sleep diagnoses that are not going to be identified with portable monitoring, I would just like to reiterate one data point. Repeatedly we heard the assertion that elderly individuals over 65 are resistant to going to the laboratory. Basically what we've heard is a lot of anecdotal data. To the best of our knowledge, there is one study that has examined this. In that study, elderly individuals reported almost a two-to-one preference for going to the laboratory versus having a home monitor.
DR. DAVIS: Further discussion on that question, or we can move into another area. Barbara, did you want to move into another area?
DR. MCNEIL: I have a question, it's actually to Rita, because one of our questions says, it's actually question number four, that the use of these devices will lead to improvement, measured either directly or indirectly, directly to changes in patient management, and I noticed

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that you raised your eyebrows several times when some of the speakers --

DR. REDBERG: My poker face.

DR. DAVIS: What's the treatment for that?

DR. MCNEIL: Home monitoring.

(Laughter.)

DR. MCNEIL: When several individuals mentioned that there was an improvement in health outcomes, and I wondered if you could give the data on that.

DR. REDBERG: Because I did a list search on outcomes and didn't come up with anything. And then the CMS analyst, I think Tiffany and Francina did come up with two articles which I pulled. One was a study of 44 middle-aged, I think it was 13 women and 31 men where they looked at daytime sleepiness, and found a slight improvement in the CPAP group, although actually more people preferred placebo than CPAP, which I took to be an issue that it wasn't that comfortable.

And then the other was all men, it was also a very small study, all middle-aged men with an age of 48, and it was another quality of life.

I mean, I was looking for some more hard outcomes in the way of, you know, because somebody in the studies had referred to the cardiovascular morbidity, I was looking for evidence that treatment was associated with reduction in cardiovascular morbidity and mortality and that's what I couldn't find in the literature search, or with the help of CMS. I did ask Brian Boehleche that at the earlier break and he said that there is a publication from the Sleep Heart Health Study which I haven't seen so I can't quote any of the details, that show a reduction in hypertension.

My concern is that this obviously is a group with a lot of comorbidities, a lot of other reasons for hypertension and cardiovascular morbidity, most of them are morbidly obese, so I think it's very hard to separate. And I'm not saying there is not benefit to the treatment for sleep apnea, but it's hard to separate all the comorbidities from the fact that they have hypertension, you know. I tend to believe that some of them do have an improvement in quality of life, but it's very limited data.

MR. LACEY: Just one clarification.

Are you referring to the treatment of CPAP, or whether or not home or facility-based diagnosis is equivalent?

DR. REDBERG: No, this was not the question of home versus, I was looking at okay, once you've made the diagnosis by whatever method, what is the benefit of treatment, and there was some benefits also to weight loss, but few of the studies seemed to indicate that.

DR. DAVIS: Dr. Whites.

DR. WHITES: If you do a MEDLINE search, I think you will find it if you limit it to the last four to six, or even ten years, trying to find data showing benefit of injury to the heart. If you go back 20 or 25 years when the treatment was tracheostomy or nothing, and I used to have patients tell me thanks a lot, Doc, I appreciate it, but I think I will be able to talk and there won't be a problem. I think there is data out there, it's old data, because we don't really go back and look at the consequences of diabetes or treating or not treating somebody with antibiotics versus treating them now, with certain diseases. You really have to go back and look at some old data. Data 25 or 30 years ago showed a

morbidity of five years of a third in severe obstructive sleep apnea untreated, so I think we've got some pretty good data, it's older data untreated, and we had one of the few diseases which we've had a natural history that we could follow in those who refused the primary treatment at that time, which was a tracheostomy, but it takes some old data to go look at.

DR. DAVIS: Dr. Gazelle.

DR. GAZELLE: I'm not sure it's really fair to go back 30 years, though, because the treatment of all these conditions has changed so much that I don't think it's really relevant to our decision today to look at 30-year-old data.

DR. WHITES: I think that with respect to the natural history of the disease, that's the only data you have. I think that if you know when somebody has untreated, when you have a treatment for a disease, you can compare those two.

DR. GAZELLE: But it's not the disease itself, it's not obstructive sleep apnea that's causing the morbidity, it's the other things that are resulting from it that are causing the morbidity, the cardiovascular events and whatnot, and we now have better care of those events. So

what we would have observed 30 years ago we're not going to observe today because we're managing the other conditions better. I mean, it's not the end event, OSA is not the end event, it's leading to these other things which are better managed today.

DR. DAVIS: Dr. Satya-Murti.

DR. SATYA-MURTI: We heard the gold standard being assailed. This often happens with a diagnostic test as to what truly represents a gold standard. And I see the problems here, which in turn leads to the question that if there weren't a true gold standard, how are we even diagnosing OSA? So I wondered if we could have anyone comment on either side of the issue, what is then truly a gold standard or, is it going to change, and if so, does that in itself require a prima facie study before we start comparing?

DR. DAVIS: Sure. Let's take maybe two or three and see where we are.

DR. LAVIE: Peretz Lavie. I think that you have a very ripe question. If you look at the spectrum within the whole area of sleep, you start with upper airway resistance syndrome, nobody mentioned it yet, but it's part of the spectrum, a very light breathing disordered sleep. And on the

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other extreme means the patient with an apnea per minute. The question is, where do you put the line? Where is the point where a patient deserves treatment? And you must have hard end points in order to go back and decide which patient deserved the treatment.

For instance, in my laboratory in Israel, we have a cutoff point of ten, ten events per hour. Now we believe it's 15, because when you look at the biochemical markers of oxidative damage and low grade inflammation, you don't start to see them before 15 events per hour. You start to see them with 15 events per hour.

If you look at the data now accumulated from the American Sleep Heart Health Study, they also convert to 15. So there is a kind of wandering target, where is the point that you start to define a patient as a patient. And only natural history, which we do not have, will tell us what is the criterion using only RDI, only RDI. I'm not talking about symptoms, I'm not talking about proneness to accidents caused by sleepiness, I'm talking about one number, RDI. So the question is, which RDI is translated to long-term cardiovascular morbidity? In this we need natural

history, and we do not have in this disease, natural history.

And most of the studies with natural history show that endothelial dysfunction starts many years before any overt cardiovascular morbidity. In most of the patients of a young age, they have endothelial dysfunction many years before any overt heart attack. So I believe that there is a gray area there. A patient with RDI 40 is a patient, an ambulatory device would find it, anybody would find it, even observation, as you suggested before. The gray area is somewhere between ten events and 20 to 25 events, and here we need long-term studies with good history.

DR. IBER: Conn Iber from the American Academy of Sleep Medicine. I would like to mention that there is some cross-sectional data from the Sleep Heart Health Study which shows a graded response, which is what we expect I think in normal physiology. That is the relative risk of hypertension, both in the Sleep Heart Health Study and the Wisconsin study was graded not as absolute threshold, and the same was true for cardiovascular events including myocardial infarction and stroke. So that's cross-sectional

data. They're collecting longitudinal data similar to the Wisconsin State study. To ask, or to address the question regarding what constitutes a gold standard, I think there is maybe a little bit more precision here than we acknowledge, in the sense that there have been some accepted definitions. I believe Medicare definitions for treatment of CPAP include a specific test definition for hypopnea, so there are some accepted definitions and they represent one handle on this disease. It's not perfect, but it is a measurable outcome, it is part of what we do when we evaluate the patients clinically. We get information about their sleepiness, their cardiovascular risk factors, their expressed cardiovascular disease, their respiratory disturbance index, the severity of desaturation. It gets pretty complicated but it is a handle and there is cross-sectional data suggesting that collected in a laboratory setting, that that handle does correlate with cardiovascular disease with the same sort of monitoring that's done in facility-based studies.

DR. SATYA-MURTI: If that's the case, have you built in a response to CPAP or BIPAP as a

criterion to establish a diagnosis, as often is done in cognitive studies like headache?

DR. IBER: I'm sorry, to answer your question, I'm not sure. Could you rephrase that?

DR. SATYA-MURTI: Can you use the response to a period of treatment and go backwards to establish the diagnosis? This is not unknown in clinical medicine, is it?

DR. IBER: I think that's one option that requires some evidence collected to determine whether -- I mean, I think that whatever approach we can have on this disease has to be based on evidence, and our responses here need to be based on that too. But I would agree, anything that could be explored in terms of therapy would be good.

DR. KIMOFF: John Kimoff, from American Thoracic Society. I think that's actually exactly what happens in the real world. I think that the issue with a number or a cutoff value from a test, the test has to be taken in the context of the patient, what symptoms does the patient have, and there are some times when it's not clear in the clinical context that the symptoms are related to a minor or moderate abnormality on a sleep test.

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And very often we do a therapeutic trial to establish exactly what you've determined and in fact, you know, I advocate for patients on a regular basis based on their response to treatment.

This point comes back to the issue of outcomes, and could I have your permission to just address the issue of outcomes very briefly, because it has come up twice.

DR. DAVIS: Sure.

DR. KIMOFF: And I think it's a critical point. I am astonished by your summary of a literature search, and without any disrespect intended, I would question how thorough that search was.

In about 1993 in the Lancet, there was a metaanalysis published by some epidemiologists, the first author was Wright. And Wright basically criticizes the apnea community for exactly what you said. It said there's no proof, there are no randomized controlled trials to show that CPAP leads to benefit and outcomes. Well, in fact there is a whole slew of editorials that follow that from all the major sleep centers in America and otherwise, and that actually stimulated the

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field.
It was an excellent thing in fact, because if you look then at the literature in the last five or six years, there is a whole series of randomized controlled trials, including sham CPAP placebo controlled trials, which unequivocally demonstrate a specific effect of nasal CPAP on important measures of outcome measures, so neuropsychiatric outcomes, concentration, memory, mood disturbances, which are measured by standard instruments, psychometric instruments. That's number one.
Number two, several groups have developed disease-specific quality of life indices. So there's the Pittsburgh group, the Calgary quality of life index, and there's several others. And these have been shown to be sensitive and validated measures of quality of life that respond to CPAP.
There are harder outcomes. There are car crash data. There is a diversity of studies looking at the effects of CPAP treatment on the rate of car crashes, and I would cite notably a study by Charles George in Thorax a couple of years ago, where they show a threefold increase in

the rate of auto accidents in untreated OSA patients that responded to CPAP therapy, and this was a very carefully done study.

So, it is true that cardiovascular cohort outcomes are not yet well established with CPAP intervention. There are many now randomized trials looking at the effect of CPAP on blood pressure. I would refer you to a study in the New England Journal of Medicine, Konecko, et al., Bradley's the senior author, for nasal CPAP in a randomized fashion in patients with left ventricular dysfunction and OSA, resulted in a significant improvement in left ventricular ejection fraction. That was published early in 2003. There are many more to come, there are many studies that are in progress.

So outcomes, there is data on outcomes, and if you folks request, then I'm sure that some of us here would be willing to provide that in a summary form, but there are now excellent data in that regard.

DR. DAVIS: Thank you. Dr. Boehleche.

DR. BOEHLECHE: Just quickly, I was going to bring up the car crash thing. I did give Dr. Redberg three articles during the break

concerning CPAP treatment and improvement in car crash rates with sleep apnea. There is also limited evidence but some evidence published on improvement in pulmonary hypertension after the treatment with CPAP.
DR. DAVIS: Thank you. Other issues?
Dr. Goodman.
DR. GOODMAN: Back on Barbara McNeil's quest for data. I may have missed it, but two kind of data questions, publishable data. Among patients who present for testing, in what percentage of those cases does sleep stage information, EEG, EMGOG, in what percentage of cases does sleep stage information materially affect a decision to treat? Is it 50 percent, is it 10 percent, is it 1 percent, is it less than 1 percent? Has anything provided any evidence about that, how that information might inform the treatment decision?
DR. BURTON: There are two studies we talked about. One of them was a published study where they had 200 patients and --
DR. GOODMAN: Whose study was that?
DR. BURTON: Douglas? It was the mid '90s, I can provide that information as a

follow-up. And the other study was a study conducted in Chicago on 250 patients and in that one, 97 percent received the same treatment outcome with time in bed as they did with knowing sleep stage.

DR. GOODMAN: So, the first one was what percent?

DR. BURTON: 100 percent had the same therapeutic decision.

DR. GOODMAN: So sleep stage made no material difference?

DR. BURTON: No material.

DR. GOODMAN: And in the second one it was --

DR. BURTON: In the other one, 97 percent had the exact same therapy, and two of them -- of the difference, those patients were in the variability of mild to moderate, and so there was a question of whether or not on another night the patient variability in that group tends to be such a swing that studying them a second night may have decided better.

DR. GOODMAN: So of the two published studies of which you are aware, treatment decisions were materially affected or not in zero

or 3 percent --
DR. BURTON: In three patients out of 450 studies.
DR. GOODMAN: Thank you.
DR. LAVIE: A quick answer. In a split night, in the middle of the night there is no time to do sleep state distribution. The decision whether to put a patient on CPAP or not is done by a technician based on RDI 20. Nobody is looking at sleep stage distribution, they only try to make sure that there is some minutes of REM and that's it.
DR. GOODMAN: You're saying in practice this information is not used, the sleep stage information is not used?
DR. LAVIE: That's true.
SPEAKER: All the portable monitoring studies, almost all of them use as follow-up because you have a negative, sending the patient back to the sleep laboratory. And what is it that is added by going there? It's the ability to make sure that all the data is collected and the ability to use other things such as arousals which aren't available to help you, particularly in people with mild to moderate, particularly with

mild obstructive sleep apnea. So it does contribute something, but you're right, there is not another study that I'm aware of that specifically addresses that.

DR. GOODMAN: That quantifies that effect?

SPEAKER: Correct.

DR. DAVIS: Dr. Boehleche.

DR. BOEHLECHE: Just quickly, I don't have data but I think the point that was just made is the important one and that is if a patient has severe sleep apnea, and you're giving them a split study, it's unlikely that there will be need for sleep staging. It's the more borderline cases in which the technician doesn't put on CPAP, and then we read the next day and look at the whole night and get a better picture of whether or not there are frequent arousals and so forth that might lean us toward treating the more mild sleep apnea versus not treating.

And then the other conditions, spontaneous arousals that could explain symptoms that are not related to sleep apnea but are still related to the patient and why they are there.

DR. GOODMAN: It might lean you, but

how often does that happen?
DR. BOEHLECHE: Well, as I said, I don't have data. I mean, I don't want to give an opinion, because that's what you don't want, opinion. I mean, it certainly is not a rare event, though, that we look at a study with an RDI or an HI of 10 and say, is this patient having lots of arousals, we should probably treat, versus not many arousals, let's try more conservative therapy than treating with CPAP. So I don't have data, that's the problem, but I think the mild cases, and there was the one study that there were data from, the one study in the review that looked at that, and 23 percent of the time they had a different treatment than they would have recommended with the home study.
DR. DAVIS: Dr. Lacey.
MR. LACEY: Hopefully this will answer that question. It was just in your sleep practice, is there any data on the distribution of severity that refer to the sleep practice, and the answer to that question sounded like it wasn't clear.
DR. IBER: As I was sitting there, I was thinking maybe one way to get at this question

is the percent of disease misclassification, and if you look at most of the studies, the percent of disease misclassification runs about 15 to 20 percent in portable monitoring as compared to laboratory facility-based studies, so I don't know, but that is based on the differences, some of which reflect differences that sleep stage adds to it.

I might also comment that one of the responses that is seen is not just correction of obstructive sleep apnea but improvement in sleep architecture, which is a very common if not uniform response, increasing REM sleep, slow wave sleep. Part of the response, for instance, in the upper airway resistance syndrome is an improvement in the quality of sleep that's seen, but I don't think it's a very well studied area.

DR. REDBERG: Do you know what percentage of people who go to sleep labs have a positive study?

DR. IBER: You're asking me?

DR. REDBERG: Since you were talking a little bit about misclassifications, so that's why I thought that maybe --

DR. IBER: Well, I'm referring to the

portable monitoring studies, many of which are cited in here, and they range, you know, most of those patients, probably 60 to 70 percent of the patients have sleep disordered breathing who are referred for these studies. So I would agree, it tends to be near the lower end of the threshold that it's a problem. That's where the disease misclassification tends to occur.

MR. LACEY: That's the question. So we don't know if it's 10 percent of the patients that are in the 10 to 15 range, or is it 50 percent of the patients where there'd be a gray area in terms of diagnosis.

DR. IBER: If you look at overall disease misclassification, again, if that's running 15 to 20 percent, that's of the total number.

DR. MCNEIL: But that could be different, that might not be in the form of the different degrees of sleep apnea.

DR. IBER: Absolutely. I think that applies to the total number, but that is generally the lower end of the group, I would guess.

DR. KIMOFF: I think it depends on local access. If you have a problem with access,

you're going to have 80 or 90 percent of your studies positive. Dr. Iber cited a figure of about 50 or 60 percent, and I think if you look back in the literature, that's what, you know, sort of consecutive patients assessed are identified at that rate. The concept is, it's like having, if you do appendectomies, you have to take out a certain percentage of normal appendices so that you don't miss cases. We're concerned, you know, that if we're seeing 80 to 90 percent positive studies, we're probably not getting the referrals, not making the diagnoses.

DR. DAVIDSON: Terry Davidson. I do about 250 sleep tests a year, all of which are multichannel sleep home tests, and we've kept the data carefully for the past ten years, so I'm looking at approximately 2,000 patients. And the patients are referred primarily for snoring and the other pieces of information such as daytime sleeping, hypertension are simply ancillary pieces of history that help me make clinical decisions. We have with these 2,000 patients, 93 percent have an AHI of 5 or more, so positive tests as measured by an AHI of 5 is found in 93 percent. They don't all go on to treatment,

because they may not have criteria for treatment, may not have comorbidities, but 93 percent hits. And 73 percent or so have an AHI of 15 or more, so in fact the hit rate for sleep tests for patients suspected by primary care physicians of having this disorder is very high.

DR. PHURROUGH: Dr. Davidson, if I had a diagnostic test as a clinician that agreed with my clinical assessment 93 percent of the time, why would I ever do the test? I mean, it seems to me you're pretty good at your clinical assessment.

DR. DAVIDSON: That should be the question of next year, and I have been percolating that in my head, and the only reason that I do a test today is because that's the only way I can get CPAP authorized. If I were not required to have an abnormal sleep test for treatment of sleep disordered breathing, I would take everyone who came to me with suspicion of sleep disordered breathing, I would give them a CPAP trial. If they liked it, the diagnosis is confirmed and off they go with their CPAP. If they didn't like the CPAP, then I wouldn't know the correct answer. Then I would do a sleep test and if it were an AHI of 30 or more, I'd tell them they had to revisit

this because they've got things that are going to probably kill them, and if it was less than 30, I'd say you know, you've got a snoring problem, come back when it gets worse, or look at some surgical therapies.

DR. PHURROUGH: So you would buy some CPAP machines and treat them like home sleep monitors and give them out to your patients and try them out?

DR. DAVIDSON: Well, we already do this. We do CPAP auto-PAP titrations from the office, so if somebody has an abnormal sleep test, we give them an auto-titrating machine which we give them for three to seven days, just sort of depending on our schedule. And they come back at that time period, we download the data, and we can either get the fixed pressure if that's what their insurance requires or we can say that they have done well with this and recommend that they use an auto-titrating machine. And if they don't use the machine, then we don't go ahead and recommend further CPAP therapy because it's just going to be a waste of money.

DR. DAVIS: Dr. Gazelle had his hand up a while ago. Did you still want to get in on

this?
DR. GAZELLE: Yeah. It relates to two things, the outcomes question and the generalizability or the extension to the Medicare population. So we heard I believe earlier today that about 50 percent of people who are recommended for CPAP actually comply with it, I believe that was the number, and I didn't know if that was short-term or long-term compliance. And then we heard there are limited data with respect to improvement in outcomes of patients who are treated with CPAP.
So what I don't think we know or I don't think we've heard is, first of all, are people in the Medicare age group more or less likely to comply with a recommendation to be treated with CPAP? And second of all, if they are, are they more or less likely to have a positive response from it? And I think that's a critical issue, because it's one thing, you know, we don't have a gold standard, we accept that. The gold standard probably should be response to therapy, frankly, but it's one thing to say that this new test, the portable test may be as good or almost as good, or within some range of accuracy

of the established test, the in-facility testing, but then if what we're doing is we're disagreeing on patients who are more or less likely to respond or we don't know, then I think we're on shaky ground in terms of recommending coverage for it on the grounds of equivalent or improved outcomes. So my specific question is, do we have any information on long-term compliance with CPAP, on differential compliance with CPAP according to age, or on differential response to CPAP according to age?

DR. DAVIDSON: You probably have lots of information, but it was never organized exactly as you asked the question, so it won't be as cute as you like it. Basically we have never really divided the world at age 65 like you do, so it's not something that I normally think about.

DR. GAZELLE: But to be clear, I'm not asking to divide. I'm saying that we have a spectrum of ages and is there anything known about what happens as we get older, not necessarily before and after 65.

DR. DAVIDSON: I think the general wisdom is that as we get older with the disease it progresses, and that that continues within a

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number of --
DR. GAZELLE: But again, that's not the question. The question is, as we get older, are people more or less likely to comply with CPAP, are they more or less likely to respond to CPAP? Those are the questions.
DR. DAVIDSON: I'm trying to get to that and I'm obviously not doing it well. Basically, the worse your sleep apnea, the more likely you are to comply with CPAP, that we know. Secondly, compliance varies from lab to lab depending on how much energy you put into it and how severe your patients are. There are some labs that, as they say, just throw the CPAP machine over the fence to the patient and run, and they are the ones that run this 50 percent compliance rate. There are other groups that are very aggressive about following up with the patients, working with the spouse, nurturing CPAP compliance, and they advertise rates that are in the 85 to 90 percent success rate.
And everybody will say that the worse the disease, give me a 55 or 60-year-old with an AHI of 50 or 60, much easier to get long-term compliance than it is for a 30-year-old with an

AHI of just 15.
DR. GAZELLE: How about a 30-year-old with the same score as a 60-year-old, any difference, or is that not known?
DR. DAVIDSON: I don't personally know that.
DR. DAVIS: Does anybody else know that?
SPEAKER: I can address some of the compliance issues. The initial studies were all done using subjective reports of compliance, yes, I use it. They got initially 70 to 80 percent compliance rates. When they first put meters onto the machines and measured it surreptitiously, it came back that about 45 percent of the people were using it about 70 percent of the time. Since that time, a lot of work has been done in looking at either predictive parameters or interventions to improve compliance. There aren't real good predictors at this point; probably the best one is waking up the next morning after first using the device, and saying I feel better. There may be some benefit for those people who have more severe disease better than people who have less severe disease in terms of long-term compliance.

There isn't a breakdown by age. The studies that have shown they were able to improve compliance have been based upon a couple of principles, the first being intervention and maximizing benefit during the early treatment period. There was one study that came out of England where if you take somebody and hospitalize them for three days so they're under constant observation, you can get upwards of 90 percent compliance, not realistic for us, but even with less intervention but early interventions, that seems to be the key in improving compliance, and more recent compliance studies are in the 70 to 80 percent range for longer term, either six months to a year of compliance.

I just wanted to go back to a question you had earlier, if I could. I don't have our published data but we keep track on people in our laboratory. We have five labs in the Boston area and did 6,000 sleep studies last year. And people who come in and present for the their first night of study in our laboratory, about 50 percent end up meeting criteria for what's called a split night study. Therefore, they have to have an RDI of greater than 20, so we're looking for severity

in the lab. Of those people who then have, it doesn't mean they don't have sleep apnea, they just have a lower severity, about half of those still have obstructive sleep apnea. So I guess in our hands, the rate would be in the 70 to 75 percent who initially present, to give you an idea of severity, and about 50 percent would be greater than, in the moderate to severe range of sleep apnea.

I think, however, as we get better at recognizing sleep apnea, and this is something I've seen clinically, we are going to begin -- right now it's pretty easy to pick off the people who are snorers, very heavy falling asleep. As you start now moving all these things into a more general public screening, you're going to begin taking people who don't meet that sort of demographic and you're going to be shifting it towards people with milder, or mild to moderate disease.

DR. DAVIS: Let me go to Dr. Maves now and then we will pick up with our presenters.

DR. MAVES: Actually, I just wanted to reiterate, and I was going to bring this point up, but I think the algorithm that Dr. Davidson

outlined, which is one where essentially in a circumstance you could fit folks, you do a history, physical, and then would give them a trial of CPAP, and then would come back and look at them is actually one of the things that as I sat here today, I wondered if that's, to a certain extent, perhaps a better way to skin the cat than what we're doing.

We're talking about a diagnostic test with a fairly high accuracy no matter what state it's done, and I understand also the conundrum that we have from the various payers of having to have the sleep study done before you get to the CPAP, or before you get to any surgery that can be done. But we haven't really talked about the outcomes. It's as if we're spending -- and I understand we're here on the test today, but it may well be that we don't have exactly the right question being asked in terms of a public policy position.

DR. DAVIS: Another vote for a new gold standard. Is there any research on that approach, trial on CPAP and seeing response by the patient, and comparing that to some of the other technologies we're talking about?

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DR. EPSTEIN: Larry Epstein. Again, there isn't one using that. There are some clinical evaluation parameters that have been developed which predict a high correlation in some cases with sleep studies upwards of 60 to 70 percent, but typically most of the studies looking at history find them poorly predictive of, things such as sleepiness is a poor predictor of RDI, and so I think you have to be very cautious that you're either going to miss people who have apnea by going purely on history, and you're going to find people who have other sleep disorders if you just put them on CPAP because they tell you they're sleepy.

I can tell you, there are people who come to my lab with a diagnosis of narcolepsy just because they are sleepy, and that's what people have done.

DR. DAVIS: So we haven't had an RCT that might randomize people to either a trial of CPAP versus an in-facility test to look at sensitivity and specificity or that type of thing, I guess we haven't had that.

DR. KRIST: Can I just say, this kind of touches on one of the things that I'm having

trouble with in the data that we're looking at, just from a very basic stance. I mean, we're looking at sensitivity and specificity and we're asking, is this a good surrogate to predict who would benefit from treatment. I mean, what we're hearing is that there's this wide range of variation in our gold standard, variation with patient-to-patient tests, and then the data that we're looking at, there's a variation of results and study quality.

And so I'm still kind of just struggling with being able to, without any concrete outcomes data, to say that the sensitivity and specificity would then predict that we're identifying the correct patients and will have the correct benefit. I mean, much more basic than some of the details of what we're talking about here.

DR. DAVIS: Yes, please.

DR. DALE: My skepticism is in that same area, and that is the narrowness of the population who's been tested. There's so many people, even if we hear that 30 percent or something like that of truck drivers have sleep apnea or have hypopnea episodes, I've lost

confidence that we've tested enough people to know who are the true positives and who are the true negatives.

DR. SATYA-MURTI: In other words, just age-related normative data from patients that come into the clinic at large.

DR. DALE: Right.

DR. SATYA-MURTI: Right. I also wondered about that, but maybe some of you have done so. And we do have, because when you do extend this to just normal or not so much normal, just population that comes to a medical clinic at large, I'm wondering if we would find some more so-called hits and that would give us a true prevalence, and then we may readjust our sensitivity and specificity.

DR. DAVIS: Yes, please.

DR. KIMOFF: John Kimoff. Perhaps Dr. Iber would speak to Sleep Heart Health, but in the Wisconsin cohort study, the data that was shown this morning, depending on the definition, 2 percent of women and 4 percent of men were identified. This is just working people in three government agencies, about 700 people underwent sleep studies. So 2 percent of the women and 4

percent of the men had sleep apnea defined as an apnea-hypopnea index more than 5 and a complaint of sleepiness. 85 five percent of those people were undiagnosed, okay? They had never had a diagnosis, 85 to 90 depending on men or women. So, you know, many people in the community, I mean the community prevalence is low, but many people in the community haven't come to diagnosis. And that's one of the huge issues of access, just talking about access today and access to testing, but the access issue is much more complex, I think, than just availability of the test. Physicians have to be educated and they have to be sensitive to the diagnosis. And once they're sensitized, they have to have someone to send the patient to.

If I could just comment on the indication for testing before treatment, the issue of CPAP compliance is a major issue, and we didn't get from 15 percent to 75 or 80 without a lot of hard work. CPAP compliance is not a trivial thing, and applying CPAP is not trivial. That's one of the difficulties in bringing this to general practitioners. In our experience, patients need to know that they need it and that's

why the diagnostic test is important. It convinces them.

DR. REDBERG: Wouldn't their symptoms convince them, their symptoms of daytime sleepiness would not be enough to convince them to try a therapy?

DR. KIMOFF: They need to know why they're sleepy and, you know, there are many reasons, especially I would say in the elderly population, there's a lot of reasons to be sleepy. And while specific compliance is not well studied systematically in the elderly population, I think probably many of the people here would say from their clinical experience that it is tougher to get an older person to agree to try the treatment. They can still benefit enormously and may be very compliant, but they need a reason, they have to understand why. You say here's a test that shows you stop breathing while you sleep, this is going to fix it, that's what this is about.

DR. PHURROUGH: Dr. Kimoff, you said in your Wisconsin study you had 700 patients, 2 to 4 to diagnosis, 85 percent undiagnosed. Did you follow them at all to determine if they were treated, was there improvement?

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DR. KIMOFF: Just to be very clear, I'm not involved in the Wisconsin study. Those of us in the field take it to heart because it's so important. It's a longitudinal study, not an interventional study. They also found that cross-sectional prevalence and then they followed those patients. Dr. Young estimates that the incidence, the annual rate of new cases is about .6 percent of the population, so there's a substantial new incidence as well.

DR. DAVIS: Dr. McNeil.

DR. MCNEIL: Before you leave, what is it if the patients are older, the moderately or severe sleep patients have CPAP, what is it that they tell you they're just thrilled with after they have this treatment?

DR. KIMOFF: They haven't slept like this in ages, they wake up in the morning and they feel wonderful. They're not foggy and cloudy, they don't feel like they haven't slept all night, they feel rested. They can concentrate, they're not as irritable and cranky.

DR. MCNEIL: So it's a quality of life for most of them?

DR. KIMOFF: Absolutely. The reason

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that the field was criticized by Wright, I believe, is that for sleep docs working in this area, the response to CPAP for very symptomatic patients is so dramatic that all of us just knew about it, okay?

DR. MCNEIL: So I don't understand, and this may be where I'm having the disconnect. If it's so dramatic as you're now describing, why does it take so much work to get patients to comply?

DR. KIMOFF: It can be dramatic, it's not always that dramatic. And I can tell you that there is some people who will struggle with CPAP for weeks or months and have difficulty tolerating it and sleep poorly, where after five or six months of trying, finally they get it, and then they can't sleep without their machine, and objective testing of sleepiness or what have you will show an improvement.

DR. MCNEIL: Is it the more severely ill patients who take to it right away, and the less severe --

DR. KIMOFF: There is a disconnect between the severity of apnea measured on a sleep study and the severity of symptoms, and that's why

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one of the things that's confusing in this field. So somebody with an index of 15 usually isn't symptomatic, somebody with an index of 60 usually is, but sometimes exactly the opposite happens. You have somebody with terrible apnea on the sleep study that got dragged in by their wife who sees them stop breathing, they never fall asleep, they don't have a problem, even when we test them objectively.

But this person with 15 events, okay, is very symptomatic and dramatically responds to CPAP. And the reason for that is probably disease severity but also disease duration, and then inherent biological susceptibility to the effects of the sleep fragmentation, genetic predisposition. Some of us are worse after a night on call than others. So it's complex, and that's one of the difficulties when we're talking about cutoffs and severity. It's not like a blood pressure measurement. There's an AHI that helps us to define a disease complex but it's the recording, the physiological recording and then the symptom complex that when you deal with the patient you have to decide, okay, has he or she got it, meaning do they have a test that's

consistent and do they have a symptom complex that's consistent. And usually you can make that decision as an experienced and trained clinician, but sometimes you have to rely on the response to the therapy to establish that diagnosis.

DR. MCNEIL: So why after all these years with so many individuals in the audience talking about the merits of these devices and thousands and thousands of patients having this treatment, why at this point hasn't somebody put together a database that looks at patient symptoms coming in, their responses to the tests, or the results of the tests and the responses to therapy, and looked at some kind of predictive algorithm?

DR. KIMOFF: There are many such studies.

DR. MCNEIL: And how do they do? I mean, I haven't heard it brought up much here today, so I'm just wondering.

DR. KIMOFF: Well, no, because the focus has been testing.

DR. MCNEIL: But you don't do an expensive test if the prior probability is 5 percent.

DR. KIMOFF: Sure. So there's some

predictive equations. I can cite an article in Sleep, James Rowley is the first author. They prospectively tested three prediction equations for sleep apnea that are based on either symptoms or body habitus, neck circumference, okay?

DR. MCNEIL: And what happened?

DR. KIMOFF: They were developed by other people and then they tested them prospectively, and they looked at the ability of those predictive equations to either rule out or rule in apnea. And the ROC curves were pretty good, the AUC was about .7 for ruling out mild apnea and about .8 and over on an ROC curve, the area under the curve, so --

DR. MCNEIL: I know what it is.

DR. KIMOFF: I'm sorry, pardon me. So the ROC was very good for identifying people at risk for an AHI greater than 20. That's a specific answer to your question. Those predictions help.

And what we do in the clinic is to use that clinical prediction, combine it with a test, and decide what testing algorithm is appropriate. I think many people feel that portable monitoring is appropriate for people with a high pretest

probability, you confirm the diagnosis and then move on.

DR. MCNEIL: I guess -- this is the last thing I will say. I guess one of the things that I would have benefitted a lot from this discussion would be just the kind of comment that you're making now. That if you had been talking and started off the discussion by saying okay, here are the data, we all know about ROC curves, old stuff, we know sensitivity and specificity, whatever, let's look at the marginal contribution that these tests are making on top of one, or whichever these predictive algorithms is the best. And not having seen them, I don't know whether they've been validated independently or not. That to me would help me enormously in making a judgment about this, because I really feel as if I'm being flooded with lots of different pieces of data and I don't really have a coherent story that starts with a patient coming in with some symptoms and moves through a normal diagnostic and treatment pattern.

DR. KIMOFF: Can I just comment, the reason you're confused is because the data doesn't exist.

DR. MCNEIL: But you just said it did.
DR. KIMOFF: Sorry. The pieces are there, okay? But what has not been tested, and Dr. LaGrelius alluded to this, what hasn't been tested is an algorithm where clinical prediction, diagnostic treatment and testing are all rolled into one. So you have the patient at one end and at the other end you have outcomes, functional outcomes, validated neuropsychiatric cardiovascular outcomes. And in fact, the joint task force reports, if you look at those in all three of the journals, but noticeably the paper in Sleep and the Blue Journal, that were published in this last year, the focus is on future research, and the focus is on outcomes-based research. These studies just haven't been done and they need to be done.
DR. MCNEIL: Well, I'd take just the first two, frankly, for the purposes of this discussion. I would be just interested in looking at the marginal impact of this test on diagnosis.
DR. KIMOFF: There is data that has been done on that, combining clinical prediction with diagnostic testing. There are some studies published and there is additional benefit.

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DR. IBER: I have lost track of the question, but there was an answer that came to me regarding a question that was asked earlier that I thought I would address, and what that was, is the misclassification rate, and I think it was your question, higher in people with lower RDIs? And if I could use the Sleep Heart Health Study data, the answer is yes, that once you get down below an RDI, lower than an RDI of 20, there is a much higher misclassification rate and it's very uncommon at higher RDIs.

The other comment I would make about prevalence is that again, if you look at this cohort of 7,000 people in the Sleep Health Heart Study, these were free living individuals without a preexisting diagnosis of sleep apnea. They were obtained from jury lists, random populations. The median RDI which was used -- by the way, the definition for hypopneas used is the CMS definition, the same definition, and the median RDI in that population of normal individuals, free living individuals was 9, which would meet criteria for symptomatic treatment for patients with sleep apnea.

And the Wisconsin cohort, by the way,

identifying prevalence of 2 to 4 percent in a population of state workers was based on the combination of the RDI of 15 and symptoms of sleepiness. And so, I think there is a wisdom in CMS's policy of incorporating a lower RDI and some symptomatology. There might be other rationale for incorporating risk factors, cardiovascular risk factors in that as well perhaps, but I do think it's important that the patient comes in with a test and an evaluation, and that those three pieces come together and we not just look at the RDI, as much of a handle as it is, as a single metric for the disease intensity. Otherwise, we would be treating a very large percentage of our normal population.

DR. SATEIA: A couple of points.

Dr. Kimoff mentioned that the access issue is a complex one and indeed it is. We have heard Dr. Young's epidemiological study cited on several occasions, suggesting that there are these millions of people who cannot access care. In fact, I just want to make clear that nowhere in Dr. Young's paper was there any suggestion that these individuals were undiagnosed because of any problems related to access of care.

I think most of us believe that the biggest problem here is recognition of the signs and symptoms of the disorder by physicians. I presented data earlier this morning suggesting that from a very large and ongoing survey of centers, that the waiting list for studies is actually not that long. One of the reasons that that is occurring is because there is very rapid expansion of services available. This same survey was conducted in a slightly different form in 2002, demonstrated 1.1 million polysomnograms being performed per year. As I mentioned this morning, the extrapolated data suggests that that number is now in two years' time up to about 1.5 million. So we have seen very rapid expansion of the available services. We support recognition, we support increasing access, but the access question is much more complex than has been laid out.

In response to Dr. Goodman's question earlier about the utility of the EEG and sleep data, I do just want to make the point that as we increase access, we are going to be more successful at identifying individuals with mild to moderate forms of the disorder. And so the more

successful we are at that, the more the sleep data evaluation of arousals become critical in the diagnosis, the less capable Type 3 monitors will be in identifying that population.

DR. GOODMAN: At present, there is very little evidence presented that differentiates among the types of technologies insofar as the effect of treatment decision, let alone health care outcomes. So you're supposing that as these things become more available, we will have a different shift in patient population and maybe better information, but that's all supposition.

DR. SATEIA: Well, there is some data that demonstrates, for example in one study, and I can't cite the author, disease misclassification rates of up to 65 percent. Dr. Iber also mentioned that disease misclassification rises as AHI falls. So no, we don't have excellent data on that but I think that there are at least pieces of data that suggest that disease misclassification is a concern here and is a particular concern vis-a-vis portal monitoring, in the mild to moderate obstructive sleep apnea population.

DR. GOODMAN: It would be a concern if the disease misclassification showed a material

effect on how people are treated and what happens to them.

DR. SATEIA: That data obviously we don't have.

MR. KONIGSBERG: My name's Robert Konigsberg. I feel sorry for you. I'm with SleepWatch. 75 to 80 percent has been mentioned by a few people here as the compliance level with CPAP. That is not true. The compliance level in the United States delivered by home care companies is in the range of 35 to 45 percent and a study going back to I believe 1991 said exactly that it was 41 percent. And the reason this is important is these 75 to 80 percent were controlled studies done in sleep laboratories and following patients closely.

What we're dealing with in the United States is large home care companies like Apria and Link Care. Those home care companies by definition are responsible for 1,500 different products, of which CPAP and sleep treatment is just one product. So it's applying the generalist model, generalist product allocation to a specific disease, and that is why what we need and what we should be talking about here is disease

management, and what we should be talking about here is as Dr. Gazelle and Dr. Maves brought out so clearly, is focusing on outcomes.

And along those lines, we're right now doing a study on 30 patients and we're measuring things such as psychomotor vigilance testing, to determine not the subjective level of daytime alertness afterwards, but doing a pre-psychomotor vigilance testing and a post-psychomotor vigilance testing. And so, what needs to happen in the industry is we need more and more novel approaches towards this issue of focusing on getting people well instead of deciding how we do the diagnosis.

One last point. The reimbursement structure right now is $800 to $1,000 for an in-lab study. I'm recommending a range between 300 to 500 for portable studies. Portable studies are important. Why are they important? They're important because you're working with physicians that are medically managing patients. We happen to use board certified sleep physicians to interpret all our studies, but my point is, and I'll end with this, that CPAP isn't the only treatment. There's six different treatments; there's advanced surgical treatments for, upper

airway surgeries and radio frequency, and now implants. There's weight loss reduction. There are oral appliances. There's other treatments. So if you can keep the diagnostic cost low enough, you can do the diagnosis, and on those mild to moderate or RDI of less than 30, let's say, you can work with those patients to determine what the best outcome is for that patient. Without doing a diagnostic, you can't determine that. Thank you.

DR. MCNEIL: Just one comment on that with regard to the cost, though. The assumption is that, I think you made a slightly faulty assumption here, that by having lots of home-based or non-facility-based testing, that you wouldn't add on more tests for patients who, were they to go to a facility, wouldn't have had to in the first place. So all you have to do is do a two-to-one, and you have lost any savings.

MR. KONIGSBERG: Well, you haven't, because the comorbidities and the -- Meyer Kreiger did an article that showed the patients that are undiagnosed cost the hospital system twice as much as diagnosed patients.

DR. MCNEIL: That wasn't the point I was making. The point I was making was that there

would be patients who might not really need the test, the low probability ones, the ones that we were talking about earlier who on some discriminate score had low priors and didn't really need to be worked up at all. If they started to get moved through the system, that would add to the expense and offset the savings you had on a unit cost.

MR. KONIGSBERG: Okay. I'll let Dr. Coppola answer that.

DR. MCNEIL: I'm sure he's dying to.

DR. COPPOLA: If I might, I would like to take a stab at your big picture that you requested in terms of what's going on in the sleep community. I think there's three parts to the evaluation of the patient, there's history, there's some sort of testing, which quite honestly is semiqualitative, and there is treatment. I think the history is always important. The testing you heard today, night-to-night, test-to-test, it is semiqualitative at best. The arousals, I love looking at arousals. You can't get a better correlation coefficient than 50 percent observer to observer.

So that, we've heard today that the

measurement of these things don't make a difference. The things that make a difference is treatment. Neal Douglas in Scotland showed the most important predictor of success with sleep apnea is sitting down with an experienced clinician in the first several weeks after therapy. The dirty little secret in our profession is we're doing testing, we're writing prescriptions to sleep labs. People are followed up by a DME and never see the sleep physician again, and that's a problem. And I think that response to therapy and care of the patient on CPAP is critical, I think the response to CPAP is of diagnostic value.

I'm sorry that Dr. Redberg stepped out for a moment. The other comment is a thought about what we do know about women; we know a couple things. Women and skinny people are grossly underrecognized because they don't fit our prejudices about sleep apnea. And there's a marked increase in sleep disordered breathing in postmenopausal women that may ameliorate with estrogen therapy.

The other comment is that you're getting very different perspectives from different

people who seem to be well meaning, and that's because we're looking at the same problem from a different perspective. If I'm a sleep lab and a tertiary care center with 16 beds, I'm going to see lots of insomnia, lots of restless legs, lots of non-sleep disordered breathing. 50 percent sleep apnea in that population. But yet, you look at a community-based study like Group Health, it's 90 percent. So these people are all telling the truth, they're looking at the problem from different perspectives. The reality is in the general population, the incidence is very large.

DR. DAVIS: Yeah, Dr. Hoover.

DR. HOOVER: I find interesting your dirty little secret because you know, I'm trying to envision what the world would be like two or three years from now in a world where portable sleep studies are covered. And you know, at least in the paradigm as it's currently established, there is not necessarily follow-up with the sleep physician again, but my hope would be that in the end facility study that the test is interpreted by someone trained in sleep medicine and that they are not just looking at the automated scoring. We've seen what has been happened with

a number of medical devices with direct consumer marketing and so forth. These things are presented as being so easy to put on, so easy to use, that you call a 1-800 number if you're a little sleepy, you answer a touch tone questionnaire, this WatchPAT, whatever happens to be the market of the day, gets sent to the beneficiary with a little note on how to put it on. They plug it into the phone at the bedside when they are finished. The results are sent off for some automated scoring and reported to the primary care physician, who is not trained in sleep medicine. And the next thing you know, the Link Care or the Apria, or whomever, is showing up with the CPAP device on them.

And I say that semi-jokingly because there are some things now, and a lot of pulmonologists out here recognize, that are very close to that in the Medicare world and the DME world, and I think that scenario is not too far off the mark for what might happen.

DR. COPPOLA: I actually share your concerns, but for the record, I do not support automatic scoring on any sleep study.

DR. DAVIS: Let me jump in here and

remind folks that we've been going for about an hour and 45 minutes since we got back from lunch. I think we need to take a ten-minute break and at a minimum give our reporter a little bit of a rest.
And I'm hoping, but I don't want to push us too quickly, but I'm hoping that people can start thinking about how they want to answer those questions during the break. We can finish up with some more questions if we need to after the break and then move towards voting, and finish up well before what the agenda says, which is 4:30. Are people comfortable with that, are people getting to the point where most of their questions are getting answered? Okay. Are you able to wait until after our break?
SPEAKER: I can, yes.
DR. DAVIS: I appreciate that. So let's take a ten-minute break, we'll give these gentlemen at the microphone a chance to weigh in, and move forward.
(Recess.)
DR. DAVIS: We'll reconvene. Please proceed.
MR. HEFT: Thank you. Robert Heft, a

registered respiratory therapist out of CareHome Medical. I just want to quickly address the compliance issues that were stated before. I haven't heard anybody talk about respiratory therapy follow-up. Age is not an issue if you have quality follow-up programs. There are companies that don't have follow-up programs and that's why there's lousy percentages of compliance.

I have ongoing studies which I can provide data for at a later date. We are consistently above 80 percent and have been in the 90 percents over the last five years. The reason it doesn't fall below that is because of me. I'm a therapist and I follow up with these patients regularly. Where I'm from out in Los Angeles, the doctors depend on me to do the follow-up. They may see the patient six weeks later or four weeks later, or two months later, but they're not calling the patient once a week to find out how they're doing. They're not calling them to see if they have blisters on their nose from their mask. They're not calling them to find out if they are not breathing for other reasons, maybe they have some central apnea going on,

things that the family, spouse specifically may notice. These are things that a quality follow-up program follows up with that increases the compliance rate into the high numbers. You can test and test and test and put your patients on CPAP and then say good-bye. It will end up in the closet, I guarantee you. Thank you.

DR. DAVIS: We will be happy to hear from presenters, but are there any other questions that members of the committee would like to get on the table? And we will have time too, after we finish with this latest round, I think we should reserve time for any discussion just among the committee members if people would like to do that. This to and fro, back and forth has been quite valuable, but yet the committee may wish to have a discussion amongst itself as well without interruption before we proceed to a vote.

DR. WEINER: I do have -- perhaps you can tell me whether or not it's a naive question, but how do the private payers handle these issues and how do the leading edge managed care companies handle these coverage issues, particularly the IPA models? In other words, to they grapple with

these same decisions? I don't know if that's an appropriate question to ask or something we should talk about later, or not.

DR. DAVIS: Generally we steer clear of coverage issues and focus on evidence, but if somebody would like to give a quick answer to that, if we have time --

DR. WEINER: Careful. Last time we asked a question 20 people stood up.

DR. DAVIS: I wouldn't object too strenuously, but again, let's keep this one very very brief so that we can focus on the evidence and these other questions about compliance and so forth.

DR. RAVIV: I see looking from the side a lot of confusion. You are hearing about a lot of variability, lack of agreement between the sleep laboratories themselves and the PSG about what is the threshold, et cetera. So I will try to put a little order for that to where the agreement I think what I heard here, what I think is agreement between everybody.

DR. DAVIS: If you could keep it concise, I'd appreciate it.

DR. RAVIV: Yeah, it's two minutes, no

problem. If the patient is severe, very high RDI, everybody here agrees that treatment is helping and needs to be done, and everybody agreed also that both types of tests are repeating itself, a complete agreement between home tests and the PSG. If the patient is normal, everybody here, which means RDI close to zero, very low, everybody here agreed that A, the patient is normal and doesn't need to be treated, and also that both types of tests are giving the same results.

The disagreement was around the border, and I heard it more from the sleep guys here when they came one after another to say the problem is just around the cross-line between normal and abnormal. And on that, if you want to have facts, I have here two articles addressing the elderly, both of them. One is Sarah Moscow, and the other one Susie Lord, and I'll just read to you what they're saying, just a summary. They ran multinight and wanted to find out how well the first night predicted the second, third and fourth night.

So in one of them, I'm reading, the accuracy of the first night's recording in predicting classification agreements from

recording on three or four was only 83 percent. On another one, accurate in predicting finding of the second consecutive night to be 79 percent, that means 21 percent missed on RDI of 15 was used, and 64 only, that means 36 percent missing when RDI of 5 was chosen.

This means around -- you can look at yourself. There are nights you sleep well, there are nights you don't sleep well, not all nights are equal, there are variations. I have high blood pressure. If I'm going to the doctor and one time they measure 125 and the next time 115 doesn't mean that one day I have high pressure and then the other night I don't. It's very well known in the industry that there are large variations but still if somebody went and got an RDI of 60, he's still very sick, and maybe only one in 10 times or one in 20 times he will come normal on a specific night. If somebody came completely normal it would be rarely that another night he will be severe, although even that can happen. If he's around the borderline, yeah, it will move just as like you know from yourselves, not all nights are equal. One night maybe they drink a little bit before the test, they slept

better, they were a little less tired, so around that line none of the tests, there is going to be a gray level that no test can tell you what happened here.

And I think what happened here, the whole discussion is going to that gray level, and that gray level, it doesn't matter if you be here two months, you won't resolve. The thing you have to keep in focus, there is a group of severe and there is no doubt about it, both are agreeing. There is a group of normal, there's no doubt, and around the line of uncertain, it will be uncertain. Thank you.

DR. DAVIS: Why don't we allow the folks who are in line to make their comments and then stop at that point, allow the committee to have its own discussion, and then proceed to a vote. We have 24 items that we're voting on, just to give you a warning. If you count up the cells and so on, it's 24, but we have a process in place to move us quickly through that, so don't despair too much.

DR. SATEIA: Michael Sateia.

Dr. Coppola indicated that the clinical evaluation and particularly follow-up is a rather important

part of this. I couldn't agree more. He suggested that it is a, quote, dirty little secret, end quote, that this does not happen. Well, that is certainly not the standard of practice that the academy supports and in fact not the standard that is practiced by most of our members, including our own laboratory.

I wanted to go back on that issue to what Dr. Hoover, I believe, pointed out just before the break, which was the scenario in which portable monitoring is indiscriminately applied by individuals with very poor training, it is applied by technologists with limited training, it is put through a computerized automated scoring system and the data is delivered to a physician who has little or no understanding of what the data output actually means, let alone the ability to interpret that in a sophisticated manner to apply treatment and to follow that patient for a positive clinical outcome. We're concerned about clinical outcomes in the current practice. I think approval of this with the indiscriminate application of portable monitoring, and have no doubt that that will occur. We have seen industry already develop programs that are turnkey programs marketed to

individuals who know nothing about sleep medicine for the purpose of applying portable monitoring in exactly this fashion, and that will produce an unprecedented poor clinical outcome. If we're concerned about the clinical outcomes now, I think we need to be deeply concerned about the outcomes that will arise with that scenario.

DR. DAVIDSON: I want to comment about, you asked about reimbursement from other organizations and I think there is something to be learned here. Kaiser Hospital, which is one of the most careful money groups in California, has moved almost entirely to portable home sleep testing and home CPAP titrations, auto-CPAP titration. The VA hospital is moving strongly in that direction. And Managed Care, five years ago, ten years ago I had difficulty getting Managed Care to pay for sleep tests; now they won't pay for in-house tests unless there is a problem, so increasingly in southern California, Managed Care is moving towards it.

DR. WEINER: Do they have clear guidelines, quality guidelines in terms of a criteria for who is allowed to do it and a criteria for who can get the test?

DR. DAVIDSON: For Managed Care?
DR. WEINER: Yes.
DR. DAVIDSON: No, they are referred to me as a sleep physician, not board certified but self-appointed if you will, but with experience, and then I make the decision who has it. They can make their own decisions in order to sleep test, but they tend not to. There is geographic variation, so what is true for me in San Diego may not be true in the middle of Iowa, but if you look at the pattern over the years, increasingly Managed Care and other fiscally responsible organizations have moved towards the less expensive paradigm believing that they are equally good in getting them the same information for less money.
MR. BARONE: David Barone. I just want to make a number of very few brief comments in response to a number of questions and comments that were made here. There was a lot of discussion earlier on about participation of Medicare-age patients in the various studies. I just want to make the comment that generally you find out that Medicare patients, in spite of the high prevalence of the disease, that the age group

are underrepresented in sleep labs and as such, I expect them to be underrepresented also in studies, not deliberately, just because that's what happens within sleep labs. You find out nationally that the percentage of Medicare patients presenting to sleep studies in sleep labs, hospital based or free standing, is between 10 to 15 percent, fairly consistent across the country.

The second comment is again, just making the comment that I think that everyone here realizes that we're dealing with a world of imperfection, which is probably not related to sleep. One can shoot a lot of darts in any one of the testing modalities that has been discussed here and I think, again, that the common modality for all this or the common solution for all this is understanding the role of the physicians. And the question in front here, in front of the committee is, are patients in general or Medicare beneficiaries better off letting physicians that do know what they are doing, only with the option of using sleep lab test, polysomnography, or no test, or is there sufficient evidence and support based on that published evidence as well as the

practice, to provide those physicians that know how to manage the patients with another option. Thank you.

MR. CAREY: Good afternoon. My name is Bill Carey. I'm president of Work Alert; we do sleep diagnostics treatment compliance monitoring for the transportation industry. I have no other conflicts to report. I would simply serve to confirm what Dr. Davidson reported. Our experience in California has been we have not been denied for in-home unattended sleep diagnoses. Our OEBs range from a low of $250 reimbursed to $850 reimbursed for a one-night unattended home study.

I think if you also look at the Kaisers, they do in San Diego about 3,500 unattended studies a year, and 3,000 in Denver. They are also now doing unattended studies for their pediatric population.

And the VA system is moving more towards a paradigm of unattended sleep diagnostics. The Dallas VA had a backlog of two-and-a-half years, which is not unusual in the VA system. So, I think it is instructive that other federal agencies and at-risk providers are

adopting this technology successfully, and I don't think there is anything in the literature to suggest that there's an increased liability risk or incidents of damage done to these patients either by misdiagnosis or failure to treat. And in my own experience and our company's own experience, what we are finding is that the self-insured employer who is at risk, in many cases self-insured for their health insurance as well as their liability insurance, they are looking at accidents caused by fall-asleep drivers where we've had multimillion dollar losses, and they are looking at an operational opportunity to address that in their population and are willing to spend the additional dollars in their health care program to save dollars on their liability insurance, their long-term health insurance, and increase quality of life and productivity. Thank you.

DR. DAVIS: Thank you. Well, let's have an opportunity for some discussion among the committee members. Would anybody like to express any feelings or doubts or raise questions for people on the committee that you want?

DR. WEINER: I have a noncontroversial

one. And that is, we're supposed to vote for two, Type 2 and Type 3, but the Type 2, if we could get help from the committee members or the special studies, about where the Type 2 evidence is. I know that there wasn't a lot of new Type 2 evidence since the original review, but how much was in the original review that we didn't get, since we're supposed to discern the Type 2 evidence from the Type 3.

DR. GAZELLE: We have the original review, the full published paper as well as the summary, it's in our packet here. I believe there were four Type 2 studies and there were no new ones found in the review, so I think we can presume that that's the sum total.

DR. KRIST: Two evidence level four studies and one evidence level three study.

DR. DAVIS: Dr. Sanders, or would anybody else from CMS or AHRQ like to comment?

DR. SANDERS: I believe that there were four studies, three of which provided sensitivity and specificity data. Two of those studies should be included within the packet. And the range of sensitivity and specificity for Type 2 was, one study reported a sensitivity of 81 percent and a

specificity of 98 percent, defining AHI of 15. Another study reported sensitivity of 80 percent, specificity of 90 percent, with an AHI of 10. And the third study reported sensitivity of 100 percent, specificity of 93 percent with an AHI of 15. Two of the studies were reported as level four evidence, one was a level two evidence, and just one of the studies was performed in the home setting, the other two were done in the laboratory setting.

MR. LACEY: Do you know how much data loss there was in the unattended versus the laboratory?

DR. SANDERS: I don't see that reported here. I think it was consistent with the other studies.

DR. MCNEIL: Just one question. Of those, you gave us three studies with sensitivities and specificities?

DR. SANDERS: Yes.

DR. MCNEIL: Is only one of those a home-based study?

DR. SANDERS: That is correct.

DR. MCNEIL: The first one?

DR. SANDERS: Yes. All of it is

home-based equipment. I just mean that the other two were performed simultaneously in the lab.
DR. KRIST: The other two in the facility, were they attended or unattended?
DR. SANDERS: I don't have that information readily available, although I believe there was some attendance.
DR. DAVIS: Yeah, Dr. Satya-Murti.
DR. SATYA-MURTI: We learned that there is the spectrum of severity of this OSA and in the later stages of deliberation we found that the applicability of the evidence and ability to sense the disease varies depending on the degree of OSA and so forth. But our task is to congeal them all together and assess them as a whole irrespective of the degree of OSA. Isn't that correct?
DR. DAVIS: I believe that is.
Dr. Phurrough is nodding his head as well. When we go through the voting after we're finished with the numerical tallies, we will give each member of the committee the opportunity to explain their votes, so you can feel free to explain some of these nuances that wouldn't otherwise arise out of the numerical votes.
DR. PHURROUGH: It is very common that

we arrive at these meetings with what we think are these perfect questions that need to be answered and you've got to answer them, even though the six hours we've been here may demonstrate to you that they are not perfect questions. So I would like you to answer the question and then tell us what the perfect questions ought to be and what we really ought to be looking at, and certainly the kinds of information we're looking for, but we do need you to respond to the questions.

DR. GAZELLE: Just a quick answer to that question about the Type 2 monitors. There were three that reported sensitivity and specificity. Two were in the sleep lab and were attended and the third was home and was unattended.

DR. DAVIS: Thank you, Dr. Gazelle.

MR. LACEY: Just to clarify also, are there commercial products available that have these Type 2 monitors or are they specific, because no one here represents a technology company that has them.

SPEAKER: They exist.

MR. LACEY: Are they similar in function to what you have in the lab? Okay.

DR. DAVIS: Other questions? Comments?
DR. GAZELLE: Just a comment. To make sure my understanding is clear and I guess to make a point of clarification. We're being asked really simply to evaluate the level of evidence, our confidence in the evidence, our confidence that the evidence allows us to make decisions about relative performance. Most of the comments or many of the comments have focused on, you know, let's get these devices out there, it will be good for patients to have these devices out there, but those are really, the focus of those comments is very different, it seems to me, from what we have to vote on now, which is how good is the evidence. And to me it's different from saying what would we like to see happen, and so personally, I think we need to keep that in mind.
DR. DAVIS: I agree with what you said, the only caveat being we do have a question that gets at accessibility of the test, which moves into that issue that goes beyond that pure evidence.
DR. GAZELLE: My interpretation of that evidence, how confident are you that the sleep testing devices are as accessible is still very

different from saying do you want them to be accessible.

DR. DAVIS: Correct.

DR. BOEHLECHE: Could I respond to the question? The published study which you have talks about data loss, because someone asked about data loss in the home Type 2 studies, and it says the one study in the home unattended Type 2 monitor had a rate of data loss of 20 percent. That's in your packet.

DR. SATYA-MURTI: And the data loss would be from sensors coming unhooked and so on.

DR. BOEHLECHE: Right.

DR. DAVIS: Yeah, Dr. Goodman.

DR. GOODMAN: Two clarifying questions about the questions. Number one asks about how well does the evidence address the effectiveness of this type of unattended portable testing device in the diagnosis, so effectiveness there is a measure of a diagnostic capability, sensitivity, specificity, not outcomes kind of effectiveness, and I just wanted to make sure that's true. The other has to do with 4.B and I don't mean to sound like I'm asking a Socratic question here, but question B asks how confident

are you that the use of these sleep testing devices in the diagnosis of obstructive sleep apnea will lead to similar or improved health outcomes. Now, if I may be unsure about what the health outcomes are for laboratory testing, then it's possible that since I'm not sure about that and if I'm not sure about home testing, it's possible that I would be confident that there is no difference. In other words, if it didn't appear to me, for example, that I'm aware of data demonstrating the connection between laboratory testing and any improvement in health outcomes, I don't see any connection there. So if I don't know what health outcomes are achieved by the standard of care, the gold standard, then it could be that if I'm also not aware of any connection between home testing and medical outcomes, that I might be confident that there is no difference between those. Is that a possible interpretation?

DR. MCNEIL: This isn't a comparative question, is it?

DR. GOODMAN: It's how confident are you, 4.B. It's asking if, it presumes that PSG is associated with some certain known health outcomes, and then how does the lab test outcomes,

how do those outcomes compare to the outcomes.
DR. GAZELLE: But it says similar or improved, but it doesn't say similar or improved compared to what, does it?
DR. GOODMAN: Well, the assumption is that it compares home to laboratory, because these sleep testing devices refer to the home testing as was done for A, the comparisons between the home testing and the lab testing.
DR. DAVIS: Yeah, all the questions up to now on this initial set have been Type 2 versus Type 1.
DR. GOODMAN: Right. But the point is, they are comparisons between two different types of devices.
DR. DAVIS: I agree with Barbara, or somebody else here at the corner of the table, that similar or improved implies a comparison.
DR. GAZELLE: Between what and what?
DR. GOODMAN: Between Type 2 devices and lab type devices.
DR. GAZELLE: It doesn't say that.
DR. GOODMAN: But that's the implication of the lead question. The same thing applies to 4.B in the second set of questions

about the Type 3 devices.
MR. LACEY: The way I would interpret it is that we're saying that the two diagnostic methods are no worse than each other, and so if you are quite confident that nobody has shown that there is a big difference, so therefore you would be highly confident.
DR. DAVIS: Similar to 4.C, is that what you're saying, the same sort of comparison as we see in 4.C, is that what you're presuming?
DR. GOODMAN: The same things are being compared but for different reasons. In 4.C it's about diagnosis, and 4.D it's about -- excuse me -- 4.B it's about health outcomes.
DR. DAVIS: Right, but the treatment options or the testing options are the same that are being compared between 4.B, I think we're in agreement.
DR. GAZELLE: If we are, then the question should be changed, because every other one clearly states that the comparison is to a facility-based test and this one does not clearly state that, and so I think it's a little ambiguous, and it could be interpreted does this do better than not testing, for example, or does

it do better than, because we expect that if you went to home testing you would test more people, is that the result it's leading to. I think it's a vague question, so we could agree to amend it to say as compared to facility-based testing, but right now it doesn't say that, and every other question does say facility-based testing.

MR. LACEY: So that led to what I think Barbara was talking about, how did this fit into the overall treatment paradigm.

DR. DAVIS: Okay. So the proposal is to add wording to 4.B that would be something like as compared to facility-based testing or a facility-based test.

DR. WEINER: If that was the intention, I think I would go with that.

DR. PHURROUGH: And as I look at my staff, we're all nodding our head, that it would be comparative between 1 and 2 or 1 and 3, was what the intention was.

DR. GOODMAN: And for 4.B the comparison is with regard to health outcomes.

DR. DAVIS: That's correct, and we defined health outcomes, I thought we defined health outcomes in a footnote, but at least at the

last meeting and I think at the next meeting we had a footnote or will have a footnote that refers to the fact that health outcomes reflects benefits and risks in aggregate. Is that somewhere in the footnotes? Maybe it got dropped inadvertently, but it has been in the past, and we're working on questions for the meeting in November, which I think also includes that footnote. For some reason it must have just gotten dropped, but health outcomes I think refers to the totality of the effectiveness of the test or the diagnostic test plus any disadvantages that might occur, plus access, all of that in its totality, that's how I would interpret that.

DR. GOODMAN: Access is a health outcome?

DR. DAVIS: Well, if you can improve access, then that's a factor that would have to be weighed into this question, as I would interpret it.

DR. PHURROUGH: Yes, it can affect outcomes.

DR. GOODMAN: Yes, in addition to the more traditional ones of mortality and morbidity.

DR. GAZELLE: I don't think access is

an outcome. I think access can affect outcomes.
DR. GOODMAN: Correct.
DR. DAVIS: Well, if access leads to more diagnosis and more treatment, then it affects total health outcomes.
DR. GOODMAN: Actually, it doesn't necessarily, and this is the lack of a chain of evidence here. Access may not improve health care outcomes.
DR. HOOVER: I mean, if you just say outcomes, you could say it could positively or negatively affect outcomes. Access, if you have a test that has a horrible sensitivity and specificity and you have a high false positive rate, you could do anything, you know, you could result in more secondary testing and so forth.
DR. DAVIS: That's correct, so you look at access through your own prism. If you think expanding access is good, then that weighs in favor of a positive health outcome. If you think improving access is a negative then you're going to address it the other way.
DR. SATYA-MURTI: Is there a merit to having more than this five, such as cannot determine? I don't mean to be flippant here, but

this question, I wonder if cannot determine yet.
DR. DAVIS: Yeah, you can abstain if you feel that you can't answer the question with the choices that are provided. You can abstain and then explain it when we go around the table. Are we clarifying or are we muddying the waters? Any last comments or questions before we move toward voting? Okay, why don't we do that. Rita, are you walking out?
DR. REDBERG: Yes, but I have filled out my form and have given Janet my proxy.
DR. DAVIS: Okay, good. Well, Janet has some statements of fact before we get to the voting.
MS. ANDERSON BROCK: The comments I'm making are for the record. For today's panel meeting, voting members present are David Dale, Scott Gazelle, Cliff Goodman, Alex Krist, Mike Maves, Barbara McNeil, Rita Redberg, and Jonathan Weiner.
I do want to mention that although these are the voting members and these are the members of record, we will take the entire panel's scores and show them on the screen.
A quorum is present. No one has been

recused because of conflicts of interest. Dr. Rita Redberg, who you just saw leave, will proxy her ballot, I will report her scores on her behalf. At this time the chairperson, Dr. Ron Davis, will call for the motion and we will have the voting members vote.

DR. GOODMAN: Can we have a few minutes more?

DR. DAVIS: Sure.

(Pause.)

MS. ANDERSON BROCK: Just a minor announcement. Don't feel that you need to hurriedly scribble these down. At the end of the voting, we will put the entire voting score sheet up on the screen before us so that you can write them down at the end of the meeting.

DR. PHURROUGH: But scribble away if you wish.

(Pause.)

DR. DAVIS: All right. Well, it's going to take me a few minutes to orient you to the voting process so why don't I just get started with that. So we're going to get started with the first set of questions, which says at the top, MCAC evaluative questions on portable devices that

measure the same sleep and respiratory parameters as facility-based polysomnography, i.e., EEG, EOG, EMG, respiratory movement, airflow, oxygen saturation, and heart rate or ECG. So that's the set of questions that we're going to begin with. And the first question is, how well does the evidence address the effectiveness of this type of unattended portable multichannel home sleep testing devices as an alternative to facility-based polysomnography in the diagnosis of obstructive sleep apnea, or OSA?

And the way we'll do this is I'm just going to run through numbers and I'm going to start with one, which is poorly, and when I get to the number that any of you has chosen, then you'll raise your hand. And we'll just go up to five and then repeat that process for the other questions. And this is just the voting members that Janet read. So, all set? Oh, you want everybody's vote, okay. So we will invite all to vote, okay.

So, we're going to go from one, poorly, through three, reasonably well, up to five, very well, and I will start with one, which is poorly.

(Dr. McNeil, Dr. Krist and Dr. Gazelle

raised their hands.)
DR. DAVIS: Two.
(Dr. Weiner, Dr. Maves, Dr. Dale, Dr. Hoover and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Mr. Lacey and Dr. Goodman raised their hands.)
DR. DAVIS: Four.
(Ms. Anderson Brock and Dr. Satya-Murti raised their hands.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: Okay. We will move to question two, how confident are you in the validity of the scientific data on the following outcomes? And the choices run from one for no confidence through three, moderate confidence, up to five, high confidence. And we will begin with acquisition of interpretable data. So we will begin with one.
(No Response.)
DR. DAVIS: Two.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Ms. Anderson Brock, Dr. Dale, Dr. Gazelle, Dr. Hoover, Dr. Satya-Murti and Dr. Whites raised their

hands.)
DR. DAVIS: Three.
(Dr. Maves and Mr. Lacey raised their hands.)
DR. DAVIS: Four.
(Dr. Goodman raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: We will move down to B, ability to accurately diagnose OSA (sensitivity). One?
(No response.)
DR. DAVIS: Two.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Maves, Ms. Anderson Brock, Dr. Gazelle and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. Dale, Mr. Lacey, Dr. Goodman, Dr. Hoover and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four?
(No response.)
DR. DAVIS: And five?
(No response.)
DR. DAVIS: 2.C, ability to accurately identify those without OSA (specificity). One, no

confidence.
(No response.)
DR. DAVIS: Two.
(Dr. Maves, Ms. Anderson Brock, Dr. Gazelle and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Dale, Mr. Lacey, Dr. Goodman, Dr. Hoover and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(No response.)
DR. DAVIS: Five?
(No response.)
DR. DAVIS: 2.C, ability to accurately -- that's what we just finished. Sorry.
3.A, how likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnography for the following outcomes? And A, again, is acquisition of interpretable data ranging from one, not likely, to three, reasonably likely, up to five, very likely. Starting with one, not likely.
(Dr. Gazelle raised his hand.)
DR. DAVIS: Two.

(Dr. McNeil, Dr. Weiner, Dr. Krist, Ms. Anderson Brock, Dr. Dale, Dr. Goodman, Dr. Hoover and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. Maves, Mr. Lacey and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(No response.)
DR. DAVIS: Five.
(No response.)
DR. DAVIS: 3.B, ability to accurately diagnose OAS. One, not likely?
(No response.)
DR. DAVIS: Two?
(Dr. Krist, Dr. Gazelle, Dr. Hoover and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Weiner, Dr. Maves, Ms. Anderson Brock, Dr. Dale, Dr. Goodman and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Mr. Lacey raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 3.C, abilities to

accurately identify those without OSA (specificity). One, not likely?
(No response.)
DR. DAVIS: Two.
(Ms. Anderson Brock and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Krist, Dr. Maves, Dr. Dale, Dr. Gazelle, Dr. Goodman, Dr. Hoover and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Dr. Weiner and Mr. Lacey raised their hands.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: Question 4.A, how confident are you that these sleep testing devices are as accurate in the diagnosis of obstructive sleep apnea as is a facility-based test, ranging from one, no confidence, up three, moderate confidence, up to five, high confidence. One?
(No response.)
DR. DAVIS: Two?
(Dr. McNeil, Dr. Krist, Ms. Anderson Brock, Dr. Dale, Dr. Gazelle, Dr. Hoover and Dr.

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Whites raised their hands.)
DR. DAVIS: Three.
(Dr. Weiner, Dr. Maves, Mr. Lacey and
Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Dr. Goodman raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 4.B, this is the one that
we added some wording to so I will read it with
the amendment. How confident are you that use of
these sleep testing devices in the diagnosis of
obstructive sleep apnea will lead to similar or
improved health outcomes measured either directly
or indirectly through changes in patient
management as compared to a facility-based test?
Ranking from one for no confidence up to five for
high confidence. One, no confidence?
(No response.)
DR. DAVIS: Two?
(Dr. Krist, Ms. Anderson Brock, Dr.
Gazelle, Dr. Hoover and Dr. Whites raised their
hands.)
DR. DAVIS: Three?
(Dr. Weiner, Dr. Maves, Dr. Dale and

Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Dr. McNeil, Mr. Lacey and Dr. Goodman raised their hands.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: Question 4.C, how confident are you that these sleep testing devices are as accessible as is a facility-based test for the diagnosis of obstructive sleep apnea, ranging from one, no confidence, to five, high confidence. One, no confidence?
(No response.)
DR. DAVIS: Two?
(No response.)
DR. DAVIS: Three?
(No response.)
DR. DAVIS: Four?
(Dr. McNeil, Dr. Weiner, Dr. Krist, Ms. Anderson Brock, Dr. Dale, Dr. Gazelle, Mr. Lacey, Dr. Hoover, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: Five.
(Dr. Maves, and Dr. Goodman raised their hands.)

DR. DAVIS: This is question five, based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to the Medicare population, age 65 and older, ranging from one for not likely up to three for reasonably likely up to five for very likely. One, not likely.

(Ms. Anderson Brock and Dr. Satya-Murti raised their hands.)

DR. DAVIS: Two.

(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Dale, Dr. Gazelle, Dr. Goodman, Dr. Hoover and Dr. Whites raised their hands.)

DR. DAVIS: Three.

(Dr. Maves and Mr. Lacey raised their hands.)

DR. DAVIS: Four.

(No response.)

DR. DAVIS: And five.

(No response.)

DR. DAVIS: 5.B, based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep test devices can be generalized to

providers (facilities and physicians) in community practice, ranging from one, not likely, to five, very likely. One, not likely?
(Ms. Anderson Brock raised her hand.)
DR. DAVIS: Two.
(Dr. Weiner, Dr. Krist, Mr. Lacey, Dr. Goodman, Dr. Hoover, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Maves, Dr. Dale and Dr. Gazelle raised their hands.)
DR. DAVIS: Four.
(No response.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: Halfway home.
So the second set of questions says at the top, evaluative questions on portable devices that measure cardiorespiratory parameters only, i.e., respiratory movement, airflow, oxygen saturation, and heart rate or ECG.
Question one, how well does the evidence address the effectiveness of this type of unattended portable multichannel home sleep testing device as an alternative to facility-based

polysomnography in the diagnosis of obstructive sleep apnea or OSA, ranging from one, poorly, to five, very well. One, poorly.
(Dr. McNeil raised her hand.)
DR. DAVIS: Two.
(Ms. Anderson Brock, Dr. Dale, Dr. Goodman, Dr. Hoover and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. Weiner, Dr. Krist, Dr. Maves, Dr. Gazelle, Mr. Lacey and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(No response.)
DR. DAVIS: Five.
(No response.)
DR. DAVIS: Question 2.A, how confident are you in the validity of the scientific data on the following outcomes, ranging from one, no confidence, up to five, high confidence. First, important acquisition of interpretable data. One, no confidence?
(No response.)
DR. DAVIS: Two?
(Dr. McNeil, Dr. Maves, Ms. Anderson

Brock, Dr. Dale, Dr. Hoover and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. Weiner, Dr. Krist, Dr. Gazelle, Mr. Lacey, Dr. Goodman and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(No response.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 2.B, ability to accurately diagnose OSA (sensitivity). One, no confidence?
(No response; however, Ms. Anderson Brock related that Dr. Redberg indicated a confidence level of 1.5 on both this question and the following question.)
DR. DAVIS: Two?
(Dr. Whites raised his hand.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Maves, Dr. Dale, Dr. Gazelle, Dr. Goodman, Dr. Hoover and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Mr. Lacey raised his hand.)
DR. DAVIS: And five.

(No response.)
DR. DAVIS: 2.C, ability to accurately identify those without OSA (specificity). One, no confidence.
(No response.)
DR. DAVIS: Two.
(No response.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Maves, Dr. Dale, Dr. Gazelle, Dr. Goodman, Dr. Hoover, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: Four.
(Mr. Lacey raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 3.A, how likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnogram for the following outcomes, and the choices go from one, not likely, up to five, very likely. Beginning with A, acquisition of interpretable data. One, not likely?
(Dr. Gazelle raised his hand.)
DR. DAVIS: Two.

(Dr. McNeil, Dr. Weiner, Dr. Krist, Ms. Anderson Brock, Dr. Dale, Dr. Goodman, Dr. Hoover and Dr. Whites raised their hand.
DR. DAVIS: Three.
(Dr. Maves and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(No response.)
DR. DAVIS: And five.
(Mr. Lacey raised his hand.)
DR. DAVIS: 3.B, ability to accurately identify OSA (sensitivity). One, not likely?
(No response.)
DR. DAVIS: Two.
(Ms. Anderson Brock, Dr. Gazelle and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Maves, Dr. Dale, Dr. Goodman, Dr. Hoover and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Mr. Lacey raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 3.C, ability to accurately

identify those without OSA (specificity). One, not likely?
(No response.)
DR. DAVIS: Two?
(Dr. Maves, Ms. Anderson Brock, Dr. Gazelle, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Krist, Dr. Goodman and Dr. Hoover raised their hands.)
DR. DAVIS: Four.
(Dr. Weiner and Mr. Lacey raised their hands.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 4.A, how confident are you that these sleep testing devices are as accurate in the diagnosis of obstructive sleep apnea as is a facility-based test, ranging from one, no confidence, up to five, high confidence. One, no confidence?
(No response.)
DR. DAVIS: Two?
(Dr. McNeil, Dr. Krist, Ms. Anderson Brock, Dr. Dale, Dr. Gazelle, Dr. Hoover and Dr.

Whites raised their hands.)
DR. DAVIS: Three.
(Dr. Maves, Dr. Goodman and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four.
(Dr. Weiner and Mr. Lacey raised their hands.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 4.B, how confident are you that the use of these sleep testing devices in the diagnosis of obstructive sleep apnea will lead to similar or improved health outcomes measured either directly or indirectly through changes in patient management as compared to a facility-based test? Ranging from one, no confidence, up to five, high confidence. One, no confidence?
(No response.)
DR. DAVIS: Two?
(Dr. Krist, Ms. Anderson Brock, Dr. Hoover and Dr. Whites raised their hands.
DR. DAVIS: Three.
(Dr. Maves, Dr. Dale, Dr. Gazelle and Dr. Satya-Murti raised their hands.)
DR. DAVIS: Four?

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(Dr. McNeil, Dr. Weiner, Mr. Lacey and Dr. Goodman raised their hands.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 4.C, how confident are you that these sleep testing devices are as accessible as is a facility-based test for the diagnosis of obstructive sleep apnea, ranging from one, no confidence, up to five, high confidence. One, no confidence?
(No response.)
DR. DAVIS: Two?
(No response.)
DR. DAVIS: Three?
(No response.)
DR. DAVIS: Four.
(Dr. McNeil, Dr. Krist, Dr. Maves, Ms. Anderson Brock, Dr. Dale, Dr. Gazelle, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: And five.
(Dr. Weiner, Mr. Lacey, Dr. Goodman and Dr. Hoover raised their hands.)
DR. DAVIS: 5.A, based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing

these sleep testing devices can be generalized to the Medicare population (those 65 and older), ranging from one, not likely, up to five, very likely. One, not likely.
(Ms. Anderson Brock, Dr. Hoover, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: Two.
(Dr. McNeil, Dr. Weiner, Dr. Krist, Dr. Dale and Dr. Goodman raised their hands.)
DR. DAVIS: Three.
(Dr. Maves and Dr. Gazelle raised their hands.)
DR. DAVIS: Four.
(Mr. Lacey raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: 5.B, based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to providers (facilities/physicians) in community practice. One, not likely?
(No response.)
DR. DAVIS: Two?
(Dr. Weiner, Dr. Krist, Ms. Anderson

Brock, Dr. Goodman, Dr. Hoover, Dr. Satya-Murti and Dr. Whites raised their hands.)
DR. DAVIS: Three.
(Dr. McNeil, Dr. Maves, Dr. Dale and Dr. Gazelle raised their hands.)
DR. DAVIS: Four.
(Mr. Lacey raised his hand.)
DR. DAVIS: And five.
(No response.)
DR. DAVIS: Thank you, done with the voting. Now we'll go around the table and allow folks to say anything they would like to explain their votes. Dr. Whites?
DR. WHITES: I think the overall comment that I would have is looking at the evidence presented, the study from Duke and RTI certainly influenced me more than anything else that the evidence is just not there yet. I think that possibly we will be getting there but I don't think it's there yet, and I'm sure we'll have this coming up again.
DR. SATYA-MURTI: I felt the spectrum of OSA hasn't been fully defined yet, we still have definitional questions, and that these devices are very good at acquiring data so I gave

them high rank. But would they be applicable and translate to Medicare patients, I did not think so. Medicare patients have lots of other problems, Parkinson's disease, peripheral neuropathy, drugs, and depression. So I believe when you extend this to the population at large, I believe that their performance characteristics will dip down.

DR. HOOVER: I think one of the other panel members, Barbara said it most accurately at one point here today, and that is that we're supposed to be looking at the evidence, and I firmly believe in evidence-based medicine. I think we have a technology assessment that says it's not ready yet and we have an evidence-based report from three prominent societies. Regardless of the biases that you may say will be there, if you dig behind what was there, I think there is very little bias in those studies.

We have a Sleep Heart Health Study co-investigating that cautions extrapolation of the results of that study to this discussion. There are very few Medicare patients. I agree with Dr. Phurrough that if we waited for studies that included Medicare-age population patients

then we wouldn't be covering a lot of things, but given the numbers of patients that are Medicare eligible, it would be nice to see some of the data.

Talking about the data, there are clearly some problems with the studies that we've seen. I think not necessarily the inclusion-exclusion criteria, but I think the quality indicators of the study were really the first thing that you need to look at in the way these were done, and unfortunately the quality indicators left us with fair or poor studies.

If you look at one of the studies, using an example the Dingli study that was reported to be of good quality, you had an 18 percent data loss, the average age was 50. They had two thresholds which left you with a 36 percent indeterminate results. It reminds me of VQ scans, I mean that they are either really positive but there is a whole group of them that we don't know, and so we don't know what to do with those results.

The Golpe study, again a Type 4 device, but 33 percent date loss in a 52-year-old age population, and looking at a 23 percent

discordance between taking a home study and the in-house study and asking physicians to look at them. That's almost a one-to-four disagreement. And I like using analogies, but that would be like every time you got on your fourth airline flight, the pilot took you to the wrong city and for those of us that are flying this afternoon, you know, pilots all get the same instruction, you go to Baltimore every week, but every fourth week you end up in Kansas City.

DR. SATYA-MURTI: That would be good for me.

(Laughter.)

DR. HOOVER: Well, it might be good for you. So, like Satyi, I think the potential is there to potentially get it, but I don't think it's there at this time.

DR. GOODMAN: The difficulties we have with the evidence reflect a couple things. One is that it appears that the comparison of the devices involved and the channels used, the types of data generated by the devices are at least in part an artifact of a time when evidence requirements were far lower than they are now. And for that reason, we don't know much at all about a direct or

indirect link between the use of these tests and true health outcomes, which I consider to be mortality, morbidity and quality of life. So we've been operating in the absence of that evidence. It's also an artifact of payment policy which through history has come to require this test as a gate to CPAP and other interventions. So again, we're working with a historical scientific artifact in the time of less evidence and a reimbursement artifact that has emerged over time.

And I hope that the next time when we look at data on this subject, it will be after the community has decided to run a three-arm prospective randomized controlled trial that has well-defined patients who are randomized in three groups, one, history and exam only; two, PSG plus history and exam; three, home monitoring plus history and exam. And we follow all patients on an intention to treat analysis, we follow the decisions made as a result of that data, we follow compliance of patients, we track intermediate outcomes, we track long-term health outcomes and resource use. And until that time, it's going to be very hard to answer any question about the

health impact of this testing.
MR. LACEY: My comments will also echo what Cliff just mentioned as well, and the need for us to really look at this young science of sleep medicine as it is in a process of evolution. And it's very difficult often when you're looking at areas where there are multiple new technologies and multiple new improvements in both the understanding of the disease as well as the optimal way to manage patients, where you have a very difficult time comparing one practice with another in a pristine and perfect way in terms of having the ultimate randomized trial to do those comparisons.
So, when I looked at these data, one of the questions we seemed to be focusing really on the relative efficacy of the two technologies, and I would say in both cases, there really is a need for better data as well as increased research into the Medicare population specifically. But when you look at the technologies that we have, many of the newer generations look like they have a major enabling component to them where they will potentially lower the barriers of care and I was convinced that many of the concerns and issues

around control of utilization as well as getting appropriate outcomes and minimizing loss of data are being appropriately managed. When you look at the technology as it relates to the overall context of care, and many of the care models that have been laid out in terms of overall disease management or within the at-risk populations in a managed care setting show that if properly managed and dealt with in its totality, these technologies as they interplay with patient care can be done very very effectively, as effectively as the sleep centers.

DR. GAZELLE: I can be brief because I agree with what's been said and probably anything else I have to say will be said by someone else. But I'll just say that my voting, it was very clear, the difference between the Type 2 and the Type 3 devices for me. I thought that the evidence regarding the Type 2 devices was poor and it was because of that that I felt that all of my votes really for the Type 2 depended on that issue, really. There are a couple studies out there, they're not very good studies, and so it's hard to know, hard to make conclusions. Whereas I think the evidence on the Type 3 devices was

relatively better in terms of the quality of the evidence than of the Type 2 devices, but it just didn't support them yet in terms of having either an accuracy that's comparable to the facility-based testing or a beneficial test on health outcomes.

DR. MAVES: I will simply reiterate what Scott said because that's essentially the same reason for my votes. On the other hand, I will say that the need for analysis of health outcomes for these people I think is an important part of helping to shape public policy on this important diagnosis. To me today, it was sort of a study of contrast. You've got a huge number of potential patients but a few that are diagnosed and treated. You've got, one of the presenters said, $2 billion worth of expenditures in diagnosis, $1 billion worth of treatment. You've got long wait times at the labs reported along with the ready accessibility of these home testing devices. So it sort of is kind of almost a tale of two cities.

And I think that as Scott indicated, particularly on the Type 3 devices, I think the data is improving from the last analysis and I

would look to the individuals involved in this field to conduct studies that will obviously push this to a point where we will have an easier time accepting that information. Thanks.

DR. KRIST: It seems like there is some consensus in our thoughts here at the end and I'll echo that. I agree with what Cliff said. You know, I think the devices have some future use and I think that what we need to look at for is focusing on future research that's looking at outcomes and how this technology affects clinical decision-making.

DR. WEINER: Just to add to the consensus, I think that clearly the outcomes is the answer, and I was impressed with the sincerity of the speakers on both sides of the argument. It would be wonderful if you guys could get together, and not focusing on the test, and again, we're not familiar with all the literature, but on the outcomes. And I am thoroughly convinced that in the right hands, there is room for both technologies. I think we all share the concern that it is in the right hands.

And being a big supporter of good population-based medicine and "good managed care"

I listened very carefully to Group Health and Kaiser and ICSI, I wish there were more evidence. So those organizations which I have great respect for have to get the evidence out working hand in hand with the scientists and clinicians both in the laboratories and outside the laboratory, but until that's the case, we just don't have the scientific basis which is what we're about, I think, at this table.

DR. MCNEIL: Well, I'm not adding too much more, but I was concerned that this was a very highly prevalent population at least according to the remarks, that the technologies are old, some older than others, that despite both of these facts the data are extraordinarily poor. There are no outcome data associated with even the primitive diagnostic data. And that in addition to all of that, in my view there is the possibility of really quite large indiscriminate use that would wipe out any potential savings in costs that we would have in going from a facility-based to a home-based test. So all of those things made me say this is something that could really be a red flag at a time when health costs are rising, so we have to

be much, much more careful about what we're doing. So I would plead for all of the good parties who are interested in this to make me more convinced through better data that this is the right thing to do.
DR. DAVIS: I'm going to hand it over to Janet and Dr. Phurrough to close things up in a moment but I just wanted to express my appreciation to members of the committee for the time that they spent to be here today and to prepare for the meeting and for engaging in this issue so effectively, and also to acknowledge all the hard work that CMS staff did, AHRQ, RTI, and also to thank all the presenters for sharing their expertise with us throughout the whole day.
MS. ANDERSON BROCK: Just some final remarks. For continuing information, please visit the CMS web site at www.cms.hhs.gov\coverage or www.cms.hhs.gov and click on coverage. At the appropriate time, CMS will post the proposed decision on this web site for public comment, so stay tuned.
To conclude today's session, would someone move that this meeting be adjourned?
DR. PHURROUGH: Can I make some

comments first?
MS. ANDERSON BROCK: I'm sorry. Sure.
DR. PHURROUGH: Just quickly, first of all let me thank the panel too. These are always challenging issues, we do appreciate your deliberations and your recommendations to us. I recognize it is a challenge to take this time out of your schedule and I appreciate you doing that. I also want to thank my staff who work long and hard hours to put these together.
A particular thank you to Janet Anderson. Janet has been an executive secretary for a number of years and this is her last meeting as executive secretary, so we thank Janet.
(Applause.)
And finally, I would like to thank those who have taken time out of their schedule to come and advise us and to give us your opinions and impressions. We think this is valuable, they have raised some significant other questions that we have not considered. We encourage you to provide input in writing to us about your perceptions of what occurred today. We also would like you to follow our web site because I suspect this will lead us to perhaps some additional

requests for public comments that we would like you to make in the future. We have an open decision, as you're aware. I think our due date for our proposed decision is early January, but I suspect we will be requesting some information between now and then. So again, thank you very much for your help and attendance.

DR. DAVIS: Is there a motion to adjourn.

DR. GAZELLE: So move.

DR. MAVES: Second.

DR. DAVIS: Any objection to adjourning? We are adjourned.

(Whereupon, the meeting adjourned at 4:15 p.m.)